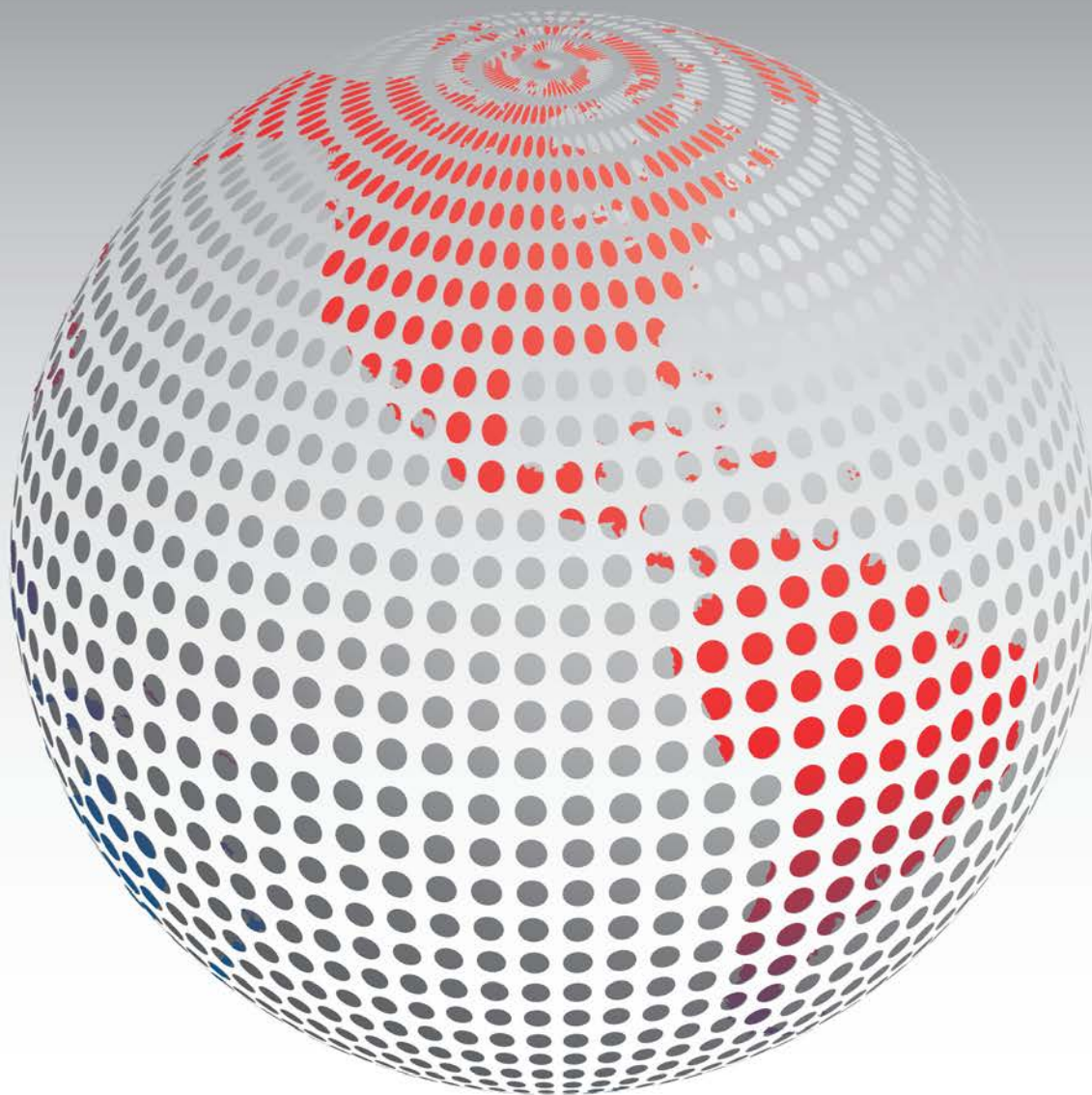


# NEWBORN SCREENING

Annual Summary Report  
volume 30

# 2012

Quality Assurance Program



National Center for Environmental Health  
Division of Laboratory Sciences



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

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## ***Newborn Screening Quality Assurance Program***

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

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

FROM THE

# EDITOR

## *Carol J. Bell . . . An Essential and Valued Part of Newborn Screening*

After 42 years of federal service Carol Bell has hung up her blood spots and retired. She was an essential and valued part of the Newborn Screening Quality Assurance Program (NSQAP).

Carol received her bachelor's degree in medical technology from West Virginia University and began her career working in the chemistry laboratory of West Virginia University Hospital, Morgantown, West Virginia.

She started her federal career in 1970 as a medical technologist at what was then Walter Reed General Hospital (now Walter Reed Army Medical Center), Washington, D.C. She moved to Atlanta in 1976 and worked in the chemistry laboratory of the Atlanta Veteran's Affairs Medical Center. She accepted a position at the Centers for Disease Control and Prevention in the Nutrition Branch in 1978. In 1991, Carol transferred to the Clinical Biochemistry Branch and accepted the position of program administrator in what is now the Newborn Screening and Molecular Biology Branch.

Carol is very well known in the Newborn Screening community and was a vital part of the NSQAP. She received the Newborn Screening Community Service Award in March 2012 from the Association of Public Health Laboratories (APHL) Newborn Screening Quality Assurance/Quality Control Subcommittee. She was recognized for her outstanding service to newborn screening and quality assurance/quality control for newborns across the globe.

Carol's ties to West Virginia have always been strong, and the tune "Take Me Home, Country Roads" is always in the back of her mind. She plans to move back to her hometown of Wheeling, West Virginia, to be closer to family and friends. She looks forward to rekindling her love of history through local genealogical and preservation societies, and she also plans to travel and spend time in Scotland.

She has been a wonderful co-worker and friend to those of us here at CDC. You also can send well wishes to Carol at [carol.bell@alum.wvu.edu](mailto:carol.bell@alum.wvu.edu).



*Photo Courtesy of Carol Bell*

Carol, we wish you all the best - Happy Retirement.

Editor and Program Administrator



## INTRODUCTION

Today, screening newborns for treatable, inherited metabolic diseases is a common occurrence throughout the United States and throughout many parts of the world. The screening process starts with collection of dried-blood spot (DBS) specimens, which a certified laboratory then analyzes for inborn metabolic errors and for other disorders that might require intervention. Healthcare professionals routinely collect DBS specimens from more than 98% of all newborns in the United States. This report summarizes all phases of the Centers for Disease Control and Prevention's (CDC) Newborn Screening Quality Assurance Program's (NSQAP) Proficiency Testing (PT) activities and summarizes all quality control (QC) data reported in 2012.

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 volumes of DBS specimens daily. By working closely with participant laboratories, the NSQAP helps laboratories process those specimens quickly and accurately. Our job is to serve our participant newborn screening laboratories. And in that regard, we always welcome comments and suggestions about how we can do our job better.

The newborn screening process has six parts: Education, Screening, Follow-up, Diagnosis, Management, and Evaluation. State public health laboratories or their associated laboratories routinely screen DBS specimens for inborn metabolic errors and for other disorders that require intervention. It's a well-known medical fact that effective, DBS-based newborn screening, combined with follow-up diagnostic studies and treatment, helps prevent mental retardation and premature death.

For more than 34 years, CDC, with its cosponsor the Association of Public Health Laboratories (APHL), has researched development of DBS-screening test materials and has assisted laboratories with DBS-related Quality Assurance. Although QA services primarily support newborn screening tests performed by state laboratories, CDC also accepts into the QA project private laboratories and even international participants. All U.S. laboratories that test DBS specimens participate voluntarily in the QA program. The project provides QA services for Congenital Hypothyroidism (CH), Congenital Adrenal Hyperplasia (CAH), Galactosemia, Phenylketonuria, Maple Syrup Urine Disease (MSUD), Homocystinuria, Tyrosinemia, Citrullinemia, Argininemia, Biotinidase Deficiency, Cystic Fibrosis (CF), Hemoglobinopathies, urea cycle

disorders, fatty acid oxidation disorders, and organic acid metabolic disorders.

Quality Assurance has two DBS distribution components: 1) Quality Control materials for periodic use, and 2) quarterly PT. The QC program helps laboratories maintain high levels of technical proficiency and continuity even while dealing with changes in commercial assay reagents. QC 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.

Proficiency Testing offers laboratories quarterly panels of blind-coded DBS specimens, which 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 kits manufactured by various commercial sources. Because of the limited availability of appropriate blood sources, however, the program does not distribute QC materials for Biotinidase Deficiency, galactose-1-phosphate uridylyltransferase (GALT) deficiency, hemoglobins, CF Mutation Detection (CFDNA), T-cell Receptor Excision Circle (TREC), and *Toxoplasma gondii* antibodies.

Over the last 10 years, the NSQAP has grown substantially—both in the number of domestic participants and in the number of international participants. In 2012, active program participants included 550 newborn screening laboratories in 71 countries (at least one laboratory per country) (Figure 1). Of these, 469 participated in PT (Figure 2) and 398 in QC (Figure 3). The program distributed DBS materials to participating laboratories for 40 analytes covering primary markers for 48 disorders (Figures 2–3). In PT, 260 laboratories used tandem mass spectrometry<sup>1</sup> (MS/MS) to report their data—of these, 53 were domestic laboratories.

Tandem mass spectrometry has had a major impact on the data that laboratories report to the Newborn Screening Program. MS/MS-based methods for the detection of phenylalanine (Phe) in DBS have revolutionized the practice of newborn screening for amino acid, fatty acid oxidation, and organic acid metabolic disorders. Specifically, the introduction of MS/MS programs added over 25 biomarkers into the Newborn Screening Program's PT and QC projects. These biomarkers cover 42 disorders from the U.S. Department of Health and Human Services Recommended Uniform Screening Panel (RUSP).

<sup>1</sup>MS/MS is a multi-analyte platform capable of detecting several disease biomarkers in one specimen aliquot.

## Newborn Screening Quality Assurance Program

### 2012 NSQAP BY THE NUMBERS

**100** percentage of states covered

**71** countries participated

**871,710** DBS produced

**27** employees

**43** new enrollments

**22** labs moved to inactive status

**550** labs enrolled at year end

**546** labs reported data

**469** labs participated in PT

**398** labs participated in QC

**22** reports provided to participants

**2** filter paper lots evaluated

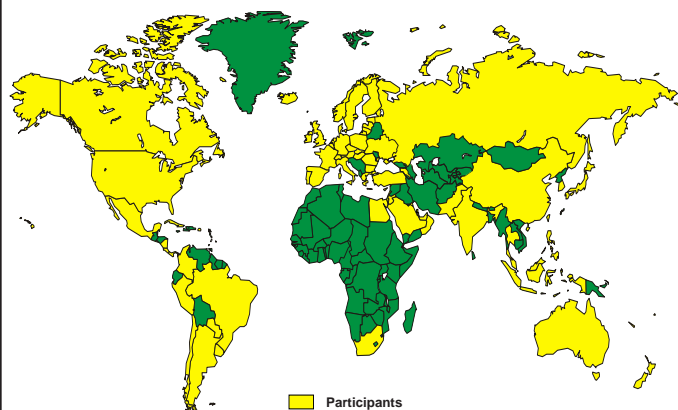
**31** US labs participated when NSQAP  
was established in 1978

Source: Newborn Screening  
Quality Assurance Program,  
December 2012

### 2012 NEWBORN SCREENING AND MOLECULAR BIOLOGY BRANCH ACTIVITIES

- In March, the APHL-sponsored QA/QC Subcommittee of the Newborn Screening and Genetics in Public Health Committee met in Atlanta. One subcommittee mission was to provide guidance to the NSQAP on procedures, policies, and activities for quality assessment of laboratory testing. Input from this subcommittee will enhance our continuing efforts to serve our participants better.
- NSQAP continued the CFDNA PT project, which included 66 participants. Reports posted at [www.cdc.gov/labstandards/nsqap\\_reports.html](http://www.cdc.gov/labstandards/nsqap_reports.html) summarize the quarterly CFDNA data. The CDC CFDNA DBS repository includes all 23 of the American College of Medical Genetics recommended mutation panel [1] for population screening and other less common mutations or sequence polymorphisms.
- The NSQAP finalized the protocol for making QC materials for CF molecular assays using immortalized cell lines. The program sent pilot materials containing 13 of the 23 ACMG-recommended mutations to newborn screening laboratories in the United States for evaluation. We plan to start a pilot domestic laboratory QC project in 2013.
- Through collaboration with the California Department of Public Health, Sequoia Foundation, and CF Centers in California, the NSQAP received 60 blood specimens for the CFDNA PT project. This replenished the program's CF Mutation DBS repository with ACMG-recommended mutations and other mutations not previously available. We confirm the mutations of these donor specimens and distribute them as PT specimens.
- In May, the NSQAP and APHL hosted a Webcast entitled "*Newborn Screening by Tandem Mass Spectrometry: State Experiences and Consideration with Derivatized and Non-Derivatized Methods.*" Look for other newborn screening workshops and conference proceedings at [www.aphl.org](http://www.aphl.org).
- In quarter three, the NSQAP added another new analyte, alanine (Ala), to the amino acid QC panel as well as analyte C10:2 to the acylcarnitine PT panel. One hundred forty-one participants reported results for C10:2 and 135 reported Ala QC results.
- In July, APHL and CDC's Molecular Quality Improvement Program cosponsored the Newborn Screening Molecular Training Workshop.

**FIGURE 1. Seventy-one Countries Participated in the Newborn Screening Quality Assurance Program in 2012**



Argentina	Iceland	Peru
Armenia	India	Philippines
Australia	Indonesia	Poland
Austria	Ireland	Portugal
Bahrain	Israel	Qatar
Belgium	Italy	Romania
Brazil	Japan	Russia
Bulgaria	Jordan	Saudi Arabia
Canada	Kuwait	Singapore
Chile	Latvia	Slovak Republic
China	Lebanon	South Africa
Colombia	Lithuania	South Korea
Costa Rica	Luxembourg	Spain
Cuba	Malaysia	Sweden
Czech Republic	Mexico	Switzerland
Denmark	Netherlands	Taiwan
Egypt	New Zealand	Thailand
El Salvador	Nicaragua	Turkey
Estonia	Norway	Ukraine
Finland	Oman	United Arab Emirates
France	Palestinian Authority	United Kingdom
Germany	Pakistan	United States
Greece	Panama	Uruguay
Hungary	Paraguay	

One or more laboratories represented for each country listed.

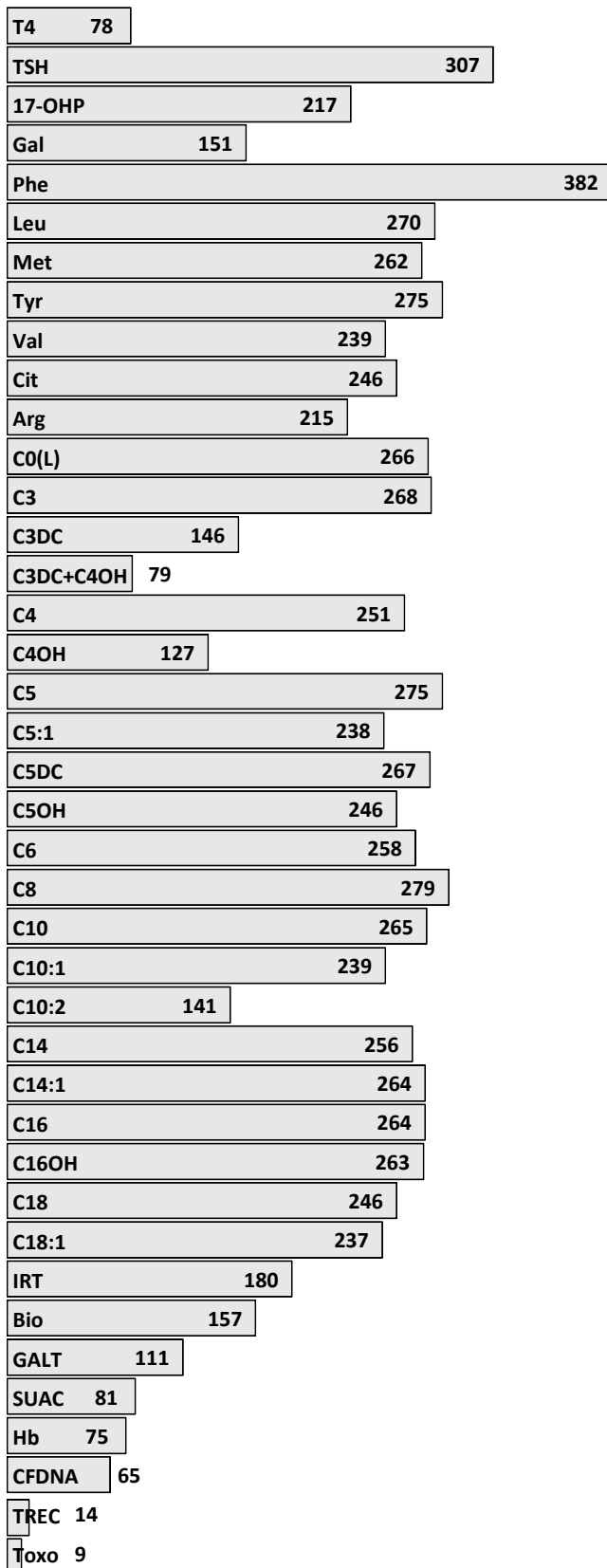
This annual 4-day, hands-on workshop was held in Atlanta, GA and was comprised of lectures and laboratory training activities that directly relate to detection of newborn disorders using molecular methods. Topics included molecular laboratory design and unidirectional workflow, comparison of instrument platforms for DBS genotyping, and assay requirements for multiplex assay design, as well as data reporting and clinical interpretation.

- Also in July, the Newborn Screening and Molecular Biology Branch and APhL officially launched the Newborn Screening Molecular Assessment Program (MAP). This program offers onsite molecular laboratory visits to assist state newborn-screening laborato-

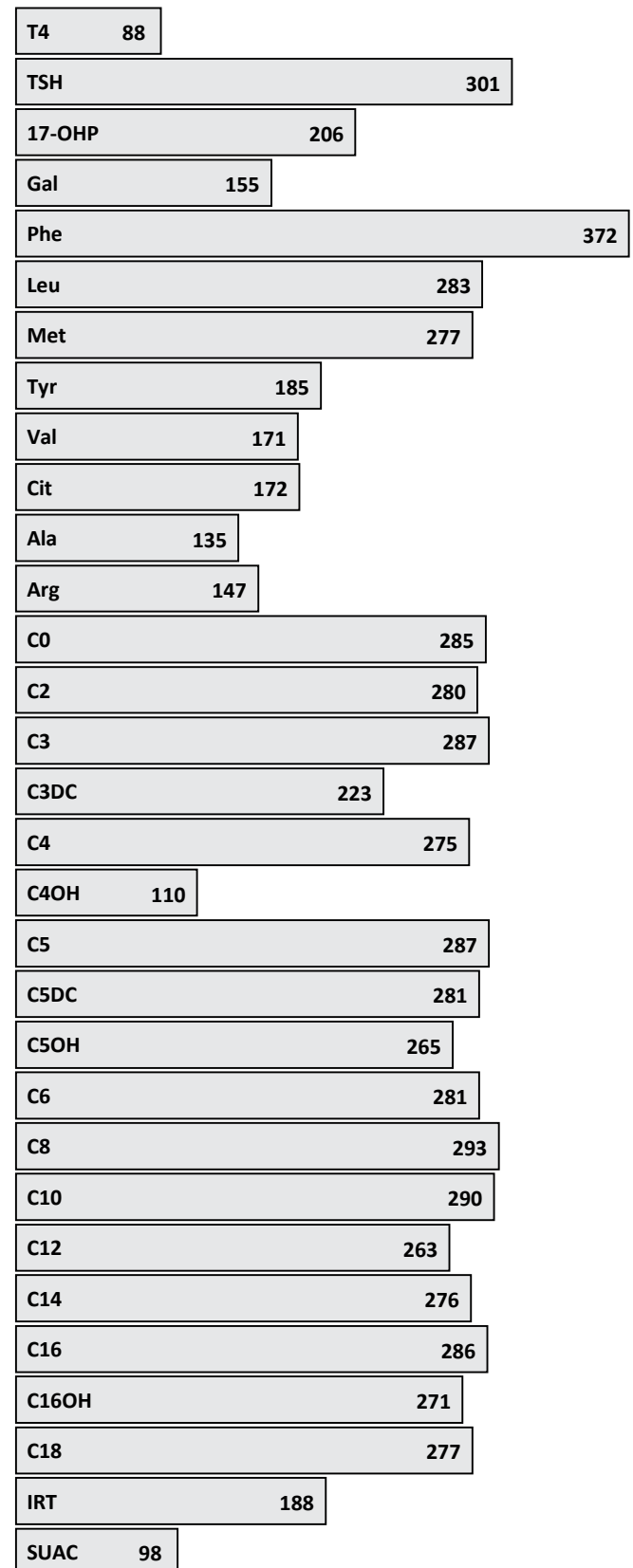
ries in quality assessments of their molecular programs. For more information, see the 2012 Molecular Quality Improvement Program section of this report.

- In August, APhL-sponsored Molecular Subcommittee of the Newborn Screening and Genetics in Public Health Committee met in Atlanta. Established in November 2011, the subcommittee guides state newborn screening public health laboratories on molecular screening procedures, policies, and activities. The subcommittee also provides input to the Molecular Quality Improvement Program, whose mission is quality improvement through molecular methods that aid public health laboratories in improving newborn disorder detection.
- During the year, because of scarce resources and high demand, the NSQAP and the Biochemical Mass Spectrometry Laboratory limited the number of DBSs sent to participants enrolled in the amino acids PT program. The participating laboratories now receive one spot per DBS PT specimen.
- Also during the year, the NSQAP established a pilot PT project to test DNA for TREC content in newborn infants' peripheral blood. The TREC PT project is currently limited to U.S. laboratories that 1) have validated methods for the screening of newborns for Severe Combined Immunodeficiency (SCID) and 2) have demonstrated proficiency through previous participation in the Newborn Screening Translation Research Initiative's Model Performance Evaluation Survey for TREC. For information on how to participate in the Model Performance Evaluation Survey for TREC, contact Dr. Robert Vogt at [rvogt@cdc.gov](mailto:rvogt@cdc.gov) or Dr. Francis Lee at [flee1@cdc.gov](mailto:flee1@cdc.gov).
- During 2012, the NSQAP continued its PT program to investigate materials and clinical interpretations based on the ratio of 17  $\alpha$ -hydroxyprogesterone (17-OHP), androstenedione, cortisol, 21-deoxycortisol, and 11-deoxycortisol for second-tier CAH screening by use of liquid chromatography-tandem mass spectrometry. Thirteen laboratories participated in three quarterly surveys.
- The NSQAP found that a growing number of participants used a nonderivatized MS/MS method for acylcarnitine analysis. Nonderivatized MS/MS, however, cannot resolve C3DC+C4OH. To accommodate this user group, the NSQAP began offering reporting alternatives. For PT and QC, the program combined C3DC and C4OH for reporting by those laboratories using

**Figure 2. Number of Participants in Proficiency Testing Program, 2012**  
Total - 469



**Figure 3. Number of Participants in Quality Control Program, 2012**  
Total - 398





nonderivatized MS/MS methods. Laboratories using derivatized MS/MS methods continue to report C3DC and C4OH separately. The 2013 program cutoffs, the program's QC certification, and the PT reports reflect these analyte updates.

- During 2012, the NSQAP worked on and is currently working on enhancements to the data-reporting Web site. The program's also planning to create reporting areas for CF and hemoglobins. Our goal is to make reporting easy and efficient for participants.

We encourage participants to continue reporting their program QC data by the e-mail data-reporting system. Electronic reporting streamlines data processing, makes accumulation of statistical data easier, and allows better data sharing with our participants.

## 2012 BIOCHEMICAL MASS SPECTROMETRY LABORATORY ACTIVITIES

Established in 2011, the Newborn Screening and Molecular Biology Branch's Biochemical Mass Spectrometry Laboratory (BMSL) serves as a clearinghouse for program participants. The laboratory offers newborn screening Tandem Mass Spectrometry (MS/MS) services, education, and research opportunities. The laboratory now houses the filter paper evaluation program, as well as the biotinidase, TGal, and GALT programs. The seven-member laboratory staff provides NSQAP participants with QC and PT materials for amino acids, acylcarnitines, second-tier CAH, and MSUD testing. In addition, laboratory staff research helps to expand the NSQAP's analytical capabilities beyond the DBS.

In 2012, BMSL hosted a highly successful laboratory workshop on newborn screening using MS/MS instrumentation. The 5-day intensive workshop was entitled "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, held on October 22–26 at the CDC's Newborn Screening Molecular Biology Branch's laboratories in Atlanta, GA. Attendees participated in four MS/MS hands-on exercises designed to help them understand the workshop's didactic portions. The exercises covered routine MS/MS newborn screening tests as well as second tier and confirmatory testing using MS/MS methods applicable to the modern newborn screening system. Participants from eight states attended the workshop.

In June 2012, BMSL also conducted an MS/MS Program Review. Selected program participants attended the

# 5

New countries  
joined NSQAP:  
Indonesia, Nicaragua,  
Palestinian Authority,  
Romania, and Russia

90-minute session. Review topics included program's analyte offerings and a history of the NSQAP's MS/MS initiative. A comprehensive QC and PT materials review resulted in changes to the amino acids and acylcarnitines QC materials. As of January 2013, amino acids and acylcarnitines QC DBS materials reflect updated analyte concentrations as noted in the certification pages.

In July 2012, BMSL and the NSQAP introduced a new analyte to the acylcarnitine PT panel: decadienoylcarnitine (C10:2). This analyte is a marker for 2,4-dienoyl-coA reductase deficiency. In addition, the amino acid alanine was introduced into the program's amino acid QC materials. Many laboratories use alanine as an informative marker to evaluate amino acid ratios for MSUD. Furthermore, 3-hydroxybutyrylcarnitine (C4OH) is now included in the acylcarnitine QC materials. As a result, QC and PT MS/MS panels now cover all primary biomarkers for the 42 MS/MS-detectable core and secondary target disorders listed in the U.S. Recommended Uniform Screening Panel (RUSP). This is a major program milestone, given that our goal is to provide high-quality DBS materials for all the disorders in the RUSP.

A new analyte will be added to the acylcarnitine PT panel: 3-hydroxystearoylcarnitine (C18OH) is a marker for Long-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency (LCHADD) and Tri-functional protein deficiency (TPD). C18OH will be included in the PT specimens scheduled for shipment in July 2013.

Back in January 2011, the NSQAP launched a pilot PT project to evaluate the use of MS/MS analyte ratios. The project consisted of DBS specimens prepared to simulate specific disorders. During routine screening, laboratory technicians might identify these disorders using concentration ratios for two or more amino acid or acylcarnitine biomarkers. We asked laboratories to identify and quantify any abnormal biomarkers present, as well as the concentration ratios used to establish a presumptive, positive classification on the specimens. We also asked

laboratories to comment on the specimens' presumptive disorder profiles. In 2012, fifty-five participating laboratories in the United States and Canada that perform MS/MS analysis submitted results via Excel spreadsheet. BMSL will continue to offer this pilot project in 2013.

BMSL staff is working to expand its QC and PT offerings for Galactosemia. New adult galactosemic patients have been identified and their blood donations will expand existing GALT PT inventory. In addition, BMSL is conducting research into developing QC materials for GALT. The laboratory is evaluating different types of blood treatments (e.g., heat, humidity) and matrices (i.e., lamb blood) to achieve low GALT activity levels in DBS. The laboratory will present a summary of findings at the 2013 Newborn Screening and Genetic Testing Symposium scheduled for Atlanta.

Laboratory staff 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](mailto:vdejesus@cdc.gov).

## **2012 NEWBORN SCREENING TRANSLATION RESEARCH INITIATIVE ACTIVITIES**

CDC's Newborn Screening Translation Research Initiative (NSTRI) is an ongoing collaboration between the CDC Foundation and CDC's Newborn Screening Molecular Biology Branch. In 2012, the NSTRI completed its seventh year of operation. The NSTRI's vision is the methodical expansion of newborn screening to detect more conditions in more infants around the world. The goal is for all infants with identified congenital disorders to have a better chance for a healthy childhood. The NSTRI assembles public, academic, foundation, and corporate partnerships for the scientific and financial support of translational research efforts in newborn screening.

People often describe translation research as the process of moving biomedical research findings "from bench to bedside." A better description for the NSTRI's work is moving biomedical research findings "from bench to bassinet." Integration of quality assurance systems is one of the most critical processes in translating laboratory research methods into practical newborn screening assays. The NSTRI's ultimate goal is to help transform promising research methods into newborn screening assays suitable for routine, population-based newborn screening. All NSTRI projects include collaboration with public health newborn screening programs. The NSTRI also works closely with the Clinical and Laboratory Standards

Institute (CLSI) to develop a consensus on newborn screening guidelines.

During its seventh year of operation, NSTRI continued support to public health newborn screening programs by implementing NBS to detect severe combined immunodeficiency (SCID). In four laboratory-training workshops, participants from six state newborn-screening programs produced and analyzed DBS reference materials for the TREC assay used to detect SCID. The NSQAP also established a SCID PT project. The NSTRI, meanwhile, continued multi-laboratory evaluations of TREC reference materials. The NSTRI also expanded support for newborn screening tests to detect lysosomal storage disorders. The NSTRI produced the first condition-specific DBS reference materials for Pompe and Krabbe disorders from immortalized cell lines, and evaluated an alternative platform using digital microfluidics. More than a dozen partnerships were involved in these projects, and many of the 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](mailto:rvogt@cdc.gov). We welcome ideas for new projects and partnerships.

## **2012 MOLECULAR QUALITY IMPROVEMENT PROGRAM ACTIVITIES**

The Molecular Quality Improvement Program (MQIP) provides comprehensive assistance to newborn-screening laboratories. Specifically, the MQIP helps laboratories address molecular specific, quality assurance issues. Forty states now use at least one molecular test to screen their newborn populations. The MQIP provides molecular services for laboratory quality improvement, helps with the exchange of molecular practices, and provides educational resources for newborn screening laboratories engaged in molecular testing.

The Newborn Screening Molecular Resources is a new tool on APHL's Web site available as of January 2013 ([www.aphl.org/aphlprograms/newborn-screening-and-genetics/molecular/](http://www.aphl.org/aphlprograms/newborn-screening-and-genetics/molecular/)), which is overseen by the Newborn Screening Molecular Subcommittee and MQIP. This resource includes the ability to browse detailed summaries and contact information for ongoing molecular assays, access the Newborn Screening MAP site visit information and checklists, and view archived presentations from newborn screening molecular workshops and webinars. This resource will be expanded in the coming year to include additional information specific to molecular assays and procedures useful to newborn screening laboratories.

In May 2012, MQIP and APHL officially launched the NBS Molecular Assessment Program (MAP). This program provides a unique laboratory assessment tailored to the specific needs of molecular programs. Included in the MAP visit is guidance for laboratory specified needs and assistance in evaluating ongoing or imminent molecular testing procedures. The onsite MAP evaluation team consists of both CDC and state public health molecular biologists that work with the laboratory personnel to provide a broad assessment of all components of their molecular testing procedures. To request a MAP visit, visit the Newborn Screening Molecular Resources Web site at: [www.aphl.org/aphlprograms/newborn-screening-and-genetics/molecular/Pages/Molecular-Assessment-Program.aspx](http://www.aphl.org/aphlprograms/newborn-screening-and-genetics/molecular/Pages/Molecular-Assessment-Program.aspx).

The MQIP laboratory recently completed the development of a DNA sequencing reference method to characterize abnormal hemoglobinopathy samples. This method characterizes the complete regions that encompass the *HBB*, *HBA1*, and *HBA2* genes and will be used to validate CDC's proficiency testing materials.

For more information about the Molecular Quality Improvement Program, please contact Dr. Suzanne Cordovado at [scordovado@cdc.gov](mailto:scordovado@cdc.gov).

## OTHER 2012 NSQAP ACTIVITIES

### FILTER PAPER

Each year, with the cooperation of GE Healthcare Biosciences Corporation (formerly Whatman Inc), Westborough, MA, and PerkinElmer Health Sciences (formerly Ahlstrom Filtration LLC), Greenville, SC, we evaluate new filter paper lots and compare these lots with previous filter paper lots approved (cleared) by the FDA for blood collection. The criteria for acceptable performance are the limits established in the CLSI standard [2]. A manufacturer also is expected to establish its own testing program using the CLSI standard and to make available to the user its certification data for each lot of paper distributed. CDC'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 degree of uniformity among and within production lots. As part of the QA program, we use an isotopic method developed at CDC to evaluate and compare different lots of filter paper [2]. Mean counts per minute of added isotope-labeled thyroxine ( $T_4$ ) contained within a 3.2 mm disk are equated with the serum volume of the disks from the dried 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 [2]. Initially, lysed-cell whole blood was used to avoid variability contributed by uncontrolled red blood cell (RBC) lysis during the 4-day QC production span. Results of later studies concluded, however, that 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 lots of filter paper.

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 [2]. The mean values and CIs are the filter-paper evaluation parameters published in the CLSI standard [2]. 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 [2]. Participants in the routinely scheduled review periods for revision of the LA4 standard examined and discussed the mean value and CI for the intact-cell measurements. In the revised standard, the CLSI committee retained the original values (not produced at CDC) for intact cells. The mean value and 95% CI for intact cells (Figure 4) are the values based on CDC data covering more than 10 filter paper lots.

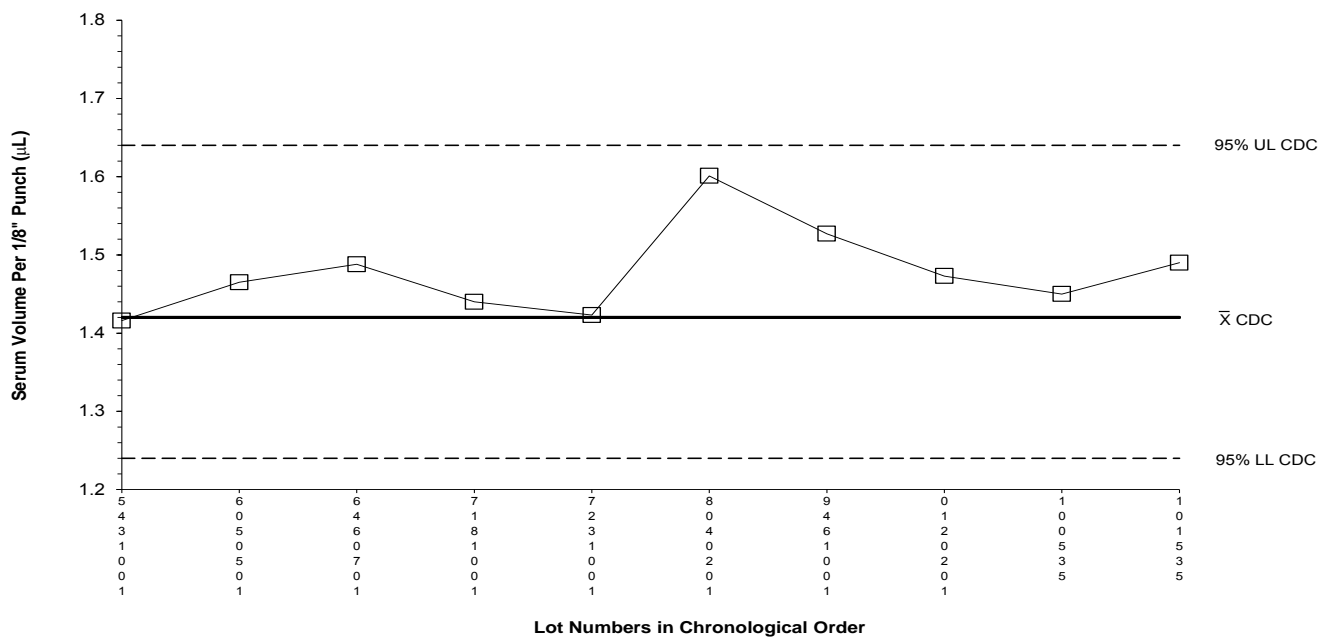
Filter paper lots used in the CDC production of QC and PT specimens distributed in 2012 were W111 of Whatman 903 and 0120201 of PerkinElmer 226. All filter paper lots were analyzed for agreement with the evaluation parameters according to the CLSI-approved standard [2].

In 2008, the FDA approved the PerkinElmer 226 filter paper as a blood collection device. CDC evaluated PerkinElmer 226 according to the criteria previously described [2]. The serum-absorbance volumes for 10 lots of PerkinElmer 226 filter paper determined from intact RBCs are shown in chronological order (Figure 4). For lot 101535, the most recent production lot of PerkinElmer 226 filter paper, we found the mean serum absorbance volume was  $1.49 \mu\text{L}$  for a 3.2 mm disk for intact-cell blood. Each mean value was within the acceptable range for the matrix used. Lot 101535 was homogeneous (i.e., the measured variance was within the acceptable limits).

The serum-absorbance volumes of 22 lots determined from intact RBCs (Figure 5) appear in chronological order. For W113, the most recent production lot tested of Whatman 903 filter paper, we found the mean serum-absorbance volume was  $1.44 \mu\text{L}$  per 3.2 mm disk for intact-cell blood. Each mean value is within the acceptable range for the matrix used. Lot W113 was homo-

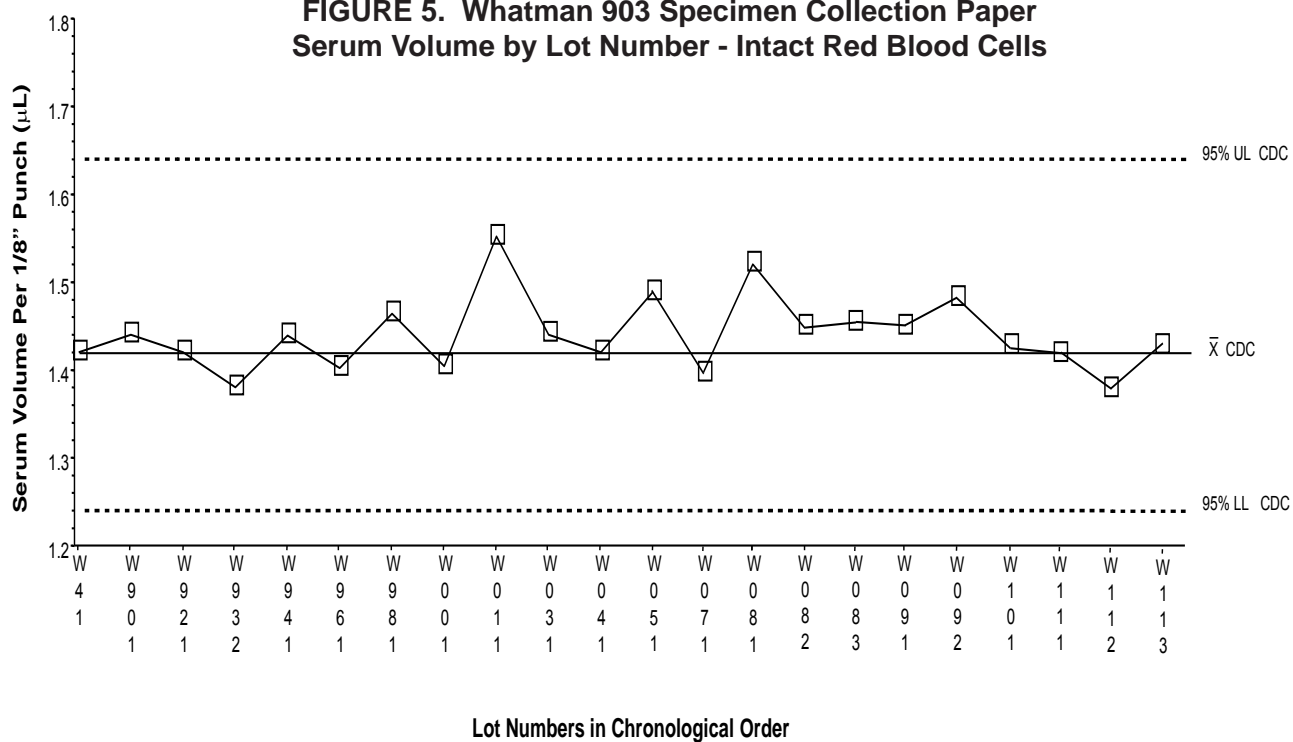
## *PerkinElmer (formerly Ahlstrom)*

**FIGURE 4. PerkinElmer 226 Specimen Collection Paper  
Serum Volume by Lot Number - Intact Red Blood Cells**



## *GE Healthcare Bio-Sciences (formerly Whatman Inc.)*

**FIGURE 5. Whatman 903 Specimen Collection Paper  
Serum Volume by Lot Number - Intact Red Blood Cells**





neous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within acceptable limits). The NSQAP's data for a production lot depended on the filter paper sample provided by the manufacturer as being representative of the entire production batch (i.e., statistically valid sampling).

#### SPECIMEN PREPARATION AND DATA HANDLING

Tables and figures show the enriched concentrations of PT specimens and QC lots as well as the summarized quantitative data. The total concentration of each specimen or lot equals the sum of the enriched concentration and the endogenous concentration (nonenriched). Because of differences in the blood sources used for DBS production of T<sub>4</sub> PT specimens, we reported the CDC assayed values. Some specimens were enriched above the endogenous T<sub>4</sub> concentration, and some were enriched with T<sub>4</sub> after T<sub>4</sub> depletion of the base serum. All PT and QC specimens were prepared from whole blood of 50% hematocrit. Purified analytes or unaltered donor blood were used for all enrichments, with the exception of TSH, which used the Third International Reference Preparation (81/565). For galactosemia (TGal), enrichments were made 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 GALT and some of the biotinidase pools from individual donor blood from adults with these disorders, with the hematocrit adjusted to 50%. Other Biotinidase pools were made using heat-treated serum combined with compatible donor red cells. CDC assayed values were used as PT-expected values for T<sub>4</sub>, IRT, and GALT. CFDNA PT materials were made with blood from individual donors expressing CF mutations, without hematocrit adjustment. We excluded from the quantitative result summaries all reported analytic values outside the 99% CI.

For obtaining 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 of the observed endogenous analyte concentration for each method category. 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.

**TABLE 1. 2012 Summary of Non-MS/MS Cutoff Values of Domestic and Foreign Laboratories**

<b>Domestic</b>						
Analyte	N	Mean	Median	Mode	Min	Max
T4	25	5.9	6.0	5.0	3.5	8.0
TSH	46	31.7	26.8	20.0	3.0	58.0
17-OHP	44	35.8	33.0	33.0	19.0	75.0
Galactose	24	11.0	10.0	10.0	6.0	20.0
Phenylalanine	9	153.9	151.5	181.8	121.0	206.0
Tyrosine	3	237.3	160.0	-	138.0	414.0
IRT	45	70.1	62.0	62.0	34.7	140.0
GALT	15	3.1	3.1	2.4	2.0	4.1
<b>Foreign</b>						
Analyte	N	Mean	Median	Mode	Min	Max
T4	31	5.7	6.0	6.0	4.0	9.3
TSH	211	23.2	20.0	20.0	6.0	44.0
17-OHP	136	30.1	21.9	19.8	4.5	180.0
Galactose	96	11.8	10.0	10.0	5.0	29.1
Leucine	6	294.7	302.5	-	228.9	381.5
Methionine	4	78.5	74.1	-	65.0	101.0
Phenylalanine	186	166.1	166.6	121.2	102.9	255.0
Tyrosine	4	363.0	402.5	-	95.0	552.0
SUAC	4	1.7	1.8	-	1.0	2.5
IRT	107	68.8	65.0	70.0	40.0	150.0
GALT	34	2.9	3.0	3.5	1.2	6.0



**TABLE 2. 2012 Summary of MS/MS Cutoff Values of Domestic Laboratories**

Analyte	N	Mean	Median	Mode	Min	Max
Phenylalanine	51	144.10	150.00	155.00	97.00	190.00
Leucine	50	289.04	289.00	250.00	175.00	500.00
Methionine	50	77.59	73.50	100.00	35.00	134.50
Tyrosine	51	415.96	355.00	850.00	88.00	850.00
Valine	35	295.19	280.00	250.00	200.00	444.60
Citrulline	49	54.71	56.00	60.00	18.00	100.00
Arginine	37	67.57	52.00	50.00	20.00	125.00
SUAC	27	2.85	3.00	4.50	0.50	5.42
C0(L)	51	10.11	8.00	7.00	3.80	60.00
C3	52	5.72	6.00	6.30	1.20	8.00
C3DC	25	0.24	0.20	0.20	0.10	0.45
C3DC + C4OH	17	0.49	0.40	0.40	0.30	1.33
C4	48	1.30	1.32	1.40	0.05	1.90
C4OH	19	0.68	0.72	0.75	0.27	1.00
C5	51	0.71	0.70	1.00	0.40	1.20
C5:1	51	0.27	0.19	0.60	0.05	1.00
C5DC	51	0.37	0.32	0.60	0.05	0.80
C5OH	51	0.81	0.80	0.90	0.19	1.50
C6	50	0.42	0.30	0.95	0.04	0.95
C8	52	0.46	0.41	0.35	0.25	0.72
C10	48	0.47	0.43	0.65	0.22	0.80
C10:1	47	0.32	0.30	0.45	0.14	0.53
C10:2	24	0.14	0.13	0.10	0.06	0.32
C14	49	0.77	0.74	0.70	0.17	1.20
C14:1	52	0.62	0.65	0.80	0.17	1.00
C16	50	7.73	7.80	7.00	0.41	10.00
C16OH	52	0.14	0.12	0.10	0.08	0.33
C18	44	2.45	2.26	4.00	0.41	4.00
C18:1	46	3.56	3.00	3.00	0.22	7.00

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

### CUTOFFS

When reporting cutoff values, the NSQAP requested reporting the decision level for sorting test results as presumptive positive (outside normal limits) from results reported as negative (within normal limits). Tables 1–3 summarize the reported cutoff values for domestic and foreign laboratories. The values for mean (arithmetic average), median (middle value), and mode (most frequent value) are shown for each analyte. This year the program is expanding the cutoff tables seen in Tables 4–7 by summarizing the mean, median, mode, and min/max range for domestic cutoffs for select analytes and methods. To

assess differences in reported cutoffs by method, we used data from domestic laboratories only. The mean cutoff values in Table 1 for non-MS/MS domestic and foreign laboratories are similar except for Tyr. For both domestic and foreign laboratories the range (min/max) of cutoff values is large for analytes 17-OHP, Tyr, Leu, Val, Arg, C0(L), and IRT. Among all laboratories, the mean and median cutoff summary values for the MS/MS amino acids seen in Tables 2 and 3 are similar except for Tyr. The mode value for domestic MS/MS Tyr, however, differed widely among methods the domestic participants used. This result indicates that a group of laboratories is using a cutoff value different from the mean of the other labs.

The new cutoff tables (Tables 4–7) contain cutoff distributions of non-MS/MS methods for TSH, IRT, 17-OHP, and TGal. The results show similar median cutoffs but variability within methods. The median cutoffs for Phe and Met are similar across all non-MS/MS and MS/MS methods. For Arg and Tyr, nonderivatized kit methods

**TABLE 3. 2012 Summary of MS/MS Cutoff Values of Foreign Laboratories**

Analyte	N	Mean	Median	Mode	Min	Max
Phenylalanine	186	142.77	130.00	120.00	48.00	514.80
Methionine	50	77.59	73.50	100.00	35.00	134.50
Valine	165	277.01	270.00	250.00	143.00	651.20
Arginine	141	57.25	50.00	60.00	10.00	150.00
C0(L)	172	14.05	8.76	10.00	3.00	90.00
C3DC	98	0.35	0.30	0.32	0.04	2.00
C4	158	1.05	1.00	1.40	0.06	2.00
C5	51	0.71	0.70	1.00	0.40	1.20
C5DC	177	0.30	0.25	0.35	0.03	1.02
C6	165	0.33	0.25	0.50	0.07	1.12
C10	172	0.42	0.40	0.50	0.12	1.77
C10:2	84	0.22	0.15	0.10	0.02	2.12
C14:1	170	0.48	0.43	0.40	0.11	1.50
C16OH	173	0.15	0.12	0.10	0.03	0.89
C18:1	154	2.94	2.90	3.00	0.10	27.00

have a broad range of cutoffs compared with other mass spectrometry-based methods. Extreme outlier cutoffs were seen for methods used to measure C0(L) and C3. Examples of the variability of cutoffs within and between methods include C5DC, C8, and C10:2.

#### PROFICIENCY TESTING

All PT panels consisted of five blind-coded 75- $\mu$ L DBS specimens. PT specimens either contained endogenous levels or were enriched with predetermined levels of  $T_4$ , TSH, 17-OHP, TGal, IRT, SUAC, amino acids (Phe, Leu, Met, Tyr, Val, Cit, Arg), and acylcarnitines (C0[L], C3, C3DC, C3DC+C4OH, C4, C4OH, C5, C5:1, C5DC, C5OH, C6, C8, C10, C10:1, C10:2, C14, C14:1, C16, C16OH, C18, and C18:1). CFDNA panels were made from the blood of a normal adult or adult or adolescent carrying at least 1 *CFTR* gene mutation. Separate panels for Biotinidase Deficiency and for GALT deficiency were prepared with purchased blood from donors who had

these enzyme deficiencies. Some Biotinidase pools were made using heat-treated serum combined with compatible donor red cells. Specimens for the Sickle Cell and Hemoglobinopathies panel were prepared from umbilical cord blood.

We packaged specimen sets in a zip-closed, metalized plastic bag with desiccant, instructions for analysis, and instructions for reporting data. We prepared and distributed quarterly reports of all results received by the deadline dates. In this annual report, we illustrate the comparisons of results by different methods (Figures 7–41) with the participants' reported PT data for one selected challenge for each analyte during the year. We compared these 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 (i.e., CDC-measured endogenous level plus enrichment). For  $T_4$ , IRT, and GALT, the reported value has been subtracted from the CDC assayed value. Note the scale-changes of the Y-axis

**Table 4. 2012 Domestic Cutoff Summary by Analyte and Method - Hormones and Galactose**

Analyte	Method	CUTOFF VALUE					
		Mean	Median	Mode	Min	Max	N
<b>T4</b>	AutoDelfia	6.0	6.0	5.0	4.0	8.0	18
	Delfia*	6.1	-	-	-	-	1
	Neo-Genesis Accuwell*	3.5	-	-	-	-	1
	PerkinElmer GSP Neonatal	6.1	6.0	-	4.6	8.0	5
	<b>ALL METHODS</b>	<b>5.9</b>	<b>6.0</b>	<b>5.0</b>	<b>3.5</b>	<b>8.0</b>	<b>25</b>
<b>TSH</b>	AutoDelfia	34.3	30.0	20.0	20.0	58.0	37
	Delfia*	20.0	-	-	-	-	1
	Neo-Genesis Accuwell*	20.0	-	-	-	-	1
	PerkinElmer GSP Neonatal	23.7	25.0	25.0	19.4	25.0	6
	Siemens Healthcare Diagnostics*	3.0	-	-	-	-	1
	<b>ALL METHODS</b>	<b>31.7</b>	<b>26.8</b>	<b>20.0</b>	<b>3.0</b>	<b>58.0</b>	<b>46</b>
<b>17-OHP</b>	AutoDelfia	42.2	35.0	30.0	30.0	65.0	10
	AutoDelfia Neonatal 17-OHP (B024)	33.2	33.0	35.0	19.0	75.0	27
	PerkinElmer GSP Neonatal	37.2	37.5	40.0	25.0	50.0	6
	Neo-Genesis Accuwell*	35.0	-	-	-	-	1
	<b>ALL METHODS</b>	<b>35.8</b>	<b>33.0</b>	<b>33.0</b>	<b>19.0</b>	<b>75.0</b>	<b>44</b>
<b>Galactose</b>	Astoria-Pacific 50 Hour Reagent Kit	10.9	10.0	10.0	6.5	15.0	10
	Bio-Rad Quantase*	14.5	14.5	-	14.0	15.0	2
	Fluorometric manual (e.g. Hill or Misuma)	12.3	10.0	10.0	10.0	20.0	6
	Neo-Genesis Accuwell*	9.5	9.5	-	7.0	12.0	2
	PerkinElmer Neonatal Kit	8.3	8.0	8.0	6.0	11.0	4
	<b>ALL METHODS</b>	<b>11.0</b>	<b>10.0</b>	<b>10.0</b>	<b>6.0</b>	<b>20.0</b>	<b>24</b>

\*Low participation rate method. Non-applicable statistics are not indicated.

**Table 5. 2012 Domestic Cutoff Summary by Analyte and Method - IRT, SUAC, and GALT**

Analyte	Method	CUTOFF VALUE					
		Mean	Median	Mode	Min	Max	N
<b>IRT</b>	AutoDelfia	69.0	62.0	62.0	34.7	140.0	33
	Delfia	71.1	70.0	-	43.2	100.0	3
	MP Biomedicals ELISA*	110.5	-	-	-	-	1
	PerkinElmer GSP Neonatal	73.6	57.5	55.0	45.0	130.0	8
	<b>ALL METHODS</b>	<b>70.1</b>	<b>62.0</b>	<b>62.0</b>	<b>34.7</b>	<b>140.0</b>	<b>45</b>
<b>SUAC</b>	Derivatized - MS/MS non-kit	2.52	3.00	3.00	0.50	5.42	9
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	3.01	3.00	4.50	1.00	4.50	18
	<b>ALL METHODS</b>	<b>2.85</b>	<b>3.00</b>	<b>4.50</b>	<b>0.50</b>	<b>5.42</b>	<b>27</b>
<b>GALT</b>	Astoria-Pacific Neonatal Microplate Reagent Kit*	2.5	2.5	-	2.0	2.9	2
	PerkinElmer Neonatal Kit	3.2	3.1	2.4	2.4	4.1	13
	<b>ALL METHODS</b>	<b>3.1</b>	<b>3.1</b>	<b>2.4</b>	<b>2.0</b>	<b>4.1</b>	<b>15</b>

\*Low participation rate method. Non-applicable statistics are not indicated.

Table 6. 2012 Domestic Cutoff Summary by Analyte and Method - Amino Acids

Analyte	Method	CUTOFF VALUE					
		Mean	Median	Mode	Min	Max	N
<b>PHE</b>	Derivatized - MS/MS non-kit	137.0	135.0	150.0	97.0	182.0	19
	Derivatized - MS/MS PerkinElmer NeoGram Kit	142.1	130.0	130.0	120.0	182.0	11
	Non-derivatized - MS/MS non-kit*	150.0	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	151.7	155.0	155.0	120.0	190.0	20
	<b>ALL MS/MS METHODS</b>	<b>144.1</b>	<b>150.0</b>	<b>155.0</b>	<b>97.0</b>	<b>190.0</b>	<b>51</b>
	PerkinElmer Neonatal Kit	161.5	159.4	-	121.0	206.0	4
	Fluorometric manual (e.g. Hill or Misuma)*	181.8	-	-	-	-	1
	High-performance liquid chromatography (HPLC)	145.3	151.5	151.5	133.0	151.5	3
	MP Biomedicals Enzyme Assay*	121.2	-	-	-	-	1
	<b>ALL NON-MS/MS METHODS</b>	<b>153.9</b>	<b>151.5</b>	<b>181.8</b>	<b>121.0</b>	<b>206.0</b>	<b>9</b>
<b>LEU</b>	Derivatized - MS/MS non-kit	282.3	300.0	300.0	200.0	357.0	17
	Derivatized - MS/MS PerkinElmer NeoGram Kit	291.7	300.0	300.0	250.0	325.0	12
	Non-derivatized - MS/MS non-kit*	305.0	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	292.4	270.0	250.0	175.0	500.0	20
	<b>ALL METHODS</b>	<b>289.0</b>	<b>289.0</b>	<b>250.0</b>	<b>175.0</b>	<b>500.0</b>	<b>50</b>
<b>MET</b>	Derivatized - MS/MS non-kit	66.8	66.0	70.0	35.0	100.0	16
	Derivatized - MS/MS PerkinElmer NeoGram Kit	84.1	77.5	100.0	59.7	100.0	12
	Non-derivatized - MS/MS non-kit*	87.5	-	-	-	-	2
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	81.4	80.0	100.0	55.0	100.0	20
	<b>ALL METHODS</b>	<b>77.6</b>	<b>73.5</b>	<b>100.0</b>	<b>35.0</b>	<b>134.5</b>	<b>50</b>
<b>TYR</b>	Derivatized - MS/MS non-kit	299.1	300.0	400.0	88.0	442.0	18
	Derivatized - MS/MS PerkinElmer NeoGram Kit	328.6	300.0	300.0	200.0	552.0	12
	Non-derivatized - MS/MS non-kit*	360.0	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	576.4	490.0	850.0	300.0	850.0	20
	<b>ALL MS/MS METHODS</b>	<b>416.0</b>	<b>355.0</b>	<b>850.0</b>	<b>88.0</b>	<b>850.0</b>	<b>51</b>
	High-performance liquid chromatography (HPLC)	237.3	160.0	-	138.0	414.0	3
<b>VAL</b>	Derivatized - MS/MS non-kit	277.2	280.0	300.0	200.0	420.0	13
	Derivatized - MS/MS PerkinElmer NeoGram Kit	310.5	281.0	280.0	250.0	444.6	10
	Non-derivatized - MS/MS non-kit*	250.0	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	306.7	300.0	250.0	200.0	400.0	11
	<b>ALL METHODS</b>	<b>294.5</b>	<b>280.0</b>	<b>250.0</b>	<b>200.0</b>	<b>444.6</b>	<b>35</b>
<b>CIT</b>	Derivatized - MS/MS non-kit	46.8	50.0	65.0	27.0	75.0	17
	Derivatized - MS/MS PerkinElmer NeoGram Kit	59.1	55.0	55.0	40.0	100.0	11
	Non-derivatized - MS/MS non-kit*	55.0	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	59.1	60.0	60.0	45.0	75.0	20
	<b>ALL METHODS</b>	<b>54.7</b>	<b>56.0</b>	<b>60.0</b>	<b>18.0</b>	<b>100.0</b>	<b>49</b>
<b>ARG</b>	Derivatized - MS/MS non-kit	51.6	40.0	30.0	20.0	125.0	13
	Derivatized - MS/MS PerkinElmer NeoGram Kit	81.2	80.0	100.0	49.9	100.0	9
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	73.3	50.0	50.0	50.0	120.0	15
	<b>ALL METHODS</b>	<b>67.6</b>	<b>52.0</b>	<b>50.0</b>	<b>20.0</b>	<b>125.0</b>	<b>37</b>

\*Low participation rate method. Non-applicable statistics are not indicated.

Table 7. 2012 Domestic Cutoff Summary by Analyte and Method - Acylcarnitines

Analyte	Method	CUTOFF VALUE					
		Mean	Median	Mode	Min	Max	N
<b>C0(L)</b>	Derivatized - MS/MS non-kit	12.42	10.46	10.00	5.00	60.00	19
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11.19	10.46	15.00	6.00	15.00	11
	Non-derivatized - MS/MS non-kit*	3.80	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	7.65	7.00	7.00	3.80	14.00	20
	<b>ALL METHODS</b>	<b>10.11</b>	<b>8.00</b>	<b>7.00</b>	<b>3.80</b>	<b>60.00</b>	<b>51</b>
<b>C3</b>	Derivatized - MS/MS non-kit	5.10	5.13	6.00	1.20	8.00	20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	5.87	5.94	5.25	5.00	7.21	11
	Non-derivatized - MS/MS non-kit*	6.92	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	6.21	6.30	6.30	4.00	8.00	20
	<b>ALL METHODS</b>	<b>5.72</b>	<b>6.00</b>	<b>6.30</b>	<b>3.10</b>	<b>8.00</b>	<b>52</b>
<b>C3DC</b>	Derivatized - MS/MS non-kit	0.2	0.2	0.2	0.1	0.45	16
	Derivatized - MS/MS PerkinElmer NeoGram Kit*	0.3	0.3		0.22	0.42	9
	<b>ALL METHODS</b>	<b>0.24</b>	<b>0.20</b>	<b>0.20</b>	<b>0.10</b>	<b>0.45</b>	<b>25</b>
<b>C3DC+C4OH</b>	Non-derivatized - MS/MS non-kit*	1.33	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.43	0.40	0.40	0.30	0.60	16
	<b>ALL METHODS</b>	<b>0.49</b>	<b>0.40</b>	<b>0.40</b>	<b>0.30</b>	<b>1.33</b>	<b>17</b>
<b>C4</b>	Derivatized - MS/MS non-kit	1.15	1.23	1.40	0.05	1.90	18
	Derivatized - MS/MS PerkinElmer NeoGram Kit	1.22	1.26	1.40	0.81	1.57	10
	Non-derivatized - MS/MS non-kit*	1.20	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	1.49	1.40	1.70	1.20	1.70	19
	<b>ALL METHODS</b>	<b>1.30</b>	<b>1.32</b>	<b>1.40</b>	<b>0.05</b>	<b>1.90</b>	<b>48</b>
<b>C4OH</b>	Derivatized - MS/MS non-kit	0.63	0.69	0.75	0.27	1.00	14
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.82	0.75	1.00	0.65	1.00	5
	<b>ALL METHODS</b>	<b>0.68</b>	<b>0.72</b>	<b>0.75</b>	<b>0.27</b>	<b>1.00</b>	<b>19</b>
<b>C5</b>	Derivatized - MS/MS non-kit	0.67	0.63	0.50	0.40	1.20	20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.63	0.63	0.54	0.45	0.87	10
	Non-derivatized - MS/MS non-kit*	0.60	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.80	0.77	1.00	0.50	1.00	20
	<b>ALL METHODS</b>	<b>0.71</b>	<b>0.70</b>	<b>1.00</b>	<b>0.40</b>	<b>1.20</b>	<b>51</b>
<b>C5:1</b>	Derivatized - MS/MS non-kit	0.24	0.15	0.15	0.05	1.00	20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.20	0.20	0.25	0.15	0.25	11
	Non-derivatized - MS/MS non-kit*	0.19	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.34	0.22	0.60	0.08	0.60	19
	<b>ALL METHODS</b>	<b>0.27</b>	<b>0.19</b>	<b>0.60</b>	<b>0.05</b>	<b>1.00</b>	<b>51</b>
<b>C5DC</b>	Derivatized - MS/MS non-kit	0.20	0.18	0.21	0.05	0.32	20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.32	0.32	0.30	0.28	0.40	11
	Non-derivatized - MS/MS non-kit*	0.43	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.56	0.60	0.60	0.40	0.80	19
	<b>ALL METHODS</b>	<b>0.37</b>	<b>0.32</b>	<b>0.60</b>	<b>0.05</b>	<b>0.80</b>	<b>51</b>
<b>C5OH</b>	Derivatized - MS/MS non-kit	0.76	0.80	1.00	0.19	1.18	20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.76	0.70	0.70	0.60	1.03	11
	Non-derivatized - MS/MS non-kit*	0.77	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.90	0.90	0.90	0.60	1.50	19
	<b>ALL METHODS</b>	<b>0.81</b>	<b>0.80</b>	<b>0.90</b>	<b>0.19</b>	<b>1.50</b>	<b>51</b>
<b>C6</b>	Derivatized - MS/MS non-kit	0.50	0.29	0.95	0.04	0.95	19
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.27	0.25	0.24	0.20	0.40	11
	Non-derivatized - MS/MS non-kit*	0.30	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.42	0.30	0.30	0.20	0.95	19
	<b>ALL METHODS</b>	<b>0.42</b>	<b>0.30</b>	<b>0.95</b>	<b>0.16</b>	<b>0.95</b>	<b>50</b>

\*Low participation rate method. Non-applicable statistics are not indicated.



Table 7. 2012 Domestic Cutoff Summary by Analyte and Method - Acylcarnitines (cont't)

Analyte	Method	CUTOFF VALUE					
		Mean	Median	Mode	Min	Max	N
C8	Derivatized - MS/MS non-kit	0.41	0.38	0.35	0.25	0.72	20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.40	0.38	0.40	0.32	0.60	11
	Non-derivatized - MS/MS non-kit*	0.50	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.53	0.60	0.60	0.35	0.70	20
	<b>ALL METHODS</b>	<b>0.46</b>	<b>0.41</b>	<b>0.35</b>	<b>0.25</b>	<b>0.72</b>	<b>52</b>
C10	Derivatized - MS/MS non-kit	0.42	0.40	0.30	0.22	0.80	18
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.46	0.42	0.40	0.30	0.68	10
	Non-derivatized - MS/MS non-kit*	0.34	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.53	0.55	0.65	0.22	0.70	19
	<b>ALL METHODS</b>	<b>0.47</b>	<b>0.43</b>	<b>0.65</b>	<b>0.22</b>	<b>0.80</b>	<b>48</b>
C10:1	Derivatized - MS/MS non-kit	0.26	0.25	0.25	0.17	0.44	17
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.35	0.32	0.30	0.21	0.53	11
	Non-derivatized - MS/MS non-kit*	0.40	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.35	0.43	0.45	0.14	0.50	18
	<b>ALL METHODS</b>	<b>0.32</b>	<b>0.30</b>	<b>0.45</b>	<b>0.14</b>	<b>0.53</b>	<b>47</b>
C10:2	Derivatized - MS/MS non-kit	0.15	0.12	0.10	0.06	0.32	11
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.15	0.15	0.15	0.10	0.20	7
	Non-derivatized - MS/MS non-kit*	0.12	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.10	0.10	0.10	0.07	0.14	5
	<b>ALL METHODS</b>	<b>0.14</b>	<b>0.13</b>	<b>0.10</b>	<b>0.06</b>	<b>0.32</b>	<b>24</b>
C14	Derivatized - MS/MS non-kit	0.65	0.70	0.70	0.17	0.84	18
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.72	0.71	0.70	0.52	0.89	11
	Non-derivatized - MS/MS non-kit*	0.80	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.92	0.80	1.20	0.58	1.20	19
	<b>ALL METHODS</b>	<b>0.77</b>	<b>0.74</b>	<b>0.70</b>	<b>0.17</b>	<b>1.20</b>	<b>49</b>
C14:1	Derivatized - MS/MS non-kit	0.55	0.60	0.60	0.17	0.84	20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.62	0.65	0.70	0.40	0.80	11
	Non-derivatized - MS/MS non-kit*	0.60	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.67	0.68	0.80	0.43	1.00	20
	<b>ALL METHODS</b>	<b>0.62</b>	<b>0.65</b>	<b>0.80</b>	<b>0.17</b>	<b>1.00</b>	<b>52</b>
C16	Derivatized - MS/MS non-kit	6.63	7.29	8.00	0.41	9.00	19
	Derivatized - MS/MS PerkinElmer NeoGram Kit	7.52	7.48	7.00	7.00	8.53	10
	Non-derivatized - MS/MS non-kit*	8.70	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	8.74	8.55	10.00	7.00	10.00	20
	<b>ALL METHODS</b>	<b>7.73</b>	<b>7.80</b>	<b>7.00</b>	<b>0.41</b>	<b>10.00</b>	<b>50</b>
C16OH	Derivatized - MS/MS non-kit	0.14	0.15	0.10	0.08	0.33	20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	0.18	0.17	0.18	0.12	0.30	11
	Non-derivatized - MS/MS non-kit*	0.12	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	0.11	0.10	0.10	0.08	0.20	20
	<b>ALL METHODS</b>	<b>0.14</b>	<b>0.12</b>	<b>0.10</b>	<b>0.08</b>	<b>0.33</b>	<b>52</b>
C18	Derivatized - MS/MS non-kit	1.75	1.83	2.00	0.41	2.50	15
	Derivatized - MS/MS PerkinElmer NeoGram Kit	2.30	2.25	2.50	1.89	3.00	10
	Non-derivatized - MS/MS non-kit*	2.47	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	3.05	2.90	4.00	1.55	4.00	19
	<b>ALL METHODS</b>	<b>2.45</b>	<b>2.26</b>	<b>4.00</b>	<b>0.41</b>	<b>4.00</b>	<b>44</b>
C18:1	Derivatized - MS/MS non-kit	2.54	2.50	2.50	0.22	3.50	17
	Derivatized - MS/MS PerkinElmer NeoGram Kit	2.93	2.85	-	2.22	3.50	9
	Non-derivatized - MS/MS non-kit*	3.53	-	-	-	-	1
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	4.59	3.70	7.00	2.27	7.00	19
	<b>ALL METHODS</b>	<b>3.56</b>	<b>3.00</b>	<b>3.00</b>	<b>0.22</b>	<b>7.00</b>	<b>46</b>

\*Low participation rate method. Non-applicable statistics are not indicated.

relative to the expected value for each plot. A reported value matching the expected value will show the illustrated value as falling on the plot's "0" line. A summary of the specimen data for the selected quarter PT challenge in 2012 is tabulated in the left margin for each figure. Ideally, a reasonable bias is less than  $\pm 20\%$  of the expected value (EV). It is noted that the bias for twenty-five of the 35 analytes is less than  $\pm 20\%$  of the EV, and 10 analytes have a bias greater than  $\pm 20\%$  of the expected value.

We selected a wide range of PT challenge specimens for the bias plots (Figures 7–41). When comparing data scatter among figures, note that the scale (Y-axis) might differ. We included the 95% CI for the mean participant bias. A tight scatter within this interval indicates a method

or group of methods' good performance. In general, the quantitative comparisons (Figures 7–41) for PT challenges are reasonable within a method but vary among methods. The PT quantitative results are grouped by kit or method to illustrate any method-related differences in analyte recoveries. 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 analytes distributed in PT challenges during 2012 that required a quantitative measurement to determine the presumptive clinical assessments. The bias scatter plots for  $T_4$  and TSH (Figures 7 and 8) indicate reasonable performance

**TABLE 8. 2012 Summary of Proficiency Testing Errors by Domestic Laboratories**

	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Congenital Hypothyroidism	182	0.0	498	0.0
Congenital Adrenal Hyperplasia	178	0.0	492	0.0
Galactosemia	71	1.4	284	0.0
Phenylketonuria	178	1.7	712	0.3
Maple Syrup Urine Disease (Leu)	99	0.0	646	0.2
Homocystinuria	99	2.0	646	0.3
Tyrosinemia 1,2,3	161	0.0	644	0.0
Maple Syrup Urine Disease (Val)	69	1.4	441	0.0
Citrullinemia	98	0.0	637	0.2
Argininemia	150	0.0	415	0.5
C0(L) Screen	103	1.0	672	0.0
C3 Screen	105	0.0	685	0.0
C3DC Screen	51	0.0	334	0.0
C3DC + C4OH Screen	32	0.0	213	1.4
C4 Screen	98	0.0	632	0.3
C4OH Screen	44	0.0	271	0.0
C5 Screen	261	0.4	524	0.0
C5:1 Screen	153	1.3	612	0.0
C5DC Screen	103	0.0	672	0.0
C5OH Screen	155	3.9	620	2.6
C6 Screen	101	2.0	659	0.0
C8 Screen	105	0.0	685	0.0
C10 Screen	98	0.0	637	0.6
C10:1 Screen	143	0.0	572	0.2
C10:2 Screen	49	0.0	196	0.5
C14 Screen	199	3.5	546	0.0
C14:1 Screen	106	0.0	684	0.0
C16 Screen	203	0.5	557	0.0
C16OH Screen	104	0.0	681	0.1
C18 Screen	91	0.0	584	0.0
C18:1 Screen	92	7.6	598	0.3
Biotinidase Deficiency	219	0.0	480	0.6
GALT Deficiency	134	0.0	536	0.0
Immunoreactive Trypsinogen	318	3.8	362	0.0
Succinylacetone	189	2.1	216	0.5

among all the users. Over the years, the number of T<sub>4</sub> users has remained stable, while the number of TSH users has grown. Most of the T<sub>4</sub> and TSH methods show good agreement among users, with a tight scatter of values. The recovery relative to expected value (EV) by participants is good, with a small mean bias for all participants for T<sub>4</sub>. In Figure 9, the bias plot for IRT shows excellent recovery for the participants' mean relative to the CDC assayed value. In Figure 10, the GALT expected value is very small, and the scatter of values is distinctly higher for one method and lower for another. For 17-OHP in Figure 11, the participant mean value is in excellent agreement with the EV and yields a minimal positive mean bias. For TGal in Figure 12, the scatter for one method is higher than that for all other methods, and the overall participants' mean

bias is small. The bias plot for Phe in Figure 13 shows good agreement between laboratories and among methods and has a small participant bias compared with the EV. In Figure 14, the Leu values show a negative bias compared with the EV for all methods. Met (Figure 15) shows a consistently negative bias. The scatter for the Tyr (Figure 16) shows a negative bias but good among-method variance. Val (Figure 17) illustrates a negative bias with a large participant bias. The Cit plot (Figure 18) shows some methods with a tight cluster of values but with distinct differences between nonkit and kit methods. Arg in Figure 19 shows a strong negative bias due to reduced recovery of the analyte by all methods. The SUAC data (Figure 20) shows a highly clustered set of values, with a negative bias for a nonderivatized MS/MS kit method.

**TABLE 9. 2012 Summary of Proficiency Testing Errors by Foreign Laboratories**

	Positive Specimens Assayed (N)	False- Negative Errors (%)	Negative Specimens Assayed (N)	False- Positive Errors (%)
Congenital Hypothyroidism	858	0.9	2362	1.4
Congenital Adrenal Hyperplasia	562	0.7	1553	0.8
Galactosemia	297	1.0	1188	0.8
Phenylketonuria	833	0.8	3332	1.2
Maple Syrup Urine Disease (Leu)	378	0.8	2367	0.6
Homocystinuria	359	1.4	2326	0.6
Tyrosinemia 1,2,3	565	0.0	2260	0.1
Maple Syrup Urine Disease (Val)	354	2.3	2226	1.1
Citrullinemia	336	0.0	2109	0.9
Argininemia	589	1.4	1621	0.2
C0(L) Screen	371	7.0	2354	1.0
C3 Screen	351	1.1	2344	0.7
C3DC Screen	200	3.0	1300	1.5
C3DC + C4OH Screen	90	1.1	565	3.5
C4 Screen	339	1.8	2186	1.1
C4OH Screen	163	4.3	1072	2.4
C5 Screen	941	1.7	1854	0.7
C5:1 Screen	484	0.8	1891	1.0
C5DC Screen	350	3.7	2355	1.2
C5OH Screen	498	4.4	1902	5.4
C6 Screen	344	2.0	2266	0.4
C8 Screen	372	0.8	2488	0.7
C10 Screen	353	2.0	2362	1.8
C10:1 Screen	482	1.2	1928	1.6
C10:2 Screen	191	2.1	764	1.2
C14 Screen	690	2.6	1920	1.3
C14:1 Screen	361	1.1	2324	1.2
C16 Screen	713	3.1	1987	1.0
C16OH Screen	369	5.4	2311	1.6
C18 Screen	327	3.1	2173	0.6
C18:1 Screen	314	5.7	2091	0.6
Biotinidase Deficiency	371	2.7	1019	2.1
GALT Deficiency	163	0.0	652	0.2
Immunoreactive Trypsinogen	769	3.5	881	1.7
Succinylacetone	305	0.7	350	0.0

The bias values for SUAC have a wide scatter and a large difference among methods and users. Only a few SUAC participants show good recoveries relative to the EV. We observed a marked difference for the derivatized nonkit and kit MS/MS methods.

Bias plots for derivatized and nonderivatized MS/MS methods are shown for all acylcarnitines as selected representative PT challenges in 2012. Enrichments made with purchased or special synthesized acylcarnitines are based on weighed quantities. Small variances in enrichments and recoveries might be attributed to impurities in the purchased (synthesized) materials and endogenous analyte concentrations. For C0(L), Figure 21 shows a tight scatter for all methods. The bias data for C3 (Figure 22) and C4 (Figure 25) show a slight positive participant bias with consistent scatter across all methods.

A growing number of NSQAP participants use a non-derivatized MS/MS method for acylcarnitine analysis. Analytes C3DC and C4OH cannot be resolved by non-derivatized MS/MS. Laboratories using a nonderivatized MS/MS method report C3DC+C4OH while derivatized MS/MS users continue to report those analytes separately. C3DC (Figure 23) shows a small negative bias for the nonkit MS/MS methods and a positive bias for the MS/MS kit methods. C3DC+C4OH (Figure 24) shows a negative bias among all participants across all methods. For C4OH (Figure 26), most laboratories show a positive bias.

In Figure 27 for C5, the values are minimally scattered, with good agreement with the EV. The data for C5:1 (Figure 28) show a negative bias for most kit methods, and the participant mean value is slightly lower than the EV. For C5DC (Figure 29) a tight scatter is within each method, with nonkit methods showing a negative bias and kit methods showing a positive bias. The bias plot for C5OH (Figure 30) illustrates good scatter for all methods, with the mean bias in good agreement to the EV. C6 (Figure 31) shows a slight negative participant bias. For C8

**TABLE 10. 2012 Summary of Proficiency Testing Errors for Hemoglobinopathies by Domestic and Foreign Laboratories**

Hemoglobinopathies	Domestic	Foreign
Specimens assayed	720	320
Phenotype errors	1.11%	0.31%
Clinical assessment errors	1.11%	0.31%

*Overall, there were 9 phenotype errors.*

(Figure 32), the data demonstrate a tight scatter around the EV. For C10 (Figure 33) and C10:1 (Figure 34), the bias values show reasonable scatter among all laboratories and methods, with good agreement for the EV; still, we noted a negative method bias between the MS/MS kit and the nonkit methods.

C10:2 was a new analyte added in 2012. Its bias plot (Figure 35) shows a large negative bias due to lower recoveries by all methods. For C14 (Figure 36), all methods show reasonable scatter, but the C14 kit methods show a negatively clustered bias. C14:1 (Figure 37) shows a negative participant bias, with a negative scatter for some kit methods. C16 (Figure 38) data demonstrate a tight cluster of values, with most laboratories showing a negative bias. For C16OH (Figure 39), the data demonstrate consistent scatter among all methods, with most laboratories showing a negative bias. Figure 40 for C18 illustrates good agreement with the EV and reasonable scatter of values within and among methods while showing a slight negative participant bias. C18:1 (Figure 41) shows a negative participant bias but with good scatter among all methods.

Tables 8 and 9 show the PT errors reported by domestic and foreign laboratories in 2012 for qualitative assessments reported per disorder. We applied the laboratory-

**TABLE 12. Sickle Cell and Hemoglobinopathies Methods Used in Multi-Tier Testing for Proficiency Testing in 2012**

Method	Isoelectric Focusing	BioRad HPLC	Extended Gradient HPLC	Primus Uita2 HPLC	Electrophoresis Citrate Agar	Electrophoresis Alkaline Cellulose	PCR Amplification of DNA
1st tier testing	32	33	1	3	0	1	0
2nd tier testing	18	10	5	4	1	1	2
3rd tier testing	0	2	0	0	2	0	0

**TABLE 11. Hemoglobin Phenotype Challenges Distributed in 2012**

Phenotype	N
FA	11
FAC	1
FAS	3

reported specific cutoff values to our grading algorithm for clinical assessments (Figure 6). Because of specific clinical assessment practices, presumptive clinical classifications (qualitative assessments) of some specimens might differ by participant. If participants provided us with their cutoff values, we applied these cutoffs in our final appraisal 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. False-positive misclassifications are a cost-benefit issue and a credibility factor for follow-up programs; they should be monitored and kept as low as possible. Many of the misclassifications were in the false-positive category, with false-positive rates ranging from 0% to 5.4%. For domestic laboratories, the rate was 0.6% or lower for 33 of 35 biomarkers or disorders, with C5OH having the highest rate of false-positive errors. The foreign laboratories had an error rate of 1.8% or lower for 31 of 35 biomarkers or disorders, with C5OH having the highest rate of false-positive errors.

Screening programs are designed to minimize false negative reports. But this precautionary design contributes to false-positive reports and might cause many of the false-positive misclassifications. The false-negative rate, expected to be zero, ranged from 0% to 7.6%. For domestic laboratories, we found no false-negative errors for 21 of the 35 biomarkers or disorders. Foreign laboratories had at least one false-negative error for 32 of the 35 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 distributed as not-evaluated specimens—as such, they are not included in Tables 8 and 9. We used participants’ data for these specimens to examine the relative analytical performance of the assays.

Table 10 shows the performance errors for hemoglobinopathies. The percentage of errors for qualitative assessments for sickle cell disease and other hemoglobinopathies ranged from 0.3% to 1.1% for both the phenotype and clinical assessment errors. Overall, in 2012 nine phenotype errors occurred for data reported by 71 laboratories. The classification errors were essentially the same for phenotype and clinical assessments within the domestic and foreign laboratory groups. Table 11 shows the phenotype challenges distributed in 2012 for hemoglobinopathies. Participants use multi-tier testing schemes to enhance the specificity of screening for Hemoglobinopathies as shown in Table 12. Most screening laboratories use Isoelectric Focusing and HPLC methods in only a single tier of testing. Many laboratories use second-tier testing with these same methods in repetitive or different combinations. Only a few used a third-tier test. Some laboratories report the application of DNA testing for their scheme.

**TABLE 13. Genotype Analysis of Cystic Fibrosis Mutation Detection Specimens in 2012**

	Specimens Assayed (N)	Correct Results	Incorrect Results	Not Evaluated*	Sample Failure
Q1, 2012	295	100%	0%	1.7%	2.4%
Q2, 2012	290	99.6%	0.4%	6.6%	0.7%
Q3, 2012	285	100%	0%	0%	1.4%
Q4, 2012	300	99.6%	0.4%	6.3%	0.7%
Total	1170	99.8%	0.2%	3.7%	1.3%

\*If one or both mutations are not on a laboratory’s panel, it is not evaluated.



**TABLE 14. Cystic Fibrosis  
Mutation (*CFTR* gene)  
Challenges Distributed in 2012**

<b>Mutation (Legacy Name)</b>	<b>Mutation (HGVS Nomenclature)</b>	<b>Number Sent</b>
Wild type/no mutation	Wild type/no mutation	16
F508del	p.Phe508del	13
1898+1G→A	c.1766+1G→A	1
R347P	p.Arg347Pro	1
3120+1G→A	c.2988+1G→A	1
3659delC	c.3528delC	1
3849+10kbC→T	c.3718-2477C→T	1
G542X	p.Gly542X	1
711+1G→T	c.579+1G→T	1
2184delA	c.2052delA	1
394delTT	c.262_263delTT	1
R334W	p.Arg334Trp	1
2183AA→G	c.2051_2052delAAinsG	1

Table 13 shows the performance errors for CF mutation detection. The percentage of errors for qualitative assessments for genotype analysis ranged from 0% to 0.4%. Table 14 shows the CF mutation (*CFTR* gene) challenges distributed in 2012 for CFDNA.

#### QUALITY CONTROL

For QC shipments of T<sub>4</sub>, TSH, 17-OHP, IRT, TGal, amino acids (Phe, Leu, Met, Tyr, Val, Cit, Arg, Ala), SUAC, and acylcarnitines (C0, C2, C3, C3DC, C4, C5, C5DC, C5OH, C6, C8, C10, C12, C14, C16, C16OH, C18), each lot within a set contained a different analyte concentration. To ensure that a laboratory received representative sheets of the production batch, for each laboratory we used randomizing systems to select sheet sets from across the production batch. The QC materials were distributed semiannually. They included the DBS sheets, instructions for storage and analysis, and data-report forms. Data from five analytic runs of each lot and shipment were compiled in the midyear, and annual summary reports were distributed to each participant. Because each participant's

reported data cover a different time span, intervals between runs were not the same for all laboratories.

Tables 15a–15ee summarize the reported QC data. The tables show the analyte by series of QC lots, the number of measurements (N), the mean values, and the 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 15a–15ee provide data about method-related differences in analytic recoveries and method biases. Because we prepared each QC lot series from one batch of hematocrit-adjusted, nonenriched 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 251, 252, and 253). 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 also measured the endogenous concentrations by analyzing the nonenriched QC lots; the Y-intercepts and measured endogenous levels for these analytes were similar for most methods. Ideally, the slope should be 1.0, and most slopes fell within a range from 0.7–1.2. Some analytes and methods continue to produce data with slopes as high as 1.8 and as low as 0.1. Slopes for Arg and SUAC are low due to recovery difficulties. We noted that a method for TGal has a slope of 2.7. 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.

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**Staff Peer-Reviewed Publications**

Adam BW, Hall EM, Meredith NK, Lim TH, Haynes CA, De Jesús VR, Hannon WH. Performance of Succinylacetone Assays and Their Associated Proficiency Testing Outcomes. *Clinical Biochemistry* 2012; 45(18):1658-1663.

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**Staff Posters and Presentations**

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**Figure 6. 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 FALSE POSITIVE:**

There are three steps to the grading algorithm that is used in the evaluation of PT specimens:

- 1- Comparison of the NSQAP Certified Expected Value and NSQAP Cutoff Value
- 2- Comparison of the NSQAP Certified Expected Value and Participant Cutoff
- 3- Participant Reported Clinical Assessment

**Example of TSH False Positive –**

NSQAP Certified Expected Value= 13  $\mu$ IU/mL

NSQAP Cutoff = 30  $\mu$ IU/mL

Participant cutoff = 35  $\mu$ 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  $\mu$ IU/mL

NSQAP Cutoff = 30  $\mu$ 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  $\mu$ IU/mL

Participant Cutoff = 35  $\mu$ 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	onl	Cutoff Difference

wnl – “1- Within Normal Limits”

onl – “2- Outside Normal limits”

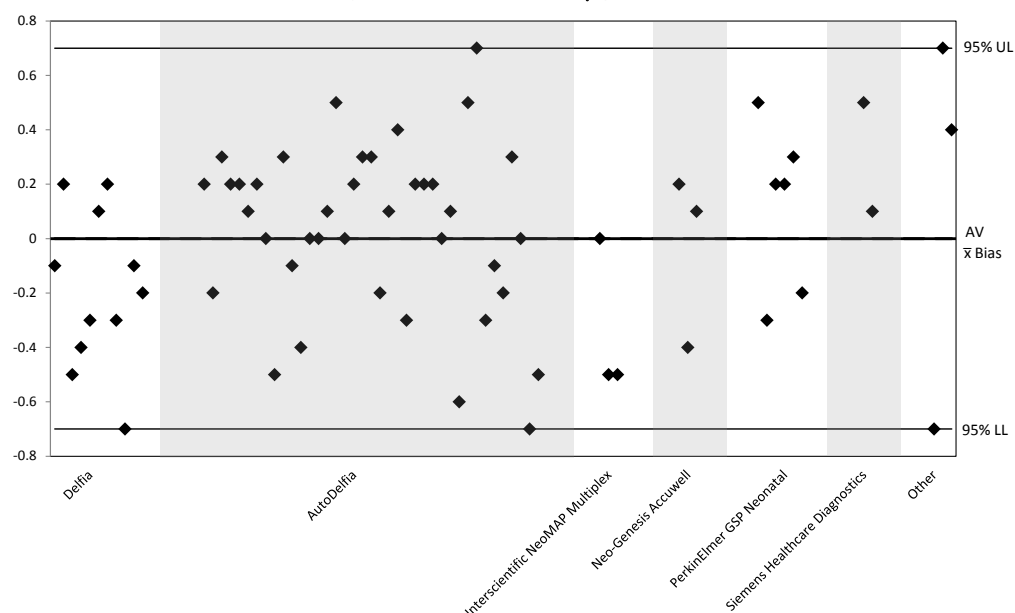
**Note that the grade is based on the Participant Reported Clinical Assessment, not on the reported value.**

Reference: CLIA Regulations Subpart I—Proficiency Testing Programs for Nonwaived Testing. [Updated 2004 July 7; accessed 2012 January 31]. Available from [http://wwwn.cdc.gov/clia/regs/subpart\\_i.aspx#493.931](http://wwwn.cdc.gov/clia/regs/subpart_i.aspx#493.931)

## FIGURES 7-8. Reproducibility of Results by Different Methods – Thyroxine (T<sub>4</sub>) and Thyroid-Stimulating Hormone (TSH)

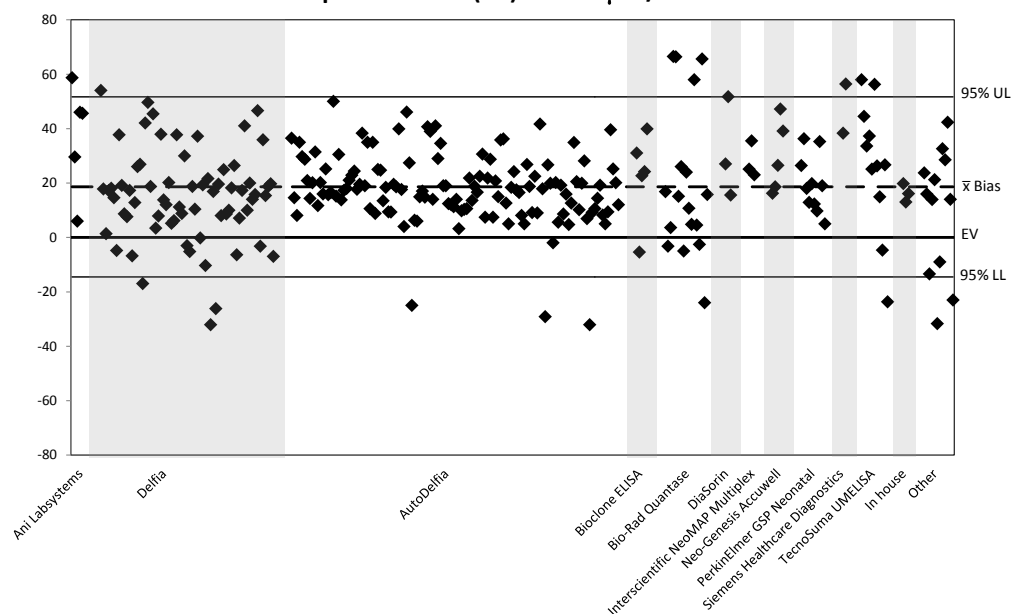
**Bias Plot of Thyroxine (T<sub>4</sub>) Values by Method**  
Quarter 1, Specimen 11211  
Assayed Value (AV)<sup>3</sup> = 1.5 µg/dL serum

<u>Quarter 1</u>	
<i>Specimen 1</i>	
CDC Assayed	1.5
Participant Mean	1.5
Participant Bias <sup>2</sup>	0.0



**Bias Plot of Thyroid-Stimulating Hormone (TSH) Values by Method**  
Quarter 1, Specimen 11211  
Expected Value (EV)<sup>1</sup> = 80.0 µIU/mL serum

<u>Quarter 1</u>	
<i>Specimen 1</i>	
Enriched	80.0
CDC Assayed	92.1
Participant Mean	98.6
Participant Bias <sup>2</sup>	18.6

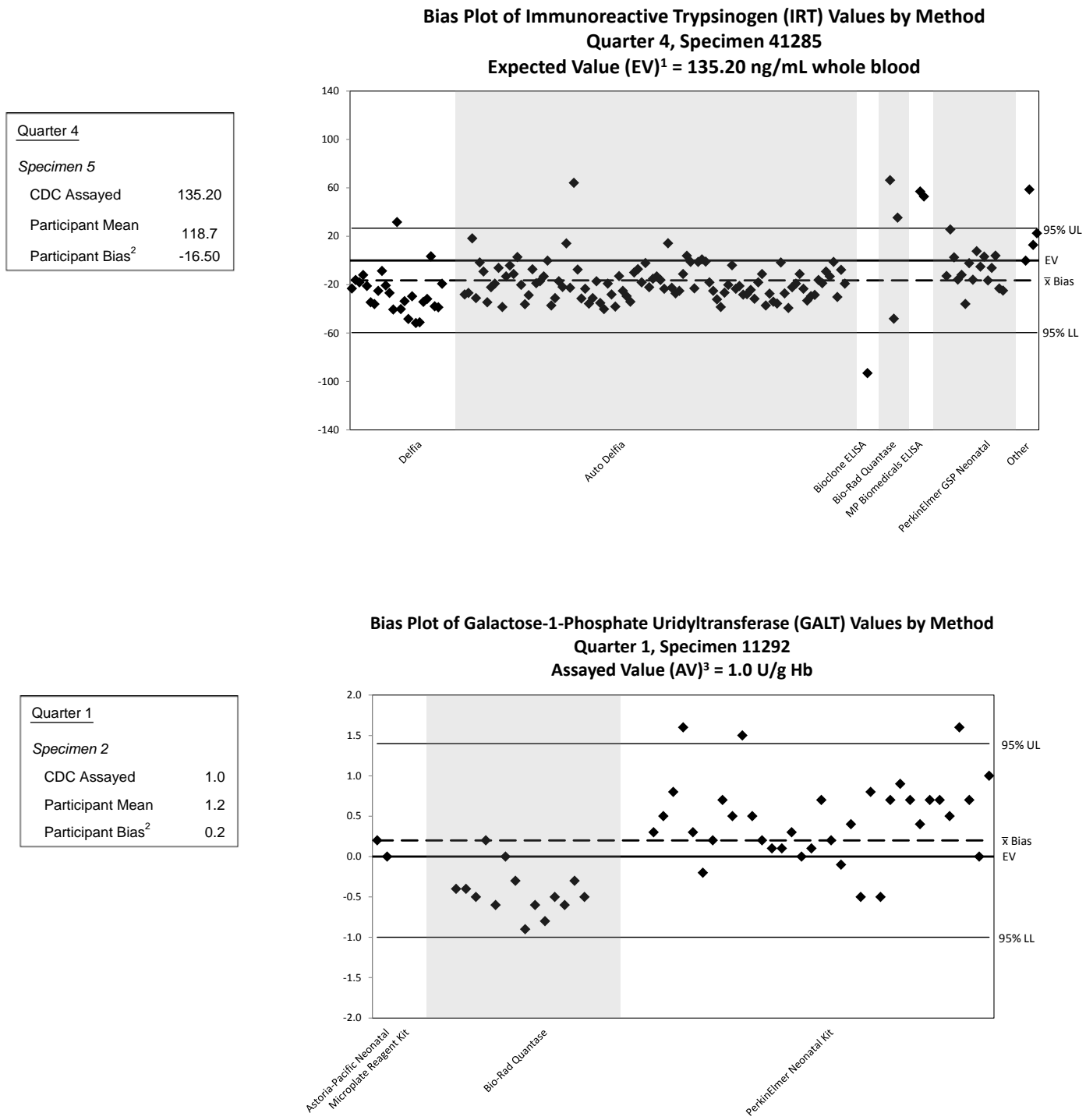


<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

<sup>2</sup>Participant 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.

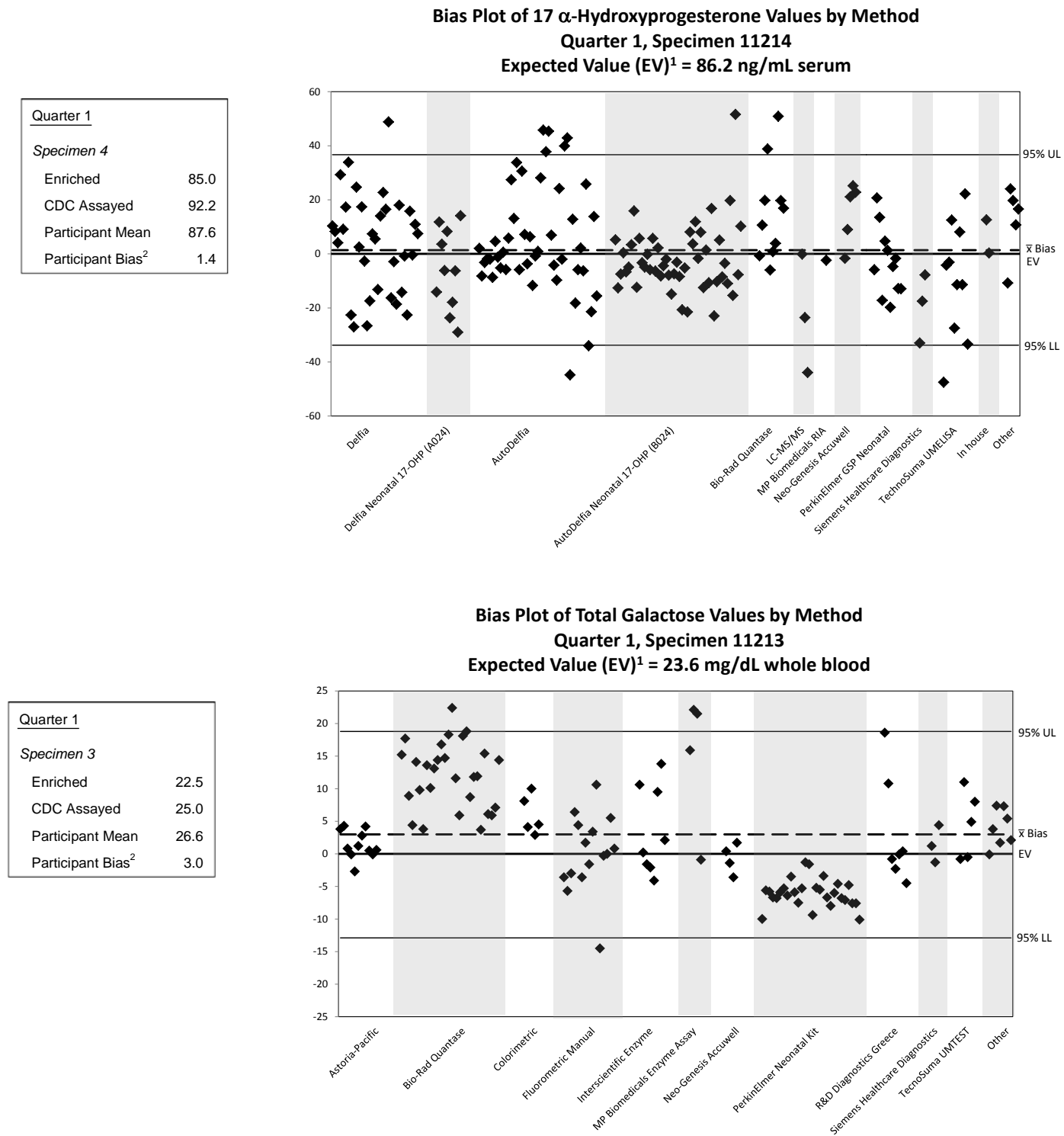
<sup>3</sup>AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 9-10. Reproducibility of Results  
by Different Methods – Immunoreactive Trypsinogen (IRT) and Galactose-1-  
Phosphate Uridyltransferase (GALT)



<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant 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.  
<sup>3</sup>AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 11-12. Reproducibility of Results  
by Different Methods – 17  $\alpha$ -Hydroxyprogesterone and Total Galactose

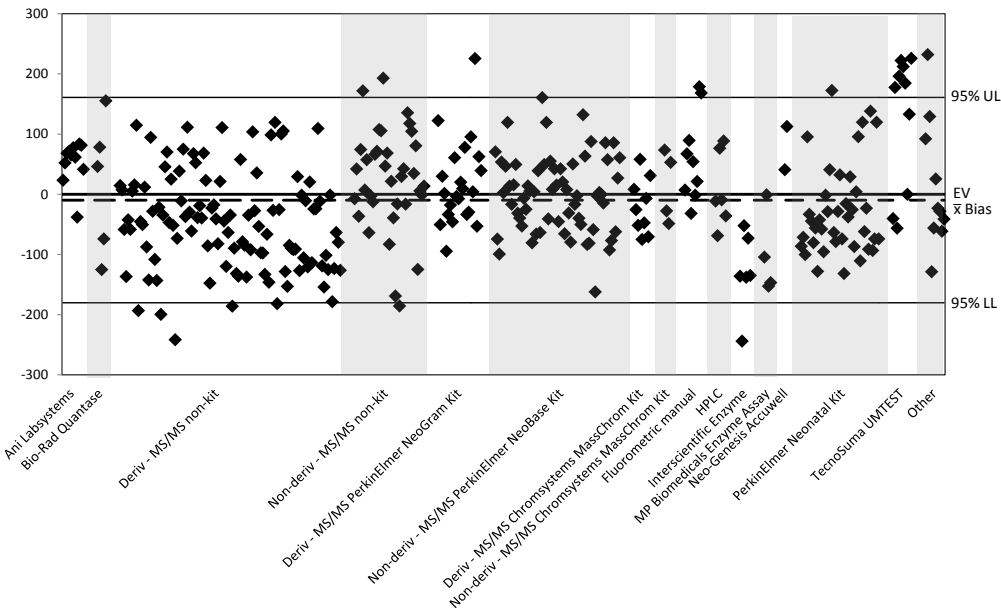


<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant bias ( $\bar{X}$ ) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ( $\bar{X}$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

FIGURES 13-14. Reproducibility of Results by Different Methods – Phenylalanine and Leucine

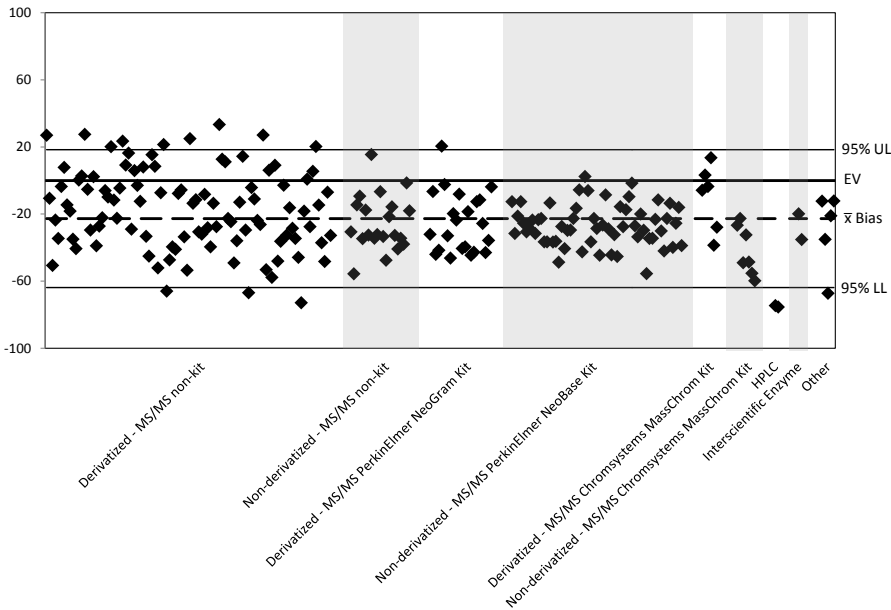
Bias Plot of Phenylalanine Values by Method  
Quarter 3, Specimen 31252  
Expected Value (EV)<sup>1</sup> = 516.62 μmol/L whole blood

Quarter 3	
Specimen 2	
Enriched	450.00
CDC Assayed	476.66
Participant Mean	507.00
Participant Bias <sup>2</sup>	-9.62



Bias Plot of Leucine Values by Method  
Quarter 1, Specimen 11251  
Expected Value (EV)<sup>1</sup> = 149.61 μmol/L whole blood

Quarter 1	
Specimen 1	
CDC Assayed	147.20
Participant Mean	126.94
Participant Bias <sup>2</sup>	-22.67



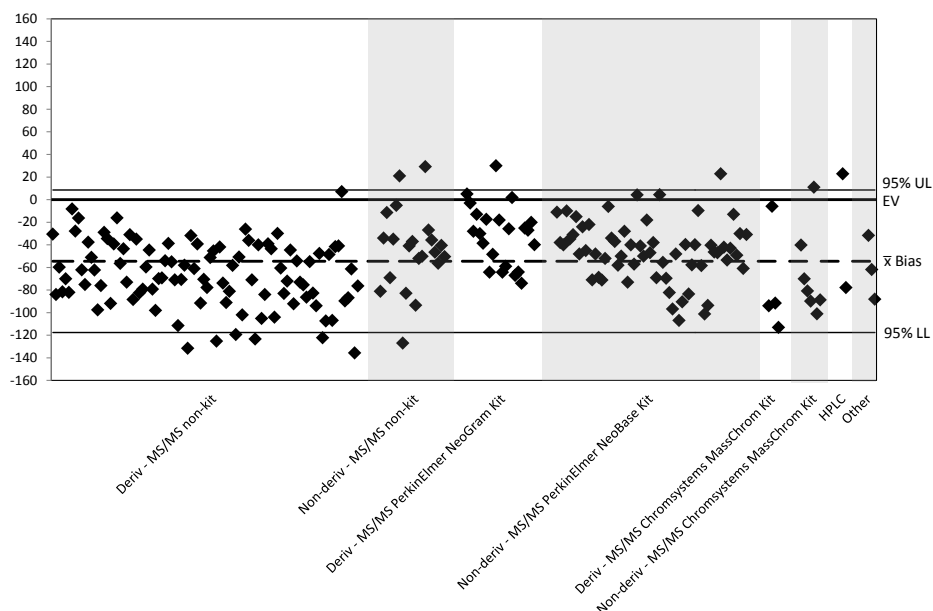
<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant bias ( $\bar{X}$ ) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ( $\bar{X}$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



## FIGURES 15-16. Reproducibility of Results by Different Methods – Methionine and Tyrosine

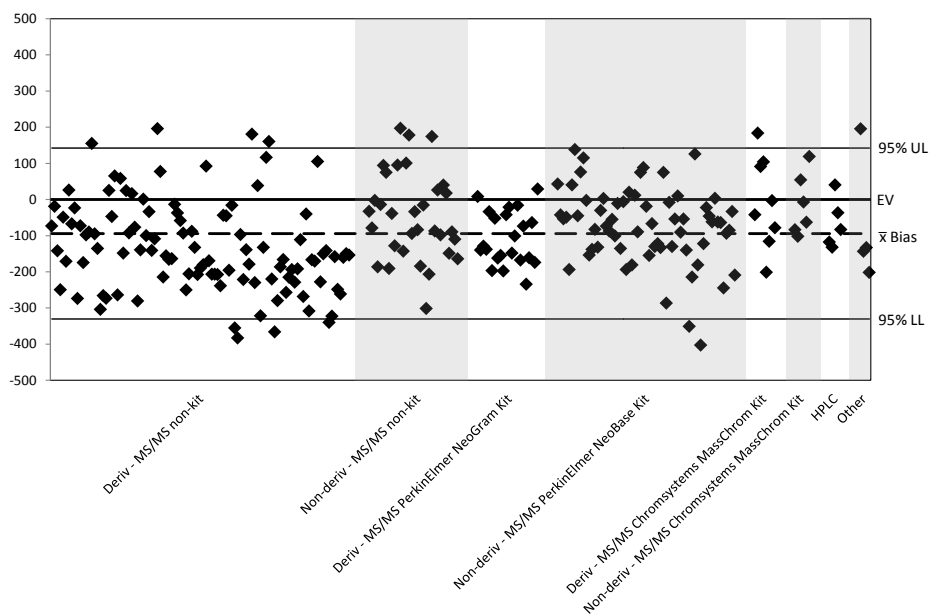
**Bias Plot of Methionine Values by Method**  
**Quarter 1, Specimen 11252**  
**Expected Value (EV)<sup>1</sup> = 274.08  $\mu$ mol/L whole blood**

<b>Quarter 1</b>	
<i>Specimen 2</i>	
Enriched	250.00
CDC Assayed	204.39
Participant Mean	219.49
Participant Bias <sup>2</sup>	-54.59



**Bias Plot of Tyrosine Values by Method**  
**Quarter 3, Specimen 31255**  
**Expected Value (EV)<sup>1</sup> = 798.92  $\mu$ mol/L whole blood**

<b>Quarter 3</b>	
<i>Specimen 5</i>	
Enriched	750.00
CDC Assayed	722.50
Participant Mean	704.68
Participant Bias <sup>2</sup>	-94.22



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

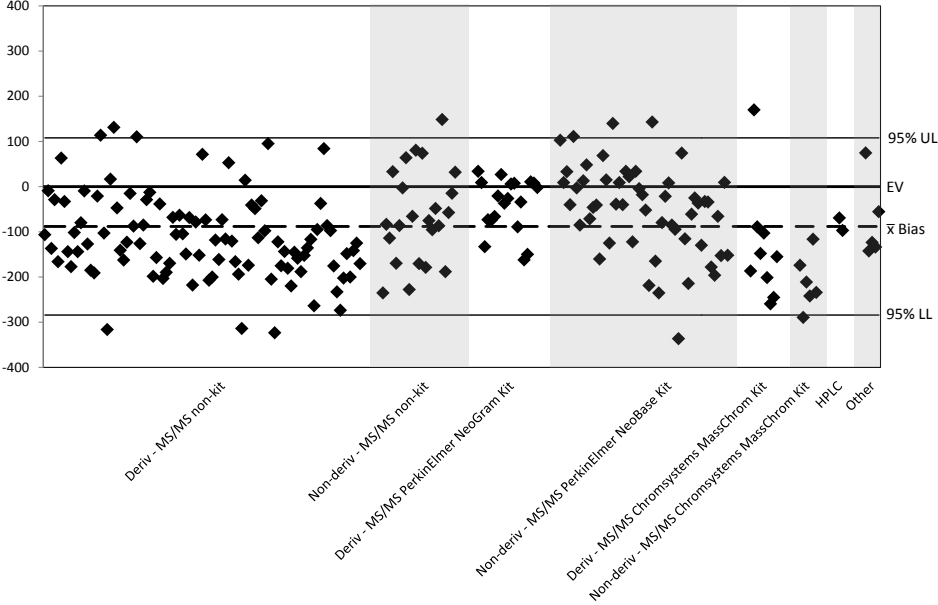
<sup>2</sup>Participant bias ( $\bar{X}$ ) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ( $\bar{X}$ ) excludes outlier values. The 95% confidence interval is shown.

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

FIGURES 17-18. Reproducibility of Results by Different Methods – Valine and Citrulline

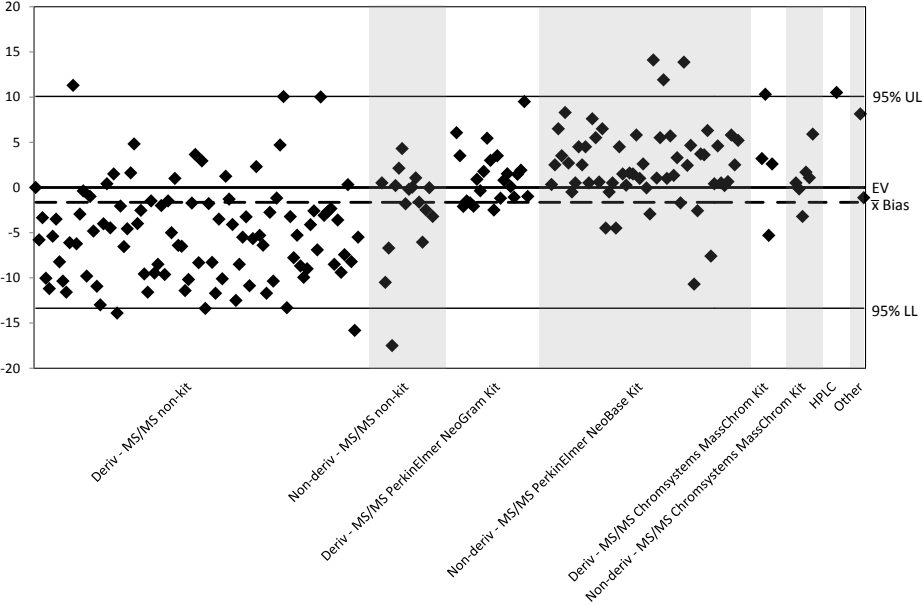
Bias Plot of Valine Values by Method  
Quarter 3, Specimen 31254  
Expected Value (EV)<sup>1</sup> = 564.13 μmol/L whole blood

Quarter 3	
Specimen 4	
Enriched	400.00
CDC Assayed	468.17
Participant Mean	476.03
Participant Bias <sup>2</sup>	-88.10



Bias Plot of Citrulline Values by Method  
Quarter 1, Specimen 11251  
Expected Value (EV)<sup>1</sup> = 26.50 μmol/L whole blood

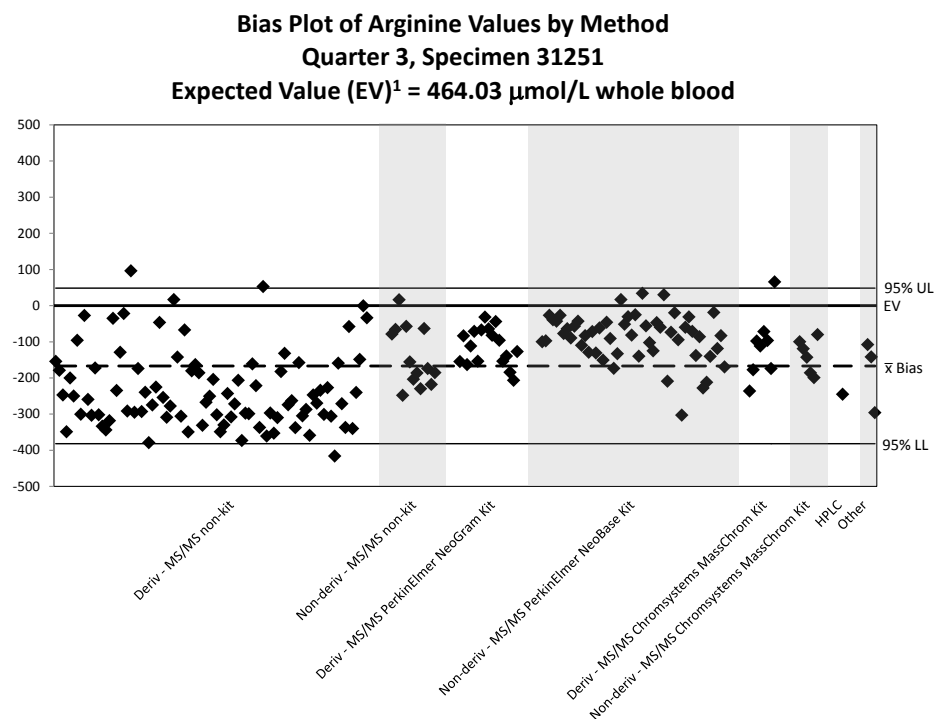
Quarter 1	
Specimen 1	
CDC Assayed	43.05
Participant Mean	24.86
Participant Bias <sup>2</sup>	-1.64



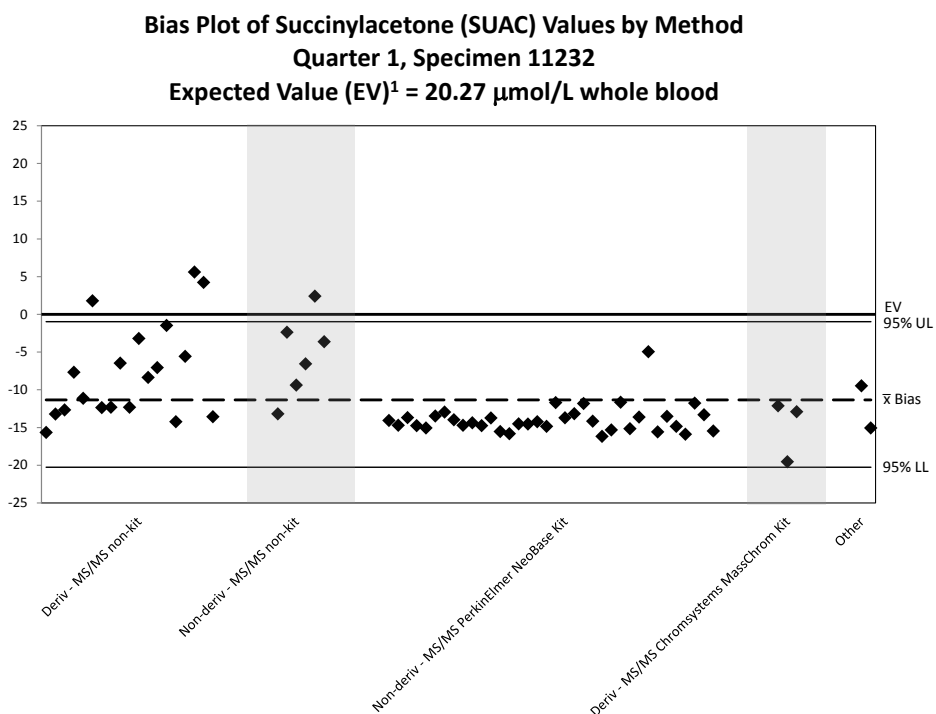
<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant bias ( $\bar{X}$ ) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ( $\bar{X}$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

## FIGURES 19-20. Reproducibility of Results by Different Methods – Arginine and Succinylacetone (SUAC)

<b>Quarter 3</b>	
<i>Specimen 1</i>	
Enriched	400.00
CDC Assayed	463.13
Participant Mean	297.19
Participant Bias <sup>2</sup>	-166.84



<b>Quarter 1</b>	
<i>Specimen 2</i>	
Enriched	20.00
CDC Assayed	6.25
Participant Mean	8.92
Participant Bias <sup>2</sup>	-11.35



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

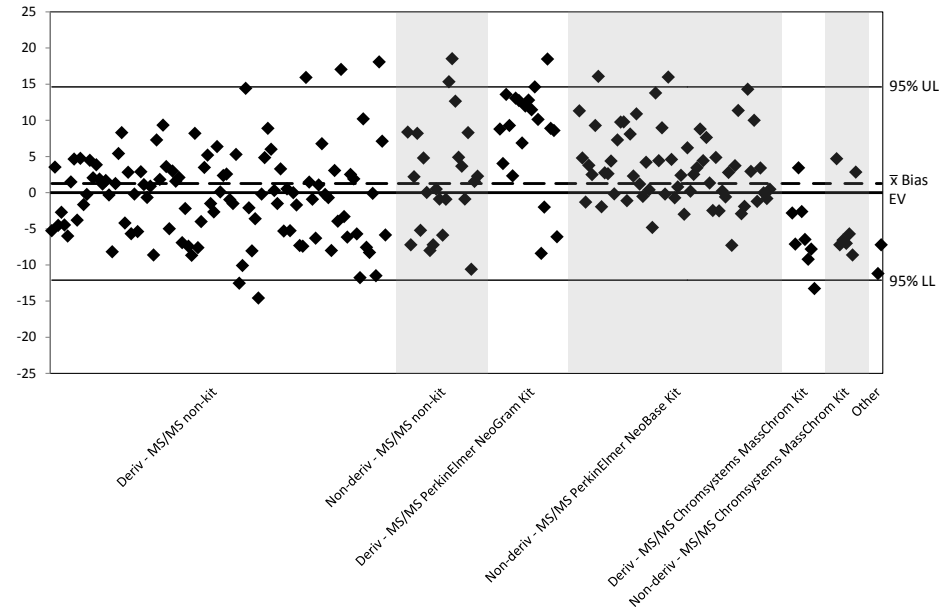
<sup>2</sup>Participant bias ( $\bar{X}$ ) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ( $\bar{X}$ ) excludes outlier values. The 95% confidence interval is shown.

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

FIGURES 21-22. Reproducibility of Results  
by Different Methods – Free Carnitine C0(L) and Propionylcarnitine (C3)

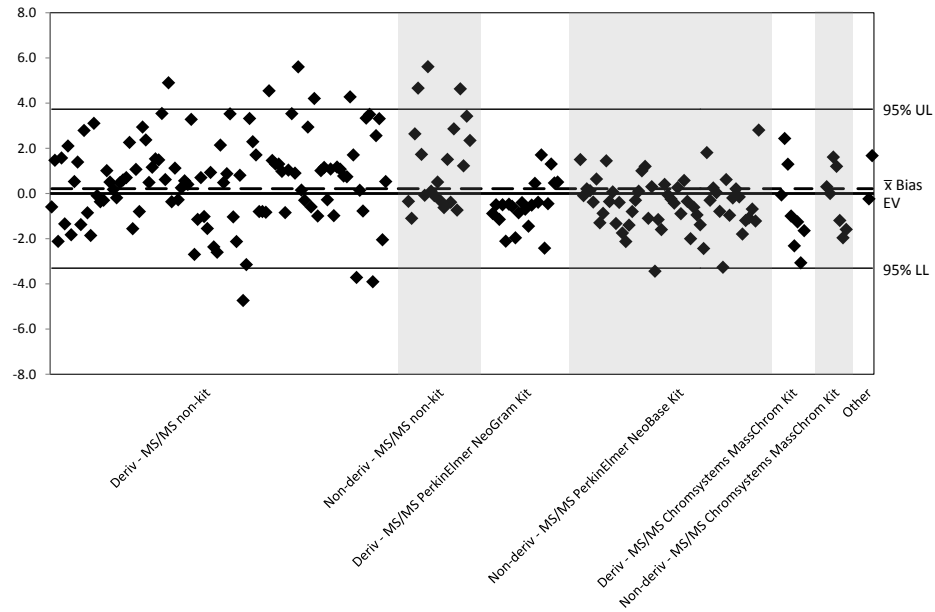
Bias Plot of Free Carnitine (C0(L)) Values by Method  
Quarter 1, Specimen 11262  
Expected Value (EV)<sup>1</sup> = 35.22 µmol/L whole blood

Quarter 1	
Specimen 2	
CDC Assayed	36.50
Participant Mean	36.49
Participant Bias <sup>2</sup>	1.29



Bias Plot of Propionylcarnitine (C3) Values by Method  
Quarter 1, Specimen 11263  
Expected Value (EV)<sup>1</sup> = 11.10 µmol/L whole blood

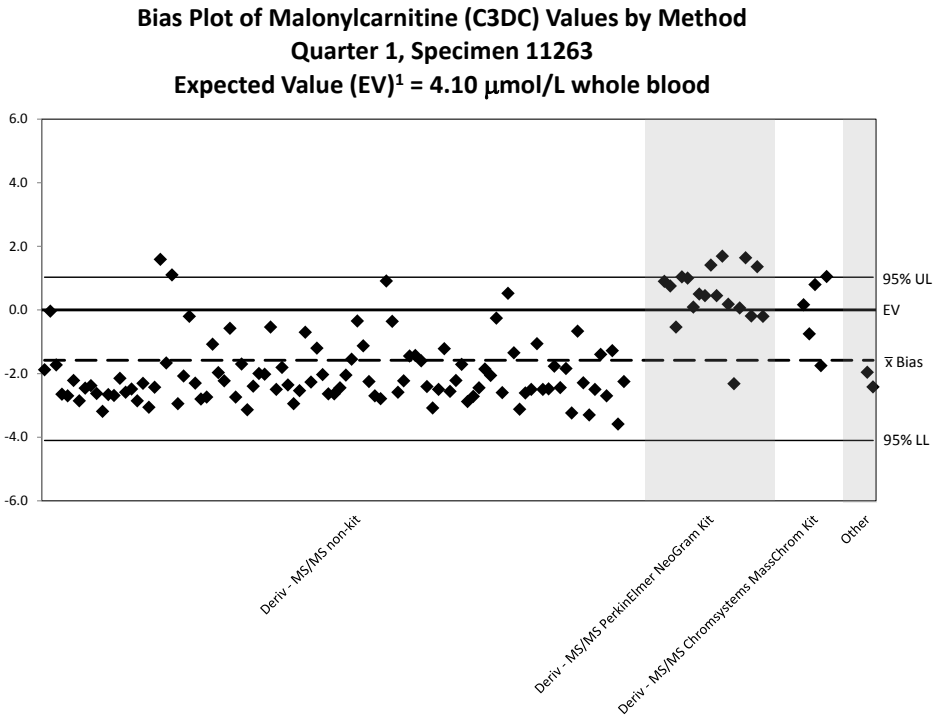
Quarter 1	
Specimen 3	
CDC Assayed	13.25
Participant Mean	11.30
Participant Bias <sup>2</sup>	0.20



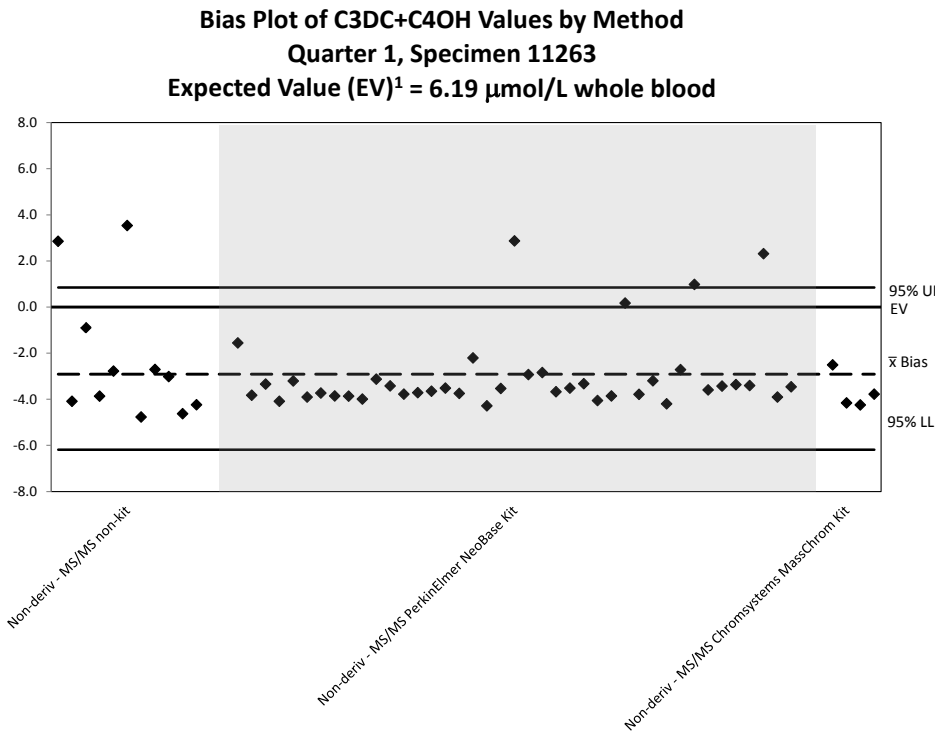
<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant bias ( $\bar{X}$ ) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ( $\bar{X}$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

FIGURES 23-24. Reproducibility of Results  
by Different Methods – Malonylcarnitine (C3DC) and  
C3DC+C4OH Non-derivatized

Quarter 1	
Specimen 3	
Enriched	4.00
CDC Assayed	2.75
Participant Mean	2.52
Participant Bias <sup>2</sup>	-1.58



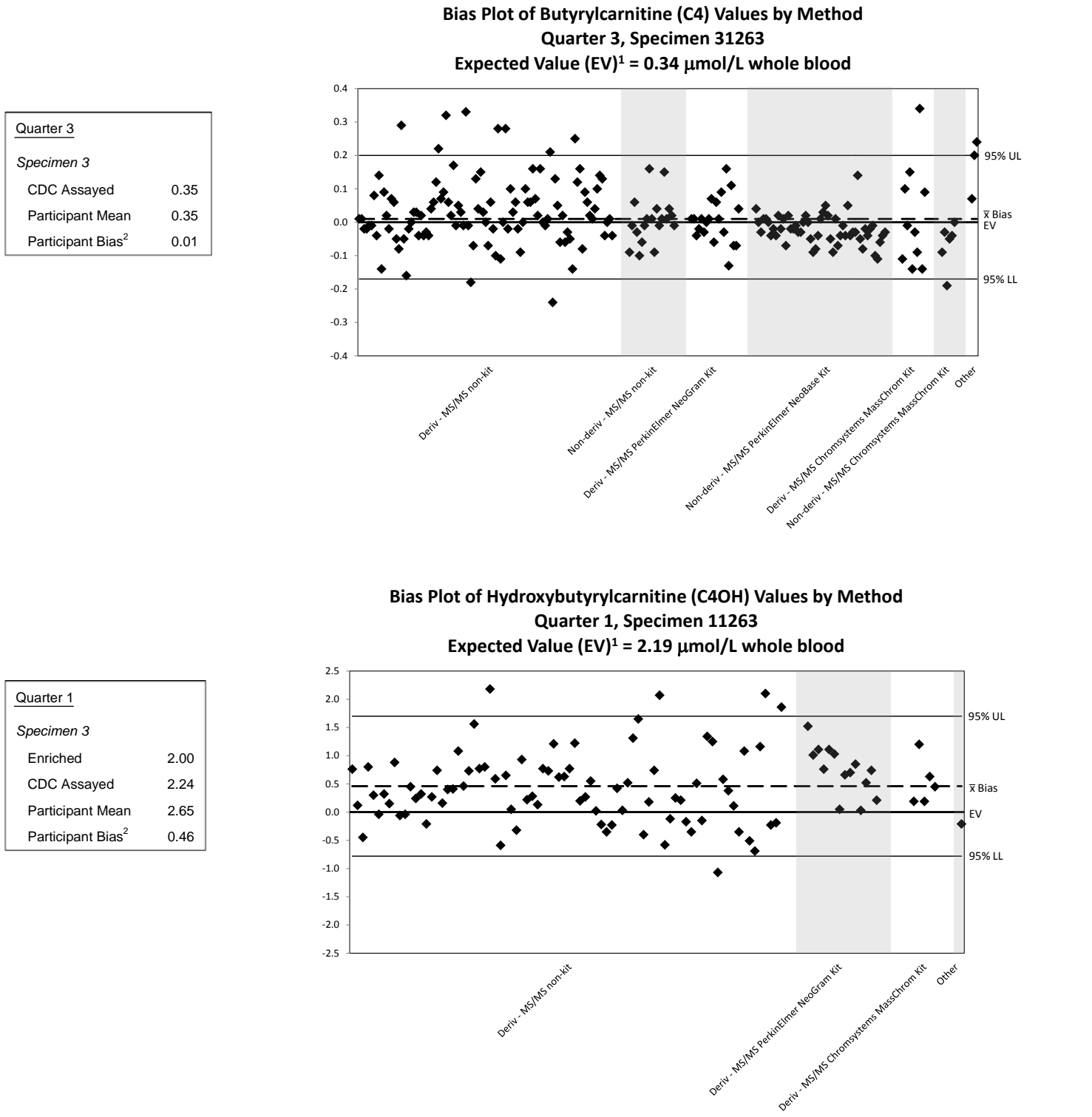
Quarter 1	
Specimen 3	
Enriched	6.00
CDC Assayed	2.75
Participant Mean	3.28
Participant Bias <sup>2</sup>	-2.91



<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant 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.  
<sup>3</sup>AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

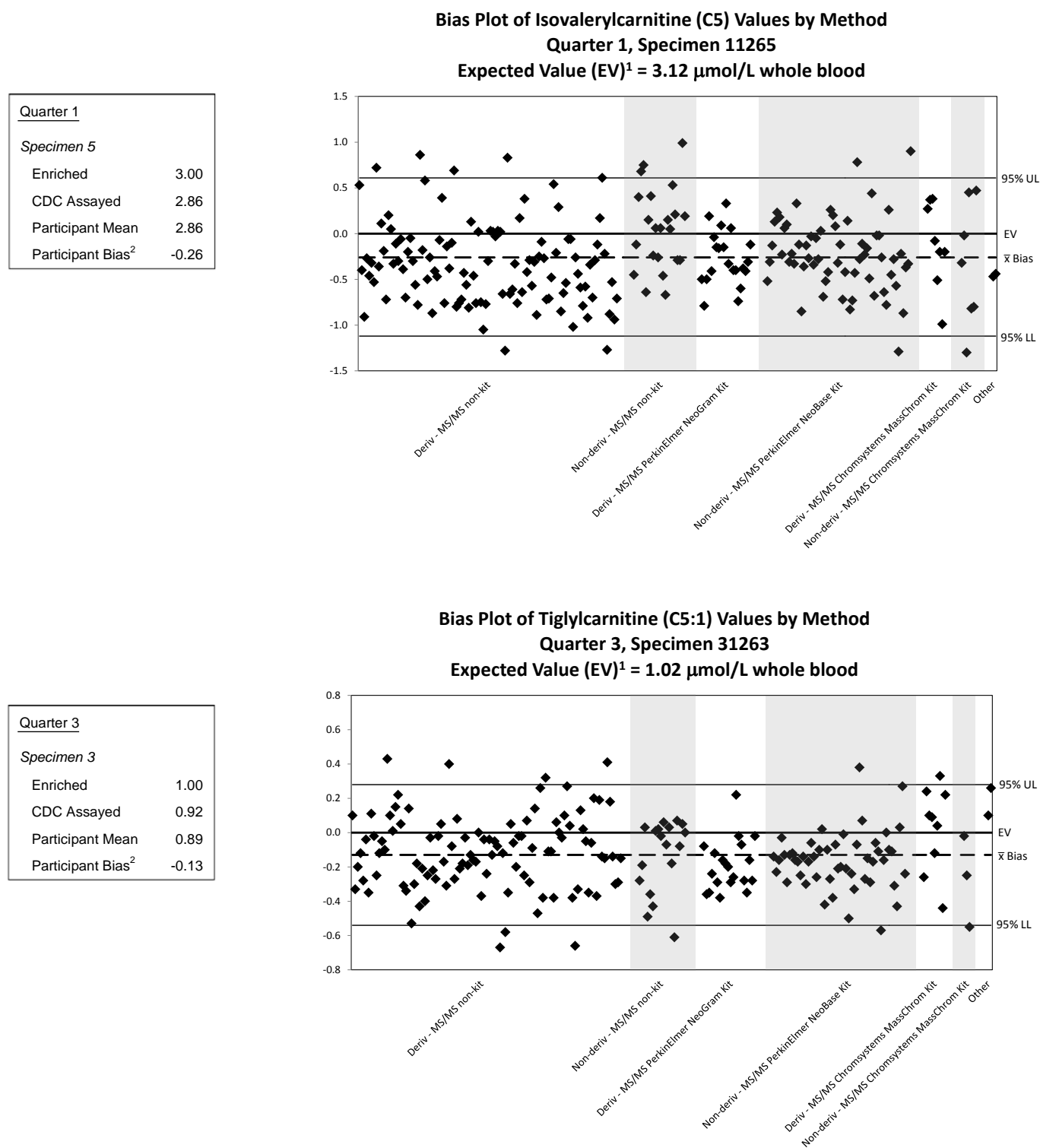


FIGURES 25-26. Reproducibility of Results  
by Different Methods – Butyrylcarnitine (C4) and Hydroxybutyrylcarnitine (C4OH)



<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant 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.  
<sup>3</sup>AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

## FIGURES 27-28. Reproducibility of Results by Different Methods – Isovalerylcarnitine (C5) and Tiglylcarnitine (C5:1)



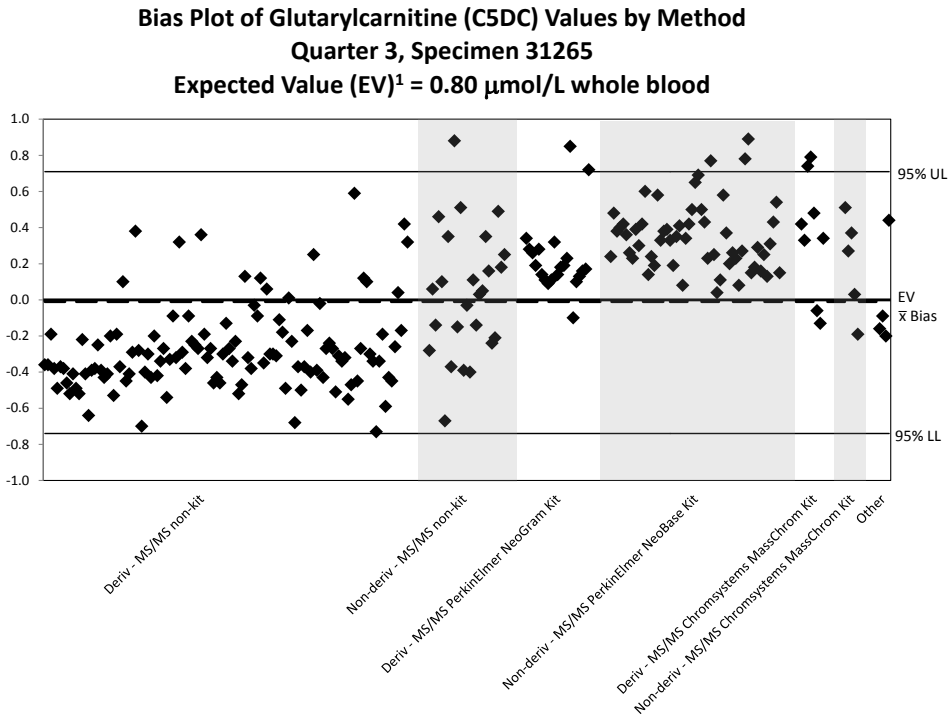
<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

<sup>2</sup>Participant 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.

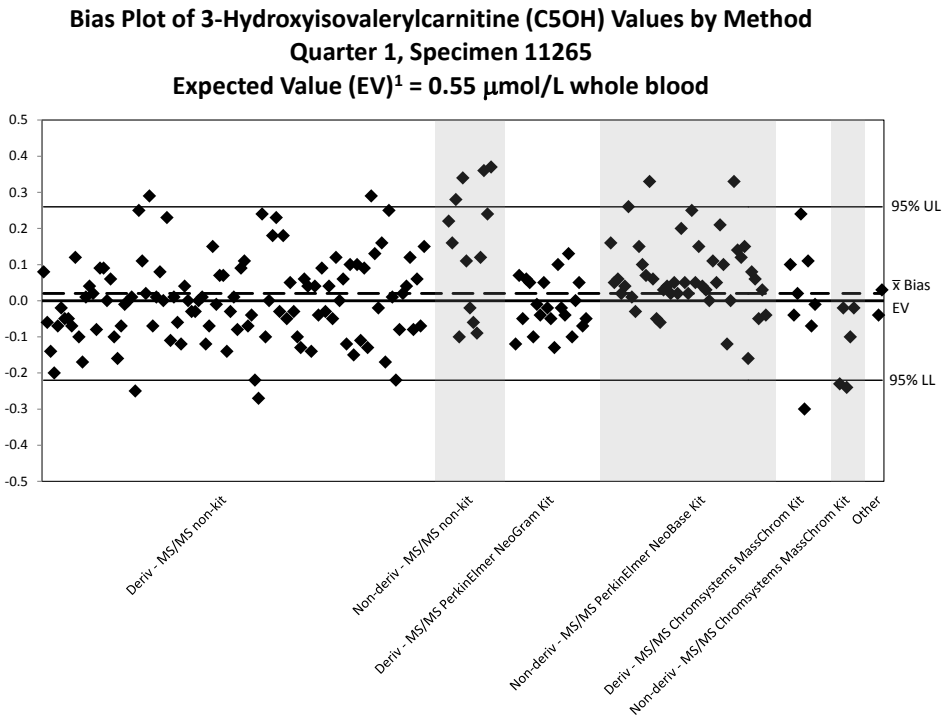
<sup>3</sup>AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 29-30. Reproducibility of Results  
by Different Methods – Glutarylcarnitine (C5DC) and  
3-Hydroxyisovalerylcarnitine (C5OH)

Quarter 3	
Specimen 5	
Enriched	0.75
CDC Assayed	0.61
Participant Mean	0.79
Participant Bias <sup>2</sup>	-0.01

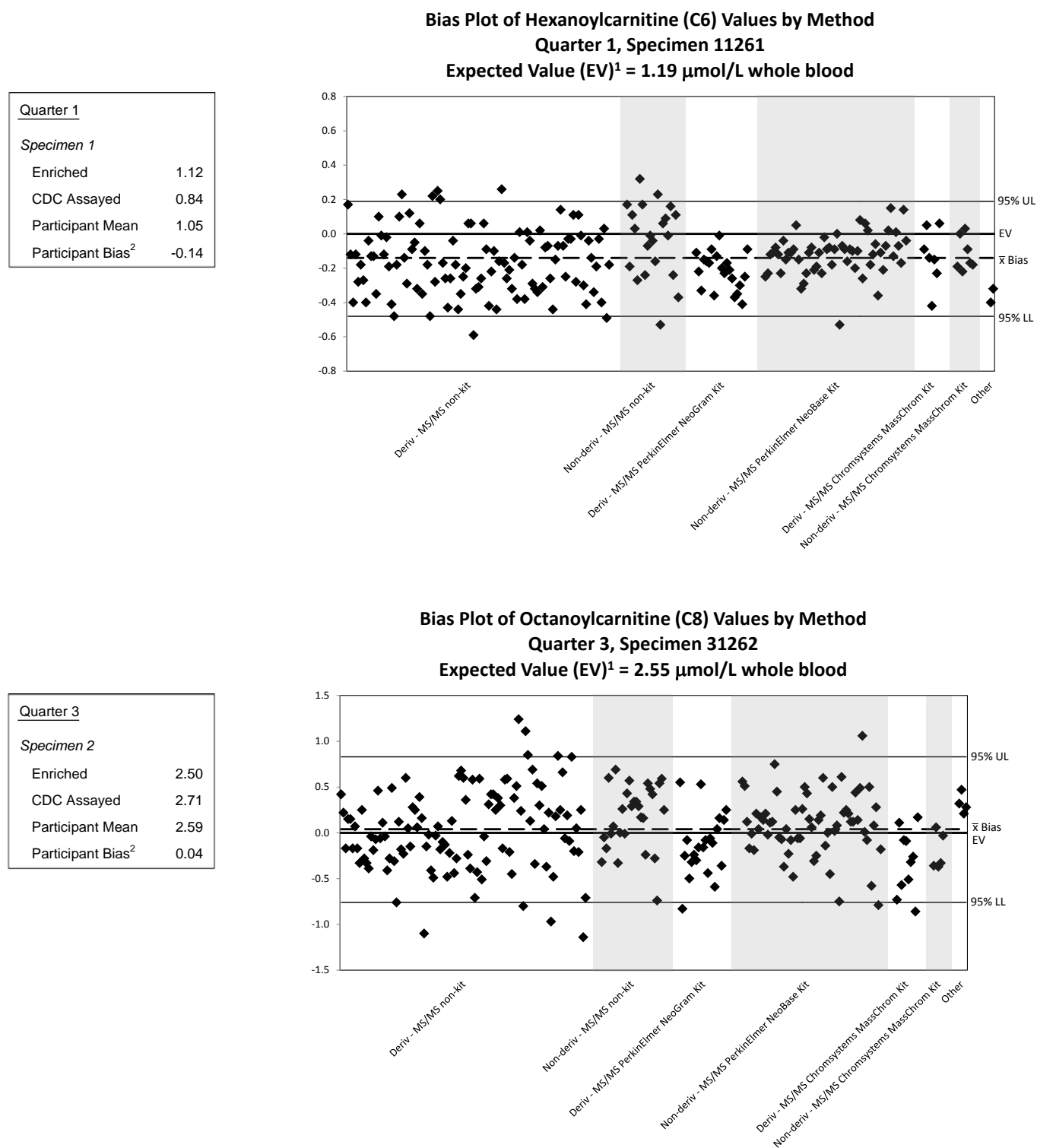


Quarter 1	
Specimen 5	
CDC Assayed	0.58
Participant Mean	0.57
Participant Bias <sup>2</sup>	0.02



<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant 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.  
<sup>3</sup>AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

## FIGURES 31-32. Reproducibility of Results by Different Methods – Hexanoylcarnitine (C6) and Octanoylcarnitine (C8)

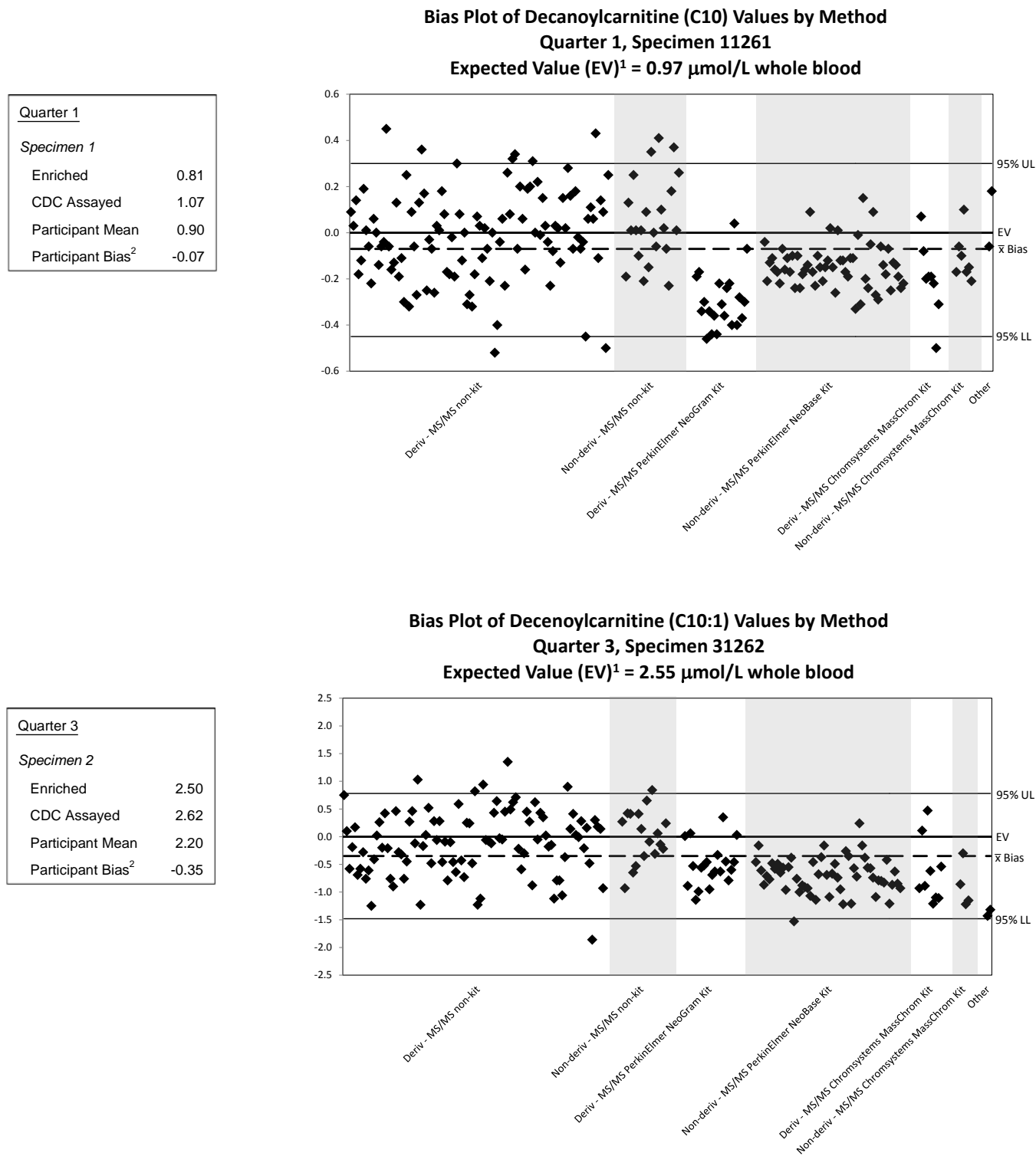


<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

<sup>2</sup>Participant 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.

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

FIGURES 33-34. Reproducibility of Results  
by Different Methods – Decanoylcarnitine (C10) and Decenoylcarnitine (C10:1)



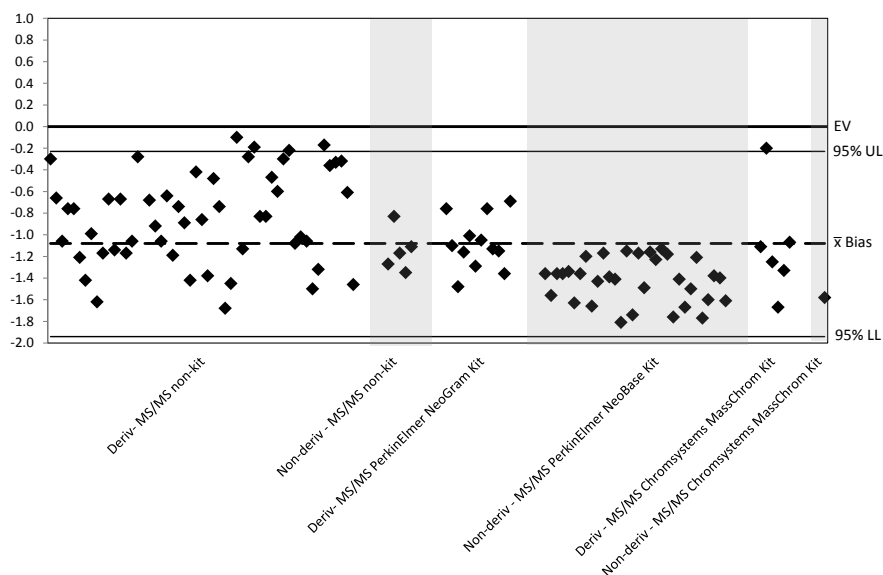
<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant bias ( $\bar{X}$ ) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ( $\bar{X}$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



## FIGURES 35-36. Reproducibility of Results by Different Methods – Decadienoylcarnitine (C10:2) and Myristoylcarnitine (C14)

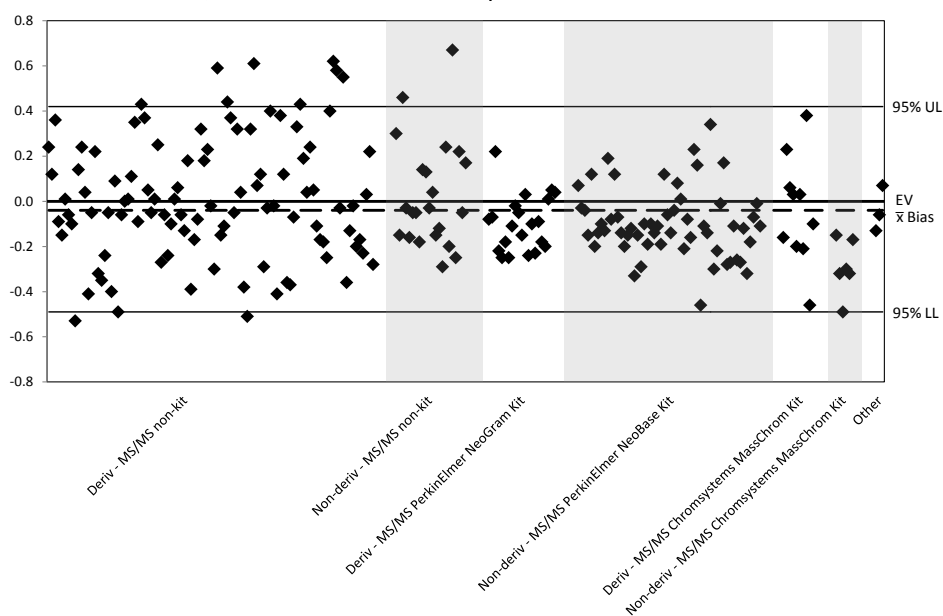
**Bias Plot of Decadienoylcarnitine (C10:2) Values by Method**  
Quarter 3, Specimen 31262  
Expected Value (EV)<sup>1</sup> = 2.51  $\mu\text{mol/L}$  whole blood

<u>Quarter 3</u>	
<i>Specimen 2</i>	
Enriched	2.50
CDC Assayed	1.76
Participant Mean	1.43
Participant Bias <sup>2</sup>	-1.08



**Bias Plot of Myristoylcarnitine (C14) Values by Method**  
Quarter 3, Specimen 31264  
Expected Value (EV)<sup>1</sup> = 1.39  $\mu\text{mol/L}$  whole blood

<u>Quarter 3</u>	
<i>Specimen 4</i>	
Enriched	1.32
CDC Assayed	1.52
Participant Mean	1.35
Participant Bias <sup>2</sup>	-0.04



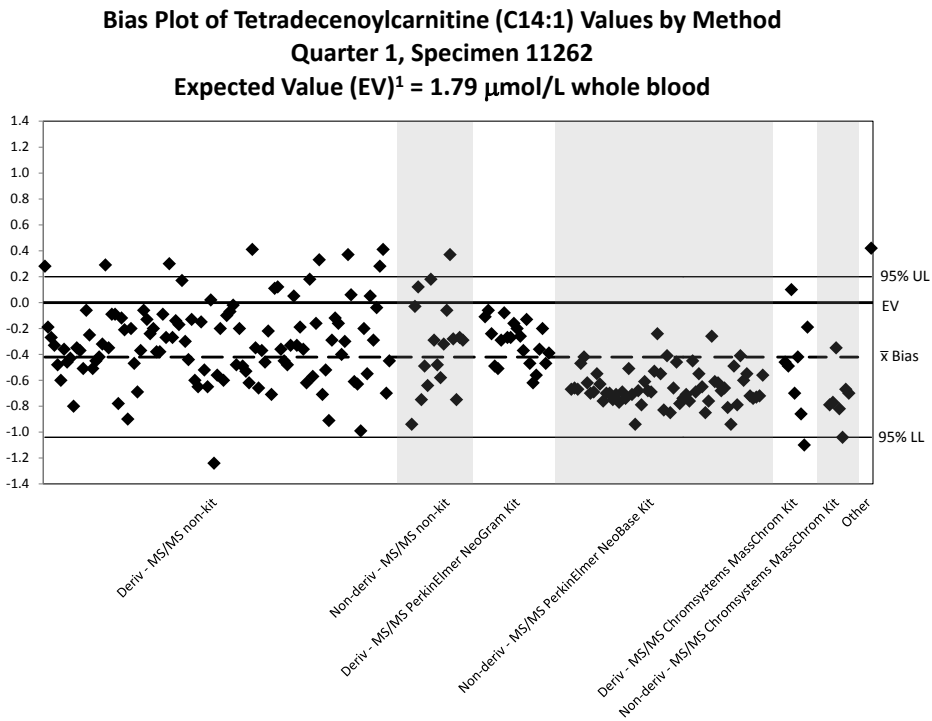
<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

<sup>2</sup>Participant 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.

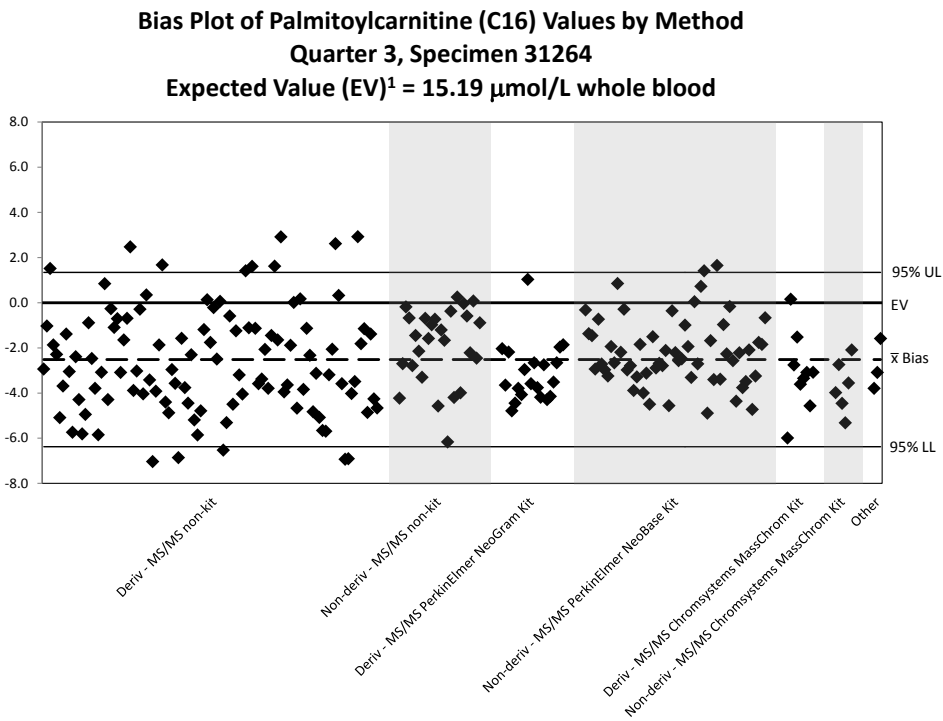
<sup>3</sup>AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 37-38. Reproducibility of Results  
by Different Methods – Tetradecenoylcarnitine (C14:1) and  
Palmitoylcarnitine (C16)

Quarter 1	
Specimen 2	
Enriched	1.75
CDC Assayed	1.54
Participant Mean	1.37
Participant Bias <sup>2</sup>	-0.42



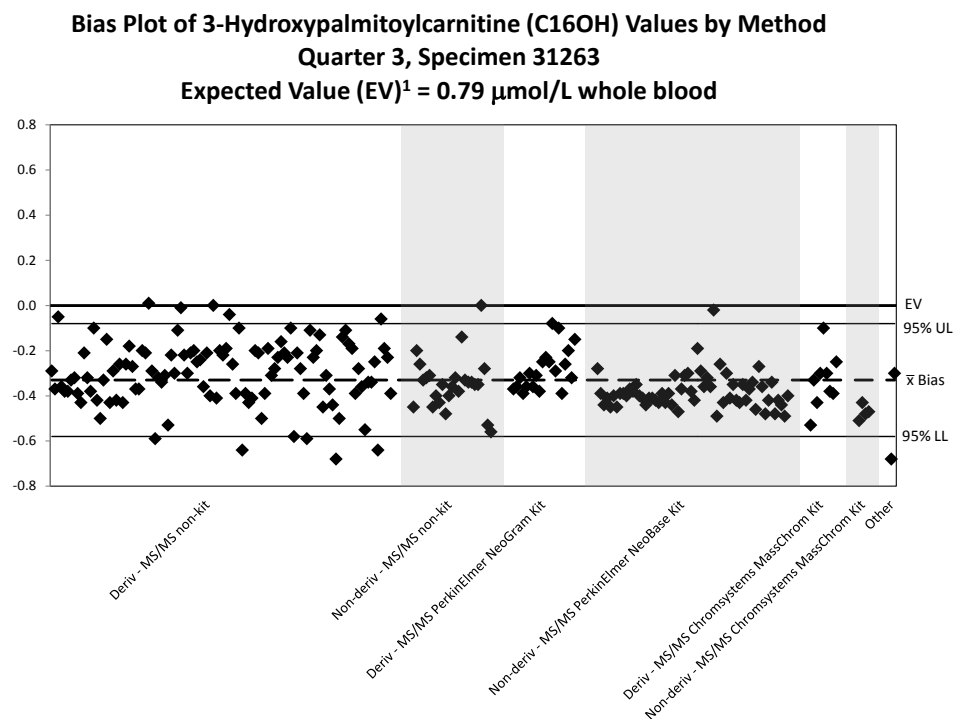
Quarter 3	
Specimen 4	
Enriched	14.47
CDC Assayed	12.45
Participant Mean	12.67
Participant Bias <sup>2</sup>	-2.52



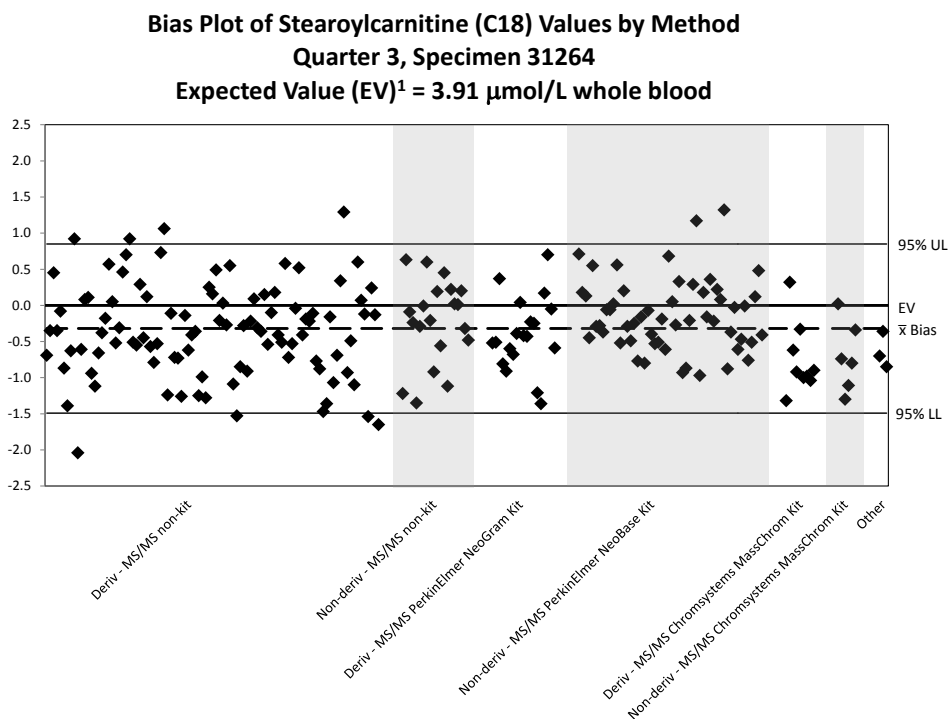
<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant bias ( $\bar{X}$ ) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ( $\bar{X}$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

## FIGURES 39-40. Reproducibility of Results by Different Methods – 3-Hydroxypalmitoylcarnitine (C16OH) and Stearoylcarnitine (C18)

Quarter 3	
Specimen 3	
Enriched	0.75
CDC Assayed	0.48
Participant Mean	0.46
Participant Bias <sup>2</sup>	-0.33



Quarter 3	
Specimen 4	
Enriched	3.30
CDC Assayed	3.40
Participant Mean	3.59
Participant Bias <sup>2</sup>	-0.32



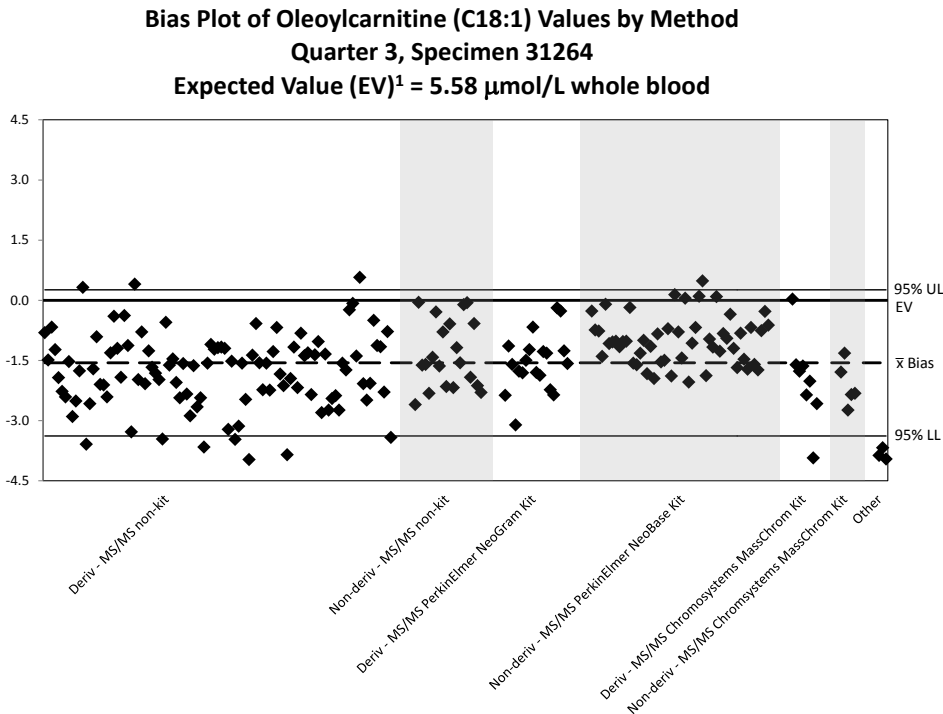
<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

<sup>2</sup>Participant 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.

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

FIGURE 41. Reproducibility of Results  
by Different Methods – Oleoylcarnitine (C18:1)

Quarter 3	
Specimen 4	
Enriched	4.45
CDC Assayed	4.43
Participant Mean	4.02
Participant Bias <sup>2</sup>	-1.56



<sup>1</sup>EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.  
<sup>2</sup>Participant 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.  
<sup>3</sup>AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

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Table 15a. 2012 Quality Control Data  
Summaries of Statistical Analyses

**IMMUNOREACTIVE TRYPSINOGEN (ng IRT/mL whole blood)**

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 291 - Assayed 15.2 ng/mL whole blood						
MP Biomedicals ELISA	50	21.8	3.1	8.3	15.9	0.5
Delfia	381	13.2	2.0	2.5	-2.3	1.0
AutoDelfia	1303	12.7	1.3	1.7	-2.1	1.0
Bio-Rad Quantase	108	12.3	2.0	4.5	0.5	0.6
Bioclone ELISA	40	9.5	2.0	4.0	2.8	0.4
PerkinElmer GSP Neonatal	195	13.7	1.1	1.2	-2.6	1.0
Lot 292 - Assayed 45.2 ng/mL whole blood						
MP Biomedicals ELISA	50	39.6	5.6	16.0	15.9	0.5
Delfia	384	43.0	4.6	5.8	-2.3	1.0
AutoDelfia	1329	42.1	3.8	4.7	-2.1	1.0
Bio-Rad Quantase	110	28.4	4.8	10.3	0.5	0.6
Bioclone ELISA	40	21.8	2.6	13.6	2.8	0.4
PerkinElmer GSP Neonatal	195	43.8	3.0	3.1	-2.6	1.0
Lot 293 - Assayed 85.1 ng/mL whole blood						
MP Biomedicals ELISA	50	60.8	7.9	25.2	15.9	0.5
Delfia	378	80.8	9.2	11.4	-2.3	1.0
AutoDelfia	1277	80.4	6.4	7.9	-2.1	1.0
Bio-Rad Quantase	106	52.6	10.1	18.2	0.5	0.6
Bioclone ELISA	40	36.8	6.2	26.0	2.8	0.4
PerkinElmer GSP Neonatal	190	81.6	5.0	5.3	-2.6	1.0
Lot 294 - Assayed 139.9 ng/mL whole blood						
MP Biomedicals ELISA	50	84.8	10.9	33.4	15.9	0.5
Delfia	386	137.5	14.7	18.7	-2.3	1.0
AutoDelfia	1334	134.2	11.3	13.8	-2.1	1.0
Bio-Rad Quantase	108	92.2	18.7	29.8	0.5	0.6
Bioclone ELISA	40	61.3	9.3	32.0	2.8	0.4
PerkinElmer GSP Neonatal	200	141.2	10.8	11.3	-2.6	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 15b. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 101 - Assayed 1.8 $\mu\text{g}/\text{dL}$ serum						
Siemens Healthcare Diagnostics	50	2.1	0.4	0.5	0.6	1.0
Neo-Genesis Accuwell	38	1.6	0.3	0.3	0.0	0.9
Delfia	197	1.7	0.3	0.3	0.2	0.8
AutoDelfia	483	1.6	0.3	0.3	0.2	0.8
Interscientific NeoMAP Multiplex	48	1.8	0.5	0.5	0.0	1.0
PerkinElmer GSP Neonatal	134	1.6	0.3	0.3	0.1	0.8
Lot 102 - Assayed 7.1 $\mu\text{g}/\text{dL}$ serum						
Siemens Healthcare Diagnostics	50	8.2	1.0	1.8	0.6	1.0
Neo-Genesis Accuwell	39	6.1	1.0	1.7	0.0	0.9
Delfia	200	6.2	0.6	0.8	0.2	0.8
AutoDelfia	492	5.9	0.5	0.6	0.2	0.8
Interscientific NeoMAP Multiplex	47	7.5	0.9	0.9	0.0	1.0
PerkinElmer GSP Neonatal	135	6.1	0.6	0.6	0.1	0.8
Lot 103 - Assayed 11.2 $\mu\text{g}/\text{dL}$ serum						
Siemens Healthcare Diagnostics	50	11.1	1.1	1.5	0.6	1.0
Neo-Genesis Accuwell	40	9.6	1.0	2.5	0.0	0.9
Delfia	200	9.5	0.9	1.3	0.2	0.8
AutoDelfia	493	9.1	0.8	0.9	0.2	0.8
Interscientific NeoMAP Multiplex	50	11.4	0.8	1.9	0.0	1.0
PerkinElmer GSP Neonatal	137	9.4	0.8	0.9	0.1	0.8

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

Table 15c. 2012 Quality Control Data  
Summaries of Statistical Analyses

**THYROID-STIMULATING HORMONE** ( $\mu$ IU TSH/mL serum)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 111 - Enriched 25 μU/mL serum						
Siemens Healthcare Diagnostics	28	29.4	3.1	3.4	-3.6	1.3
Neo-Genesis Accuwell	48	24.3	2.3	2.3	-4.0	1.1
Delfia	472	25.7	2.4	3.9	-2.1	1.1
AutoDelfia	830	26.4	1.9	2.9	-1.5	1.1
Ani Labsystems	74	25.7	3.3	3.6	-2.5	1.1
Bio-Rad Quantase	110	31.5	3.0	11.1	3.7	1.1
TecnoSuma UMELISA	20	28.6	3.4	6.0	-7.5	1.4
Bioclone ELISA	30	33.8	4.2	12.2	6.8	1.1
DiaSorin	98	27.6	1.9	3.0	1.2	1.0
PerkinElmer GSP Neonatal	133	24.7	2.6	2.9	-5.4	1.2
In House	70	25.3	2.3	4.3	-1.9	1.1
Lot 112 - Enriched 40 μU/mL serum						
Siemens Healthcare Diagnostics	26	48.5	4.0	5.4	-3.6	1.3
Neo-Genesis Accuwell	50	41.1	3.7	4.7	-4.0	1.1
Delfia	479	40.3	4.1	6.3	-2.1	1.1
AutoDelfia	833	42.2	3.4	4.9	-1.5	1.1
Ani Labsystems	77	42.8	4.0	6.0	-2.5	1.1
Bio-Rad Quantase	109	48.8	3.9	8.9	3.7	1.1
TecnoSuma UMELISA	18	49.9	4.1	4.1	-7.5	1.4
Bioclone ELISA	30	52.2	6.1	23.2	6.8	1.1
DiaSorin	99	41.4	3.7	7.2	1.2	1.0
PerkinElmer GSP Neonatal	134	39.5	3.2	3.7	-5.4	1.2
In House	69	40.7	3.8	6.8	-1.9	1.1
Lot 113 - Enriched 80 μU/mL serum						
Siemens Healthcare Diagnostics	29	101.3	9.6	14.0	-3.6	1.3
Neo-Genesis Accuwell	48	86.3	7.8	10.2	-4.0	1.1
Delfia	468	84.9	6.9	10.4	-2.1	1.1
AutoDelfia	837	86.9	6.0	8.7	-1.5	1.1
Ani Labsystems	74	87.9	10.2	18.9	-2.5	1.1
Bio-Rad Quantase	106	93.4	12.2	19.4	3.7	1.1
TecnoSuma UMELISA	20	107.7	16.5	22.0	-7.5	1.4
Bioclone ELISA	30	95.2	7.5	18.4	6.8	1.1
DiaSorin	96	83.8	6.2	8.8	1.2	1.0
PerkinElmer GSP Neonatal	133	87.7	6.2	8.0	-5.4	1.2
In House	70	84.3	6.6	13.5	-1.9	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.

**THYROID-STIMULATING HORMONE** (μIU TSH/mL serum)

- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 211 - Enriched 25 μIU/mL serum						
Siemens Healthcare Diagnostics	20	33.2	3.9	4.7	6.4	1.1
Neo-Genesis Accuwell	10	28.7	3.4	3.4	7.9	0.9
Delfia	520	27.0	2.6	3.9	7.3	0.8
AutoDelfia	849	28.4	2.2	3.0	8.0	0.9
Ani Labsystems	70	26.9	2.7	3.4	3.8	1.0
Bio-Rad Quantase	120	33.9	2.2	9.4	12.0	0.9
TecnoSuma UMELISA	20	24.9	4.4	4.4	11.9	0.6
Bioclone ELISA	20	26.3	4.5	4.5	7.7	0.8
DiaSorin	77	29.0	2.7	4.1	10.9	0.8
Interscientific NeoMAP Multiplex	10	20.3	0.6	0.6	2.8	0.7
PerkinElmer GSP Neonatal	162	28.0	2.7	3.3	8.4	0.8
In House	50	24.4	3.3	6.3	3.1	0.9
Lot 212 - Enriched 40 μIU/mL serum						
Siemens Healthcare Diagnostics	20	52.7	5.2	7.7	6.4	1.1
Neo-Genesis Accuwell	10	43.7	3.7	3.7	7.9	0.9
Delfia	519	41.5	3.6	5.6	7.3	0.8
AutoDelfia	856	43.6	3.4	4.6	8.0	0.9
Ani Labsystems	67	42.8	4.1	4.2	3.8	1.0
Bio-Rad Quantase	120	48.7	3.8	13.5	12.0	0.9
TecnoSuma UMELISA	20	38.5	5.3	5.3	11.9	0.6
Bioclone ELISA	19	44.8	7.7	8.9	7.7	0.8
DiaSorin	78	42.8	4.5	7.0	10.9	0.8
Interscientific NeoMAP Multiplex	10	33.0	1.0	1.0	2.8	0.7
PerkinElmer GSP Neonatal	163	42.2	3.3	5.4	8.4	0.8
In House	50	39.4	3.9	11.8	3.1	0.9
Lot 213 - Enriched 80 μIU/mL serum						
Siemens Healthcare Diagnostics	20	95.5	11.0	13.2	6.4	1.1
Neo-Genesis Accuwell	10	76.9	10.1	10.1	7.9	0.9
Delfia	519	72.9	6.4	9.8	7.3	0.8
AutoDelfia	841	76.2	5.8	7.6	8.0	0.9
Ani Labsystems	70	79.6	7.2	10.2	3.8	1.0
Bio-Rad Quantase	118	83.6	7.4	23.6	12.0	0.9
TecnoSuma UMELISA	19	59.0	7.3	9.9	11.9	0.6
Bioclone ELISA	20	74.1	8.6	12.4	7.7	0.8
DiaSorin	77	71.6	5.9	8.9	10.9	0.8
Interscientific NeoMAP Multiplex	10	60.9	3.2	3.2	2.8	0.7
PerkinElmer GSP Neonatal	162	73.4	6.3	7.9	8.4	0.8
In House	50	73.4	6.7	24.3	3.1	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 15d. 2012 Quality Control Data  
Summaries of Statistical Analyses

**17  $\alpha$ -HYDROXYPROGESTERONE** (ng 17-OHP/mL serum)

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 151 - Enriched 25 ng/mL serum						
Siemens Healthcare Diagnostics	20	23.8	2.3	6.3	-1.0	1.0
Neo-Genesis Accuwell	39	32.7	2.3	3.4	2.8	1.2
Delfia	156	25.0	2.6	4.8	-5.8	1.2
Delfia Neonatal 17-OHP (A024)	90	23.9	3.2	7.0	-2.4	1.0
AutoDelfia	203	25.4	2.1	4.1	-0.5	1.0
AutoDelfia Neonatal 17-OHP (B024)	353	23.7	1.9	2.3	-1.4	1.0
Bio-Rad Quantase	78	28.2	3.8	5.6	-5.4	1.2
TecnoSuma UMELISA	19	27.9	2.8	3.0	-0.5	1.1
LC-MS/MS	20	33.3	6.9	8.1	-3.2	1.4
MP Biomedicals RIA	30	37.9	5.2	13.9	-1.2	1.5
PerkinElmer GSP Neonatal	108	24.1	2.0	2.6	-3.4	1.1
In House	30	29.9	2.7	5.1	1.5	1.1
Lot 152 - Enriched 50 ng/mL serum						
Siemens Healthcare Diagnostics	20	45.6	2.9	6.4	-1.0	1.0
Neo-Genesis Accuwell	39	59.7	5.7	5.9	2.8	1.2
Delfia	154	52.3	4.7	10.8	-5.8	1.2
Delfia Neonatal 17-OHP (A024)	86	49.5	5.2	10.1	-2.4	1.0
AutoDelfia	200	49.1	3.7	5.7	-0.5	1.0
AutoDelfia Neonatal 17-OHP (B024)	343	47.6	3.7	4.5	-1.4	1.0
Bio-Rad Quantase	76	52.7	7.0	8.9	-5.4	1.2
TecnoSuma UMELISA	19	55.6	3.9	3.9	-0.5	1.1
LC-MS/MS	20	63.2	11.2	15.3	-3.2	1.4
MP Biomedicals RIA	30	67.9	10.4	31.7	-1.2	1.5
PerkinElmer GSP Neonatal	109	48.0	3.6	4.1	-3.4	1.1
In House	30	57.4	6.9	9.6	1.5	1.1
Lot 153 - Enriched 100 ng/mL serum						
Siemens Healthcare Diagnostics	20	95.1	8.6	14.3	-1.0	1.0
Neo-Genesis Accuwell	38	119.4	14.6	16.9	2.8	1.2
Delfia	156	114.0	9.3	24.5	-5.8	1.2
Delfia Neonatal 17-OHP (A024)	90	102.1	12.1	22.1	-2.4	1.0
AutoDelfia	195	100.9	8.2	12.9	-0.5	1.0
AutoDelfia Neonatal 17-OHP (B024)	347	97.9	8.6	11.5	-1.4	1.0
Bio-Rad Quantase	76	120.0	18.7	27.2	-5.4	1.2
TecnoSuma UMELISA	19	112.6	14.4	14.7	-0.5	1.1
LC-MS/MS	20	136.0	16.9	20.5	-3.2	1.4
MP Biomedicals RIA	30	146.1	19.3	77.6	-1.2	1.5
PerkinElmer GSP Neonatal	109	103.1	7.3	9.2	-3.4	1.1
In House	30	114.3	8.9	14.2	1.5	1.1

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

**17  $\alpha$ -HYDROXYPROGESTERONE** (ng 17-OHP/mL serum)

- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 251 - Enriched 25 ng/mL serum						
Siemens Healthcare Diagnostics	20	25.1	2.4	3.0	5.4	0.8
Neo-Genesis Accuwell	10	26.9	2.5	2.5	5.5	0.8
Delfia	181	24.5	2.2	4.9	1.0	0.9
Delfia Neonatal 17-OHP (A024)	48	18.9	2.0	2.5	-3.0	0.8
AutoDelfia	223	23.6	2.2	3.7	0.3	0.9
AutoDelfia Neonatal 17-OHP (B024)	370	22.6	1.8	2.5	0.5	0.8
Bio-Rad Quantase	86	27.0	3.4	5.1	1.5	1.0
TecnoSuma UMELISA	10	25.3	0.6	0.6	-4.9	1.1
LC-MS/MS	10	26.6	1.4	1.4	0.1	1.0
MP Biomedicals RIA	30	25.2	3.3	4.2	-2.8	1.1
PerkinElmer GSP Neonatal	128	23.8	2.1	2.1	0.1	0.9
In House	20	24.1	11.7	11.7	2.2	0.8
Lot 252 - Enriched 50 ng/mL serum						
Siemens Healthcare Diagnostics	20	44.2	4.6	4.6	5.4	0.8
Neo-Genesis Accuwell	10	46.9	4.7	4.7	5.5	0.8
Delfia	175	42.5	4.2	7.8	1.0	0.9
Delfia Neonatal 17-OHP (A024)	47	34.2	4.1	4.1	-3.0	0.8
AutoDelfia	228	43.2	3.6	7.0	0.3	0.9
AutoDelfia Neonatal 17-OHP (B024)	375	41.3	3.6	4.9	0.5	0.8
Bio-Rad Quantase	86	46.8	5.9	9.4	1.5	1.0
TecnoSuma UMELISA	10	49.2	1.0	1.0	-4.9	1.1
LC-MS/MS	10	48.0	2.4	2.4	0.1	1.0
MP Biomedicals RIA	30	49.6	8.4	10.1	-2.8	1.1
PerkinElmer GSP Neonatal	126	44.4	3.4	3.5	0.1	0.9
In House	20	42.8	16.0	16.0	2.2	0.8
Lot 253 - Enriched 100 ng/mL serum						
Siemens Healthcare Diagnostics	20	83.7	9.4	12.4	5.4	0.8
Neo-Genesis Accuwell	10	89.8	12.8	12.8	5.5	0.8
Delfia	176	89.4	10.0	16.9	1.0	0.9
Delfia Neonatal 17-OHP (A024)	47	78.1	7.7	9.4	-3.0	0.8
AutoDelfia	228	89.7	6.9	15.5	0.3	0.9
AutoDelfia Neonatal 17-OHP (B024)	374	85.5	7.9	11.0	0.5	0.8
Bio-Rad Quantase	84	97.8	9.7	19.8	1.5	1.0
TecnoSuma UMELISA	10	109.6	3.9	3.9	-4.9	1.1
LC-MS/MS	10	101.0	5.9	5.9	0.1	1.0
MP Biomedicals RIA	30	105.6	12.3	14.7	-2.8	1.1
PerkinElmer GSP Neonatal	129	91.9	7.9	9.2	0.1	0.9
In House	18	86.7	23.2	23.2	2.2	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 15e. 2012 Quality Control Data  
Summaries of Statistical Analyses

**TOTAL GALACTOSE** (mg Gal/dL whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 125 - Enriched 5 mg/dL whole blood						
Siemens Healthcare Diagnostics	30	5.2	0.6	0.6	1.5	0.8
Fluorometric Manual	137	5.0	0.6	1.4	0.3	1.0
Colorimetric	30	5.0	1.4	2.3	-1.7	1.3
PerkinElmer Neonatal Kit	181	5.0	0.7	0.9	1.5	0.8
Neo-Genesis Accuwell	30	5.0	0.5	0.5	0.1	1.0
Bio-Rad Quantase	126	6.1	1.0	2.0	-0.9	1.3
MP Biomedicals Enzyme Assay	20	8.9	2.1	2.1	-0.3	1.8
Interscientific Enzyme	10	5.0	0.5	0.5	2.7	0.7
Astoria-Pacific	100	6.3	0.5	0.8	1.2	1.0
TecnoSuma UMTEST	19	7.1	1.1	1.3	0.5	1.3
R&D Diagnostics Greece	60	4.7	0.6	1.7	0.3	0.9
Lot 126 - Enriched 10 mg/dL whole blood						
Siemens Healthcare Diagnostics	29	9.7	0.7	0.9	1.5	0.8
Fluorometric Manual	129	9.7	0.9	1.8	0.3	1.0
Colorimetric	30	10.9	2.1	3.6	-1.7	1.3
PerkinElmer Neonatal Kit	184	9.2	1.2	1.4	1.5	0.8
Neo-Genesis Accuwell	30	9.4	0.9	0.9	0.1	1.0
Bio-Rad Quantase	128	11.5	1.9	2.9	-0.9	1.3
MP Biomedicals Enzyme Assay	20	18.1	2.3	3.8	-0.3	1.8
Interscientific Enzyme	10	10.4	0.5	0.5	2.7	0.7
Astoria-Pacific	97	10.8	0.6	1.0	1.2	1.0
TecnoSuma UMTEST	20	13.5	1.9	4.9	0.5	1.3
R&D Diagnostics Greece	60	8.7	0.7	1.8	0.3	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.



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

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 127 - Enriched 15 mg/dL whole blood						
Siemens Healthcare Diagnostics	30	14.4	1.1	1.4	1.5	0.8
Fluorometric Manual	130	14.8	1.1	2.6	0.3	1.0
Colorimetric	30	17.5	3.2	5.5	-1.7	1.3
PerkinElmer Neonatal Kit	180	13.2	1.3	1.4	1.5	0.8
Neo-Genesis Accuwell	28	14.2	1.3	1.3	0.1	1.0
Bio-Rad Quantase	128	18.4	2.7	4.4	-0.9	1.3
MP Biomedicals Enzyme Assay	20	26.1	4.3	5.9	-0.3	1.8
Interscientific Enzyme	10	15.5	0.9	0.9	2.7	0.7
Astoria-Pacific	100	16.2	1.1	1.7	1.2	1.0
TecnoSuma UMTEST	19	20.1	1.3	5.2	0.5	1.3
R&D Diagnostics Greece	60	13.6	1.2	2.9	0.3	0.9
Lot 128 - Enriched 30 mg/dL whole blood						
Siemens Healthcare Diagnostics	30	25.7	2.0	5.6	1.5	0.8
Fluorometric Manual	131	28.8	2.6	5.3	0.3	1.0
Colorimetric	30	36.9	4.9	9.9	-1.7	1.3
PerkinElmer Neonatal Kit	186	24.1	2.5	2.9	1.5	0.8
Neo-Genesis Accuwell	29	28.7	2.6	3.4	0.1	1.0
Bio-Rad Quantase	128	38.0	4.9	8.3	-0.9	1.3
MP Biomedicals Enzyme Assay	20	54.0	11.7	17.4	-0.3	1.8
Interscientific Enzyme	10	23.8	1.2	1.2	2.7	0.7
Astoria-Pacific	99	31.0	1.8	2.8	1.2	1.0
TecnoSuma UMTEST	20	39.7	4.2	12.4	0.5	1.3
R&D Diagnostics Greece	60	26.3	1.7	8.2	0.3	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.

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

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 221 - Enriched 5 mg/dL whole blood						
Siemens Healthcare Diagnostics	29	5.2	0.2	0.3	1.3	0.8
Fluorometric Manual	111	5.1	0.7	2.0	0.5	0.9
Colorimetric	39	4.7	1.4	1.5	-0.3	1.1
PerkinElmer Neonatal Kit	195	4.8	0.6	0.8	1.1	0.7
Neo-Genesis Accuwell	29	5.0	0.4	0.5	1.1	0.9
Bio-Rad Quantase	132	6.4	1.1	1.9	0.4	1.3
MP Biomedicals Enzyme Assay	30	9.4	1.6	1.8	-6.6	2.7
Interscientific Enzyme	39	5.2	0.6	0.7	0.2	0.9
Astoria-Pacific	88	6.5	0.6	0.9	1.8	0.9
TecnoSuma UMTEST	10	10.7	0.7	0.7	6.7	0.9
R&D Diagnostics Greece	50	5.4	0.5	1.3	0.6	1.0
Lot 222 - Enriched 10 mg/dL whole blood						
Siemens Healthcare Diagnostics	30	9.5	0.6	0.7	1.3	0.8
Fluorometric Manual	112	9.6	0.8	1.6	0.5	0.9
Colorimetric	40	11.0	1.6	2.7	-0.3	1.1
PerkinElmer Neonatal Kit	197	8.4	0.8	1.1	1.1	0.7
Neo-Genesis Accuwell	28	9.8	0.5	0.6	1.1	0.9
Bio-Rad Quantase	140	13.1	1.9	3.1	0.4	1.3
MP Biomedicals Enzyme Assay	30	19.4	2.6	3.7	-6.6	2.7
Interscientific Enzyme	40	9.2	0.8	0.8	0.2	0.9
Astoria-Pacific	88	10.9	0.7	1.4	1.8	0.9
TecnoSuma UMTEST	10	15.5	1.0	1.0	6.7	0.9
R&D Diagnostics Greece	50	10.6	0.6	2.0	0.6	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.

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

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 223 - Enriched 15 mg/dL whole blood						
Siemens Healthcare Diagnostics	30	14.0	0.9	1.3	1.3	0.8
Fluorometric Manual	120	15.3	1.2	3.4	0.5	0.9
Colorimetric	40	16.5	1.9	3.0	-0.3	1.1
PerkinElmer Neonatal Kit	195	12.2	1.1	1.7	1.1	0.7
Neo-Genesis Accuwell	30	13.9	0.8	1.3	1.1	0.9
Bio-Rad Quantase	139	20.8	2.7	6.0	0.4	1.3
MP Biomedicals Enzyme Assay	29	29.5	2.9	3.5	-6.6	2.7
Interscientific Enzyme	39	13.2	1.1	1.7	0.2	0.9
Astoria-Pacific	90	15.6	1.1	2.1	1.8	0.9
TecnoSuma UMTEST	10	21.0	1.0	1.0	6.7	0.9
R&D Diagnostics Greece	50	15.5	0.9	2.8	0.6	1.0
Lot 224 - Enriched 30 mg/dL whole blood						
Siemens Healthcare Diagnostics	30	26.0	1.4	7.2	1.3	0.8
Fluorometric Manual	126	28.6	2.1	5.2	0.5	0.9
Colorimetric	40	32.4	3.5	4.9	-0.3	1.1
PerkinElmer Neonatal Kit	197	23.0	1.8	3.2	1.1	0.7
Neo-Genesis Accuwell	29	26.4	2.0	2.0	1.1	0.9
Bio-Rad Quantase	140	38.7	4.6	10.7	0.4	1.3
MP Biomedicals Enzyme Assay	30	74.7	5.1	25.6	-6.6	2.7
Interscientific Enzyme	40	27.7	2.6	4.1	0.2	0.9
Astoria-Pacific	90	29.5	2.2	3.3	1.8	0.9
TecnoSuma UMTEST	10	33.0	2.1	2.1	6.7	0.9
R&D Diagnostics Greece	50	30.2	1.4	2.6	0.6	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 15f. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 125 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Fluorometric Manual	70	106.75	17.00	33.85	110.41	1.0
PerkinElmer Neonatal Kit	247	82.69	12.46	15.61	81.60	0.9
Neo-Genesis Accuwell	20	68.73	9.44	10.08	60.79	1.0
Ani Labsystems	107	82.64	8.92	16.35	83.05	1.1
Bio-Rad Quantase	50	88.59	19.22	30.20	78.02	1.1
MP Biomedicals Enzyme Assay	20	42.88	6.36	17.56	14.50	1.0
Interscientific Enzyme	56	67.96	6.77	10.95	62.07	0.6
IBL International Neonatal Screening Kit	90	77.75	11.28	18.82	72.58	1.2
Astoria-Pacific	10	65.81	2.48	2.48	62.35	0.8
HPLC	30	71.54	6.18	13.20	68.64	0.9
TecnoSuma UMTEST	30	118.03	24.67	34.53	99.21	1.2
Derivatized - MS/MS non-kit	860	65.23	5.72	10.15	62.69	0.8
Non-derivatized - MS/MS non-kit	256	74.03	5.91	11.54	72.33	0.9
Derivatized - MS/MS PE NeoGram Kit	168	72.14	6.76	9.08	70.63	0.9
Non-derivatized - MS/MS PE NeoBase Kit	381	69.59	5.01	7.32	67.38	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	58	72.33	5.23	5.79	69.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	86.44	8.53	21.06	82.17	1.0
Lot 126 - Enriched 150 $\mu\text{mol/L}$ whole blood						
Fluorometric Manual	70	262.06	27.59	58.09	110.41	1.0
PerkinElmer Neonatal Kit	254	215.28	20.69	32.66	81.60	0.9
Neo-Genesis Accuwell	20	190.46	21.37	58.24	60.79	1.0
Ani Labsystems	109	244.00	18.50	36.93	83.05	1.1
Bio-Rad Quantase	49	237.76	36.27	54.00	78.02	1.1
MP Biomedicals Enzyme Assay	29	148.83	35.19	45.01	14.50	1.0
Interscientific Enzyme	60	144.21	13.50	70.59	62.07	0.6
IBL International Neonatal Screening Kit	90	243.21	23.60	48.12	72.58	1.2
Astoria-Pacific	10	171.27	7.17	7.17	62.35	0.8
HPLC	30	193.72	11.55	25.48	68.64	0.9
TecnoSuma UMTEST	29	257.24	21.40	37.72	99.21	1.2
Derivatized - MS/MS non-kit	856	178.20	14.20	25.33	62.69	0.8
Non-derivatized - MS/MS non-kit	258	208.42	13.24	34.00	72.33	0.9
Derivatized - MS/MS PE NeoGram Kit	166	197.28	18.07	21.35	70.63	0.9
Non-derivatized - MS/MS PE NeoBase Kit	378	193.83	13.30	20.38	67.38	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	58	191.93	13.61	15.94	69.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	232.57	18.45	55.49	82.17	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.

**PHENYLALANINE** (μmol Phe/L whole blood)

- continued -

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 127 - Enriched 400 μmol/L whole blood						
Fluorometric Manual	60	522.97	55.05	102.77	110.41	1.0
PerkinElmer Neonatal Kit	252	433.93	36.98	63.47	81.60	0.9
Neo-Genesis Accuwell	20	496.19	58.99	58.99	60.79	1.0
Ani Labsystems	110	525.17	47.27	82.23	83.05	1.1
Bio-Rad Quantase	50	492.28	69.38	75.57	78.02	1.1
MP Biomedicals Enzyme Assay	30	389.05	64.21	73.16	14.50	1.0
Interscientific Enzyme	60	298.01	23.74	144.75	62.07	0.6
IBL International Neonatal Screening Kit	90	525.43	39.61	104.76	72.58	1.2
Astoria-Pacific	10	369.34	8.12	8.12	62.35	0.8
HPLC	29	402.42	21.78	35.54	68.64	0.9
TecnoSuma UMTEST	30	544.97	57.12	57.97	99.21	1.2
Derivatized - MS/MS non-kit	870	374.42	28.24	56.54	62.69	0.8
Non-derivatized - MS/MS non-kit	257	441.59	35.97	77.14	72.33	0.9
Derivatized - MS/MS PE NeoGram Kit	169	419.16	35.52	50.30	70.63	0.9
Non-derivatized - MS/MS PE NeoBase Kit	383	404.45	29.37	48.60	67.38	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	396.36	31.27	41.37	69.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	490.20	40.08	103.21	82.17	1.0
Lot 128 - Enriched 600 μmol/L whole blood						
Fluorometric Manual	69	707.16	73.79	111.42	110.41	1.0
PerkinElmer Neonatal Kit	254	617.93	53.27	96.29	81.60	0.9
Neo-Genesis Accuwell	20	658.78	43.90	90.62	60.79	1.0
Ani Labsystems	110	732.68	56.97	115.38	83.05	1.1
Bio-Rad Quantase	50	749.50	107.47	143.36	78.02	1.1
MP Biomedicals Enzyme Assay	30	631.81	81.31	102.26	14.50	1.0
Interscientific Enzyme	60	420.28	38.63	205.92	62.07	0.6
IBL International Neonatal Screening Kit	90	772.91	49.59	150.13	72.58	1.2
Astoria-Pacific	10	520.03	19.90	19.90	62.35	0.8
HPLC	30	579.87	38.73	56.05	68.64	0.9
TecnoSuma UMTEST	28	816.82	92.44	120.49	99.21	1.2
Derivatized - MS/MS non-kit	871	536.12	41.80	86.76	62.69	0.8
Non-derivatized - MS/MS non-kit	258	626.45	41.88	106.63	72.33	0.9
Derivatized - MS/MS PE NeoGram Kit	165	588.90	47.77	69.60	70.63	0.9
Non-derivatized - MS/MS PE NeoBase Kit	385	581.20	40.99	64.45	67.38	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	572.30	44.79	71.30	69.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	703.36	72.30	163.34	82.17	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.

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

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 221 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Fluorometric Manual	80	116.52	14.05	24.14	137.59	0.9
PerkinElmer Neonatal Kit	265	85.23	11.01	19.01	85.54	0.9
Neo-Genesis Accuwell	10	76.36	14.90	14.90	78.30	1.1
Ani Labsystems	130	81.97	13.33	18.40	81.35	1.1
Bio-Rad Quantase	40	75.81	24.16	29.33	82.07	0.9
MP Biomedicals Enzyme Assay	30	44.43	22.63	29.83	27.42	1.0
Interscientific Enzyme	55	68.06	10.53	12.02	64.66	0.8
Astoria-Pacific	20	91.35	3.89	28.30	90.04	0.9
HPLC	20	84.31	4.64	9.22	84.91	0.9
TecnoSuma UMTEST	20	136.47	25.44	35.14	106.83	1.0
Derivatized - MS/MS non-kit	858	71.60	5.36	10.69	72.18	0.8
Non-derivatized - MS/MS non-kit	256	80.67	6.07	12.76	81.07	0.9
Derivatized - MS/MS PE NeoGram Kit	179	77.06	6.33	7.63	77.86	0.9
Non-derivatized - MS/MS PE NeoBase Kit	418	75.71	5.33	7.92	74.39	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	69	73.49	5.13	9.28	75.79	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	46	87.40	7.37	12.89	83.78	1.0
Lot 222 - Enriched 150 $\mu\text{mol/L}$ whole blood						
Fluorometric Manual	90	296.95	28.73	75.08	137.59	0.9
PerkinElmer Neonatal Kit	257	214.91	16.54	32.30	85.54	0.9
Neo-Genesis Accuwell	10	245.43	26.99	26.99	78.30	1.1
Ani Labsystems	130	247.26	26.89	38.10	81.35	1.1
Bio-Rad Quantase	40	221.87	30.46	68.86	82.07	0.9
MP Biomedicals Enzyme Assay	40	158.23	19.85	26.51	27.42	1.0
Interscientific Enzyme	56	181.58	21.19	26.80	64.66	0.8
Astoria-Pacific	20	222.97	11.21	51.16	90.04	0.9
HPLC	20	217.59	6.68	14.12	84.91	0.9
TecnoSuma UMTEST	20	230.65	30.10	32.04	106.83	1.0
Derivatized - MS/MS non-kit	850	190.80	13.85	27.46	72.18	0.8
Non-derivatized - MS/MS non-kit	260	216.35	14.50	33.68	81.07	0.9
Derivatized - MS/MS PE NeoGram Kit	176	208.81	15.13	18.35	77.86	0.9
Non-derivatized - MS/MS PE NeoBase Kit	419	203.22	12.30	20.26	74.39	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	67	198.59	15.64	21.70	75.79	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	46	227.64	15.12	27.11	83.78	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.

**PHENYLALANINE** (μmol Phe/L whole blood)

- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 223 - Enriched 400 μmol/L whole blood						
Fluorometric Manual	80	498.59	51.72	141.89	137.59	0.9
PerkinElmer Neonatal Kit	259	420.04	34.30	68.60	85.54	0.9
Neo-Genesis Accuwell	10	497.34	40.29	40.29	78.30	1.1
Ani Labsystems	129	527.18	49.67	78.61	81.35	1.1
Bio-Rad Quantase	40	451.56	59.03	104.53	82.07	0.9
MP Biomedicals Enzyme Assay	40	415.60	34.70	65.83	27.42	1.0
Interscientific Enzyme	56	382.45	33.33	36.04	64.66	0.8
Astoria-Pacific	20	441.83	16.59	54.58	90.04	0.9
HPLC	20	438.96	25.55	29.70	84.91	0.9
TecnoSuma UMTEST	20	467.26	74.71	74.71	106.83	1.0
Derivatized - MS/MS non-kit	858	385.10	28.02	55.26	72.18	0.8
Non-derivatized - MS/MS non-kit	259	440.08	30.32	70.44	81.07	0.9
Derivatized - MS/MS PE NeoGram Kit	179	423.25	32.18	45.07	77.86	0.9
Non-derivatized - MS/MS PE NeoBase Kit	418	412.79	27.66	46.00	74.39	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	406.24	35.13	52.14	75.79	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	46	471.90	33.80	69.55	83.78	1.0
Lot 224 - Enriched 600 μmol/L whole blood						
Fluorometric Manual	90	670.30	82.49	257.41	137.59	0.9
PerkinElmer Neonatal Kit	257	595.99	49.36	97.82	85.54	0.9
Neo-Genesis Accuwell	10	724.78	53.54	53.54	78.30	1.1
Ani Labsystems	129	749.18	61.45	108.98	81.35	1.1
Bio-Rad Quantase	40	616.38	79.23	122.46	82.07	0.9
MP Biomedicals Enzyme Assay	40	619.62	63.73	74.19	27.42	1.0
Interscientific Enzyme	55	548.00	39.06	42.71	64.66	0.8
Astoria-Pacific	20	625.10	17.92	105.75	90.04	0.9
HPLC	20	613.55	31.54	36.76	84.91	0.9
TecnoSuma UMTEST	18	731.25	84.96	117.42	106.83	1.0
Derivatized - MS/MS non-kit	858	542.63	39.70	82.61	72.18	0.8
Non-derivatized - MS/MS non-kit	256	619.82	39.37	96.22	81.07	0.9
Derivatized - MS/MS PE NeoGram Kit	176	596.52	37.09	48.42	77.86	0.9
Non-derivatized - MS/MS PE NeoBase Kit	419	591.66	40.96	67.64	74.39	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	560.21	41.23	64.76	75.79	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	48	674.95	49.66	95.84	83.78	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 15g. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 125 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Interscientific Enzyme	20	175.19	14.03	57.14	173.63	1.0
HPLC	10	96.77	9.33	9.33	92.13	0.8
Derivatized - MS/MS non-kit	844	134.04	11.32	20.57	131.93	0.8
Non-derivatized - MS/MS non-kit	159	161.12	12.04	23.12	160.97	0.9
Derivatized - MS/MS PE NeoGram Kit	173	131.88	10.96	12.69	134.00	0.9
Non-derivatized - MS/MS PE NeoBase Kit	354	154.12	10.57	15.10	151.41	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	50	132.69	18.43	22.73	130.44	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	140.05	12.11	16.73	139.97	0.7
Lot 126 - Enriched 200 $\mu\text{mol/L}$ whole blood						
Interscientific Enzyme	20	371.30	41.58	128.43	173.63	1.0
HPLC	10	249.59	21.34	21.34	92.13	0.8
Derivatized - MS/MS non-kit	839	288.89	21.35	40.16	131.93	0.8
Non-derivatized - MS/MS non-kit	160	333.09	24.37	47.89	160.97	0.9
Derivatized - MS/MS PE NeoGram Kit	179	304.74	27.25	31.80	134.00	0.9
Non-derivatized - MS/MS PE NeoBase Kit	355	314.44	20.40	29.49	151.41	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	49	264.20	26.23	33.14	130.44	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	28	279.55	17.79	25.95	139.97	0.7
Lot 127 - Enriched 500 $\mu\text{mol/L}$ whole blood						
Interscientific Enzyme	20	634.03	40.47	187.89	173.63	1.0
HPLC	10	497.83	22.90	22.90	92.13	0.8
Derivatized - MS/MS non-kit	844	534.04	39.61	78.88	131.93	0.8
Non-derivatized - MS/MS non-kit	159	602.07	52.92	100.43	160.97	0.9
Derivatized - MS/MS PE NeoGram Kit	179	565.94	47.62	60.07	134.00	0.9
Non-derivatized - MS/MS PE NeoBase Kit	353	568.39	39.57	63.12	151.41	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	50	482.24	41.78	69.87	130.44	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	519.12	58.90	86.24	139.97	0.7
Lot 128 - Enriched 800 $\mu\text{mol/L}$ whole blood						
Interscientific Enzyme	20	947.17	39.96	272.33	173.63	1.0
HPLC	10	745.98	64.08	64.08	92.13	0.8
Derivatized - MS/MS non-kit	848	773.56	64.48	129.88	131.93	0.8
Non-derivatized - MS/MS non-kit	160	857.17	55.34	143.30	160.97	0.9
Derivatized - MS/MS PE NeoGram Kit	176	813.23	73.28	92.29	134.00	0.9
Non-derivatized - MS/MS PE NeoBase Kit	359	819.08	61.56	92.47	151.41	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	49	685.05	51.27	78.50	130.44	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	28	719.34	54.97	61.62	139.97	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.



**LEUCINE** (μmol Leu/L whole blood)  
- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 221 - Nonenriched 0 μmol/L whole blood						
Interscientific Enzyme	20	162.09	10.78	10.78	178.25	0.8
HPLC	10	131.43	7.44	7.44	123.01	0.9
Derivatized - MS/MS non-kit	818	162.37	12.99	24.84	162.57	0.8
Non-derivatized - MS/MS non-kit	200	205.06	18.95	32.92	203.27	0.9
Derivatized - MS/MS PE NeoGram Kit	178	157.00	12.51	14.58	159.31	0.9
Non-derivatized - MS/MS PE NeoBase Kit	419	185.88	13.43	22.61	184.31	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	167.76	13.12	41.06	164.56	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	171.18	15.83	28.48	166.49	0.8
Lot 222 - Enriched 200 μmol/L whole blood						
Interscientific Enzyme	20	337.20	32.51	32.51	178.25	0.8
HPLC	10	300.98	8.69	8.69	123.01	0.9
Derivatized - MS/MS non-kit	824	322.73	26.22	48.43	162.57	0.8
Non-derivatized - MS/MS non-kit	194	379.87	28.04	48.55	203.27	0.9
Derivatized - MS/MS PE NeoGram Kit	176	329.75	27.02	29.88	159.31	0.9
Non-derivatized - MS/MS PE NeoBase Kit	419	347.99	19.46	39.77	184.31	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	64	296.24	26.44	61.96	164.56	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	311.96	26.92	44.73	166.49	0.8
Lot 223 - Enriched 500 μmol/L whole blood						
Interscientific Enzyme	20	576.06	45.61	55.34	178.25	0.8
HPLC	10	564.90	32.24	32.24	123.01	0.9
Derivatized - MS/MS non-kit	831	563.24	45.61	86.30	162.57	0.8
Non-derivatized - MS/MS non-kit	195	666.18	49.38	85.78	203.27	0.9
Derivatized - MS/MS PE NeoGram Kit	177	586.08	41.85	55.72	159.31	0.9
Non-derivatized - MS/MS PE NeoBase Kit	416	595.56	40.76	70.64	184.31	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	545.44	39.88	138.07	164.56	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	544.42	45.64	72.10	166.49	0.8
Lot 224 - Enriched 800 μmol/L whole blood						
Interscientific Enzyme	20	758.67	44.35	44.35	178.25	0.8
HPLC	10	861.87	45.83	45.83	123.01	0.9
Derivatized - MS/MS non-kit	825	802.67	60.11	117.84	162.57	0.8
Non-derivatized - MS/MS non-kit	182	930.13	67.84	108.70	203.27	0.9
Derivatized - MS/MS PE NeoGram Kit	173	833.39	57.22	67.48	159.31	0.9
Non-derivatized - MS/MS PE NeoBase Kit	412	845.86	57.00	92.51	184.31	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	66	739.07	62.70	165.84	164.56	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	773.61	69.43	93.04	166.49	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 15h. 2012 Quality Control Data  
Summaries of Statistical Analyses

**METHIONINE** (μmol Met/L whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 125 - Nonenriched 0 μmol/L whole blood						
HPLC	10	14.01	1.14	1.14	8.79	0.7
Derivatized - MS/MS non-kit	839	19.45	2.67	4.13	17.45	0.8
Non-derivatized - MS/MS non-kit	160	18.31	1.74	3.25	13.96	0.8
Derivatized - MS/MS PE NeoGram Kit	163	20.57	2.60	3.00	21.43	0.8
Non-derivatized - MS/MS PE NeoBase Kit	348	16.98	1.62	2.18	12.79	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	50	15.72	2.58	3.00	14.24	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	14.33	2.17	2.31	8.58	0.6
Lot 126 - Enriched 100 μmol/L whole blood						
HPLC	10	74.48	4.82	4.82	8.79	0.7
Derivatized - MS/MS non-kit	843	91.27	7.89	12.88	17.45	0.8
Non-derivatized - MS/MS non-kit	165	92.20	7.20	13.57	13.96	0.8
Derivatized - MS/MS PE NeoGram Kit	165	102.32	10.34	12.62	21.43	0.8
Non-derivatized - MS/MS PE NeoBase Kit	355	87.15	6.18	9.46	12.79	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	50	77.44	9.08	9.75	14.24	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	66.69	7.81	13.24	8.58	0.6
Lot 127 - Enriched 250 μmol/L whole blood						
HPLC	10	183.20	8.42	8.42	8.79	0.7
Derivatized - MS/MS non-kit	837	206.08	16.81	29.19	17.45	0.8
Non-derivatized - MS/MS non-kit	161	215.70	15.06	31.57	13.96	0.8
Derivatized - MS/MS PE NeoGram Kit	169	233.84	22.77	31.47	21.43	0.8
Non-derivatized - MS/MS PE NeoBase Kit	357	204.62	15.09	25.47	12.79	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	50	172.03	18.57	25.57	14.24	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	163.20	18.17	35.66	8.58	0.6
Lot 128 - Enriched 500 μmol/L whole blood						
HPLC	10	364.60	28.83	28.83	8.79	0.7
Derivatized - MS/MS non-kit	840	397.20	32.70	57.84	17.45	0.8
Non-derivatized - MS/MS non-kit	163	425.17	24.58	61.61	13.96	0.8
Derivatized - MS/MS PE NeoGram Kit	167	434.27	40.11	50.29	21.43	0.8
Non-derivatized - MS/MS PE NeoBase Kit	358	403.83	29.55	50.38	12.79	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	50	334.69	26.61	46.02	14.24	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	327.23	32.96	42.97	8.58	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.

**METHIONINE** (μmol Met/L whole blood)  
- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 221 - Nonenriched 0 μmol/L whole blood						
HPLC	10	16.94	1.39	1.39	10.92	0.8
Derivatized - MS/MS non-kit	850	23.57	3.09	4.66	22.14	0.8
Non-derivatized - MS/MS non-kit	200	21.72	2.58	3.96	19.74	0.8
Derivatized - MS/MS PE NeoGram Kit	167	25.58	3.40	3.72	25.90	0.8
Non-derivatized - MS/MS PE NeoBase Kit	422	18.85	1.83	2.60	15.82	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	17.52	2.86	8.32	14.92	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	18.92	3.98	7.12	14.92	0.8
Lot 222 - Enriched 100 μmol/L whole blood						
HPLC	10	86.85	4.86	4.86	10.92	0.8
Derivatized - MS/MS non-kit	830	95.52	8.67	16.40	22.14	0.8
Non-derivatized - MS/MS non-kit	202	97.63	7.62	13.72	19.74	0.8
Derivatized - MS/MS PE NeoGram Kit	168	109.26	9.79	12.12	25.90	0.8
Non-derivatized - MS/MS PE NeoBase Kit	422	88.44	5.77	9.98	15.82	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	73.11	8.75	33.77	14.92	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	86.94	14.80	26.05	14.92	0.8
Lot 223 - Enriched 250 μmol/L whole blood						
HPLC	10	200.01	13.23	13.23	10.92	0.8
Derivatized - MS/MS non-kit	849	208.87	18.85	35.86	22.14	0.8
Non-derivatized - MS/MS non-kit	203	222.64	16.95	27.92	19.74	0.8
Derivatized - MS/MS PE NeoGram Kit	168	234.73	21.55	28.02	25.90	0.8
Non-derivatized - MS/MS PE NeoBase Kit	421	200.11	14.33	24.29	15.82	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	155.39	21.80	67.91	14.92	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	196.96	31.44	58.76	14.92	0.8
Lot 224 - Enriched 500 μmol/L whole blood						
HPLC	10	408.70	25.76	25.76	10.92	0.8
Derivatized - MS/MS non-kit	849	397.11	32.82	67.18	22.14	0.8
Non-derivatized - MS/MS non-kit	200	424.12	31.20	44.81	19.74	0.8
Derivatized - MS/MS PE NeoGram Kit	167	442.14	33.59	42.15	25.90	0.8
Non-derivatized - MS/MS PE NeoBase Kit	426	391.40	28.94	48.40	15.82	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	308.65	33.05	124.24	14.92	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	389.98	66.10	117.56	14.92	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 15i. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 125 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
HPLC	29	51.41	4.17	5.51	50.69	0.8
Derivatized - MS/MS non-kit	845	48.09	4.47	7.64	45.99	0.7
Non-derivatized - MS/MS non-kit	198	54.45	4.66	8.83	51.21	0.9
Derivatized - MS/MS PE NeoGram Kit	170	50.35	4.78	5.43	49.59	0.8
Non-derivatized - MS/MS PE NeoBase Kit	362	55.23	4.63	8.24	53.22	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	57	57.51	5.02	7.23	54.93	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	56.95	7.16	7.33	51.70	0.9
Lot 126 - Enriched 250 $\mu\text{mol/L}$ whole blood						
HPLC	29	252.26	15.11	34.03	50.69	0.8
Derivatized - MS/MS non-kit	840	230.34	19.22	34.92	45.99	0.7
Non-derivatized - MS/MS non-kit	194	260.93	18.05	37.86	51.21	0.9
Derivatized - MS/MS PE NeoGram Kit	175	239.87	20.67	24.70	49.59	0.8
Non-derivatized - MS/MS PE NeoBase Kit	361	262.77	21.75	35.47	53.22	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	58	272.87	24.42	33.74	54.93	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	262.13	18.80	33.21	51.70	0.9
Lot 127 - Enriched 500 $\mu\text{mol/L}$ whole blood						
HPLC	30	449.59	27.95	61.04	50.69	0.8
Derivatized - MS/MS non-kit	844	415.26	34.29	65.24	45.99	0.7
Non-derivatized - MS/MS non-kit	198	473.12	33.40	73.63	51.21	0.9
Derivatized - MS/MS PE NeoGram Kit	176	439.06	34.89	40.09	49.59	0.8
Non-derivatized - MS/MS PE NeoBase Kit	362	479.20	35.46	64.78	53.22	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	497.23	47.16	62.19	54.93	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	483.52	41.06	61.46	51.70	0.9
Lot 128 - Enriched 750 $\mu\text{mol/L}$ whole blood						
HPLC	30	655.69	48.94	90.87	50.69	0.8
Derivatized - MS/MS non-kit	852	606.70	51.62	95.88	45.99	0.7
Non-derivatized - MS/MS non-kit	194	693.15	45.50	98.21	51.21	0.9
Derivatized - MS/MS PE NeoGram Kit	172	627.44	55.84	60.93	49.59	0.8
Non-derivatized - MS/MS PE NeoBase Kit	361	692.35	52.29	92.43	53.22	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	59	720.83	56.82	86.98	54.93	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	706.23	67.21	89.56	51.70	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.

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

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 221 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
HPLC	20	64.41	3.86	8.82	67.00	0.9
Derivatized - MS/MS non-kit	832	53.99	4.74	8.15	54.68	0.8
Non-derivatized - MS/MS non-kit	219	58.69	4.54	9.41	60.49	0.8
Derivatized - MS/MS PE NeoGram Kit	156	54.41	4.87	6.20	56.24	0.8
Non-derivatized - MS/MS PE NeoBase Kit	451	57.13	4.80	8.79	57.10	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	69	63.45	6.78	12.91	68.41	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	61.87	3.99	7.24	62.84	0.8
Lot 222 - Enriched 250 $\mu\text{mol/L}$ whole blood						
HPLC	20	288.41	8.70	17.54	67.00	0.9
Derivatized - MS/MS non-kit	827	242.92	19.47	35.21	54.68	0.8
Non-derivatized - MS/MS non-kit	226	269.12	19.88	39.06	60.49	0.8
Derivatized - MS/MS PE NeoGram Kit	155	247.17	16.50	21.86	56.24	0.8
Non-derivatized - MS/MS PE NeoBase Kit	456	261.68	17.49	35.73	57.10	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	285.14	31.11	56.79	68.41	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	47	270.24	13.14	24.90	62.84	0.8
Lot 223 - Enriched 500 $\mu\text{mol/L}$ whole blood						
HPLC	20	508.37	28.96	34.53	67.00	0.9
Derivatized - MS/MS non-kit	840	431.54	35.31	66.47	54.68	0.8
Non-derivatized - MS/MS non-kit	229	470.96	33.45	70.40	60.49	0.8
Derivatized - MS/MS PE NeoGram Kit	153	440.26	32.75	39.94	56.24	0.8
Non-derivatized - MS/MS PE NeoBase Kit	455	459.69	33.65	67.22	57.10	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	523.72	55.08	82.68	68.41	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	490.15	24.72	66.39	62.84	0.8
Lot 224 - Enriched 750 $\mu\text{mol/L}$ whole blood						
HPLC	20	721.45	35.67	39.58	67.00	0.9
Derivatized - MS/MS non-kit	838	617.18	51.71	92.33	54.68	0.8
Non-derivatized - MS/MS non-kit	228	676.85	53.42	106.83	60.49	0.8
Derivatized - MS/MS PE NeoGram Kit	155	623.64	46.81	59.60	56.24	0.8
Non-derivatized - MS/MS PE NeoBase Kit	442	667.70	53.43	101.30	57.10	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	712.41	58.66	129.79	68.41	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	49	688.12	36.36	80.43	62.84	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 15j. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 125 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
HPLC	10	147.90	13.42	13.42	141.59	0.8
Derivatized - MS/MS non-kit	804	143.24	15.61	27.51	139.39	0.7
Non-derivatized - MS/MS non-kit	149	153.16	11.59	29.75	154.86	0.9
Derivatized - MS/MS PE NeoGram Kit	167	161.99	21.54	32.19	159.18	0.8
Non-derivatized - MS/MS PE NeoBase Kit	345	144.89	11.90	23.36	140.42	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	58	122.98	18.14	24.06	123.30	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	103.91	13.95	17.40	102.85	0.5
Lot 126 - Enriched 250 $\mu\text{mol/L}$ whole blood						
HPLC	10	336.49	26.63	26.63	141.59	0.8
Derivatized - MS/MS non-kit	803	308.64	31.10	54.75	139.39	0.7
Non-derivatized - MS/MS non-kit	149	368.25	29.95	75.43	154.86	0.9
Derivatized - MS/MS PE NeoGram Kit	168	354.07	41.35	61.18	159.18	0.8
Non-derivatized - MS/MS PE NeoBase Kit	347	337.81	29.73	57.13	140.42	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	58	263.16	29.96	38.78	123.30	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	235.52	26.52	37.57	102.85	0.5
Lot 127 - Enriched 600 $\mu\text{mol/L}$ whole blood						
HPLC	10	617.67	26.69	26.69	141.59	0.8
Derivatized - MS/MS non-kit	812	547.79	53.70	100.93	139.39	0.7
Non-derivatized - MS/MS non-kit	150	665.27	55.34	155.48	154.86	0.9
Derivatized - MS/MS PE NeoGram Kit	170	640.68	79.07	112.63	159.18	0.8
Non-derivatized - MS/MS PE NeoBase Kit	347	614.31	55.07	109.39	140.42	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	465.43	48.45	74.03	123.30	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	426.36	51.16	78.07	102.85	0.5
Lot 128 - Enriched 1000 $\mu\text{mol/L}$ whole blood						
HPLC	10	948.25	72.81	72.81	141.59	0.8
Derivatized - MS/MS non-kit	802	830.79	86.72	159.47	139.39	0.7
Non-derivatized - MS/MS non-kit	149	1001.52	71.78	230.63	154.86	0.9
Derivatized - MS/MS PE NeoGram Kit	167	958.14	123.77	158.08	159.18	0.8
Non-derivatized - MS/MS PE NeoBase Kit	345	944.92	84.61	165.60	140.42	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	58	686.47	54.43	93.29	123.30	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	640.76	79.92	94.35	102.85	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.

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

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 221 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
HPLC	10	184.12	10.11	10.11	174.82	0.9
Derivatized - MS/MS non-kit	790	163.09	15.94	28.29	162.20	0.7
Non-derivatized - MS/MS non-kit	150	165.96	15.62	33.99	165.13	0.8
Derivatized - MS/MS PE NeoGram Kit	166	175.91	21.04	33.08	175.00	0.8
Non-derivatized - MS/MS PE NeoBase Kit	409	170.16	13.55	30.97	167.09	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	68	155.59	21.04	50.75	149.75	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	128.66	18.43	26.34	125.59	0.6
Lot 222 - Enriched 250 $\mu\text{mol/L}$ whole blood						
HPLC	10	394.88	11.11	11.11	174.82	0.9
Derivatized - MS/MS non-kit	777	332.57	30.87	55.52	162.20	0.7
Non-derivatized - MS/MS non-kit	148	360.11	33.35	69.31	165.13	0.8
Derivatized - MS/MS PE NeoGram Kit	163	359.86	39.41	60.13	175.00	0.8
Non-derivatized - MS/MS PE NeoBase Kit	408	368.81	28.78	66.48	167.09	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	66	310.40	30.07	103.46	149.75	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	268.74	33.12	48.54	125.59	0.6
Lot 223 - Enriched 600 $\mu\text{mol/L}$ whole blood						
HPLC	10	694.50	38.81	38.81	174.82	0.9
Derivatized - MS/MS non-kit	783	565.90	49.41	97.13	162.20	0.7
Non-derivatized - MS/MS non-kit	150	629.97	56.38	134.15	165.13	0.8
Derivatized - MS/MS PE NeoGram Kit	167	631.97	67.86	111.53	175.00	0.8
Non-derivatized - MS/MS PE NeoBase Kit	409	655.01	54.55	121.23	167.09	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	66	534.53	53.84	171.19	149.75	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	482.38	58.68	82.48	125.59	0.6
Lot 224 - Enriched 1000 $\mu\text{mol/L}$ whole blood						
HPLC	10	1079.81	58.12	58.12	174.82	0.9
Derivatized - MS/MS non-kit	787	842.88	69.93	141.87	162.20	0.7
Non-derivatized - MS/MS non-kit	147	945.57	84.18	175.11	165.13	0.8
Derivatized - MS/MS PE NeoGram Kit	166	927.36	107.71	155.08	175.00	0.8
Non-derivatized - MS/MS PE NeoBase Kit	406	987.00	84.67	182.27	167.09	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	68	811.64	79.80	265.07	149.75	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	718.06	88.72	103.65	125.59	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 15k. 2012 Quality Control Data  
Summaries of Statistical Analyses

**CITRULLINE** (μmol Cit/L whole blood)

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 125 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	866	23.43	2.79	5.51	22.90	0.7
Non-derivatized - MS/MS non-kit	135	25.35	3.69	5.47	25.18	0.8
Derivatized - MS/MS PE NeoGram Kit	167	26.74	2.00	2.88	26.85	0.8
Non-derivatized - MS/MS PE NeoBase Kit	348	26.31	2.70	3.12	26.28	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	48	27.10	2.77	4.47	27.81	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	25.29	3.26	3.26	23.91	0.8
Lot 126 - Enriched 50 μmol/L whole blood						
Derivatized - MS/MS non-kit	855	56.03	5.40	12.04	22.90	0.7
Non-derivatized - MS/MS non-kit	139	66.50	8.32	14.85	25.18	0.8
Derivatized - MS/MS PE NeoGram Kit	168	66.65	4.96	6.78	26.85	0.8
Non-derivatized - MS/MS PE NeoBase Kit	353	66.07	5.30	6.41	26.28	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	50	69.39	7.45	13.37	27.81	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	59.23	6.67	6.67	23.91	0.8
Lot 127 - Enriched 150 μmol/L whole blood						
Derivatized - MS/MS non-kit	865	125.64	11.45	27.19	22.90	0.7
Non-derivatized - MS/MS non-kit	137	147.65	13.93	30.64	25.18	0.8
Derivatized - MS/MS PE NeoGram Kit	169	151.45	10.10	16.39	26.85	0.8
Non-derivatized - MS/MS PE NeoBase Kit	351	146.77	10.97	15.54	26.28	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	50	150.59	13.67	27.22	27.81	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	136.66	11.68	11.68	23.91	0.8
Lot 128 - Enriched 300 μmol/L whole blood						
Derivatized - MS/MS non-kit	858	227.26	20.55	47.70	22.90	0.7
Non-derivatized - MS/MS non-kit	137	271.94	23.94	56.12	25.18	0.8
Derivatized - MS/MS PE NeoGram Kit	167	271.25	17.79	25.93	26.85	0.8
Non-derivatized - MS/MS PE NeoBase Kit	356	266.41	23.04	27.58	26.28	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	50	272.84	25.10	52.09	27.81	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	248.30	29.11	32.82	23.91	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** (μmol Cit/L whole blood)

- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 221 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	857	24.22	2.78	5.97	24.62	0.7
Non-derivatized - MS/MS non-kit	156	28.85	4.04	5.51	28.60	0.9
Derivatized - MS/MS PE NeoGram Kit	165	27.93	1.70	2.60	28.86	0.8
Non-derivatized - MS/MS PE NeoBase Kit	419	28.01	2.69	3.42	27.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	29.30	2.22	7.79	29.29	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	38	27.21	4.35	6.14	24.83	0.8
Lot 222 - Enriched 50 μmol/L whole blood						
Derivatized - MS/MS non-kit	856	59.71	6.41	14.27	24.62	0.7
Non-derivatized - MS/MS non-kit	155	71.22	6.07	8.85	28.60	0.9
Derivatized - MS/MS PE NeoGram Kit	166	69.92	4.05	6.24	28.86	0.8
Non-derivatized - MS/MS PE NeoBase Kit	413	68.56	5.20	6.89	27.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	55	67.59	5.83	14.71	29.29	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	61.94	6.85	14.41	24.83	0.8
Lot 223 - Enriched 150 μmol/L whole blood						
Derivatized - MS/MS non-kit	856	132.06	12.93	30.94	24.62	0.7
Non-derivatized - MS/MS non-kit	153	161.56	14.19	22.44	28.60	0.9
Derivatized - MS/MS PE NeoGram Kit	167	152.79	8.88	15.76	28.86	0.8
Non-derivatized - MS/MS PE NeoBase Kit	419	151.79	12.15	17.13	27.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	58	152.75	12.00	39.51	29.29	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	143.50	12.60	33.19	24.83	0.8
Lot 224 - Enriched 300 μmol/L whole blood						
Derivatized - MS/MS non-kit	852	236.33	22.31	55.06	24.62	0.7
Non-derivatized - MS/MS non-kit	155	290.98	24.01	35.04	28.60	0.9
Derivatized - MS/MS PE NeoGram Kit	166	273.08	14.44	22.28	28.86	0.8
Non-derivatized - MS/MS PE NeoBase Kit	417	275.79	21.04	28.85	27.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	57	269.13	25.01	67.45	29.29	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	263.43	32.16	53.48	24.83	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 151. 2012 Quality Control Data  
Summaries of Statistical Analyses

**ARGININE** (μmol Arg/L whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 125 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	731	7.10	1.45	3.81	1.87	0.2
Non-derivatized - MS/MS non-kit	78	7.35	1.26	1.57	-3.08	0.4
Derivatized - MS/MS PE NeoGram Kit	129	7.36	0.85	2.01	0.31	0.4
Non-derivatized - MS/MS PE NeoBase Kit	314	7.18	0.87	1.65	0.63	0.4
Derivatized - MS/MS Chromsystems MassChrom Kit	47	9.44	2.12	2.62	2.16	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	7.46	1.84	2.24	2.89	0.3
Lot 126 - Enriched 65 μmol/L whole blood						
Derivatized - MS/MS non-kit	741	13.71	2.12	7.74	1.87	0.2
Non-derivatized - MS/MS non-kit	75	15.57	2.50	6.17	-3.08	0.4
Derivatized - MS/MS PE NeoGram Kit	130	17.46	2.30	5.26	0.31	0.4
Non-derivatized - MS/MS PE NeoBase Kit	311	19.19	2.01	4.62	0.63	0.4
Derivatized - MS/MS Chromsystems MassChrom Kit	50	22.55	4.57	7.00	2.16	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	16.33	1.60	2.31	2.89	0.3
Lot 127 - Enriched 130 μmol/L whole blood						
Derivatized - MS/MS non-kit	723	26.59	3.98	13.90	1.87	0.2
Non-derivatized - MS/MS non-kit	77	34.97	5.37	10.97	-3.08	0.4
Derivatized - MS/MS PE NeoGram Kit	120	35.73	3.19	9.22	0.31	0.4
Non-derivatized - MS/MS PE NeoBase Kit	317	40.23	4.71	9.66	0.63	0.4
Derivatized - MS/MS Chromsystems MassChrom Kit	50	47.38	6.59	13.20	2.16	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	35.94	3.55	22.32	2.89	0.3
Lot 128 - Enriched 200 μmol/L whole blood						
Derivatized - MS/MS non-kit	740	56.61	7.68	30.11	1.87	0.2
Non-derivatized - MS/MS non-kit	79	90.92	13.55	31.58	-3.08	0.4
Derivatized - MS/MS PE NeoGram Kit	130	78.06	9.92	30.01	0.31	0.4
Non-derivatized - MS/MS PE NeoBase Kit	319	81.44	9.41	19.70	0.63	0.4
Derivatized - MS/MS Chromsystems MassChrom Kit	50	90.70	11.18	18.28	2.16	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	63.57	7.11	24.65	2.89	0.3

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

Table 15m. 2012 Quality Control Data  
Summaries of Statistical Analyses

**ALANINE** (μmol Ala/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 221 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	577	337.64	30.17	105.44	335.31	0.6
Non-derivatized - MS/MS non-kit	90	387.74	35.23	84.12	385.00	0.7
Derivatized - MS/MS PE NeoGram Kit	60	403.15	29.95	94.64	402.77	0.7
Non-derivatized - MS/MS PE NeoBase Kit	307	452.20	35.89	69.86	444.44	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	60	345.01	26.13	75.89	344.76	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	323.37	39.69	57.51	315.38	0.6
Lot 222 - Enriched 250 μmol/L whole blood						
Derivatized - MS/MS non-kit	584	479.11	43.03	143.42	335.31	0.6
Non-derivatized - MS/MS non-kit	88	541.86	54.55	92.89	385.00	0.7
Derivatized - MS/MS PE NeoGram Kit	60	574.89	44.71	137.18	402.77	0.7
Non-derivatized - MS/MS PE NeoBase Kit	303	612.08	43.96	94.64	444.44	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	60	487.11	45.92	106.85	344.76	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	441.72	43.22	55.92	315.38	0.6
Lot 223 - Enriched 500 μmol/L whole blood						
Derivatized - MS/MS non-kit	580	626.55	54.51	191.92	335.31	0.6
Non-derivatized - MS/MS non-kit	90	718.30	71.05	146.84	385.00	0.7
Derivatized - MS/MS PE NeoGram Kit	60	731.76	91.27	178.39	402.77	0.7
Non-derivatized - MS/MS PE NeoBase Kit	304	824.55	65.48	128.34	444.44	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	60	634.63	54.21	114.65	344.76	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	596.82	61.03	86.89	315.38	0.6
Lot 224 - Enriched 750 μmol/L whole blood						
Derivatized - MS/MS non-kit	586	776.57	68.80	234.54	335.31	0.6
Non-derivatized - MS/MS non-kit	90	875.27	92.79	166.35	385.00	0.7
Derivatized - MS/MS PE NeoGram Kit	60	912.87	78.68	217.69	402.77	0.7
Non-derivatized - MS/MS PE NeoBase Kit	317	997.34	85.99	196.88	444.44	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	60	775.30	55.07	148.79	344.76	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	736.74	76.38	98.13	315.38	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 15n. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 125 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	192	0.75	0.19	0.47	0.83	0.5
Non-derivatized - MS/MS non-kit	49	1.68	0.35	1.81	1.67	0.5
Non-derivatized - MS/MS PE NeoBase Kit	240	0.54	0.19	0.37	0.53	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	20	1.06	0.35	0.46	1.08	0.3
Lot 126 - Enriched 2.50 μmol/L whole blood						
Derivatized - MS/MS non-kit	187	2.08	0.29	1.33	0.83	0.5
Non-derivatized - MS/MS non-kit	49	2.96	0.61	2.47	1.67	0.5
Non-derivatized - MS/MS PE NeoBase Kit	243	1.00	0.21	0.43	0.53	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	20	1.89	0.37	0.47	1.08	0.3
Lot 127 - Enriched 5 μmol/L whole blood						
Derivatized - MS/MS non-kit	188	3.33	0.39	2.09	0.83	0.5
Non-derivatized - MS/MS non-kit	49	4.37	0.77	3.28	1.67	0.5
Non-derivatized - MS/MS PE NeoBase Kit	236	1.40	0.23	0.45	0.53	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	20	2.35	0.38	0.66	1.08	0.3
Lot 128 - Enriched 10 μmol/L whole blood						
Derivatized - MS/MS non-kit	187	5.58	0.63	3.49	0.83	0.5
Non-derivatized - MS/MS non-kit	48	6.99	1.38	4.64	1.67	0.5
Non-derivatized - MS/MS PE NeoBase Kit	243	2.41	0.34	0.64	0.53	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	20	3.90	0.57	1.04	1.08	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 -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 221 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	178	0.83	0.27	0.69	0.85	0.6
Non-derivatized - MS/MS non-kit	40	2.09	0.50	1.82	2.22	0.8
Non-derivatized - MS/MS PE NeoBase Kit	259	0.47	0.16	0.29	0.47	0.2
Lot 222 - Enriched 2.50 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	167	2.48	0.51	1.65	0.85	0.6
Non-derivatized - MS/MS non-kit	40	4.28	0.53	2.18	2.22	0.8
Non-derivatized - MS/MS PE NeoBase Kit	260	0.94	0.16	0.30	0.47	0.2
Lot 223 - Enriched 5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	178	4.08	0.83	2.83	0.85	0.6
Non-derivatized - MS/MS non-kit	40	6.32	0.96	3.18	2.22	0.8
Non-derivatized - MS/MS PE NeoBase Kit	255	1.41	0.25	0.42	0.47	0.2
Lot 224 - Enriched 10 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	180	7.27	1.18	5.31	0.85	0.6
Non-derivatized - MS/MS non-kit	37	10.07	1.01	4.13	2.22	0.8
Non-derivatized - MS/MS PE NeoBase Kit	255	2.33	0.34	0.68	0.47	0.2

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

Table 15o. 2012 Quality Control Data  
Summaries of Statistical Analyses

**FREE CARNITINE** (μmol C0/L whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	873	9.42	0.98	1.96	9.16	1.2
Non-derivatized - MS/MS non-kit	158	8.88	0.94	1.84	8.77	1.0
Derivatized - MS/MS PE NeoGram Kit	168	12.94	1.18	2.59	12.29	1.8
Non-derivatized - MS/MS PE NeoBase Kit	374	9.25	0.89	1.44	9.04	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	67	7.79	1.11	2.21	7.78	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	7.67	0.63	0.92	7.77	0.8
Lot 166 - Enriched 10 μmol/L whole blood						
Derivatized - MS/MS non-kit	874	20.85	2.02	4.42	9.16	1.2
Non-derivatized - MS/MS non-kit	155	18.98	1.71	3.89	8.77	1.0
Derivatized - MS/MS PE NeoGram Kit	170	30.22	3.12	6.70	12.29	1.8
Non-derivatized - MS/MS PE NeoBase Kit	372	19.45	1.62	3.07	9.04	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	67	17.78	2.11	5.06	7.78	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	15.83	1.26	1.26	7.77	0.8
Lot 167 - Enriched 20 μmol/L whole blood						
Derivatized - MS/MS non-kit	878	31.72	2.96	7.03	9.16	1.2
Non-derivatized - MS/MS non-kit	155	28.72	2.50	5.26	8.77	1.0
Derivatized - MS/MS PE NeoGram Kit	168	46.99	4.62	10.64	12.29	1.8
Non-derivatized - MS/MS PE NeoBase Kit	377	29.38	2.66	4.90	9.04	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	65	26.68	2.90	7.16	7.78	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	23.85	1.49	1.49	7.77	0.8
Lot 168 - Enriched 30 μmol/L whole blood						
Derivatized - MS/MS non-kit	872	44.72	4.43	9.25	9.16	1.2
Non-derivatized - MS/MS non-kit	152	39.56	3.17	7.18	8.77	1.0
Derivatized - MS/MS PE NeoGram Kit	168	67.77	6.51	15.43	12.29	1.8
Non-derivatized - MS/MS PE NeoBase Kit	371	40.76	3.39	6.16	9.04	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	67	37.28	4.21	10.02	7.78	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	31.57	2.86	3.03	7.77	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.

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 261 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	904	15.25	1.54	2.90	15.03	1.4
Non-derivatized - MS/MS non-kit	154	14.90	1.58	2.88	14.78	1.2
Derivatized - MS/MS PE NeoGram Kit	180	19.37	1.45	2.79	19.07	1.9
Non-derivatized - MS/MS PE NeoBase Kit	424	14.24	1.30	2.24	14.30	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	65	13.29	1.26	2.79	13.67	1.2
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	13.54	1.69	2.82	13.84	1.1
Lot 262 - Enriched 10 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	905	28.85	2.94	5.27	15.03	1.4
Non-derivatized - MS/MS non-kit	153	27.03	2.30	4.72	14.78	1.2
Derivatized - MS/MS PE NeoGram Kit	179	38.54	3.10	6.17	19.07	1.9
Non-derivatized - MS/MS PE NeoBase Kit	425	25.96	2.24	3.89	14.30	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	69	26.81	2.54	5.46	13.67	1.2
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	25.94	3.03	6.46	13.84	1.1
Lot 263 - Enriched 20 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	909	41.97	3.79	7.27	15.03	1.4
Non-derivatized - MS/MS non-kit	154	38.21	3.45	7.21	14.78	1.2
Derivatized - MS/MS PE NeoGram Kit	175	55.47	4.79	8.59	19.07	1.9
Non-derivatized - MS/MS PE NeoBase Kit	424	36.93	3.35	5.62	14.30	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	64	37.85	4.21	7.74	13.67	1.2
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	35.49	3.30	8.00	13.84	1.1
Lot 264 - Enriched 30 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	911	56.88	5.11	10.30	15.03	1.4
Non-derivatized - MS/MS non-kit	154	51.42	4.94	9.59	14.78	1.2
Derivatized - MS/MS PE NeoGram Kit	178	77.27	6.90	12.50	19.07	1.9
Non-derivatized - MS/MS PE NeoBase Kit	423	48.75	4.47	7.40	14.30	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	65	50.79	4.31	8.50	13.67	1.2
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	47.80	5.05	11.22	13.84	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 15p. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	871	10.04	1.12	2.97	10.18	0.9
Non-derivatized - MS/MS non-kit	149	7.76	0.70	1.33	7.71	1.0
Derivatized - MS/MS PE NeoGram Kit	180	12.87	1.21	3.03	13.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	357	6.21	0.52	0.83	6.25	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	66	8.14	1.06	2.26	8.16	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	28	6.00	0.48	0.84	6.43	0.8
Lot 166 - Enriched 10 μmol/L whole blood						
Derivatized - MS/MS non-kit	867	18.94	1.80	4.63	10.18	0.9
Non-derivatized - MS/MS non-kit	137	18.33	1.86	3.60	7.71	1.0
Derivatized - MS/MS PE NeoGram Kit	178	19.18	1.39	3.01	13.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	361	14.68	1.09	1.70	6.25	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	67	16.04	1.69	3.52	8.16	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	14.27	1.25	2.67	6.43	0.8
Lot 167 - Enriched 20 μmol/L whole blood						
Derivatized - MS/MS non-kit	873	27.91	2.50	6.14	10.18	0.9
Non-derivatized - MS/MS non-kit	138	27.99	2.81	5.67	7.71	1.0
Derivatized - MS/MS PE NeoGram Kit	177	26.28	2.18	3.10	13.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	359	22.85	1.69	2.81	6.25	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	67	22.91	2.55	4.85	8.16	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	22.50	1.97	4.10	6.43	0.8
Lot 168 - Enriched 30 μmol/L whole blood						
Derivatized - MS/MS non-kit	863	36.06	3.12	7.83	10.18	0.9
Non-derivatized - MS/MS non-kit	139	39.29	4.54	8.37	7.71	1.0
Derivatized - MS/MS PE NeoGram Kit	172	31.42	2.28	3.44	13.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	357	31.28	2.27	3.63	6.25	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	67	31.21	2.27	5.70	8.16	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	28.76	2.66	5.72	6.43	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.



**ACETYL Carnitine** (μmol C2/L whole blood)

- continued -

METHOD	N	Mean	Average		Y-Intercept*	Slope
			Within Lab SD	Total SD		
Lot 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	859	11.00	1.14	2.73	11.05	0.9
Non-derivatized - MS/MS non-kit	156	9.33	0.91	1.31	9.21	1.0
Derivatized - MS/MS PE NeoGram Kit	170	13.23	0.95	1.67	13.34	0.7
Non-derivatized - MS/MS PE NeoBase Kit	411	8.07	0.59	0.99	8.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	63	9.12	1.22	3.63	9.31	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	38	7.91	0.69	0.77	7.94	0.8
Lot 262 - Enriched 10 μmol/L whole blood						
Derivatized - MS/MS non-kit	855	19.80	1.74	4.24	11.05	0.9
Non-derivatized - MS/MS non-kit	158	19.09	1.96	2.79	9.21	1.0
Derivatized - MS/MS PE NeoGram Kit	168	20.53	1.10	1.66	13.34	0.7
Non-derivatized - MS/MS PE NeoBase Kit	415	16.63	1.22	2.10	8.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	65	18.52	1.68	5.55	9.31	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	38	16.46	1.29	1.38	7.94	0.8
Lot 263 - Enriched 20 μmol/L whole blood						
Derivatized - MS/MS non-kit	855	28.03	2.45	5.52	11.05	0.9
Non-derivatized - MS/MS non-kit	158	28.72	2.69	4.49	9.21	1.0
Derivatized - MS/MS PE NeoGram Kit	167	26.55	1.51	2.03	13.34	0.7
Non-derivatized - MS/MS PE NeoBase Kit	409	24.25	1.77	3.04	8.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	66	26.75	2.26	6.81	9.31	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	24.12	1.97	2.43	7.94	0.8
Lot 264 - Enriched 30 μmol/L whole blood						
Derivatized - MS/MS non-kit	856	36.86	3.25	7.61	11.05	0.9
Non-derivatized - MS/MS non-kit	158	39.13	3.02	5.34	9.21	1.0
Derivatized - MS/MS PE NeoGram Kit	168	33.90	1.99	2.81	13.34	0.7
Non-derivatized - MS/MS PE NeoBase Kit	416	33.43	2.41	4.04	8.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	66	35.81	2.98	8.05	9.31	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	32.93	2.81	3.16	7.94	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 15q. 2012 Quality Control Data  
Summaries of Statistical Analyses

**PROPIONYLCARNITINE** (μmol C3/L whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	893	0.86	0.13	0.22	0.92	0.9
Non-derivatized - MS/MS non-kit	160	0.91	0.10	0.19	0.91	1.1
Derivatized - MS/MS PE NeoGram Kit	161	0.74	0.07	0.10	0.71	0.9
Non-derivatized - MS/MS PE NeoBase Kit	368	0.70	0.07	0.09	0.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.70	0.12	0.16	0.79	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.69	0.06	0.11	0.81	0.8
Lot 166 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	910	3.78	0.45	0.79	0.92	0.9
Non-derivatized - MS/MS non-kit	148	4.17	0.44	0.98	0.91	1.1
Derivatized - MS/MS PE NeoGram Kit	164	3.33	0.23	0.42	0.71	0.9
Non-derivatized - MS/MS PE NeoBase Kit	371	3.15	0.24	0.36	0.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	69	3.12	0.35	0.47	0.79	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	3.11	0.32	0.65	0.81	0.8
Lot 167 - Enriched 7.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	922	7.83	0.82	1.54	0.92	0.9
Non-derivatized - MS/MS non-kit	146	8.77	0.85	1.96	0.91	1.1
Derivatized - MS/MS PE NeoGram Kit	170	7.11	0.53	0.92	0.71	0.9
Non-derivatized - MS/MS PE NeoBase Kit	376	6.72	0.51	0.80	0.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	68	6.42	0.71	1.19	0.79	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	6.63	0.55	1.25	0.81	0.8
Lot 168 - Enriched 12.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	907	11.99	1.30	2.46	0.92	0.9
Non-derivatized - MS/MS non-kit	149	13.77	1.37	2.93	0.91	1.1
Derivatized - MS/MS PE NeoGram Kit	170	11.17	0.79	1.52	0.71	0.9
Non-derivatized - MS/MS PE NeoBase Kit	377	10.57	0.84	1.23	0.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	9.68	1.08	1.99	0.79	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	9.64	0.60	1.64	0.81	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.

**PROPIONYLCARNITINE** (μmol C3/L whole blood)

- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	890	1.11	0.15	0.25	1.10	1.1
Non-derivatized - MS/MS non-kit	161	1.12	0.10	0.19	1.09	1.1
Derivatized - MS/MS PE NeoGram Kit	171	0.91	0.07	0.08	0.88	0.9
Non-derivatized - MS/MS PE NeoBase Kit	423	0.91	0.08	0.12	0.85	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.96	0.13	0.26	0.91	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	37	0.96	0.09	0.09	0.94	1.0
Lot 262 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	889	4.20	0.48	0.79	1.10	1.1
Non-derivatized - MS/MS non-kit	162	4.37	0.45	0.80	1.09	1.1
Derivatized - MS/MS PE NeoGram Kit	179	3.62	0.21	0.30	0.88	0.9
Non-derivatized - MS/MS PE NeoBase Kit	427	3.61	0.27	0.39	0.85	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	3.69	0.38	0.91	0.91	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	3.92	0.41	0.52	0.94	1.0
Lot 263 - Enriched 7.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	900	9.18	1.01	1.71	1.10	1.1
Non-derivatized - MS/MS non-kit	164	9.85	0.88	1.93	1.09	1.1
Derivatized - MS/MS PE NeoGram Kit	179	7.86	0.54	0.73	0.88	0.9
Non-derivatized - MS/MS PE NeoBase Kit	424	7.88	0.58	0.88	0.85	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	8.33	0.73	1.87	0.91	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	8.46	0.74	1.11	0.94	1.0
Lot 264 - Enriched 12.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	902	13.74	1.57	2.50	1.10	1.1
Non-derivatized - MS/MS non-kit	163	14.69	1.25	2.91	1.09	1.1
Derivatized - MS/MS PE NeoGram Kit	179	12.02	0.77	1.06	0.88	0.9
Non-derivatized - MS/MS PE NeoBase Kit	429	12.14	0.95	1.39	0.85	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	12.52	0.99	2.96	0.91	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	12.99	1.25	1.44	0.94	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 15r. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	748	0.03	0.02	0.03	0.05	0.5
Non-derivatized - MS/MS non-kit	64	0.05	0.02	0.03	0.05	0.2
Derivatized - MS/MS PE NeoGram Kit	133	0.03	0.01	0.02	0.05	1.2
Non-derivatized - MS/MS PE NeoBase Kit	206	0.05	0.02	0.04	0.06	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.10	0.04	0.16	0.23	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.03	0.01	0.01	0.03	0.1
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	749	0.29	0.06	0.11	0.05	0.5
Non-derivatized - MS/MS non-kit	66	0.14	0.03	0.06	0.05	0.2
Derivatized - MS/MS PE NeoGram Kit	129	0.68	0.06	0.09	0.05	1.2
Non-derivatized - MS/MS PE NeoBase Kit	214	0.18	0.03	0.12	0.06	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	59	0.60	0.16	0.38	0.23	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	19	0.08	0.01	0.01	0.03	0.1
Lot 167 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	765	0.76	0.12	0.30	0.05	0.5
Non-derivatized - MS/MS non-kit	65	0.30	0.05	0.12	0.05	0.2
Derivatized - MS/MS PE NeoGram Kit	128	1.82	0.14	0.24	0.05	1.2
Non-derivatized - MS/MS PE NeoBase Kit	208	0.38	0.05	0.23	0.06	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	58	1.55	0.34	0.86	0.23	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.19	0.02	0.05	0.03	0.1
Lot 168 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	742	1.42	0.21	0.50	0.05	0.5
Non-derivatized - MS/MS non-kit	67	0.57	0.10	0.22	0.05	0.2
Derivatized - MS/MS PE NeoGram Kit	129	3.59	0.30	0.50	0.05	1.2
Non-derivatized - MS/MS PE NeoBase Kit	208	0.69	0.09	0.40	0.06	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	57	2.26	0.48	1.04	0.23	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.33	0.05	0.12	0.03	0.1

\*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 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	784	0.03	0.02	0.03	0.04	0.5
Non-derivatized - MS/MS non-kit	27	0.07	0.03	0.04	0.11	0.8
Derivatized - MS/MS PE NeoGram Kit	140	0.03	0.01	0.01	0.04	1.3
Non-derivatized - MS/MS PE NeoBase Kit	183	0.05	0.01	0.02	0.06	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	46	0.02	0.01	0.02	0.05	0.7
Lot 262 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	775	0.28	0.06	0.10	0.04	0.5
Non-derivatized - MS/MS non-kit	30	0.59	0.14	0.30	0.11	0.8
Derivatized - MS/MS PE NeoGram Kit	138	0.73	0.06	0.09	0.04	1.3
Non-derivatized - MS/MS PE NeoBase Kit	181	0.46	0.05	0.09	0.06	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	49	0.40	0.08	0.16	0.05	0.7
Lot 263 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	778	0.72	0.12	0.23	0.04	0.5
Non-derivatized - MS/MS non-kit	30	1.14	0.20	0.47	0.11	0.8
Derivatized - MS/MS PE NeoGram Kit	136	1.89	0.14	0.21	0.04	1.3
Non-derivatized - MS/MS PE NeoBase Kit	185	0.89	0.09	0.14	0.06	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	50	1.11	0.13	0.37	0.05	0.7
Lot 264 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	780	1.42	0.22	0.46	0.04	0.5
Non-derivatized - MS/MS non-kit	30	2.43	0.38	1.14	0.11	0.8
Derivatized - MS/MS PE NeoGram Kit	136	3.91	0.36	0.50	0.04	1.3
Non-derivatized - MS/MS PE NeoBase Kit	184	2.03	0.22	0.38	0.06	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	49	2.07	0.32	0.63	0.05	0.7

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

Table 15s. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	851	0.12	0.04	0.06	0.11	0.9
Non-derivatized - MS/MS non-kit	140	0.08	0.03	0.04	0.07	1.0
Derivatized - MS/MS PE NeoGram Kit	156	0.11	0.04	0.05	0.11	0.9
Non-derivatized - MS/MS PE NeoBase Kit	352	0.09	0.02	0.02	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	67	0.10	0.05	0.06	0.15	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.07	0.01	0.01	0.13	0.7
Lot 166 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	838	1.09	0.13	0.20	0.11	0.9
Non-derivatized - MS/MS non-kit	137	1.09	0.09	0.17	0.07	1.0
Derivatized - MS/MS PE NeoGram Kit	153	0.98	0.16	0.17	0.11	0.9
Non-derivatized - MS/MS PE NeoBase Kit	367	0.96	0.08	0.12	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	0.99	0.16	0.20	0.15	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.88	0.09	0.11	0.13	0.7
Lot 167 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	850	2.39	0.26	0.40	0.11	0.9
Non-derivatized - MS/MS non-kit	138	2.53	0.27	0.47	0.07	1.0
Derivatized - MS/MS PE NeoGram Kit	159	2.20	0.29	0.34	0.11	0.9
Non-derivatized - MS/MS PE NeoBase Kit	367	2.19	0.17	0.27	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	66	2.07	0.22	0.29	0.15	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.02	0.15	0.17	0.13	0.7
Lot 168 - Enriched 5.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	847	4.82	0.50	0.87	0.11	0.9
Non-derivatized - MS/MS non-kit	139	5.12	0.45	0.84	0.07	1.0
Derivatized - MS/MS PE NeoGram Kit	158	4.37	0.50	0.68	0.11	0.9
Non-derivatized - MS/MS PE NeoBase Kit	362	4.47	0.34	0.52	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	69	4.05	0.46	0.85	0.15	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	3.74	0.32	0.46	0.13	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.

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

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 261 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	877	0.14	0.04	0.07	0.13	0.8
Non-derivatized - MS/MS non-kit	130	0.10	0.02	0.02	0.13	0.8
Derivatized - MS/MS PE NeoGram Kit	157	0.12	0.04	0.04	0.13	0.7
Non-derivatized - MS/MS PE NeoBase Kit	406	0.11	0.02	0.03	0.11	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	57	0.10	0.03	0.04	0.11	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	0.10	0.02	0.02	0.09	0.7
Lot 262 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	865	0.93	0.12	0.18	0.13	0.8
Non-derivatized - MS/MS non-kit	134	0.95	0.08	0.15	0.13	0.8
Derivatized - MS/MS PE NeoGram Kit	165	0.84	0.14	0.18	0.13	0.7
Non-derivatized - MS/MS PE NeoBase Kit	422	0.82	0.07	0.11	0.11	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.89	0.11	0.25	0.11	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	0.80	0.07	0.09	0.09	0.7
Lot 263 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	870	2.03	0.22	0.35	0.13	0.8
Non-derivatized - MS/MS non-kit	134	2.17	0.19	0.24	0.13	0.8
Derivatized - MS/MS PE NeoGram Kit	166	1.78	0.23	0.30	0.13	0.7
Non-derivatized - MS/MS PE NeoBase Kit	430	1.87	0.15	0.25	0.11	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	60	2.05	0.21	0.56	0.11	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.77	0.10	0.21	0.09	0.7
Lot 264 - Enriched 5.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	862	4.03	0.43	0.69	0.13	0.8
Non-derivatized - MS/MS non-kit	137	4.16	0.34	0.60	0.13	0.8
Derivatized - MS/MS PE NeoGram Kit	157	3.52	0.44	0.49	0.13	0.7
Non-derivatized - MS/MS PE NeoBase Kit	415	3.65	0.26	0.46	0.11	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	58	3.97	0.36	1.04	0.11	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	3.56	0.32	0.37	0.09	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 15t. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 261 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	602	0.08	0.02	0.04	0.09	0.8
Non-derivatized - MS/MS non-kit	50	0.09	0.03	0.08	0.10	0.8
Derivatized - MS/MS PE NeoGram Kit	108	0.08	0.03	0.05	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	111	0.06	0.01	0.03	0.08	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	39	0.07	0.02	0.02	0.08	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	10	0.05	0.01	0.01	0.08	0.5
Lot 262 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	588	0.50	0.07	0.13	0.09	0.8
Non-derivatized - MS/MS non-kit	50	0.48	0.05	0.17	0.10	0.8
Derivatized - MS/MS PE NeoGram Kit	109	0.54	0.11	0.17	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	118	0.43	0.05	0.07	0.08	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	40	0.56	0.06	0.12	0.08	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	10	0.35	0.03	0.03	0.08	0.5
Lot 263 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	600	0.94	0.13	0.25	0.09	0.8
Non-derivatized - MS/MS non-kit	49	0.88	0.12	0.29	0.10	0.8
Derivatized - MS/MS PE NeoGram Kit	110	0.97	0.15	0.27	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	118	0.84	0.09	0.12	0.08	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	40	1.06	0.10	0.23	0.08	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	10	0.64	0.05	0.05	0.08	0.5
Lot 264 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	582	2.19	0.25	0.50	0.09	0.8
Non-derivatized - MS/MS non-kit	50	2.00	0.16	0.60	0.10	0.8
Derivatized - MS/MS PE NeoGram Kit	109	2.33	0.37	0.67	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	116	1.85	0.17	0.35	0.08	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	40	2.49	0.22	0.46	0.08	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	10	1.37	0.10	0.10	0.08	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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Table 15u. 2012 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 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	885	0.07	0.02	0.03	0.07	0.9
Non-derivatized - MS/MS non-kit	149	0.05	0.01	0.01	0.05	0.9
Derivatized - MS/MS PE NeoGram Kit	166	0.07	0.03	0.03	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	364	0.06	0.01	0.02	0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	0.08	0.04	0.05	0.09	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.04	0.01	0.01	0.06	0.7
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	884	0.50	0.07	0.10	0.07	0.9
Non-derivatized - MS/MS non-kit	147	0.52	0.06	0.08	0.05	0.9
Derivatized - MS/MS PE NeoGram Kit	167	0.50	0.07	0.09	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	361	0.49	0.04	0.06	0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	65	0.51	0.06	0.07	0.09	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.42	0.06	0.09	0.06	0.7
Lot 167 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	895	1.33	0.14	0.23	0.07	0.9
Non-derivatized - MS/MS non-kit	146	1.41	0.12	0.19	0.05	0.9
Derivatized - MS/MS PE NeoGram Kit	168	1.33	0.15	0.17	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	361	1.32	0.12	0.16	0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	68	1.31	0.16	0.21	0.09	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.12	0.12	0.24	0.06	0.7
Lot 168 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	910	2.61	0.27	0.47	0.07	0.9
Non-derivatized - MS/MS non-kit	147	2.83	0.27	0.41	0.05	0.9
Derivatized - MS/MS PE NeoGram Kit	169	2.67	0.32	0.44	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	361	2.66	0.23	0.32	0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	69	2.57	0.32	0.38	0.09	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.12	0.25	0.44	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.

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

- continued -

METHOD	N	Mean	Average		Y-Intercept*	Slope
			Within Lab SD	Total SD		
Lot 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	907	0.08	0.02	0.03	0.09	0.8
Non-derivatized - MS/MS non-kit	195	0.06	0.01	0.02	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	175	0.07	0.02	0.03	0.08	0.8
Non-derivatized - MS/MS PE NeoBase Kit	424	0.06	0.01	0.03	0.07	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	0.08	0.02	0.03	0.08	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	38	0.06	0.01	0.01	0.06	0.8
Lot 262 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	899	0.51	0.07	0.09	0.09	0.8
Non-derivatized - MS/MS non-kit	207	0.52	0.06	0.09	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	168	0.48	0.07	0.08	0.08	0.8
Non-derivatized - MS/MS PE NeoBase Kit	427	0.48	0.05	0.07	0.07	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	69	0.51	0.06	0.11	0.08	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.46	0.05	0.06	0.06	0.8
Lot 263 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	919	1.32	0.15	0.21	0.09	0.8
Non-derivatized - MS/MS non-kit	197	1.37	0.12	0.21	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	168	1.25	0.15	0.19	0.08	0.8
Non-derivatized - MS/MS PE NeoBase Kit	429	1.26	0.11	0.18	0.07	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	1.36	0.14	0.23	0.08	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.21	0.07	0.16	0.06	0.8
Lot 264 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	906	2.56	0.28	0.41	0.09	0.8
Non-derivatized - MS/MS non-kit	197	2.68	0.19	0.33	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	170	2.41	0.31	0.39	0.08	0.8
Non-derivatized - MS/MS PE NeoBase Kit	436	2.47	0.23	0.37	0.07	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	2.61	0.34	0.49	0.08	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	2.38	0.17	0.36	0.06	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 15v. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	883	0.02	0.01	0.02	0.01	0.5
Non-derivatized - MS/MS non-kit	158	0.04	0.02	0.03	0.03	0.8
Derivatized - MS/MS PE NeoGram Kit	161	0.02	0.01	0.02	0.02	1.0
Non-derivatized - MS/MS PE NeoBase Kit	324	0.06	0.02	0.04	0.06	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	58	0.05	0.04	0.04	0.06	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	28	0.05	0.02	0.03	0.08	1.1
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	871	0.26	0.05	0.08	0.01	0.5
Non-derivatized - MS/MS non-kit	159	0.41	0.06	0.16	0.03	0.8
Derivatized - MS/MS PE NeoGram Kit	154	0.52	0.04	0.07	0.02	1.0
Non-derivatized - MS/MS PE NeoBase Kit	330	0.55	0.06	0.10	0.06	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	59	0.68	0.17	0.18	0.06	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.60	0.08	0.20	0.08	1.1
Lot 167 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	875	0.50	0.08	0.16	0.01	0.5
Non-derivatized - MS/MS non-kit	159	0.78	0.10	0.32	0.03	0.8
Derivatized - MS/MS PE NeoGram Kit	156	1.02	0.07	0.15	0.02	1.0
Non-derivatized - MS/MS PE NeoBase Kit	326	1.04	0.10	0.18	0.06	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	58	1.41	0.40	0.40	0.06	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.18	0.13	0.38	0.08	1.1
Lot 168 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	894	1.23	0.18	0.43	0.01	0.5
Non-derivatized - MS/MS non-kit	156	1.93	0.21	0.76	0.03	0.8
Derivatized - MS/MS PE NeoGram Kit	158	2.51	0.18	0.42	0.02	1.0
Non-derivatized - MS/MS PE NeoBase Kit	326	2.49	0.23	0.42	0.06	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	60	3.29	0.63	0.72	0.06	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.69	0.18	0.77	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.

**GLUTARYLCARNITINE** (μmol C5DC/L whole blood)

- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	881	0.02	0.01	0.02	0.04	0.5
Non-derivatized - MS/MS non-kit	190	0.05	0.02	0.03	0.08	0.8
Derivatized - MS/MS PE NeoGram Kit	165	0.03	0.01	0.01	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	364	0.05	0.02	0.03	0.09	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	67	0.04	0.02	0.04	0.06	1.1
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	0.06	0.03	0.04	0.11	1.0
Lot 262 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	878	0.27	0.05	0.10	0.04	0.5
Non-derivatized - MS/MS non-kit	198	0.49	0.06	0.18	0.08	0.8
Derivatized - MS/MS PE NeoGram Kit	170	0.55	0.04	0.05	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	384	0.56	0.06	0.12	0.09	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	69	0.58	0.10	0.19	0.06	1.1
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.64	0.12	0.19	0.11	1.0
Lot 263 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	898	0.53	0.09	0.20	0.04	0.5
Non-derivatized - MS/MS non-kit	198	0.93	0.10	0.35	0.08	0.8
Derivatized - MS/MS PE NeoGram Kit	167	1.02	0.07	0.13	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	384	1.05	0.11	0.20	0.09	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	67	1.16	0.20	0.33	0.06	1.1
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.20	0.17	0.31	0.11	1.0
Lot 264 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	880	1.17	0.16	0.38	0.04	0.5
Non-derivatized - MS/MS non-kit	200	2.09	0.27	0.73	0.08	0.8
Derivatized - MS/MS PE NeoGram Kit	170	2.40	0.17	0.27	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	383	2.36	0.21	0.41	0.09	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	2.67	0.39	0.76	0.06	1.1
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	2.67	0.41	0.74	0.11	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 15w. 2012 Quality Control Data  
Summaries of Statistical Analyses

**3-HYDROXYISOVALERYLCARNITINE** (μmol C5OH/L whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	849	0.42	0.06	0.10	0.41	0.8
Non-derivatized - MS/MS non-kit	149	0.54	0.05	0.12	0.54	0.8
Derivatized - MS/MS PE NeoGram Kit	166	0.41	0.06	0.08	0.41	0.7
Non-derivatized - MS/MS PE NeoBase Kit	274	0.45	0.05	0.09	0.45	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	58	0.40	0.09	0.10	0.41	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	0.32	0.03	0.04	0.33	0.4
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	852	0.81	0.10	0.18	0.41	0.8
Non-derivatized - MS/MS non-kit	140	0.93	0.09	0.22	0.54	0.8
Derivatized - MS/MS PE NeoGram Kit	166	0.76	0.11	0.13	0.41	0.7
Non-derivatized - MS/MS PE NeoBase Kit	275	0.73	0.07	0.15	0.45	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.73	0.13	0.14	0.41	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	0.53	0.06	0.07	0.33	0.4
Lot 167 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	858	1.53	0.17	0.31	0.41	0.8
Non-derivatized - MS/MS non-kit	140	1.65	0.16	0.37	0.54	0.8
Derivatized - MS/MS PE NeoGram Kit	164	1.43	0.17	0.19	0.41	0.7
Non-derivatized - MS/MS PE NeoBase Kit	276	1.26	0.12	0.25	0.45	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	60	1.33	0.23	0.31	0.41	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	0.94	0.09	0.13	0.33	0.4
Lot 168 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	860	2.35	0.28	0.46	0.41	0.8
Non-derivatized - MS/MS non-kit	140	2.43	0.19	0.56	0.54	0.8
Derivatized - MS/MS PE NeoGram Kit	165	2.14	0.24	0.29	0.41	0.7
Non-derivatized - MS/MS PE NeoBase Kit	274	1.86	0.17	0.35	0.45	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	59	1.94	0.36	0.53	0.41	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	28	1.30	0.12	0.19	0.33	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.

**3-HYDROXYISOVALERYLCARNITINE** (μmol C5OH/L whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	876	0.40	0.06	0.10	0.41	0.7
Non-derivatized - MS/MS non-kit	149	0.57	0.06	0.12	0.59	0.8
Derivatized - MS/MS PE NeoGram Kit	176	0.37	0.07	0.11	0.40	0.7
Non-derivatized - MS/MS PE NeoBase Kit	341	0.46	0.05	0.10	0.46	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.39	0.05	0.07	0.41	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.37	0.06	0.11	0.37	0.4
Lot 262 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	872	0.79	0.10	0.17	0.41	0.7
Non-derivatized - MS/MS non-kit	150	1.00	0.10	0.20	0.59	0.8
Derivatized - MS/MS PE NeoGram Kit	178	0.76	0.12	0.14	0.40	0.7
Non-derivatized - MS/MS PE NeoBase Kit	349	0.73	0.10	0.16	0.46	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.76	0.10	0.17	0.41	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.60	0.07	0.16	0.37	0.4
Lot 263 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	885	1.51	0.19	0.31	0.41	0.7
Non-derivatized - MS/MS non-kit	144	1.85	0.16	0.33	0.59	0.8
Derivatized - MS/MS PE NeoGram Kit	175	1.44	0.18	0.24	0.40	0.7
Non-derivatized - MS/MS PE NeoBase Kit	342	1.23	0.13	0.25	0.46	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	60	1.40	0.18	0.31	0.41	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.02	0.12	0.22	0.37	0.4
Lot 264 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	878	2.26	0.27	0.45	0.41	0.7
Non-derivatized - MS/MS non-kit	150	2.61	0.26	0.53	0.59	0.8
Derivatized - MS/MS PE NeoGram Kit	168	2.05	0.27	0.34	0.40	0.7
Non-derivatized - MS/MS PE NeoBase Kit	340	1.77	0.18	0.43	0.46	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	60	2.03	0.23	0.50	0.41	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.46	0.16	0.34	0.37	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 15x. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	880	0.03	0.02	0.03	0.03	0.8
Non-derivatized - MS/MS non-kit	136	0.01	0.00	0.01	0.00	0.9
Derivatized - MS/MS PE NeoGram Kit	162	0.02	0.01	0.02	0.05	0.6
Non-derivatized - MS/MS PE NeoBase Kit	352	0.01	0.01	0.01	0.02	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	69	0.06	0.04	0.05	0.09	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	0.01	0.00	0.01	0.04	0.6
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	867	0.42	0.06	0.10	0.03	0.8
Non-derivatized - MS/MS non-kit	139	0.46	0.06	0.08	0.00	0.9
Derivatized - MS/MS PE NeoGram Kit	163	0.39	0.05	0.05	0.05	0.6
Non-derivatized - MS/MS PE NeoBase Kit	368	0.40	0.04	0.06	0.02	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	66	0.41	0.07	0.08	0.09	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.37	0.04	0.05	0.04	0.6
Lot 167 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	868	0.78	0.09	0.16	0.03	0.8
Non-derivatized - MS/MS non-kit	135	0.87	0.08	0.13	0.00	0.9
Derivatized - MS/MS PE NeoGram Kit	166	0.67	0.09	0.11	0.05	0.6
Non-derivatized - MS/MS PE NeoBase Kit	371	0.75	0.07	0.11	0.02	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	70	0.68	0.09	0.14	0.09	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.69	0.07	0.09	0.04	0.6
Lot 168 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	876	1.93	0.21	0.40	0.03	0.8
Non-derivatized - MS/MS non-kit	140	2.29	0.22	0.38	0.00	0.9
Derivatized - MS/MS PE NeoGram Kit	169	1.57	0.17	0.26	0.05	0.6
Non-derivatized - MS/MS PE NeoBase Kit	367	1.86	0.15	0.25	0.02	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	70	1.51	0.20	0.32	0.09	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.56	0.12	0.15	0.04	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.



**HEXANOYLCARNITINE** (μmol C6/L whole blood)

- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	855	0.03	0.02	0.03	0.04	0.8
Non-derivatized - MS/MS non-kit	132	0.01	0.00	0.01	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	176	0.03	0.02	0.02	0.07	0.6
Non-derivatized - MS/MS PE NeoBase Kit	414	0.02	0.01	0.01	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	57	0.05	0.02	0.03	0.09	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.01	0.01	0.01	0.03	0.7
Lot 262 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	876	0.43	0.06	0.09	0.04	0.8
Non-derivatized - MS/MS non-kit	136	0.46	0.06	0.10	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	178	0.41	0.06	0.07	0.07	0.6
Non-derivatized - MS/MS PE NeoBase Kit	431	0.43	0.05	0.07	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.45	0.06	0.14	0.09	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	0.41	0.04	0.05	0.03	0.7
Lot 263 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	889	0.80	0.09	0.17	0.04	0.8
Non-derivatized - MS/MS non-kit	134	0.86	0.10	0.17	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	174	0.69	0.08	0.10	0.07	0.6
Non-derivatized - MS/MS PE NeoBase Kit	427	0.80	0.07	0.12	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.79	0.08	0.25	0.09	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.75	0.07	0.09	0.03	0.7
Lot 264 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	882	1.91	0.21	0.35	0.04	0.8
Non-derivatized - MS/MS non-kit	137	2.14	0.22	0.49	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	178	1.56	0.17	0.26	0.07	0.6
Non-derivatized - MS/MS PE NeoBase Kit	422	1.94	0.16	0.27	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	1.73	0.17	0.61	0.09	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.80	0.14	0.17	0.03	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 15y. 2012 Quality Control Data  
Summaries of Statistical Analyses

**OCTANOYLCARNITINE** (μmol C8/L whole blood)

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	882	0.03	0.01	0.02	0.03	0.9
Non-derivatized - MS/MS non-kit	201	0.05	0.02	0.05	0.05	0.9
Derivatized - MS/MS PE NeoGram Kit	166	0.01	0.01	0.01	0.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	372	0.01	0.01	0.01	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	65	0.02	0.02	0.02	0.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	27	0.01	0.01	0.01	0.04	0.7
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	927	0.49	0.07	0.10	0.03	0.9
Non-derivatized - MS/MS non-kit	193	0.53	0.05	0.11	0.05	0.9
Derivatized - MS/MS PE NeoGram Kit	166	0.44	0.08	0.08	0.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	381	0.42	0.04	0.05	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	67	0.41	0.09	0.09	0.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.40	0.05	0.06	0.04	0.7
Lot 167 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	920	0.94	0.11	0.18	0.03	0.9
Non-derivatized - MS/MS non-kit	192	0.98	0.09	0.17	0.05	0.9
Derivatized - MS/MS PE NeoGram Kit	168	0.82	0.11	0.14	0.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	378	0.83	0.07	0.10	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.80	0.13	0.14	0.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.77	0.07	0.11	0.04	0.7
Lot 168 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	921	2.30	0.25	0.40	0.03	0.9
Non-derivatized - MS/MS non-kit	193	2.41	0.22	0.36	0.05	0.9
Derivatized - MS/MS PE NeoGram Kit	166	2.05	0.26	0.33	0.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	381	2.11	0.16	0.24	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	1.92	0.29	0.39	0.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.75	0.16	0.26	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.

**OCTANOYLCARNITINE** (μmol C8/L whole blood)

- continued -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	895	0.04	0.02	0.02	0.04	0.9
Non-derivatized - MS/MS non-kit	204	0.05	0.02	0.05	0.06	0.9
Derivatized - MS/MS PE NeoGram Kit	169	0.02	0.01	0.01	0.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	428	0.02	0.01	0.02	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	67	0.02	0.01	0.02	0.04	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	47	0.02	0.01	0.02	0.03	0.8
Lot 262 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	906	0.52	0.07	0.10	0.04	0.9
Non-derivatized - MS/MS non-kit	212	0.53	0.05	0.07	0.06	0.9
Derivatized - MS/MS PE NeoGram Kit	167	0.47	0.07	0.07	0.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	435	0.48	0.05	0.06	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	0.46	0.06	0.08	0.04	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	0.44	0.04	0.05	0.03	0.8
Lot 263 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	917	0.97	0.12	0.17	0.04	0.9
Non-derivatized - MS/MS non-kit	215	0.98	0.09	0.13	0.06	0.9
Derivatized - MS/MS PE NeoGram Kit	168	0.86	0.13	0.16	0.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	432	0.90	0.07	0.10	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	69	0.88	0.10	0.15	0.04	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	49	0.80	0.05	0.06	0.03	0.8
Lot 264 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	922	2.36	0.24	0.40	0.04	0.9
Non-derivatized - MS/MS non-kit	214	2.36	0.19	0.32	0.06	0.9
Derivatized - MS/MS PE NeoGram Kit	165	2.09	0.29	0.34	0.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	436	2.24	0.20	0.29	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	2.11	0.23	0.37	0.04	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	1.97	0.16	0.16	0.03	0.8

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

Table 15z. 2012 Quality Control Data  
Summaries of Statistical Analyses

**DECANOYLCARNITINE** (μmol C10/L whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	863	0.02	0.01	0.02	0.02	1.0
Non-derivatized - MS/MS non-kit	187	0.03	0.01	0.04	0.02	1.0
Derivatized - MS/MS PE NeoGram Kit	161	0.02	0.01	0.02	0.01	0.7
Non-derivatized - MS/MS PE NeoBase Kit	381	0.02	0.01	0.01	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	66	0.02	0.01	0.02	0.00	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	28	0.01	0.01	0.01	0.03	0.7
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	889	0.48	0.07	0.11	0.02	1.0
Non-derivatized - MS/MS non-kit	194	0.51	0.06	0.13	0.02	1.0
Derivatized - MS/MS PE NeoGram Kit	168	0.36	0.05	0.06	0.01	0.7
Non-derivatized - MS/MS PE NeoBase Kit	381	0.38	0.04	0.06	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.39	0.08	0.09	0.00	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	0.34	0.03	0.04	0.03	0.7
Lot 167 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	905	1.00	0.13	0.21	0.02	1.0
Non-derivatized - MS/MS non-kit	194	1.03	0.14	0.27	0.02	1.0
Derivatized - MS/MS PE NeoGram Kit	165	0.74	0.10	0.12	0.01	0.7
Non-derivatized - MS/MS PE NeoBase Kit	382	0.79	0.07	0.11	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	0.81	0.13	0.16	0.00	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.74	0.06	0.08	0.03	0.7
Lot 168 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	896	2.42	0.31	0.52	0.02	1.0
Non-derivatized - MS/MS non-kit	194	2.53	0.30	0.63	0.02	1.0
Derivatized - MS/MS PE NeoGram Kit	169	1.82	0.21	0.29	0.01	0.7
Non-derivatized - MS/MS PE NeoBase Kit	386	2.00	0.18	0.28	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	2.03	0.29	0.38	0.00	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.64	0.12	0.19	0.03	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.

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

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 261 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	876	0.03	0.02	0.03	0.04	1.0
Non-derivatized - MS/MS non-kit	197	0.02	0.01	0.03	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	169	0.02	0.01	0.02	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	428	0.02	0.01	0.01	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	56	0.02	0.01	0.01	0.04	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	46	0.02	0.01	0.02	0.04	0.8
Lot 262 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	879	0.53	0.08	0.12	0.04	1.0
Non-derivatized - MS/MS non-kit	202	0.55	0.06	0.10	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	167	0.42	0.08	0.09	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	441	0.46	0.05	0.06	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.47	0.06	0.12	0.04	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	47	0.43	0.06	0.06	0.04	0.8
Lot 263 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	878	1.02	0.13	0.20	0.04	1.0
Non-derivatized - MS/MS non-kit	202	1.02	0.11	0.22	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	167	0.80	0.12	0.15	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	436	0.85	0.07	0.10	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.93	0.11	0.21	0.04	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	48	0.80	0.08	0.11	0.04	0.8
Lot 264 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	882	2.46	0.29	0.50	0.04	1.0
Non-derivatized - MS/MS non-kit	198	2.46	0.23	0.56	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	166	1.87	0.25	0.31	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	438	2.14	0.18	0.29	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	60	2.18	0.21	0.52	0.04	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	47	1.94	0.20	0.21	0.04	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 15aa. 2012 Quality Control Data  
Summaries of Statistical Analyses

**DODECANOYLCARNITINE** ( $\mu\text{mol C12/L}$  whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	716	0.03	0.02	0.03	0.04	0.9
Non-derivatized - MS/MS non-kit	127	0.01	0.00	0.01	0.00	1.0
Derivatized - MS/MS PE NeoGram Kit	149	0.02	0.02	0.02	0.03	0.9
Non-derivatized - MS/MS PE NeoBase Kit	313	0.01	0.00	0.01	-0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	65	0.03	0.01	0.02	0.09	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.01	0.00	0.00	0.02	0.8
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	734	0.50	0.09	0.13	0.04	0.9
Non-derivatized - MS/MS non-kit	128	0.49	0.06	0.09	0.00	1.0
Derivatized - MS/MS PE NeoGram Kit	151	0.45	0.06	0.07	0.03	0.9
Non-derivatized - MS/MS PE NeoBase Kit	322	0.40	0.03	0.04	-0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.48	0.10	0.10	0.09	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.39	0.04	0.08	0.02	0.8
Lot 167 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	721	0.96	0.14	0.23	0.04	0.9
Non-derivatized - MS/MS non-kit	130	0.96	0.10	0.29	0.00	1.0
Derivatized - MS/MS PE NeoGram Kit	160	0.91	0.14	0.15	0.03	0.9
Non-derivatized - MS/MS PE NeoBase Kit	322	0.81	0.06	0.08	-0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.95	0.16	0.19	0.09	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.81	0.07	0.13	0.02	0.8
Lot 168 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	718	2.28	0.31	0.54	0.04	0.9
Non-derivatized - MS/MS non-kit	128	2.44	0.28	0.49	0.00	1.0
Derivatized - MS/MS PE NeoGram Kit	156	2.20	0.24	0.28	0.03	0.9
Non-derivatized - MS/MS PE NeoBase Kit	319	2.08	0.16	0.20	-0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	68	1.99	0.28	0.36	0.09	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.92	0.16	0.34	0.02	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.

**DODECANOYLCARNITINE** ( $\mu\text{mol C12/L}$  whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 261 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	797	0.04	0.02	0.03	0.07	0.9
Non-derivatized - MS/MS non-kit	131	0.01	0.00	0.01	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	158	0.04	0.02	0.02	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	374	0.01	0.00	0.01	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	56	0.06	0.02	0.03	0.12	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.01	0.00	0.00	0.01	0.7
Lot 262 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	780	0.52	0.09	0.16	0.07	0.9
Non-derivatized - MS/MS non-kit	131	0.49	0.07	0.11	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	150	0.52	0.09	0.11	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	382	0.43	0.04	0.05	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	55	0.53	0.10	0.17	0.12	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.38	0.04	0.07	0.01	0.7
Lot 263 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	772	0.95	0.15	0.25	0.07	0.9
Non-derivatized - MS/MS non-kit	131	0.91	0.11	0.21	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	150	0.92	0.14	0.16	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	384	0.81	0.07	0.10	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	56	1.00	0.20	0.28	0.12	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.71	0.04	0.10	0.01	0.7
Lot 264 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	771	2.22	0.29	0.50	0.07	0.9
Non-derivatized - MS/MS non-kit	129	2.29	0.26	0.50	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	150	2.22	0.28	0.34	0.06	0.9
Non-derivatized - MS/MS PE NeoBase Kit	377	2.06	0.18	0.25	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	56	2.06	0.28	0.46	0.12	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.79	0.12	0.21	0.01	0.7

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

Table 15bb. 2012 Quality Control Data  
Summaries of Statistical Analyses

**MYRISTOYLCARNITINE** ( $\mu\text{mol C14/L}$  whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	855	0.04	0.02	0.03	-0.08	1.1
Non-derivatized - MS/MS non-kit	141	0.03	0.01	0.02	-0.09	1.2
Derivatized - MS/MS PE NeoGram Kit	161	0.03	0.01	0.02	-0.08	1.1
Non-derivatized - MS/MS PE NeoBase Kit	374	0.02	0.01	0.01	-0.10	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	69	0.05	0.03	0.03	-0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	0.01	0.00	0.01	-0.06	0.9
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	841	0.49	0.07	0.10	-0.08	1.1
Non-derivatized - MS/MS non-kit	136	0.52	0.05	0.11	-0.09	1.2
Derivatized - MS/MS PE NeoGram Kit	168	0.45	0.07	0.07	-0.08	1.1
Non-derivatized - MS/MS PE NeoBase Kit	369	0.42	0.04	0.05	-0.10	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	66	0.44	0.08	0.09	-0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.35	0.03	0.03	-0.06	0.9
Lot 167 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	849	1.38	0.18	0.26	-0.08	1.1
Non-derivatized - MS/MS non-kit	135	1.46	0.15	0.36	-0.09	1.2
Derivatized - MS/MS PE NeoGram Kit	164	1.26	0.14	0.16	-0.08	1.1
Non-derivatized - MS/MS PE NeoBase Kit	372	1.25	0.11	0.15	-0.10	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	68	1.15	0.15	0.18	-0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	1.07	0.08	0.08	-0.06	0.9
Lot 168 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	847	3.43	0.44	0.63	-0.08	1.1
Non-derivatized - MS/MS non-kit	134	3.68	0.42	0.77	-0.09	1.2
Derivatized - MS/MS PE NeoGram Kit	164	3.18	0.30	0.37	-0.08	1.1
Non-derivatized - MS/MS PE NeoBase Kit	366	3.21	0.25	0.35	-0.10	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	69	2.77	0.44	0.57	-0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	2.57	0.18	0.19	-0.06	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.



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

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 261 - Nonenriched 0 $\mu\text{mol}$ /L whole blood						
Derivatized - MS/MS non-kit	848	0.07	0.02	0.03	0.08	0.9
Non-derivatized - MS/MS non-kit	145	0.05	0.01	0.02	0.05	1.0
Derivatized - MS/MS PE NeoGram Kit	166	0.06	0.02	0.03	0.06	0.8
Non-derivatized - MS/MS PE NeoBase Kit	431	0.04	0.01	0.02	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	59	0.08	0.03	0.04	0.10	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.03	0.01	0.01	0.05	0.7
Lot 262 - Enriched 0.5 $\mu\text{mol}$ /L whole blood						
Derivatized - MS/MS non-kit	862	0.55	0.07	0.11	0.08	0.9
Non-derivatized - MS/MS non-kit	142	0.53	0.06	0.08	0.05	1.0
Derivatized - MS/MS PE NeoGram Kit	158	0.50	0.07	0.08	0.06	0.8
Non-derivatized - MS/MS PE NeoBase Kit	427	0.48	0.05	0.06	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	0.52	0.07	0.14	0.10	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	38	0.41	0.04	0.06	0.05	0.7
Lot 263 - Enriched 1.5 $\mu\text{mol}$ /L whole blood						
Derivatized - MS/MS non-kit	869	1.42	0.17	0.26	0.08	0.9
Non-derivatized - MS/MS non-kit	144	1.45	0.14	0.22	0.05	1.0
Derivatized - MS/MS PE NeoGram Kit	157	1.27	0.16	0.17	0.06	0.8
Non-derivatized - MS/MS PE NeoBase Kit	427	1.27	0.11	0.16	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	1.26	0.15	0.30	0.10	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.09	0.08	0.15	0.05	0.7
Lot 264 - Enriched 3.0 $\mu\text{mol}$ /L whole blood						
Derivatized - MS/MS non-kit	866	2.78	0.30	0.47	0.08	0.9
Non-derivatized - MS/MS non-kit	145	2.91	0.31	0.47	0.05	1.0
Derivatized - MS/MS PE NeoGram Kit	156	2.57	0.32	0.37	0.06	0.8
Non-derivatized - MS/MS PE NeoBase Kit	421	2.56	0.23	0.35	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	60	2.46	0.25	0.60	0.10	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	2.14	0.18	0.28	0.05	0.7

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

Table 15cc. 2012 Quality Control Data  
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	885	0.48	0.07	0.10	0.49	0.8
Non-derivatized - MS/MS non-kit	157	0.50	0.06	0.08	0.48	0.9
Derivatized - MS/MS PE NeoGram Kit	165	0.44	0.06	0.07	0.44	0.7
Non-derivatized - MS/MS PE NeoBase Kit	361	0.43	0.04	0.06	0.39	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	69	0.42	0.10	0.11	0.45	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.40	0.05	0.06	0.39	0.6
Lot 166 - Enriched 4.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	897	3.65	0.34	0.56	0.49	0.8
Non-derivatized - MS/MS non-kit	147	3.96	0.35	0.61	0.48	0.9
Derivatized - MS/MS PE NeoGram Kit	167	3.35	0.27	0.34	0.44	0.7
Non-derivatized - MS/MS PE NeoBase Kit	367	3.36	0.27	0.36	0.39	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	68	3.12	0.33	0.50	0.45	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.95	0.27	0.42	0.39	0.6
Lot 167 - Enriched 8.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	910	6.64	0.61	1.03	0.49	0.8
Non-derivatized - MS/MS non-kit	146	7.10	0.63	0.96	0.48	0.9
Derivatized - MS/MS PE NeoGram Kit	166	6.14	0.53	0.65	0.44	0.7
Non-derivatized - MS/MS PE NeoBase Kit	365	6.15	0.53	0.67	0.39	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	70	5.76	0.64	1.07	0.45	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	5.53	0.43	0.70	0.39	0.6
Lot 168 - Enriched 12.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	901	9.83	0.93	1.55	0.49	0.8
Non-derivatized - MS/MS non-kit	146	10.83	0.92	1.57	0.48	0.9
Derivatized - MS/MS PE NeoGram Kit	167	9.11	0.78	0.96	0.44	0.7
Non-derivatized - MS/MS PE NeoBase Kit	367	9.36	0.74	1.07	0.39	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	70	8.37	0.88	1.83	0.45	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	8.07	0.87	1.36	0.39	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.

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

- continued -

METHOD	N	Mean	Average Within Lab SD		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	894	0.74	0.09	0.13	0.77	0.7
Non-derivatized - MS/MS non-kit	166	0.77	0.08	0.11	0.76	0.8
Derivatized - MS/MS PE NeoGram Kit	172	0.69	0.08	0.09	0.72	0.7
Non-derivatized - MS/MS PE NeoBase Kit	410	0.69	0.06	0.09	0.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	69	0.71	0.10	0.17	0.74	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	37	0.61	0.04	0.05	0.64	0.6
Lot 262 - Enriched 4.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	904	3.80	0.38	0.59	0.77	0.7
Non-derivatized - MS/MS non-kit	164	4.07	0.34	0.48	0.76	0.8
Derivatized - MS/MS PE NeoGram Kit	172	3.51	0.32	0.36	0.72	0.7
Non-derivatized - MS/MS PE NeoBase Kit	428	3.68	0.32	0.46	0.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	3.66	0.40	0.89	0.74	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	3.24	0.23	0.33	0.64	0.6
Lot 263 - Enriched 8.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	916	6.68	0.60	0.97	0.77	0.7
Non-derivatized - MS/MS non-kit	169	7.30	0.66	1.09	0.76	0.8
Derivatized - MS/MS PE NeoGram Kit	178	6.17	0.62	0.79	0.72	0.7
Non-derivatized - MS/MS PE NeoBase Kit	425	6.54	0.55	0.79	0.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	6.57	0.60	1.44	0.74	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	5.70	0.35	0.54	0.64	0.6
Lot 264 - Enriched 12.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	913	9.67	0.90	1.41	0.77	0.7
Non-derivatized - MS/MS non-kit	167	10.67	0.97	1.55	0.76	0.8
Derivatized - MS/MS PE NeoGram Kit	169	8.96	0.73	0.85	0.72	0.7
Non-derivatized - MS/MS PE NeoBase Kit	422	9.68	0.79	1.34	0.67	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	9.38	0.78	2.11	0.74	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	8.31	0.52	0.59	0.64	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 15dd. 2012 Quality Control Data  
Summaries of Statistical Analyses

**3-HYDROXYPALMITOYL CARNITINE** (μmol C16OH/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	825	0.01	0.01	0.02	0.02	0.6
Non-derivatized - MS/MS non-kit	151	0.01	0.01	0.01	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	166	0.01	0.01	0.01	0.01	0.6
Non-derivatized - MS/MS PE NeoBase Kit	355	0.01	0.00	0.01	0.00	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.01	0.01	0.01	0.02	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.01	0.00	0.01	0.01	0.4
Lot 166 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	840	0.33	0.05	0.09	0.02	0.6
Non-derivatized - MS/MS non-kit	150	0.32	0.04	0.09	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	167	0.31	0.05	0.06	0.01	0.6
Non-derivatized - MS/MS PE NeoBase Kit	348	0.27	0.03	0.05	0.00	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	65	0.25	0.05	0.07	0.02	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.19	0.02	0.02	0.01	0.4
Lot 167 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	826	0.64	0.08	0.16	0.02	0.6
Non-derivatized - MS/MS non-kit	145	0.62	0.07	0.16	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	169	0.61	0.09	0.11	0.01	0.6
Non-derivatized - MS/MS PE NeoBase Kit	344	0.53	0.05	0.09	0.00	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	70	0.46	0.12	0.21	0.02	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.39	0.03	0.04	0.01	0.4
Lot 168 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	838	1.55	0.20	0.40	0.02	0.6
Non-derivatized - MS/MS non-kit	148	1.54	0.16	0.40	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	159	1.50	0.16	0.27	0.01	0.6
Non-derivatized - MS/MS PE NeoBase Kit	346	1.34	0.12	0.24	0.00	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	70	1.13	0.24	0.48	0.02	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.94	0.09	0.13	0.01	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.

**3-HYDROXPALMITOYL CARNITINE** (μmol C16OH/L whole blood)

- continued -

METHOD	N	Mean	Average		Y-Intercept*	Slope
			Within Lab SD	Total SD		
Lot 261 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	857	0.01	0.01	0.01	0.01	0.7
Non-derivatized - MS/MS non-kit	188	0.00	0.01	0.01	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	165	0.01	0.01	0.01	0.01	0.7
Non-derivatized - MS/MS PE NeoBase Kit	397	0.01	0.00	0.01	0.00	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	65	0.01	0.01	0.01	-0.01	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	0.00	0.00	0.01	0.00	0.5
Lot 262 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	875	0.38	0.06	0.09	0.01	0.7
Non-derivatized - MS/MS non-kit	207	0.38	0.04	0.09	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	169	0.37	0.06	0.07	0.01	0.7
Non-derivatized - MS/MS PE NeoBase Kit	402	0.32	0.04	0.06	0.00	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	65	0.34	0.05	0.14	-0.01	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	0.24	0.02	0.05	0.00	0.5
Lot 263 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	864	0.71	0.08	0.14	0.01	0.7
Non-derivatized - MS/MS non-kit	205	0.71	0.07	0.18	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	170	0.68	0.10	0.12	0.01	0.7
Non-derivatized - MS/MS PE NeoBase Kit	402	0.61	0.07	0.09	0.00	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.68	0.09	0.29	-0.01	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.45	0.03	0.08	0.00	0.5
Lot 264 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	863	1.80	0.21	0.38	0.01	0.7
Non-derivatized - MS/MS non-kit	203	1.82	0.17	0.43	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	166	1.74	0.20	0.30	0.01	0.7
Non-derivatized - MS/MS PE NeoBase Kit	402	1.54	0.17	0.26	0.00	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	70	1.77	0.20	0.75	-0.01	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.18	0.09	0.26	0.00	0.5

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

Table 15ee. 2012 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 165 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS non-kit	828	0.47	0.07	0.14	0.48	0.8
Non-derivatized - MS/MS non-kit	136	0.45	0.05	0.06	0.46	0.9
Derivatized - MS/MS PE NeoGram Kit	147	0.43	0.07	0.07	0.43	0.8
Non-derivatized - MS/MS PE NeoBase Kit	361	0.44	0.04	0.06	0.44	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	69	0.41	0.10	0.10	0.42	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.43	0.04	0.09	0.43	0.8
Lot 166 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	823	1.25	0.16	0.33	0.48	0.8
Non-derivatized - MS/MS non-kit	134	1.34	0.14	0.22	0.46	0.9
Derivatized - MS/MS PE NeoGram Kit	146	1.21	0.13	0.15	0.43	0.8
Non-derivatized - MS/MS PE NeoBase Kit	361	1.27	0.10	0.16	0.44	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	65	1.06	0.13	0.17	0.42	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.20	0.09	0.28	0.43	0.8
Lot 167 - Enriched 2.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	819	2.04	0.23	0.47	0.48	0.8
Non-derivatized - MS/MS non-kit	136	2.16	0.20	0.33	0.46	0.9
Derivatized - MS/MS PE NeoGram Kit	148	2.01	0.22	0.26	0.43	0.8
Non-derivatized - MS/MS PE NeoBase Kit	362	2.08	0.17	0.28	0.44	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	70	1.74	0.24	0.34	0.42	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.90	0.17	0.29	0.43	0.8
Lot 168 - Enriched 5.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	826	4.33	0.54	1.05	0.48	0.8
Non-derivatized - MS/MS non-kit	138	4.73	0.42	0.70	0.46	0.9
Derivatized - MS/MS PE NeoGram Kit	149	4.34	0.43	0.50	0.43	0.8
Non-derivatized - MS/MS PE NeoBase Kit	366	4.58	0.38	0.65	0.44	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	69	3.64	0.45	0.78	0.42	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	4.19	0.33	0.73	0.43	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 -

<b>METHOD</b>	<b>N</b>	<b>Mean</b>	<b>Average Within Lab SD</b>	<b>Total SD</b>	<b>Y- Intercept*</b>	<b>Slope</b>
Lot 261 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	859	0.62	0.09	0.16	0.62	0.8
Non-derivatized - MS/MS non-kit	147	0.61	0.06	0.11	0.61	0.9
Derivatized - MS/MS PE NeoGram Kit	157	0.61	0.08	0.09	0.59	0.9
Non-derivatized - MS/MS PE NeoBase Kit	423	0.60	0.06	0.09	0.59	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	69	0.56	0.08	0.14	0.57	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.55	0.05	0.11	0.56	0.8
Lot 262 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	856	1.43	0.17	0.32	0.62	0.8
Non-derivatized - MS/MS non-kit	146	1.48	0.12	0.23	0.61	0.9
Derivatized - MS/MS PE NeoGram Kit	159	1.44	0.15	0.20	0.59	0.9
Non-derivatized - MS/MS PE NeoBase Kit	432	1.49	0.14	0.18	0.59	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	1.35	0.18	0.36	0.57	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.34	0.11	0.29	0.56	0.8
Lot 263 - Enriched 2.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	855	2.27	0.26	0.46	0.62	0.8
Non-derivatized - MS/MS non-kit	144	2.35	0.24	0.43	0.61	0.9
Derivatized - MS/MS PE NeoGram Kit	156	2.26	0.24	0.30	0.59	0.9
Non-derivatized - MS/MS PE NeoBase Kit	432	2.38	0.21	0.29	0.59	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	2.15	0.25	0.60	0.57	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	2.11	0.17	0.41	0.56	0.8
Lot 264 - Enriched 5.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	844	4.68	0.50	0.96	0.62	0.8
Non-derivatized - MS/MS non-kit	144	4.97	0.42	0.91	0.61	0.9
Derivatized - MS/MS PE NeoGram Kit	157	4.85	0.48	0.59	0.59	0.9
Non-derivatized - MS/MS PE NeoBase Kit	428	5.10	0.42	0.62	0.59	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	70	4.51	0.42	1.20	0.57	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	4.38	0.31	0.72	0.56	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.

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

**Director**

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

**Director**

**National Center for Environmental Health**

Christopher J. Portier, Ph.D.

**Director**

**Division of Laboratory Sciences**

James L. Pirkle, M.D., Ph.D.

**Chief**

**Newborn Screening and Molecular Biology Branch**

Carla Cuthbert, Ph.D.



**Contributors:** Barbara W. Adam  
Dana Chafin  
Suzanne Cordovado, Ph.D.  
Paul Dantonio  
Victor R. De Jesus, Ph.D.  
Zachary Detwiler  
Marie C. Earley, Ph.D.  
Christopher Greene, Ph.D.  
Sharon Flores  
Elizabeth M. Hall  
Laura Hancock  
Christopher Haynes, Ph.D.  
Miyono Hendrix  
Kevin Lanza  
Francis Lee, Ph.D.  
Lixia Li, Ph.D.  
Timothy Lim, Ph.D.  
Daniel Mandel, Ph.D.  
Joanne Mei, Ph.D.  
Nancy Meredith  
Tracey Myers  
Stanimila Nikolova, Ph.D.  
Kelsey Sheard  
Jennifer Taylor, Ph.D.  
Daniel Turner  
Robert Vogt, Ph.D.  
Irene Williams  
Golriz Yazdanpanah  
Hui Zhou, Ph.D.  
Sherri Zobel

**Production:** Sarah Brown  
Felicia Manning  
Connie Singleton



**ASSOCIATION OF PUBLIC HEALTH LABORATORIES**  
**SILVER SPRING, MD 20910**

**President**

Charles Brokopp, Dr. P.H., M.P.H.

**Chairman, Newborn Screening and Genetics in Public Health Committee**

Susan M. Tanksley, Ph.D.

**Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee**

Patrick Hopkin, B.S.

**INQUIRIES TO:**

*Sherri Zobel, Editor • Centers for Disease Control and Prevention (CDC)*  
*Newborn Screening Quality Assurance Program • Mailstop F-43*  
*4770 Buford Highway, N.E. • Atlanta, GA 30341-3724*  
*Phone (770) 488-4582 • FAX (770) 488-4255 • E-mail: SZobel@cdc.gov*









