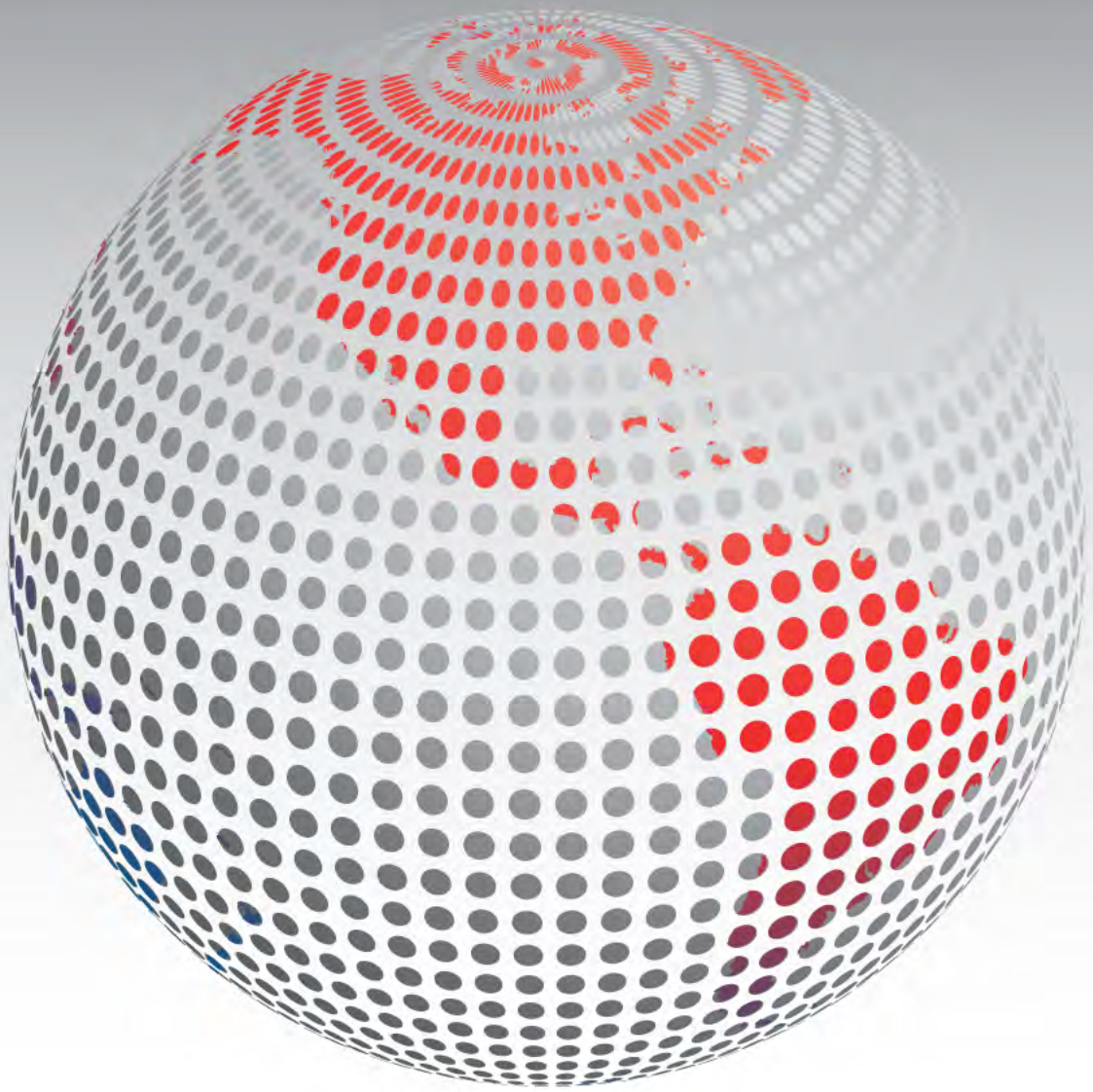
NEWBORN SCREENING

Annual Summary Report
volume 31

2013

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

Newborn Screening Quality Assurance Program

1978
CDC begins quality control (QC) pilot study for Congenital Hypothyroidism measuring Thyroxine (T_4) and Thyroid Stimulating Hormone (TSH) in dried-blood spots (DBS).

Number of participants: 31 in T4 QC and 24 in TSH QC

1980
CDC develops a test to monitor performance of filter paper matrix for collection of newborn screening DBS samples.

1988
10th Anniversary of CDC Newborn Screening Quality Assurance Program (NSQAP)

Number of analytes: Five

Number of Newborn Screening Laboratory Participants: 75

Number of participating countries: 4

1994
NSQAP adds DNA quality assurance program for DBS confirmation for Hemoglobinopathies.

1978 | 1980s | 1990s

1980
First DBS newborn screening performance surveillance survey (later called proficiency testing (PT)) for Phenylketonuria and Congenital Hypothyroidism is offered.

Italy: first country other than U.S. to join the program.

1988
HIV-1 dried-blood spot QC and PT are offered as part of a seroprevalance survey among childbearing women.

Galactosemia DBS QC is offered.

1990-1997
17-α Hydroxy-progesterone, Methionine, Leucine, Hemoglobinopathies, and Biotinidase PT materials are now available.

1998
20th Anniversary of CDC NSQAP

Number of analytes: 13

Number of Newborn Screening Laboratory Participants: 198

Number of participating countries: 33

35th Anniversary

2000 - 2003
Pilot Surveys for Amino Acid, Fatty Acid, and Organic Acid Disorders in DBS measured by Tandem Mass Spectrometry (MS/MS) begin.

2002
The first Galactose-1-phosphate uridyltransferase (GALT) and Immunoreactive Trypsinogen for Cystic Fibrosis PT offered; Tyrosine, Valine and Citrulline QC offered.

2008
30th Anniversary of CDC NSQAP

Number of analytes: 35

Number of Newborn Screening Laboratory Participants: 418

Number of participating countries: 62

2011
NSQAP established a new DBS PT program for DNA testing for T-Cell Receptor Excision Circle (TREC) used in screening for Severe Combined Immune Deficiency (SCID).

2013
35th Anniversary of CDC NSQAP

Number of analytes: 47

Number of Newborn Screening Laboratory Participants: 578

Number of participating countries: 73

2000s

2010s

2013

2001
NSQAP goes online with operation of paperless PT data-reporting system.

2005-2006
Pilot DBS PT programs were launched for *Toxoplasma gondii* and 2nd Tier Congenital Adrenal Hyperplasia.

2008
The first Succinylacetone and Lysosomal Storage Disorders DBS testing offered.

2012
PT and QC panels cover all primary biomarkers for the 42 MS/MS-detectable core and secondary disorders listed in the U.S. Recommended Uniform Screening Panel.

Newborn Screening
Quality Assurance Program

2013
NSQAP
BY THE NUMBERS

100 percentage of states covered

73 countries participated

881,325 DBS produced

43 new enrollments

12 labs moved to inactive status

578 labs enrolled at end of year

546 labs reported data

492 labs participated in PT

445 labs participated in QC

31 reports provided to participants

4 filter paper lots evaluated

31 US labs participated when NSQAP was established in 1978

Source: Newborn Screening Quality Assurance Program, December 2013

INTRODUCTION

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

It is important to note that these screening tests alone are not intended to yield a diagnostic testing outcome. However, effective screening of newborns, with the use of dried-blood spots (DBS) specimens collected at birth, combined with follow-up, diagnostic confirmation, and treatment helps prevent mental retardation and premature death. State public health laboratories or their associated laboratories routinely screen DBS specimens for inborn metabolism errors and other disorders that might require medical intervention. Healthcare professionals collect DBS specimens from more than 98% of all newborns in the United States. The Centers for Disease Control and Prevention's (CDC) Newborn Screening Quality Assurance Program (NSQAP) assists newborn screening laboratories with these testing processes. This report summarizes all phases of NSQAP's proficiency testing (PT) activities and summarizes all quality control (QC) data reported in 2013.

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 newborn screening laboratories ensure that testing accurately detects disorders, does not delay diagnosis, minimizes false-positive reports, and sustains high-quality performance. Our job is to serve our participating newborn screening laboratories. In that regard, we welcome comments and suggestions about how we can better serve participants' needs.

For more than 35 years, NSQAP, with its cosponsor the Association of Public Health Laboratories (APHL), has researched development of DBS-screening test materials and has assisted laboratories with DBS-related quality assurance (QA). Although the NSQAP services primarily support newborn screening testing by U.S. laboratories, it also allows private and international laboratories to enroll in the program. All laboratories that test newborn DBS specimens participate voluntarily. The NSQAP provides QA services for the core (primary) and secondary condi-

FIGURE 1. Seventy-three Countries Participated in the Newborn Screening Quality Assurance Program in 2013

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

One or more laboratories represented for each country listed.

tions listed in the U.S. Recommended Uniform Screening Panel (RUSP). These disorders include, but are not limited to the following: congenital hypothyroidism, congenital adrenal hyperplasia (CAH), galactosemia (TGal), 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.

NSQAP produces and distributes two types of certified laboratory DBS materials: QC materials for periodic use, and PT materials three times a year. The QC program helps laboratories maintain high levels of technical proficiency and continuity, particularly during changes in commercial assay systems or 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.
The PT program offers laboratories panels of blind-coded DBS specimens. These specimens provide an independent, external assessment of each laboratory's performance. The NSQAP certifies DBS materials for QC and PT homogeneity, accuracy, stability, and suitability for newborn screening assays. But the limited availability of appropriate blood sources means the program does not distribute QC materials for biotinidase deficiency, hemoglobins, CF Mutation Detection (CFDNA), T-cell Receptor Excision Circle (TREC), or *Toxoplasma gondii* antibodies.

Over the years, the NSQAP has grown substantially. In 2013, active program participants included 578 newborn screening laboratories in 73 countries (at least one laboratory per country) (Figure 1). Of these, 492 participated in PT (Figure 2) and 445 in QC (Figure 3). The program distributed DBS materials to participating laboratories for 47 analytes covering primary markers for 48 disorders (Figures 2–3). For PT, 317 laboratories used tandem mass spectrometry (MS/MS) to report their data—of these, 55 were domestic laboratories.

MS/MS has had a major impact on the data that laboratories report to the NSQAP. 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 NSQAP's PT and QC projects. These biomarkers cover 42 disorders from the core (primary) and secondary RUSP panels.

2013 NEWBORN SCREENING PROGRAM ACTIVITIES

- Nancy Meredith retired from NSQAP on December 31, 2013 after 28 years with the federal government; 23 of which with NSQAP. She was an integral part of the NSQAP. Although we miss her, we know she is thoroughly enjoying her retirement.

- NSQAP modified the amino acid PT panels to include Succinylacetone (SUAC). Beginning July 2014, SUAC will no longer be a separate program and will be included in the amino acid PT panels.

Figure 2. Number of Participants in Proficiency Testing Program, 2013
Total - 492

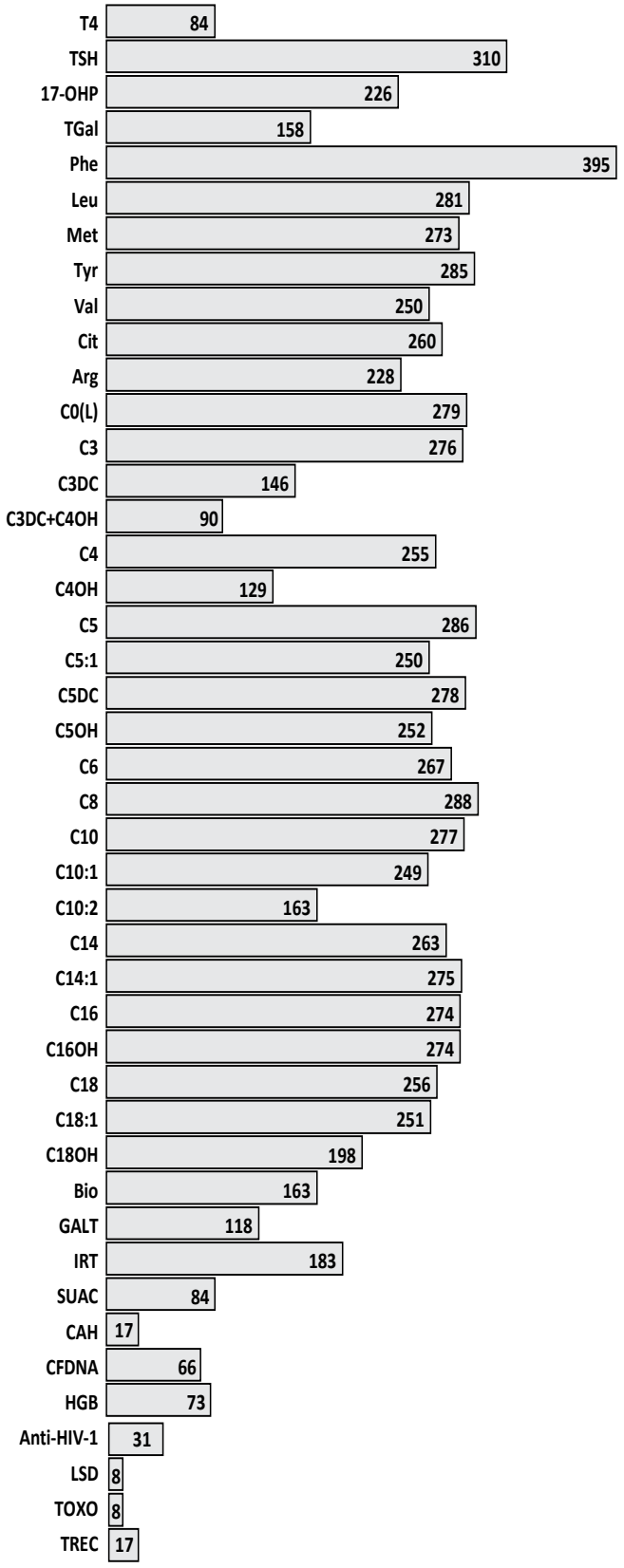
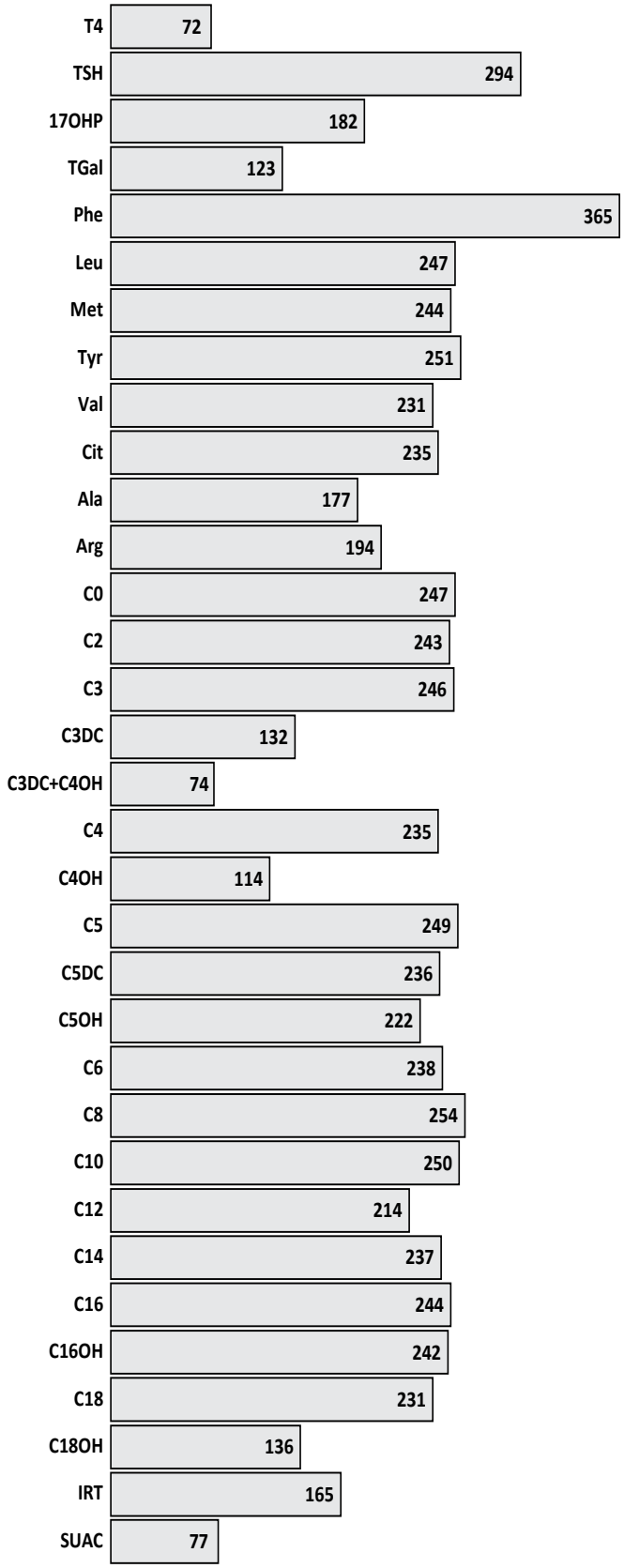


Figure 3. Number of Participants in Quality Control Program, 2013
Total - 445



- NSQAP now provides galactose-1-phosphate uridyltransferase (GALT) QC materials. The materials will include three levels of certified GALT QC. Participants in the GALT QC program will submit quantitative data on the same data QC report form that is currently in use. NSQAP will begin offering GALT QC to its participants in July 2014.

- In March, the Molecular Quality Improvement Program (MQIP) and APHL hosted a Webcast titled "Newborn Screening Molecular Resources Web site." This resource provides valuable information for newborn screening laboratories engaged in molecular testing. The Webinar is on the Newborn Screening Molecular Resources Web site at www.aphl.org

- In May, the APHL and CDC held a 5-day symposium to commemorate 50 years of Newborn Screening. The symposium was held in Atlanta, GA.

- In May, the APHL-sponsored QA/QC Subcommittee of the Newborn Screening and Genetics in Public Health Committee met in Atlanta. One subcommittee mission is to provide guidance to the NSQAP on procedures, policies, and activities for quality assessment of laboratory testing. Input from this subcommittee enhances our continuing efforts to serve our participants better.

- In May, the Molecular Subcommittee of the Newborn Screening and Genetics in Public Health Committee met in Atlanta. The subcommittee guides state newborn screening public health laboratories on molecular screening procedures, policies, and activities. The subcommittee also provides guidance to the MQIP. This valuable input assists MQIP in providing molecular quality improvement to aid public health laboratories in detection newborn disorders.

- Paul Dantonio won the Best Poster Award at the APHL symposium in May for his poster titled "Evaluation of a Newborn BloodSpot Card: The End to Subjective Analysis?" Authors: Paul D. Dantonio, Germaine Stevens, Arthur Hagar, David Ludvigson, Daron Green, Harry Hannon, and Robert F. Vogt.

- In cooperation with APHL, MQIP hosted the Newborn Screening Molecular Training Workshop. This dynamic, annual, hands-on workshop comprised lectures and laboratory training activities that directly related to detection of newborn disorders using molecular methods. Participants came from 14 state-newborn screening programs.

4 New countries joined NSQAP: Guatemala, Kazakhstan, Venezuela, Vietnam

- The Newborn Screening Molecular Assessment Program (MAP) completed nine site visits, with two more planned for early 2014. The MAP program offers onsite molecular laboratory visits to assist state newborn screening laboratories in quality assessments of their molecular programs. For more information, see the MQIP section of this report.

- NSQAP continued the CFDNA PT project, which included 66 participants. Reports posted at 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 (ACMG) mutation panel's recommended [2] population screening and other less common mutations or sequence polymorphisms.

- Through collaboration with the California Department of Public Health, the Sequoia Foundation, and CF Centers in California, the NSQAP received 69 blood specimens for the CFDNA PT project. This delivery 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 quarter three, the NSQAP added the analyte, C18OH to its acylcarnitine panels. We had 187 participants report PT results for C18OH.

- NSQAP, in collaboration with the Newborn Screening Translation Initiative, began a pilot PT program for the lysosomal storage disorders Krabbe and Pompe disease. Eight state and private laboratories participated.

- During 2013, NSQAP continued its PT program to investigate materials and clinical interpretations based on the ratio of 17 α-hydroxyprogesterone (17-OHP), androstenedione, cortisol, 21-deoxycortisol, and

11-deoxycortisol for second-tier CAH screening by use of liquid chromatography-tandem mass spectrometry. We had 13 laboratories participate in three quarterly surveys.

- NSQAP developed enhancements to the data-reporting Web site. Our goal is to make reporting easy and efficient for participants.

- Participants report the following program data by e-mail: QC, Hemoglobinopathies, TREC, Lysosomal Storage Disorders, *Toxoplasma gondii* antibodies, HIV-1-antibodies, CFDNA, and Second-tier CAH. Electronic reporting streamlines data processing, makes accumulation of statistical data easier, and allows better data sharing with our participants.

2013 BIOCHEMICAL MASS SPECTROMETRY LABORATORY ACTIVITIES

The Newborn Screening and Molecular Biology Branch's (NSMBB) Biochemical Mass Spectrometry Laboratory (BMSL) offers newborn screening MS/MS services, education, and research opportunities. BMSL also oversees the biotinidase, TGal, GALT, and filter paper evaluation programs. In addition, laboratory staff research helps to expand the NSQAP's analytical capabilities beyond the DBS.

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

Since NSQAP began offering SUAC PT in 2008, the amino acids and SUAC PT panels have been separate. SUAC will be incorporated into the amino acids PT program effective July 2014. The amino acids QC pools will continue to include SUAC.

In July 2013, BMSL and NSQAP introduced hydroxystearoylcarnitine (C18OH), a marker for Long-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency (LCHADD) and Tri-functional protein deficiency (TPD), to the acylcarnitine PT and QC panels. The QC and PT MS/MS panels cover all primary biomarkers and several secondary for the 42 MS/MS-detectable core and secondary target disorders listed in the RUSP.

BMSL staff continues to expand its QC and PT offerings for TGal. The laboratory successfully prepared high-quality GALT QC materials for distribution in July 2014. BMSL staff offered all participants enrollment into the GALT QC program. The laboratory presented a summary of the experimental development at the 2013 Newborn Screening and Genetic Testing Symposium held in Atlanta.

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

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.

2013 NEWBORN SCREENING TRANSLATION RESEARCH INITIATIVE ACTIVITIES

CDC's Newborn Screening Translation Research Initiative ("the Initiative") is an ongoing collaboration between the CDC Foundation and CDC's NSMBB. In 2013, the Initiative completed its eighth year of operation. The Initiative's vision is the methodical expansion of newborn screening to detect more conditions in more infants throughout the world. The goal is for all infants with identified congenital disorders to have a better chance for a healthy childhood. The Initiative assembles public, academic, foundation, and corporate partnerships for the scientific and financial support of translational research efforts in newborn screening.

Translation research is often described as the process of moving biomedical research findings "from bench to bedside." A better description for the Initiative's work is moving biomedical research findings "from bench to bassinet." Integration of QA systems is one of the most critical processes in translating laboratory research methods into practical newborn screening assays. The Initiative's ultimate goal is to help transform promising research methods into assays suitable for routine, population-based newborn screening. All the Initiative's projects include

collaboration with public health newborn screening programs. The Initiative also works closely with the Clinical and Laboratory Standards Institute (CLSI) to develop a newborn-screening guideline consensus.

During its eighth year of operation, the Initiative expanded support for public health newborn screening programs testing for Severe Combined Immunodeficiency (SCID). Representatives from eight programs participated in laboratory training workshops at CDC, where they produced and analyzed DBS reference materials for the TREC assay used to detect SCID. The NSQAP expanded the SCID PT project, and the Initiative continued multi-laboratory evaluations of TREC reference materials, including a new B-cell calibrator modified by inserting a TREC sequence.

The Initiative also expanded support for newborn screening tests to detect lysosomal storage disorders, including characterization of reference materials by digital microfluidic fluorometry. Working with NSQAP, the Initiative helped start the first PT challenges for Pompe and Krabbe disorders using condition-specific DBS reference materials made from immortalized cell lines. More than a dozen partnerships were involved in these projects, and many of those partners contributed both scientific and financial support.

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

2013 MOLECULAR QUALITY IMPROVEMENT PROGRAM

MQIP provides comprehensive molecular assistance to newborn-screening laboratories. In 41 states, at least one molecular test screens newborn populations. To support these states, MQIP provides technical assistance on molecular-specific QA issues, troubleshooting, and educational resources for newborn screening laboratories engaged in molecular testing. In addition, MQIP works closely with APHL's Molecular Subcommittee to facilitate the exchange of molecular best practices.

The Newborn Screening MAP site visits provide unique laboratory assessments tailored to the specific needs of newborn screening molecular programs. The MAP evaluation teams consists of both CDC and state public health molecular biologists who work with laboratory personnel to provide a broad assessment of all components of their molecular testing procedures. Included in a MAP site visit is tailored guidance for laboratory-specified needs and assistance in evaluating ongoing and new molecular testing procedures. MAP has visited nine states, with two additional programs planned in early 2014. 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

The Newborn Screening Molecular Resources Web site was developed and launched in early 2013 (http://www.aphl.org/aphlprograms/newborn-screening-and genetics/molecular/pages/default.aspx). A Webinar held in March titled, "Newborn Screening Molecular Resources Web site Webcast" provided a detailed description and overview of how to use the Web site. This resource allows the user to browse detailed summaries and information for ongoing molecular assays, access the Newborn Screening MAP site visit portal and checklists, and view archived presentations from newborn screening molecular workshops and Webinars. This resource will expand to include liquid handling robotics used for molecular assays.

In July, MQIP hosted the third annual Newborn Screening Molecular Training Course. This dynamic course consisted of both lecture and laboratory segments that directly related to the detection of newborn disorders using molecular methods. Lecture topics included the following: molecular laboratory design and unidirectional workflow, comparison of instrument platforms for DBS genotyping, assay requirements for multiplex assay design, and data reporting and clinical interpretation. Newborn screening scientists from 14 states participated in this workshop.

The MQIP laboratory completed the development of a DNA microsatellite assay to confirm sample identity and identify mixed samples for QA. In addition, DBSs for GALT mutation detection are in development for participant laboratories that use mutation detection as a second tier method.

For more information about the MQIP, please contact Dr. Suzanne Cordovado at scordovado@cdc.gov.

OTHER 2013 NSQAP ACTIVITIES

Filter paper

As a vital service to the newborn screening community, NSQAP evaluates the filter paper's absorption characteristics and other parameters of filter paper lots from manufacturers that have received FDA clearance ("approval") for their blood collection filter paper [3]. According to a mutually voluntary agreement, the filter paper manufacturers (GE Healthcare Bio-sciences Corporation and PerkinElmer Health Sciences) provide NSQAP with

PerkinElmer

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

Filter Paper Lot	Date of Evaluation	Serum Volume Per 1/8" Punch (µL)		Absorption Time (sec)		Spot Diameter (mm)	
	(month/year)	Avg	StDev	Avg	StDev	Avg	StDev
102928	Aug 2013	1.38	0.09	8.5	0.9	16.1	0.5
102277	Dec 2012	1.47	0.11	13.0	4.9	15.8	0.6
101535	Apr 2012	1.49	0.08	14.7	3.1	15.7	0.5
100535	May 2011	1.45	0.08	8.9	2.2	15.7	0.5
0120201	Apr 2010	1.47	0.11	14.0	3.7	16.0	0.6
9461001	Feb 2010	1.53	0.09	8.8	1.8	15.4	0.6
8040201	Feb 2008	1.60	0.10	7.2	1.8	15.6	0.6
7231001	Nov 2007	1.42	0.10	15.5	2.6	16.0	0.5
7181001	Nov 2007	1.44	0.10	14.5	2.3	16.0	0.5
5431001	Apr 2007	1.42	0.10	7.4	0.7	16.1	0.6

GE Healthcare Bio-Sciences

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

Filter Paper Lot	Date of Evaluation	Serum Volume Per 1/8" Punch (µL)		Absorption Time (sec)		Spot Diameter (mm)	
	(month/year)	Avg	StDev	Avg	StDev	Avg	StDev
W131	Aug 2013	1.40	0.07	10.4	1.4	16.1	0.5
W122	May 2013	1.41	0.11	14.8	2.9	16.3	0.5
W121	Jan 2013	1.49	0.09	13.7	3.8	16.0	0.6
W113	Mar 2012	1.44	0.08	9.9	2.0	15.8	0.6
W112	Oct 2011	1.38	0.13	12.9	2.1	16.0	0.5
W111	Feb 2011	1.42	0.08	10.2	1.5	16.1	0.5
W102	Oct 2010	1.54	0.08	9.6	1.7	15.7	0.6
W101	May 2010	1.44	0.08	9.5	1.3	16.1	0.5
W092	Feb 2010	1.48	0.09	11.9	2.1	16.0	0.7
W091	Apr 2009	1.46	0.09	11.7	2.6	16.0	0.7

statistically valid sample sets from different reels of the unprinted filter paper production lot for evaluation using NSQAP's standardized procedures. The manufacturers have the responsibility for establishing their own parallel evaluation laboratory. We provide NSQAP's evaluation results for comparison with those from the primary evaluator. But before releasing a new production lot of filter paper for printing and distribution, NSQAP and the manufacturer need to achieve agreement. NSQAP's independent evaluations are an impartial and voluntary service offered as a function of our QA program; they do not constitute endorsement of any product.

The disk punched from DBS specimens is a volumetric measurement that requires a high degree of uniformity among and within production lots. NSQAP uses an isotopic method developed at CDC to evaluate and compare different lots of filter paper. Description of the method is in the latest version of the CLSI Standard Newborn Screening 01-A6, Blood Collection on Filter Paper for Newborn Screening Programs [3]. Mean counts per minute of added radioisotope-labeled thyroxine (T4) 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 [3]. Initially, we used lysed-cell whole blood to avoid variability contributed by uncontrolled red blood cell (RBC) lysis during the 4-day QC production span. Results of later studies 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 filter paper lots.

The published and standardized acceptable serum volumes per 3.2-mm disk are (mean value and 95% confidence interval [CI]) 1.54 ± 0.17 µL for intact-cell blood [3]. The mean values and CIs are the filter paper evaluation parameters published in the CLSI standard. The CDC mean value for intact-cell evaluations for all lots is within the 95% CI defined by CLSI but below the mean value indicated by the CLSI standard [3].

Tables 1 and 2 contain serum absorption volumes of the last 10 lots from two FDA-approved sources, determined

TABLE 3. 2013 Summary of Non-MS/MS Cutoff Values of Domestic and Foreign Laboratories

Domestic

Analyte	N	Mean	Median	Mode	Min	Max
T4	23	6.0	6.0	5.0	4.0	8
TSH	45	32.7	28.5	20.0	3.0	61.0
17-OHP	44	33.6	33.0	33.0	7.0	65.0
Total Galactose	23	11.0	10.0	10.0	6.0	20.0
Phenylalanine	6	153.60	150.0	181.8	121.0	181.80
Tyrosine	3	237.3	160.0	-	138.0	414.00
IRT	43	66.0	62.0	67.0	31.9	106.8
GALT	16	3.1	3.2	3.5	1.7	4.0

Foreign

Analyte	N	Mean	Median	Mode	Min	Max
T4	38	6.5	6.0	6.0	1.0	20.0
TSH	211	23.2	20.0	20.0	2.0	50.0
17-OHP	136	30.5	22.0	19.8	0.4	200.0
Total Galactose	95	11.8	10.0	10.0	0.7	30.0
Leucine	6	294.8	306.5	381.5	152.6	381.5
Methionine	4	81.9	80.8	-	65.0	101.0
Phenylalanine	74	155.9	150.8	121.2	2.5	242.4
Tyrosine	3	335.0	397.0	-	200.0	408.0
Valine	3	335.7	325.0	-	282.0	400.0
SUAC	3	1.8	2.0	-	1.0	2.5
IRT	112	68.7	65.0	70.0	42.0	150.0
GALT	41	2.9	3.0	3.5	1.0	5.0

TABLE 4. 2013 Summary of MS/MS Cutoff Values of Domestic Laboratories

Analyte	N	Mean	Median	Mode	Min	Max
Phenylalanine	50	142.1	145.0	155.0	97.0	190.0
Leucine	47	287.4	275.0	250.0	175.0	400.0
Methionine	48	76.9	75.0	100.0	35.0	100.0
Tyrosine	49	413.3	337.0	400.0	88.0	850.0
Valine	33	291.4	280.0	250.0	200.0	420.0
Citrulline	48	55.1	58.0	60.0	18.0	100.0
Arginine	36	69.4	53.5	50.0	20.0	125.0
SUAC	27	2.9	3.0	4.5	0.5	5.4
C0(L)	51	8.95	8.00	7.00	3.80	27.00
C3	53	5.73	6.00	6.30	1.10	8.00
C3DC	25	0.23	0.20	0.20	0.10	0.45
C3DC + C4OH	15	0.43	0.40	0.40	0.38	0.60
C4	47	1.29	1.30	1.70	0.49	1.90
C4OH	22	0.65	0.70	0.75	0.27	1.00
C5	53	0.71	0.70	1.00	0.40	1.20
C5:1	50	0.26	0.18	0.60	0.05	0.60
C5DC	51	0.36	0.32	0.60	0.05	0.80
C5OH	52	0.80	0.80	0.90	0.19	1.18
C6	50	0.43	0.30	0.95	0.16	0.95
C8	53	0.45	0.40	0.60	0.25	0.72
C10	50	0.46	0.42	0.65	0.22	0.80
C10:1	47	0.31	0.30	0.45	0.14	0.53
C10:2	22	0.16	0.13	0.10	0.06	0.46
C14	50	0.77	0.73	0.70	0.17	1.20
C14:1	51	0.61	0.65	0.80	0.17	0.80
C16	51	7.63	7.70	10.00	0.41	10.00
C16OH	52	0.13	0.12	0.10	0.08	0.25
C18	44	2.45	2.28	4.00	0.22	4.00
C18:1	47	3.52	3.00	2.50	0.36	7.00
C18OH	29	0.11	0.10	0.10	0.04	0.26

using intact RBCs. For W131, the most recent production lot tested of Whatman 903 filter paper, we found the mean serum absorption volume was 1.40 µL per 3.2 mm disk for intact-cell blood. Lot W131 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within acceptable limits). We found the mean serum absorption volume for the most recent production lot tested of PerkinElmer 226 filter paper, lot 102928, was 1.38 µL per 3.2 mm disk for intact-cell blood. Lot 102928 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within acceptable limits). Each mean value is within the acceptable range for the matrix used. 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). The testing results provided in Tables 1 and 2 are for informational purposes only.

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2013 were W111 of Whatman 903 and 0120201 of PerkinElmer 226.

The latest CLSI Standard NBS01-A6 revision, Blood Collection on Filter Paper for Newborn Screening Programs [3], was completed in 2013. The revised standard addresses the issues associated with specimen collection, the filter paper segment of the specimen collection device (card), and the transfer of blood onto filter paper. The purpose of these activities is to produce a functional standard that will result in uniform techniques for collecting the best possible specimen for use in newborn screening programs. Issues addressed in the standard include

- Procedures for skin puncture and pain management;
- Procedures for applying blood collected by heelstick directly onto the preprinted circles of the filter paper;

TABLE 5. 2013 Summary of MS/MS Cutoff Values of Foreign Laboratories

Analyte	N	Mean	Median	Mode	Min	Max
Phenylalanine	204	137.9	129.5	120.0	51.4	300.0
Leucine	193	306.2	300.0	300.0	160.0	600.0
Methionine	190	58.7	53.5	50.0	22.0	140.0
Tyrosine	196	290.9	253.9	200.0	50.0	1000.0
Valine	184	270.3	257.5	300.0	121.7	659.9
Citrulline	177	53.3	50.0	60.0	19.5	200.0
Arginine	155	57.3	50.0	60.0	14.0	270.0
SUAC	42	2.9	2.0	1.5	0.6	10.0
C0(L)	191	12.80	8.60	10.00	3.00	125.00
C3	190	5.34	5.05	6.00	1.50	11.00
C3DC	96	0.33	0.30	0.32	0.04	2.60
C3DC + C4OH	53	0.60	0.50	0.45	0.17	2.80
C4	174	1.06	1.00	1.30	0.35	2.50
C4OH	82	0.59	0.60	0.70	0.05	1.27
C5	201	0.69	0.62	1.00	0.26	2.00
C5:1	171	0.19	0.15	0.25	0.02	1.00
C5DC	194	0.31	0.29	0.35	0.06	0.85
C5OH	175	0.79	0.80	1.00	0.02	3.60
C6	181	0.33	0.25	0.20	0.05	1.30
C8	204	0.37	0.34	0.50	0.07	1.42
C10	192	0.41	0.40	0.50	0.10	1.46
C10:1	166	0.31	0.30	0.30	0.01	1.52
C10:2	108	0.18	0.12	0.12	0.02	1.00
C14	177	0.64	0.60	0.50	0.07	1.50
C14:1	190	0.48	0.40	0.40	0.07	4.30
C16	189	6.78	7.00	7.50	1.51	14.00
C16OH	192	0.14	0.11	0.10	0.03	0.89
C18	174	2.16	2.00	2.50	0.30	9.00
C18:1	167	2.85	2.91	3.00	0.15	5.80
C18OH	130	0.13	0.10	0.10	0.01	2.00

- Recommendations on the source of blood;
- Other techniques for collection of blood spot specimens;
- Specifications for the filter paper, handling, and the mailing package;
- Specifications for the specimen collection device (card);
- Handling of bloodspots collected on filter paper for DNA/RNA analysis; and
- Storage and retention of residual specimens.

PT and QC Specimen preparation and data handling

Tables and figures in this report 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 T4 and immunoreactive trypsinogen (IRT) PT specimens, we reported the CDC assayed values.

Some specimens were enriched above the endogenous T4 concentration, and some were enriched with T4 after T4 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 thyroid stimulating hormone (TSH), which used the Third International Reference Preparation (81/565). For 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

Table 6. 2013 Domestic Cutoff Summary by Analyte and Method - Hormones and Galactose

Analyte	Method	N	CUTOFF VALUE Mean	Median	Mode	Min	Max
Thyroxine	***ALL METHODS***	***22***	***6.0***	***6.0***	***5.0***	***4.0***	***8.0***
µg/dL serum	AutoDelfia	13	6.0	6.0	5.0	4.0	8.0
	PerkinElmer GSP Neonatal	9	6.0	5.5	5.0	5.0	8.0
TSH	***ALL METHODS***	***43***	***33.7***	***30.0***	***20.0***	***14.4***	***61.0***
µIU/mL serum	AutoDelfia	32	35.0	30.4	20.0	20.0	58.0
	PerkinElmer GSP Neonatal	11	29.9	25.0	25.0	19.4	61.0
17-OHP	***ALL METHODS***	***43***	***34.2***	***33.0***	***33.0***	***19.0***	***65.0***
ng/mL serum	AutoDelfia	9	42.3	35.0	35.0	25.0	65.0
	AutoDelfia Neonatal 17-OHP (B024)	23	31.0	32.0	33.0	19.0	50.0
	PerkinElmer GSP Neonatal	11	34.1	35.0	40.0	22.0	50.0
Galactose	***ALL METHODS***	***23***	***11.0***	***10.0***	***10.0***	***6.0***	***20.0***
mg/dL blood	Astoria-Pacific 50 Hour Reagent Kit	9	10.8	10.0	10.0	6.5	15.0
	Bio-Rad Quantase*	2	14.5	-	-	-	-
	Fluorometric manual (e.g. Hill or Misuma)	5	12.8	10.0	10.0	10.0	20.0
	Neo-Genesis Accuwell*	2	9.5	-	-	-	-
	PerkinElmer Neonatal Kit	5	8.6	8.0	8.0	6.0	11.0

*Low participation rate method. Where N < 3, statistics are not applicable.

Table 7. 2013 Domestic Cutoff Summary by Analyte and Method - IRT, SUAC, and GALT

Analyte	Method	N	CUTOFF VALUE Mean	Median	Mode	Min	Max
IRT	***ALL METHODS***	***42***	***65.0***	***62.0***	***67.0***	***31.9***	***100.0***
ng/mL blood	Auto Delfia	31	66.2	65.0	67.0	31.9	100.0
	PerkinElmer GSP Neonatal	11	61.7	58.1	60.0	46.0	90.0
SUAC	***ALL METHODS***	***27***	***2.9***	***3.0***	***4.5***	***0.5***	***5.4***
µmol/L blood	Derivatized - MS/MS non-kit	9	2.7	3.0	-	0.5	5.4
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	18	3.0	2.5	4.5	1.3	4.5
GALT	***ALL METHODS***	***16***	***3.1***	***3.2***	***3.5***	***1.7***	***4.0***
U/g Hb	Astoria-Pacific Neonatal Microplate Reagent Kit	3	2.2	2.0	-	1.7	2.9
	PerkinElmer Neonatal Kit	13	3.3	3.4	3.5	2.4	4.0

Table 8. 2013 Domestic Cutoff Summary by Analyte and Method - Amino Acids

Analyte	Method	N	CUTOFF VALUE Mean	Median	Mode	Min	Max
Phenylalanine	***ALL MS/MS METHODS***	***50***	***142.1***	***145.0***	***155.0***	***97.0***	***190.0***
µmol/L blood	Derivatized - MS/MS non-kit	17	133.8	130.0	130.0	97.0	182.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	137.7	130.0	130.0	120.0	181.0
	Non-derivatized - MS/MS non-kit*	2	150.0	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	150.7	155.0	155.0	120.0	190.0
	ALL NON-MS/MS METHODS	***6***	***146.0***	***144.3***	***151.5***	***121.0***	***181.8***
	PerkinElmer Neonatal Kit	3	146.6	137.0	-	121.0	181.8
	High-performance liquid chromatography (HPLC)	3	145.3	151.5	151.5	133.0	151.5
Leucine	***ALL METHODS***	***47***	***287.4***	***275.0***	***250.0***	***175.0***	***400.0***
µmol/L blood	Derivatized - MS/MS non-kit	15	279.9	300.0	300.0	200.0	357.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	289.5	287.5	275.0	250.0	330.0
	Non-derivatized - MS/MS non-kit*	2	302.5	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	290.5	270.0	250.0	175.0	400.0
Methionine	***ALL METHODS***	***48***	***76.9***	***75.0***	***100.0***	***35.0***	***100.0***
µmol/L blood	Derivatized - MS/MS non-kit	15	65.9	60.0	100.0	35.0	100.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	12	79.6	75.0	100.0	60.0	100.0
	Non-derivatized - MS/MS non-kit*	2	87.5	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	82.3	85.5	100.0	55.0	100.0
Tyrosine	***ALL MS/MS METHODS***	***49***	***413.3***	***337.0***	***400.0***	***88.0***	***850.0***
µmol/L blood	Derivatized - MS/MS non-kit	16	292.2	290.0	400.0	88.0	442.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	310.6	290.0	300.0	200.0	552.0
	Non-derivatized - MS/MS non-kit*	2	350.0	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	572.9	465.0	850.0	300.0	850.0
	ALL NON-MS/MS METHODS						
	High-performance liquid chromatography (HPLC)	3	237.3	160.0	-	138.0	414.0
Valine	***ALL METHODS***	***33***	***291.4***	***280.0***	***250.0***	***200.0***	***420.0***
µmol/L blood	Derivatized - MS/MS non-kit	11	264.9	250.0	300.0	200.0	420.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	303.5	281.0	400.0	250.0	400.0
	Non-derivatized - MS/MS non-kit	2	275.0	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	10	311.6	320.0	250.0	250.0	384.0
Citrulline	***ALL METHODS***	***48***	***55.1***	***58.0***	***60.0***	***18.0***	***100.0***
µmol/L blood	Derivatized - MS/MS non-kit	15	45.6	40.0	40.0	18.0	75.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	58.1	55.0	55.0	40.0	100.0
	Non-derivatized - MS/MS non-kit*	2	57.5	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	60.4	60.0	60.0	45.0	85.0
Arginine	***ALL METHODS***	***36***	***69.4***	***53.5***	***50.0***	***20.0***	***125.0***
µmol/L blood	Derivatized - MS/MS non-kit	12	52.1	35.0	30.0	20.0	125.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	81.2	80.0	100.0	50.0	100.0
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	15	76.1	50.0	50.0	50.0	120.0

*Low participation rate method. Where N < 3, statistics are not applicable.

Table 9. 2013 Domestic Cutoff Summary by Analyte and Method - Acylcarnitines

Analyte	Method	N	CUTOFF VALUE Mean	Median	Mode	Min	Max
C(0)L	***ALL METHODS***	***51***	***8.95***	***8.00***	***7.00***	***3.80***	***27.00***
µmol/L blood	Derivatized - MS/MS non-kit	18	9.96	8.75	8.00	5.00	27.00
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	11.13	11.00	15.00	6.00	15.00
	Non-derivatized - MS/MS non-kit*	2	6.20	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	7.13	7.00	7.00	6.00	9.00
C3	***ALL METHODS***	***53***	***5.73***	***6.00***	***6.30***	***1.10***	***8.00***
µmol/L blood	Derivatized - MS/MS non-kit	20	5.16	5.25	6.00	1.10	7.30
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	5.71	5.94	6.00	4.50	7.21
	Non-derivatized - MS/MS non-kit*	2	6.46	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	6.25	6.30	6.30	4.00	8.00
C3DC	***ALL METHODS***	***25***	***0.23***	***0.20***	***0.20***	***0.10***	***0.45***
µmol/L blood	Derivatized - MS/MS non-kit	16	0.21	0.19	0.20	0.10	0.45
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	0.27	0.23	0.35	0.19	0.42
C3DC+C4OH	***ALL METHODS***	***15***	***0.43***	***0.40***	***0.40***	***0.38***	***0.60***
µmol/L blood	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	15	0.43	0.40	0.40	0.38	0.60
C4	***ALL METHODS***	***47***	***1.29***	***1.30***	***1.70***	***0.49***	***1.90***
µmol/L blood	Derivatized - MS/MS non-kit	18	1.18	1.23	1.40	0.49	1.90
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	1.11	1.10	-	0.80	1.40
	Non-derivatized - MS/MS non-kit*	2	1.25	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	18	1.50	1.45	1.70	1.20	1.70
C4OH	***ALL METHODS***	***22***	***0.65***	***0.70***	***0.75***	***0.27***	***1.00***
µmol/L blood	Derivatized - MS/MS non-kit	15	0.60	0.65	0.75	0.27	1.00
	Derivatized - MS/MS PerkinElmer NeoGram Kit	7	0.77	0.70	1.00	0.52	1.00
C5	***ALL METHODS***	***53***	***0.71***	***0.70***	***1.00***	***0.40***	***1.20***
µmol/L blood	Derivatized - MS/MS non-kit	20	0.67	0.63	0.50	0.40	1.20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.62	0.60	0.60	0.45	0.87
	Non-derivatized - MS/MS non-kit*	2	0.65	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	0.80	0.77	1.00	0.50	1.00
C5:1	***ALL METHODS***	***49***	***0.26***	***0.18***	***0.60***	***0.05***	***0.60***
µmol/L blood	Derivatized - MS/MS non-kit	20	0.21	0.15	0.15	0.05	0.60
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	0.20	0.19	0.25	0.15	0.25
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	19	0.34	0.22	0.60	0.08	0.60
C5DC	***ALL METHODS***	***51***	***0.36***	***0.32***	***0.60***	***0.05***	***0.80***
µmol/L blood	Derivatized - MS/MS non-kit	20	0.19	0.18	0.21	0.05	0.32
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.30	0.31	0.30	0.23	0.35
	Non-derivatized - MS/MS non-kit*	2	0.48	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	18	0.56	0.60	0.60	0.35	0.80
C5OH	***ALL METHODS***	***52***	***0.80***	***0.80***	***0.90***	***0.19***	***1.18***
µmol/L blood	Derivatized - MS/MS non-kit	20	0.74	0.78	1.00	0.19	1.18
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.76	0.70	0.70	0.60	1.03
	Non-derivatized - MS/MS non-kit*	2	0.99	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	19	0.86	0.90	0.90	0.60	1.00
C6	***ALL METHODS***	***50***	***0.43***	***0.30***	***0.95***	***0.16***	***0.95***
µmol/L blood	Derivatized - MS/MS non-kit	19	0.34	0.30	0.24	0.16	0.86
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.29	0.25	0.25	0.20	0.59
	Non-derivatized - MS/MS non-kit*	2	0.40	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	18	0.60	0.60	0.95	0.20	0.95
C8	***ALL METHODS***	***53***	***0.45***	***0.40***	***0.60***	***0.25***	***0.72***
µmol/L blood	Derivatized - MS/MS non-kit	20	0.40	0.36	0.35	0.25	0.72
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.40	0.38	0.40	0.30	0.60
	Non-derivatized - MS/MS non-kit*	2	0.50	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	0.53	0.60	0.60	0.34	0.70

Table 9. 2013 Domestic Cutoff Summary by Analyte and Method - Acylcarnitines (continued)

Analyte	Method	N	CUTOFF VALUE Mean	Median	Mode	Min	Max
C10	***ALL METHODS***	***50***	***0.46***	***0.42***	***0.65***	***0.22***	***0.80***
µmol/L blood	Derivatized - MS/MS non-kit	18	0.42	0.40	0.30	0.22	0.80
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.42	0.40	0.35	0.27	0.68
	Non-derivatized - MS/MS non-kit*	2	0.42	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	19	0.53	0.55	0.65	0.22	0.70
C10:1	***ALL METHODS***	***46***	***0.31***	***0.30***	***0.45***	***0.14***	***0.53***
µmol/L blood	Derivatized - MS/MS non-kit	17	0.26	0.25	0.25	0.17	0.44
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.33	0.30	0.30	0.21	0.53
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	18	0.33	0.38	0.45	0.14	0.45
C10:2	***ALL METHODS***	***21***	***0.16***	***0.14***	***0.10***	***0.06***	***0.46***
µmol/L blood	Derivatized - MS/MS non-kit	12	0.19	0.13	0.10	0.06	0.46
	Derivatized - MS/MS PerkinElmer NeoGram Kit	6	0.15	0.15	0.15	0.10	0.20
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	3	0.09	0.10	-	0.07	0.11
C14	***ALL METHODS***	***50***	***0.77***	***0.73***	***0.70***	***0.17***	***1.20***
µmol/L blood	Derivatized - MS/MS non-kit	18	0.65	0.70	0.70	0.17	0.84
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.70	0.70	0.70	0.52	0.89
	Non-derivatized - MS/MS non-kit*	2	0.80	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	19	0.92	0.80	1.20	0.58	1.20
C14:1	***ALL METHODS***	***50***	***0.61***	***0.65***	***0.80***	***0.17***	***0.80***
µmol/L blood	Derivatized - MS/MS non-kit	19	0.54	0.60	0.60	0.17	0.70
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.61	0.65	0.70	0.40	0.80
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	0.68	0.70	0.80	0.43	0.80
C16	***ALL METHODS***	***51***	***7.63***	***7.70***	***10.00***	***0.41***	***10.00***
µmol/L blood	Derivatized - MS/MS non-kit	19	6.57	7.00	7.00	0.41	9.00
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	7.38	7.48	-	6.00	8.53
	Non-derivatized - MS/MS non-kit*	2	8.10	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	8.72	8.57	10.00	6.71	10.00
C16OH	***ALL METHODS***	***51***	***0.13***	***0.12***	***0.10***	***0.08***	***0.25***
µmol/L blood	Derivatized - MS/MS non-kit	20	0.13	0.13	0.10	0.08	0.25
	Derivatized - MS/MS PerkinElmer NeoGram Kit	11	0.16	0.16	0.18	0.12	0.25
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	20	0.11	0.10	0.10	0.08	0.20
C18	***ALL METHODS***	***44***	***2.45***	***2.28***	***4.00***	***0.22***	***4.00***
µmol/L blood	Derivatized - MS/MS non-kit	14	1.74	1.83	2.00	0.22	2.50
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	2.26	2.20	-	1.80	3.00
	Non-derivatized - MS/MS non-kit*	2	2.49	-	-	-	-
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	19	3.05	2.85	4.00	1.55	4.00
C18:1	***ALL METHODS***	***46***	***3.52***	***3.00***	***2.50***	***0.36***	***7.00***
µmol/L blood	Derivatized - MS/MS non-kit	18	2.50	2.50	2.50	0.36	3.50
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	2.87	2.75	-	2.22	3.50
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	19	4.79	3.77	7.00	2.27	7.00
C18OH	***ALL METHODS***	***28***	***0.10***	***0.10***	***0.10***	***0.04***	***0.20***
µmol/L blood	Derivatized - MS/MS non-kit	12	0.09	0.09	0.10	0.04	0.18
	Derivatized - MS/MS PerkinElmer NeoGram Kit	8	0.13	0.13	0.10	0.10	0.20
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	8	0.09	0.10	0.10	0.04	0.11

*Low participation rate method. Where N < 3, statistics are not applicable.

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%. We made other biotinidase pools using heat-treated serum combined with compatible donor red cells. CDC assayed values were used as PT-expected values for T4, IRT, and GALT. We made CFDNA PT materials with blood from individual donors expressing CF mutations, without hematocrit adjustment. All reported analytic values outside the 99% CI were excluded from the quantitative result summaries.

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 for each method category of the observed, endogenous analyte concentration. When enrichments are accurate, these estimates are reliable. The analytical method gives a linear response across the range of the measurements. The slopes for regression lines are approximately equal to one.

For PT reporting, we apply the laboratory-reported specific cutoff values, when available, to our grading algorithm for evaluation. If no cutoff 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.

TABLE 10. 2013 Summary of Proficiency Testing Errors by Domestic Laboratories

	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Congenital Hypothyroidism	207	0.5	828	0.0
Congenital Adrenal Hyperplasia	132	0.0	528	0.4
Galactosemia	68	0.0	272	0.0
Phenylalanine Screen	171	0.0	684	0.0
Leucine Screen	142	0.0	568	0.9
Methionine Screen	143	0.0	572	0.0
Tyrosine Screen	156	0.0	624	0.0
Valine Screen	98	1.0	392	0.0
Citrulline screen	143	0.0	572	0.0
Arginine Screen	111	0.0	444	0.2
C0(L) Screen	152	0.7	608	0.5
C3 Screen	105	0.0	670	0.0
C3DC Screen	75	0.0	300	0.0
C3DC + C4OH Screen	33	3.0	167	0.0
C4 Screen	186	0.5	514	0.0
C4OH Screen	44	0.0	276	0.7
C5 Screen	155	0.0	620	0.0
C5:1 Screen	148	0.0	592	0.0
C5DC Screen	102	0.0	653	0.0
C5OH Screen	103	1.0	608	0.7
C6 Screen	147	0.0	588	0.0
C8 Screen	155	0.0	620	0.0
C10 Screen	144	0.0	576	0.4
C10:1 Screen	137	0.0	548	0.4
C10:2 Screen	72	0.0	288	0.4
C14 Screen	192	0.5	533	0.8
C14:1 Screen	152	0.0	608	0.0
C16 Screen	196	0.5	544	0.0
C16OH Screen	153	0.0	612	0.0
C18 Screen	90	0.0	532	0.0
C18:1 Screen	91	0.0	584	0.0
C18OH Screen	66	0.0	264	0.0
Biotinidase Deficiency	131	0.8	524	0.8
GALT Deficiency	132	0.0	528	0.0
Immunoreactive Trypsinogen	266	1.1	399	0.0
Succinylacetone Screen	55	10.9	274	0.4

Cutoffs

When reporting cutoff values, the NSQAP requested that participants report the decision level for sorting test results as presumptive positive (outside normal limits) from results reported as negative (within normal limits). Tables 3–5 summarize the reported cutoff values for domestic and foreign laboratories. The values for mean (arithmetic average), median (middle value), and mode (most frequent value) are shown for each analyte. Tables 6–9 summarize 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 3 for non-MS/MS domestic and foreign laboratories are similar except for Tyrosine (Tyr). For both domestic and foreign laboratories, the range (min/max) of cutoff values is large for analytes Leucine (Leu), Tyr, Valine (Val), and C0 (L). Among all laboratories, the mean and median cutoff summary values for the MS/MS amino acids seen in Tables 4 and 5 are similar except for Tyr from the domestic laboratories. Among domestic methods used for Arginine (Arg) and Tyr, the mode value for domestic MS/MS Tyr differed widely. This result indicates that a group of laboratories is using a cutoff value different from the mean of the other labs.

The cutoff tables (Tables 6–9) contain cutoff distributions of non-MS/MS methods for TSH, IRT, 17-OHP, and TGal. The results show similar median cutoffs but also show

TABLE 11. 2013 Summary of Proficiency Testing Errors by Foreign Laboratories

	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Congenital Hypothyroidism	784	0.8	3136	1.2
Congenital Adrenal Hyperplasia	439	1.8	1756	0.6
Galactosemia	315	1.0	1260	0.1
Phenylalanine Screen	861	0.4	3444	0.9
Leucine Screen	608	0.5	2432	0.3
Methionine Screen	590	0.9	2360	0.5
Tyrosine Screen	605	1.5	2420	0.1
Valine Screen	564	2.1	2256	0.6
Citrulline screen	544	0.6	2176	0.7
Arginine Screen	482	1.5	1928	0.7
C0(L) Screen	597	7.0	2388	2.8
C3 Screen	399	1.8	2546	1.4
C3DC Screen	304	2.0	1216	1.2
C3DC + C4OH Screen	117	2.6	555	0.2
C4 Screen	714	0.6	1986	0.4
C4OH Screen	176	5.1	1144	1.8
C5 Screen	614	1.5	2456	0.4
C5:1 Screen	525	1.7	2100	0.7
C5DC Screen	404	1.2	2576	0.5
C5OH Screen	365	0.6	2128	2.5
C6 Screen	563	1.6	2252	0.5
C8 Screen	624	0.5	2496	0.4
C10 Screen	595	1.0	2380	1.2
C10:1 Screen	525	1.9	2100	1.4
C10:2 Screen	346	3.8	1384	0.9
C14 Screen	733	1.8	2032	0.9
C14:1 Screen	589	1.5	2356	0.3
C16 Screen	770	4.4	2150	1.4
C16OH Screen	592	2.0	2368	0.9
C18 Screen	369	1.9	2172	0.8
C18:1 Screen	355	3.4	2270	0.8
C18OH Screen	280	5.7	1120	0.8
Biotinidase Deficiency	283	1.4	1132	0.9
GALT Deficiency	181	2.2	724	1.0
Immunoreactive Trypsinogen	714	1.7	1071	0.7
Succinylacetone Screen	97	1.0	490	1.2

variability within methods. For Arg, Leu, Methionine (Met), and Tyr, nonderivatized kit methods have a broad range of cutoffs compared with other MS-based methods. Cutoffs varied by more than 65% for some methods used to measure Leu, Phe, Val, C4, C5DC, and C16.

TABLE 12. 2013 Summary of Proficiency Testing Errors for Hemoglobinopathies by Domestic and Foreign Laboratories

Hemoglobinopathies	Domestic	Foreign
Specimens assayed	730	335
Phenotype errors	0.5%	0.0%
Clinical assessment errors	0.5%	0.3%

Overall, there were five phenotype errors.

Proficiency testing

All PT panels consisted of five blind-coded, 75-µL DBS specimens. PT specimens either contained endogenous levels or were enriched with predetermined levels of T4, TSH, 17-OHP, TGal, IRT, SUAC, Amino acids (Phe, Leu, Met, Tyr, Val, Citrulline (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, C18OH and C18:1).

Normal adults, CF-affected adults, or adolescent CF donors provided blood for the CFDNA panels. Separate panels for biotinidase deficiency and for GALT deficiency were prepared with purchased blood from donors who had these enzyme deficiencies. Some biotinidase pools used 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. For all results received by the deadline dates, we prepared and distributed quarterly reports. In this annual report, we illustrated the comparisons of results by different methods (Figures 5–40) with the participants' reported PT data during the year for one selected challenge for each analyte. For most PT analytes, 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 T4, IRT, and GALT, we subtracted the differences of the participant's reported values from the CDC assayed value. Note for each plot the scale-changes of the Y-axis relative to the expected value. A reported value matching the expected value will show the illustrated value as falling on the plot's "0" line. For each figure, we tabulated in the left margin a summary of the specimen data for the selected quarter PT challenges in 2013. Ideally, a reasonable bias is less than ± 20% of the expected value (EV). The bias for twenty-seven of the 36 analytes is less than ± 20% of the EV.

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

TABLE 14. Sickle Cell and Hemoglobinopathies Methods Used Testing for Proficiency Testing in 2013

Method	Isoelectric Focusing	BioRad HPLC	Extended Gradient HPLC	Primus Ulta2 HPLC	Electrophoresis Citrate Agar	Electrophoresis Alkaline Cellulose	PCR Amplification of DNA
Primary	33	35	1	5	0	0	0
Secondary	18	13	5	5	1	1	1
Tertiary	2	1	1	0	2	0	0

TABLE 13. Hemoglobin Phenotype Challenges Distributed in 2013

Phenotype	N
FA	12
FAC	1
FAS	2

We show representative bias plots for all those analytes distributed in PT challenges that required a quantitative measurement to determine the presumptive clinical assessments. T4, TSH, and TGal (Figures 5, 6 and 8) all show participant bias slightly above the EV, with good agreement among participants. Over the years, the number of T4 users has remained stable, while the number of TSH users has grown. For 17-OHP in Figure 7, all methods show a tight scatter, with most participants clustering in a negative bias. In Figure 9, the bias plot for IRT shows a negative bias compared with the CDC-assayed value.

In Figure 10, the GALT participant bias is small, and the scatter of values is distinctly lower for one method. The bias plot for Phe, in Figure 11, shows good agreement between laboratories and among methods; compared with the EV, the plot has a small participant bias. In Figures 12, 13, 14, and 15, the plots for Leu, Met, Tyr, and Val show a consistent negative bias, with the expected values and a reasonably consistent scatter among users and methods. The Cit plot (Figure 16) shows some methods with a tight cluster of values but with distinct differences between nonkit and kit methods. Due to reduced recovery of Arg (Figure 17) by all methods, this bias plot shows a strong negative bias. The plot also shows that the MS/MS kit methods exhibit a higher recovery than the MS/MS nonkits methods. Few SUAC (Figure 18) methods, however, show good recoveries relative to the expected value.

Bias plots for derivatized and nonderivatized MS/MS methods are shown for all acylcarnitines as selected representative PT challenges in 2013. Enrichments made with purchased or custom-synthesized acylcarnitines are based on weighed quantities. Small variances in enrichments and recoveries might result from impurities in the purchased (synthesized) materials and endogenous analyte concentrations. For C0 (L), Figure 19 shows a slight negative bias for most methods, with the exception of one method showing a positive bias for all users. The bias data for C3 (Figure 20) and C4 (Figure 23) show a slight negative participant bias, with consistent scatter across all methods.

A growing number of NSQAP participants use a nonderivatized MS/MS method for amino acids and acylcarnitine analysis. But nonderivatized MS/MS cannot resolve analytes C3DC and C4OH. Laboratories using a nonderivatized MS/MS method report C3DC+C4OH, while derivatized MS/MS users continue to report those analytes separately. C3DC (Figure 21) shows a small negative bias for the nonkit MS/MS methods and a positive bias for the MS/MS kit methods. C3DC+C4OH (Figure 22) shows a negative bias among most participants across all methods. When comparing the C4OH (Figure 24) bias plot with the C4OH bias plot in the 2012 Annual Summary Report, all methods show a reduced recovery.

TABLE 15. Genotype Analysis of Cystic Fibrosis Mutation Detection Specimens in 2013

	Specimens Assayed (N)	Correct Results	Incorrect Genotypes & Misclassifications Results	Not Evaluated*	Sample Failure
Q1, 2013	290	99.6%	0.4%	19%	0.0%
Q2, 2013	305	100%	0.0%	4.3%	0.7%
Q3, 2013	275	99.6%	0.4%	0.0%	0.0%
Q4, 2013	290	99.6%	0.4%	0.0%	2.4%
Total	1160	99.7%	0.3%	5.9%	0.8%

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

TABLE 16. Cystic Fibrosis Mutation (*CFTR* gene) Challenges Distributed in 2013

Mutation (Legacy Name)	Mutation (HGVS* Nomenclature)	Number Sent
F508del	p.Phe508del	9
Wild type/no mutation	Wild type/no mutation	7
1717-1G>A	c.1585-1G->A	3
1154insTC	c.1022_1023insTC	2
G551D	p.Gly551Asp	1
W1282X	p.Trp1282X	1
3272-26>G	c.3140-26A->G	1
G542X	p.Gly542X	1
N1303K	p.Asn1303Lys	1
R1066H	p.Arg1066His	1
R347P	p.Arg347Pro	1

**Human Genome Variation Society*

In Figure 25 for C5, the values are minimally scattered, with good agreement with the expected value. The data for C5:1 (Figure 26) show a negative bias for most kit methods, and the participant mean value is slightly lower than the expected value. For C5DC (Figure 27), a tight scatter appears within each method, with nonkit methods showing a negative bias and most kit methods showing a positive bias. The bias plot for C5OH (Figure 28) illustrates good scatter for most methods, with one kit method showing a cluster below the mean bias. C6 (Figure 29) shows a slight positive participant bias. For C8 (Figure 30), the data demonstrate a tight scatter around the expected value. For C10 (Figure 31) and C10:1 (Figure 32), the bias values show reasonable scatter among all laboratories and methods, with good agreement for the expected value. That said, we noted a negative method bias between the MS/MS kit and the nonkit methods.

C10:2 (Figure 33) data show a negative bias due to low recovery by all methods. For C14 and C14:1 (Figures 34 and 35), all methods show reasonable scatter, but the kit methods show a negatively clustered bias. C16 (Figure 36) data demonstrate a tight cluster of values, with most methods showing a positive bias. For C16OH (Figure 37), the data demonstrate consistent scatter among all methods, with most laboratories showing a negative bias. Figure 38 for C18 illustrates a reasonable scatter of values within and among methods while showing a negative participant bias. C18:1 (Figure 39) shows a negative participant bias but with good scatter among all methods. C18OH was a new analyte added in 2013. Although its bias plot—Figure 40—shows good scatter among most laboratories and methods, one method shows a negatively clustered bias.

Tables 10 and 11 show the PT errors reported by domestic and foreign laboratories in 2013 for qualitative assessments reported per disorder. We applied the laboratory-reported cutoff values to our grading algorithm for clinical assessments (Figure 4). Because of specific clinical assessment practices, presumptive clinical classifications (qualitative assessments) of some specimens might differ by participant. If participants provided 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 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 2.8%. For domestic laboratories, the rate was 0.5% or lower for 31 of 36 biomarkers or disorders, with Leu having the highest rate of false-positive errors. The foreign laboratories had an error rate of 1.8% or lower for 34 of 36 biomarkers or disorders, with C0(L) having the highest rate of false-positive errors.

Screening programs are designed to minimize false-negative reports. But this precautionary approach results in many false-positive reports and might even result in false-positive misclassifications. The false-negative rate, expected to be zero, ranged from 0% to 10.9%. For domestic laboratories, we found no false-negative errors for 25 of the 36 biomarkers or disorders. Foreign laboratories had at least one false-negative error for all 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 were not included in Tables 10 and 11. For these specimens, we used participants' data to examine the relative analytical performance of the assays.

Table 12 shows the performance errors for hemoglobinopathies. The percentage of errors for qualitative assessments for sickle cell disease and other hemoglobinopathies ranged from 0.0% to 0.5% for both the phenotype and clinical assessment errors. Overall, in 2013, five phenotype errors occurred for data reported by 70 laboratories. The classification errors were essentially the same for phenotype and clinical assessments within the domestic and foreign laboratory groups. Table 13 shows the phenotype challenges distributed in 2013 for hemoglobinopathies. Participants use multi-tier testing schemes to enhance the specificity of screening for hemoglobinopathies as shown in Table 14. Most screening laboratories use Isoelectric Focusing and HPLC methods in their primary testing. Many laboratories use secondary testing with these same methods in repetitive or different combinations. Only a few used a tertiary test. Some laboratories report the application of DNA testing for their scheme.

Table 15 shows the performance errors for CFDNA. The percentage of errors for qualitative assessments for genotype analysis ranged from 0.0% to 0.4%. Table 16 shows the CF mutation (CFTR gene) challenges distributed in 2013 for CFDNA.

Quality control

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

Tables 17a–17gg 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 17a–17gg 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 1225, 1226, 1227 and 1228). Because only three or four concentrations of QC materials are available for each analyte, a bias error in any one pool can markedly influence the slope and intercept. The Y-intercept provides one measure of the endogenous concentration level for an analyte. For amino acids and acylcarnitines, participants measured the endogenous concentrations by analyzing the nonenriched QC lots; for most methods, the Y-intercepts and measured endogenous levels for these analytes were similar. Ideally, the slope should be 1.0—most slopes fell within a range from 0.7 to 1.2. Some analytes and methods continue to produce data with slopes as high as 1.8 and as low as 0.1. Slope deviations might relate to analytic (dose-response) ranges for calibration curves or to poor recoveries for one or more specimens in a three- or four-specimen QC set. Because the endogenous concentration was the same for all QC lots within a series, it should not affect the slope of

the regression line among methods. Generally, slope values substantially different from 1.0 indicate that a method has an analytic bias. For the analytes Arg and SUAC, we have observed over time slope values below the target range. Due to notable difficulties in the detection of L-Arg, which could result in reduced recovery, samples were enriched with the isomer D-Arg. As demonstrated in Table l, this resulted in an improvement of the slope values between 2013 Lots 1225–1228 (0.3-0.5) and Lots 1321–1324 (0.4–0.8).

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Staff Peer-Reviewed Publications

Adam BW, Chafin DL, De Jesús VR. Stabilities of Hemoglobins A and S in Dried Blood Spots Stored Under Controlled Conditions. Clinical Biochemistry 2013; 46:1089-92.

Adam BW, Haynes CA, Chafin DL, De Jesús VR. Stabilities of Hemoglobin Molecules and Hemoglobin Peptides in Dried Blood Spots. Accepted for publication in Clinica Chimica Acta November 14, 2013.

Bali D, Shi Q, Dickerson G, Zhou H, De Jesús VR, Hopkins P, Klug T, Sista R, Pamula V, Millington D. Comparison of Methods for the Analysis of Lysosomal Enzyme Activities in Quality Control Dried Blood Spot Specimens. Molecular Genetics and Metabolism 2013; 108(2): S22.

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Staff Presentations

De Jesús VR. Recent Advances and Quality Assurance of Lysosomal Storage Disorders Newborn Screening Assays in Dried Blood Spots. Presented at the 5th Symposium on Mass Spectrometry, Biomarkers and Health, Sherbrooke, Quebec, Canada.

De Jesús VR, Mei JV, Cuthbert CD. Assuring Quality of Newborn Screening Dried Blood Spot Assays Worldwide: The Newborn Screening Quality Assurance Program. Presented at the IX Congress of the Latin American Society for Inborn Errors of Metabolism and Newborn Screening, Medellin, Colombia.

De Jesús VR. Newborn Screening Reference Materials. Presented at the IX Congress of the Latin American Society for Inborn Errors of Metabolism and Newborn Screening, Medellin, Colombia.

Hall EM. Developing and Optimizing Mass Spectrometry-based Methods to Screen for X-ALD. Presented at the Joint Meeting of the Newborn Screening and Genetic Testing Symposium and the International Society for Neonatal Screening, Atlanta, GA, May 2013.

Haynes CA, Guerra SL, Fontana JC, De Jesús VR. HPLC-ESI-MS/MS analysis of hemoglobin peptides in tryptic digests of dried-blood spot extracts detects HbS, HbC, HbD, HbE, HbO-Arab, and HbG-Philadelphia mutations. Presented at the 61st American Society for Mass Spectrometry Annual Meeting, Minneapolis, MN, June 2013 and the Joint Newborn Screening and Genetic Testing – International Society for Newborn Screening Symposium, Atlanta, GA, May, 2013.

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

Part 1
The **NSQAP Expected Clinical Assessment** for PT specimens is determined by comparing the NSQAP Expected Certified Value and the NSQAP Cutoff. The **NSQAP Certified Expected Value** is the sum of the endogenous value plus the enrichment value for an individual analyte. The enrichments for each PT specimen are calculated so that the 95% confidence interval falls above or below the NSQAP cutoff value. The **NSQAP Cutoff Value** is determined annually by using the mean of all domestic laboratories' reported cutoff values as a guideline.

Part 2
The participant reports the clinical assessment as "within normal limits" or "outside normal limits". This is the **Participant *Reported* Clinical Assessment**. The **Participant *Expected* Clinical Assessment** is the assessment that is expected when the NSQAP Certified Expected Value and the participant cutoff are compared. When the Participant Reported Clinical Assessment differs from the NSQAP Expected Clinical Assessment, the grading algorithm is used to evaluate test performance. The algorithm will determine if the Participant Reported Clinical Assessment is correct, False Negative, False Positive or Cutoff Difference.

- If the NSQAP *Expected* Clinical Assessment is the same as the Participant *Expected* Clinical Assessment but the Participant Reported Assessment differs, the grade will be either false-negative or false positive.

- If the NSQAP *Expected* Clinical Assessment and the Participant *Expected* Clinical Assessment differ, the Participant Reported clinical assessment will not be graded as incorrect. (If a cutoff is not provided by the participant, the evaluation will be based on the NSQAP Cutoff Value)

Part 3
Determination of a final evaluation for a specimen is based on the Clinical Laboratory Improvement Amendments (CLIA) regulations whereby the PT provider "must compare the laboratory's response for each analyte with the response that reflects agreement of either 80% of ten or more referee laboratories or 80% or more of all participating laboratories." (CLIA Regulations, 2004). An NSQAP gradable specimen must have 80% or more agreement among **domestic** laboratories. A specimen with less than 80% agreement is not-gradable/not-evaluated.

<u>Example of TSH False Positive</u> –

NSQAP Certified Expected Value= 13 µIU/mL
NSQAP Cutoff = 30 µIU/mL
Participant cutoff = 35 µIU/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 µIU/mL
NSQAP Cutoff = 30 µIU/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 µIU/mL
Participant Cutoff = 35 µIU/mL
Therefore the Participant Expected Clinical Assessment = "1- Within Normal Limits"

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

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

Participant Evaluation Result = False Positive

Sample Table: Participant Evaluation Determination

Analyte	Expected Value (EV)	NSQAP Cutoff	Participant Cutoff	Assessment: Comparison of EV and NSQAP Cutoff	Assessment: Comparison of EV and Participant Cutoff	Assessment: Participant Reported Clinical Assessment	Participant Evaluation Result
TSH	13	30	35	wnl	wnl	onl	False Positive
TSH	13	30	10	wnl	onl	onl	Cutoff Difference
TSH	50	30	35	onl	onl	wnl	False Negative
TSH	50	30	60	onl	wnl	wnl	Cutoff Difference

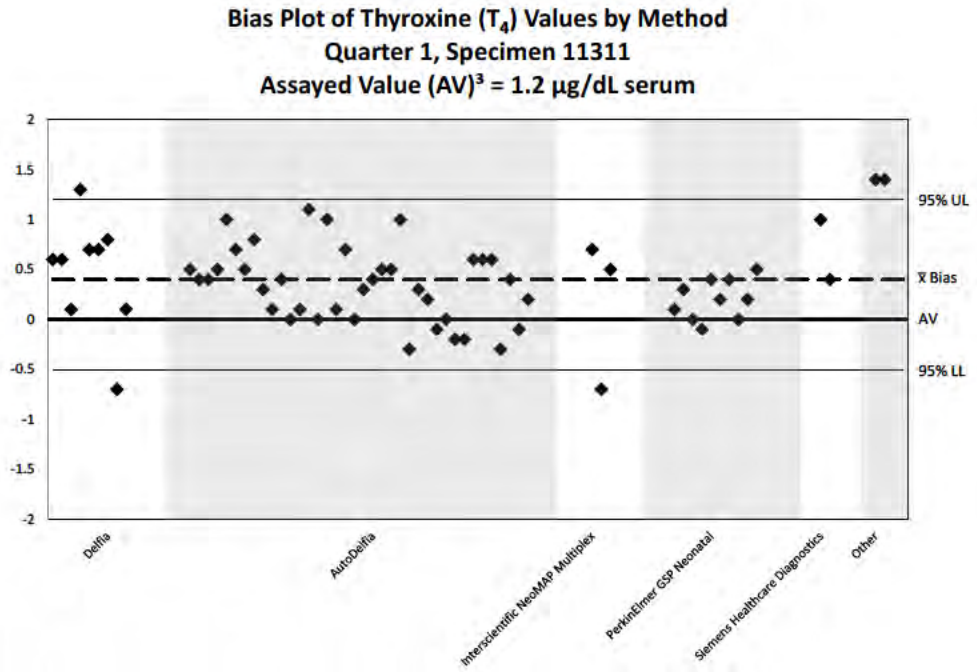
wnl – “1- Within Normal Limits”
onl – “2- Outside Normal limits”

Reference: CLIA Regulations Subpart I—Proficiency Testing Programs for Nonwaived Testing. [Updated 2004 July 7; accessed 2013 January 31]. Available from http://wwwn.cdc.gov/clia/regs/subpart_i.aspx#493.931

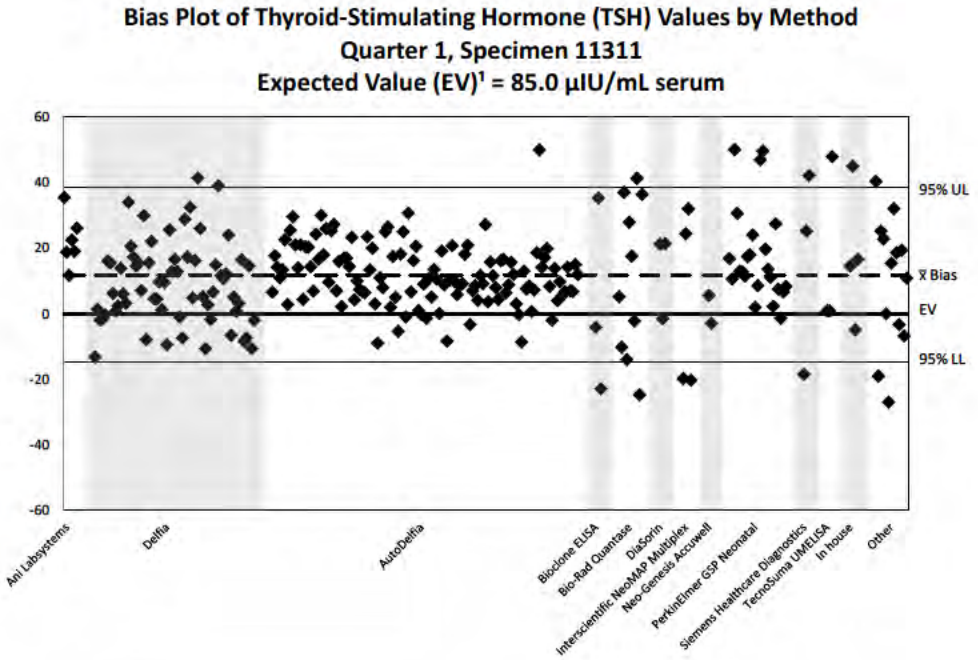
Note that the grade is based on the Participant Reported Clinical Assessment, not on the reported value. Overall Statistics, which are generated from all participant data, and Mean Reported Concentrations by method are provided on the Web site for analytical reference only.

FIGURES 5-6. Reproducibility of Results by Method Thyroxine (T_4) and Thyroid-Stimulating Hormone (TSH)

Quarter 1	
Specimen 1	
CDC Assayed	1.2
Participant Mean	1.6
Participant Bias[2]	0.4



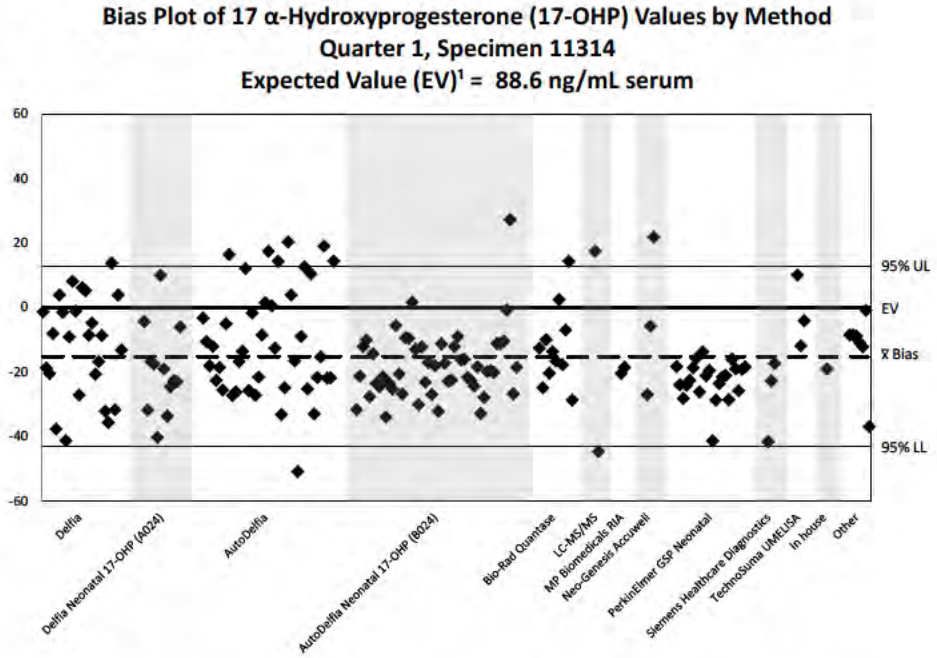
Quarter 1	
Specimen 1	
Enriched	85.0
CDC Assayed	82.7
Participant Mean	96.8
Participant Bias[2]	11.8



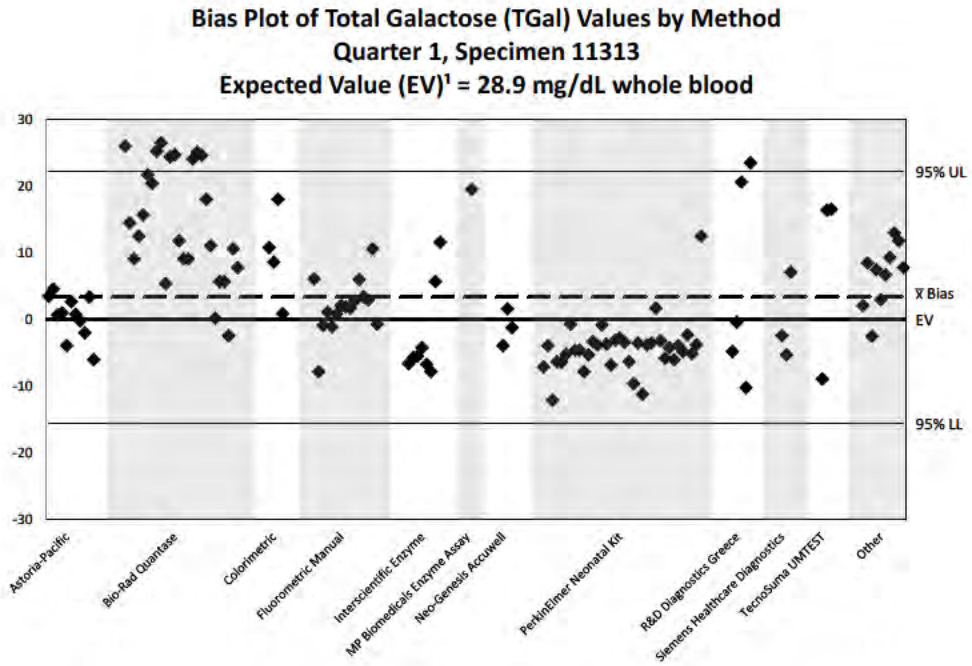
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier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

FIGURES 7-8. Reproducibility of Results by Method 17 α-Hydroxyprogesterone (17-OHP) and Total Galactose (TGal)

Quarter 1	
Specimen 4	
Enriched	85.0
CDC Assayed	88.1
Participant Mean	73.4
Participant Bias[2]	-15.2



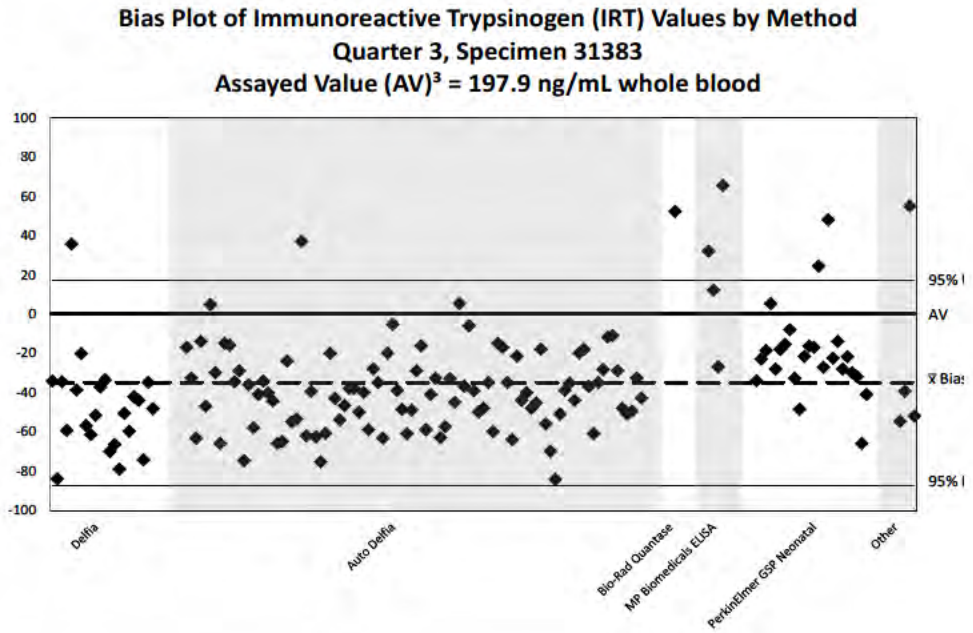
Quarter 1	
Specimen 3	
Enriched	28.0
CDC Assayed	31.0
Participant Mean	32.3
Participant Bias[2]	3.4



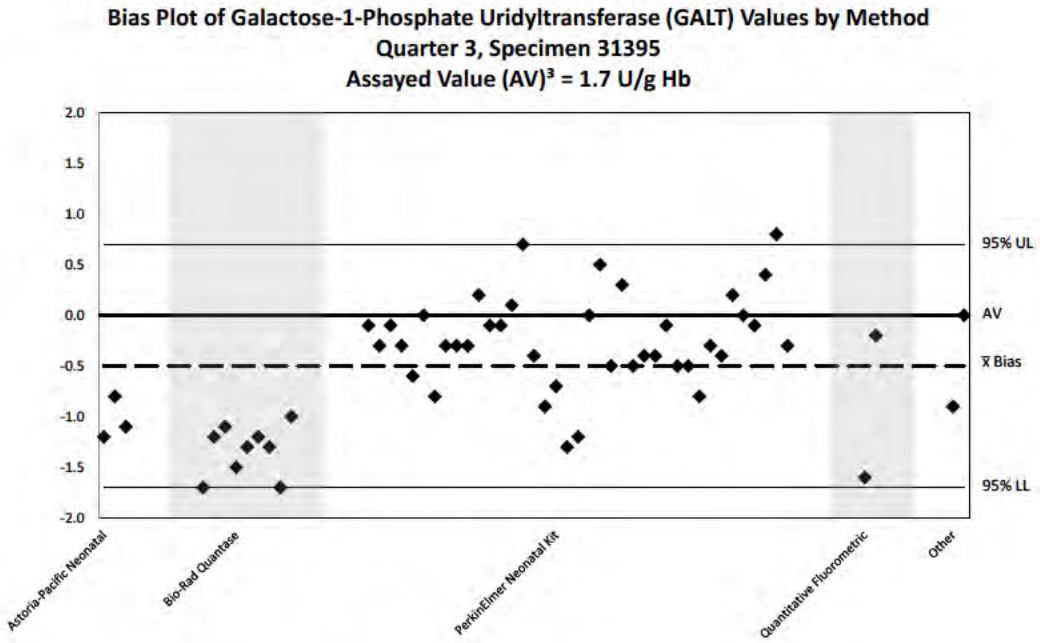
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Immunoreactive Trypsinogen (IRT) and Galactose-1-Phosphate Uridyltransferase (GALT)

Quarter 3	
Specimen 3	
CDC Assayed	197.9
Participant Mean	163.0
Participant Bias[2]	-34.9



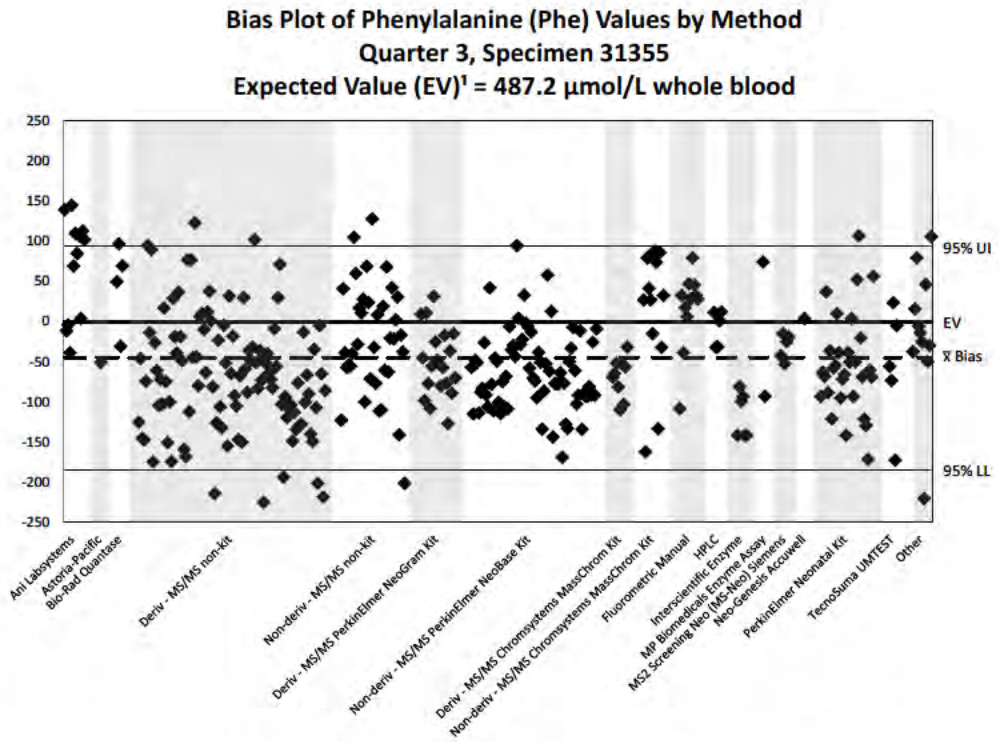
Quarter 3	
Specimen 5	
CDC Assayed	1.7
Participant Mean	1.2
Participant Bias[2]	-0.5



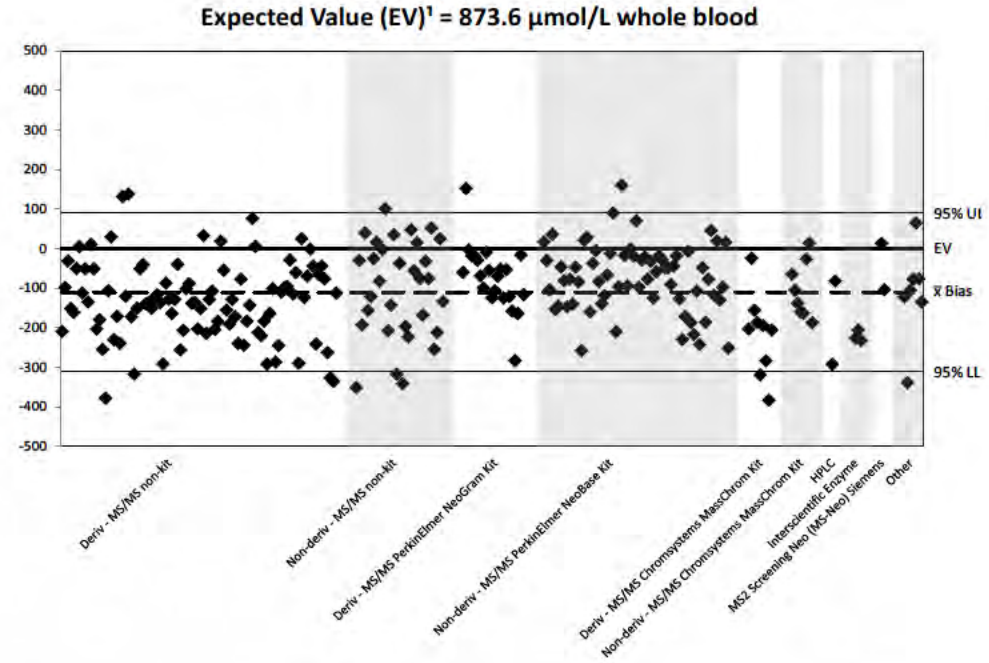
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Phenylalanine (Phe) and Leucine (Leu)

Quarter 3	
Specimen 5	
Enriched	450.0
CDC Assayed	425.4
Participant Mean	442.5
Participant Bias[2]	-44.7



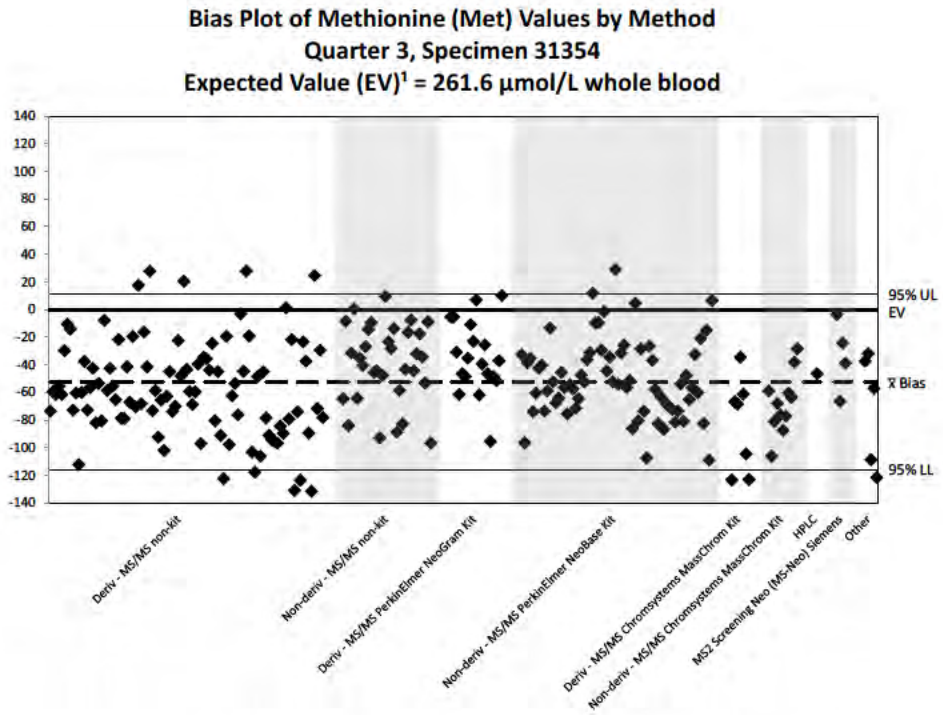
Quarter 1	
Specimen 4	
Enriched	700.0
CDC Assayed	746.2
Participant Mean	763.2
Participant Bias[2]	-110.5



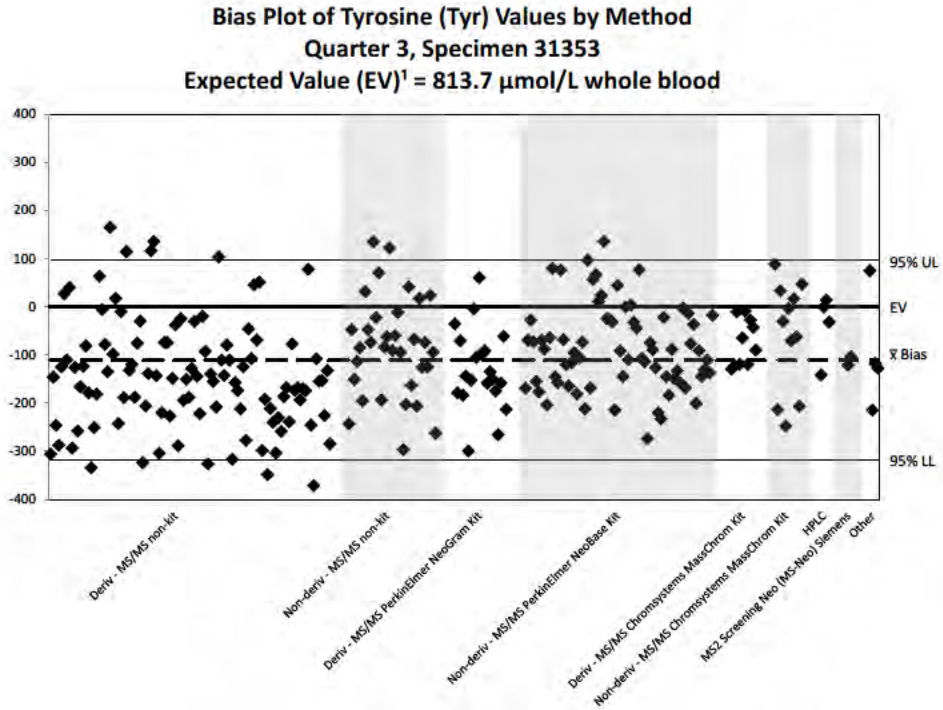
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Methionine (Met) and Tyrosine (Tyr)

Quarter 3	
Specimen 4	
Enriched	250.0
CDC Assayed	210.6
Participant Mean	209.2
Participant Bias[2]	-52.4



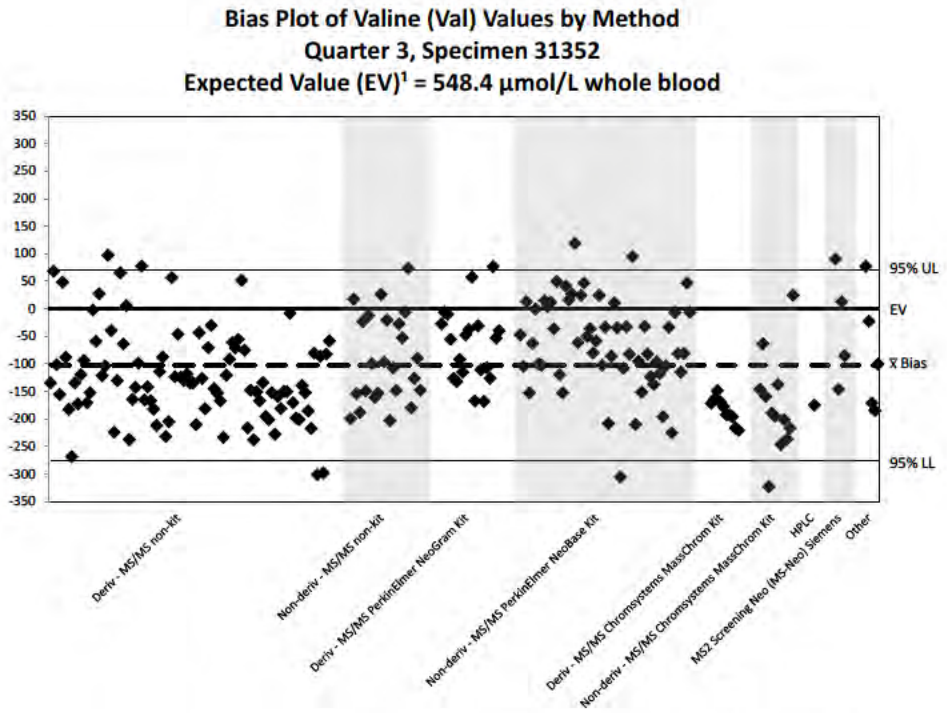
Quarter 3	
Specimen 3	
Enriched	750.0
CDC Assayed	696.0
Participant Mean	703.0
Participant Bias[2]	-110.8



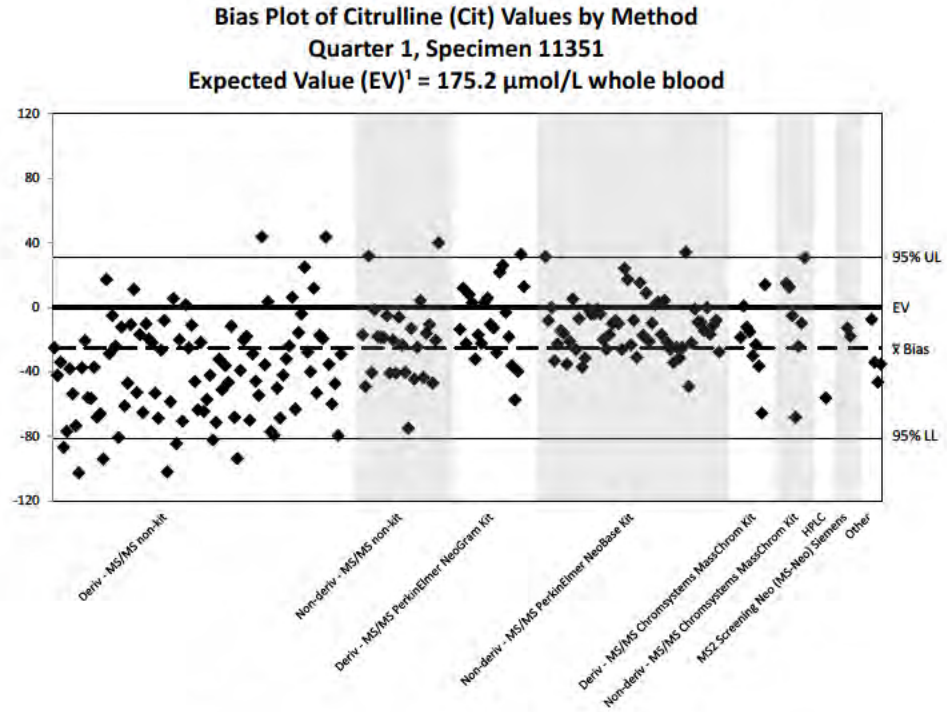
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Valine (Val) and Citrulline (Cit)

Quarter 1	
Specimen 3	
Enriched	400.0
CDC Assayed	413.4
Participant Mean	445.9
Participant Bias[2]	-102.5



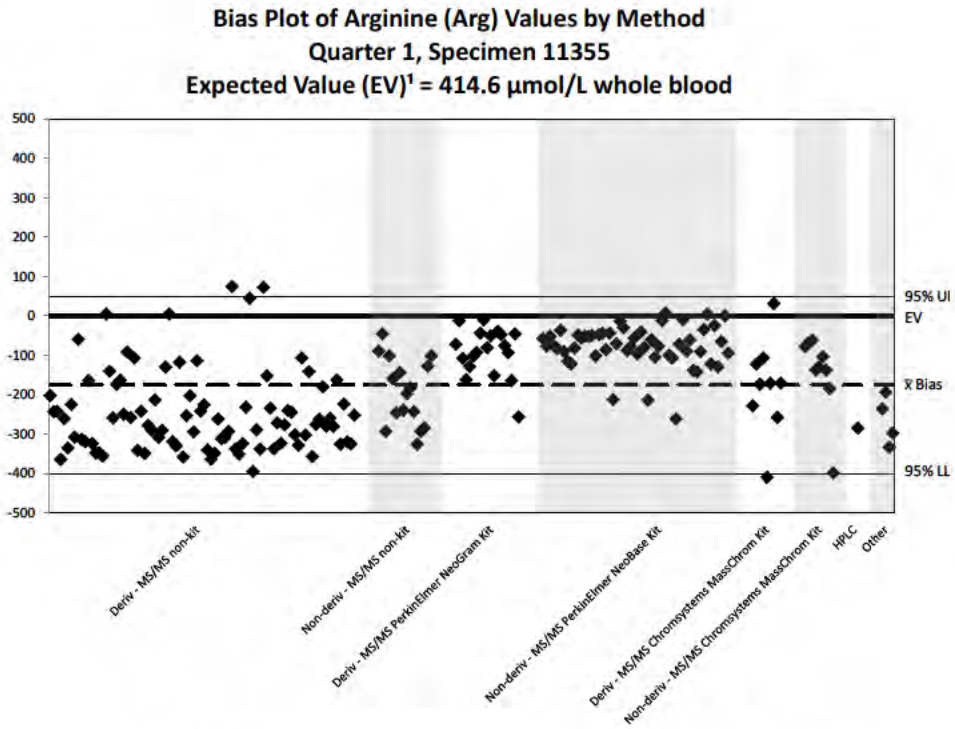
Quarter 1	
Specimen 1	
Enriched	150.0
CDC Assayed	145.8
Participant Mean	149.9
Participant Bias[2]	-25.2



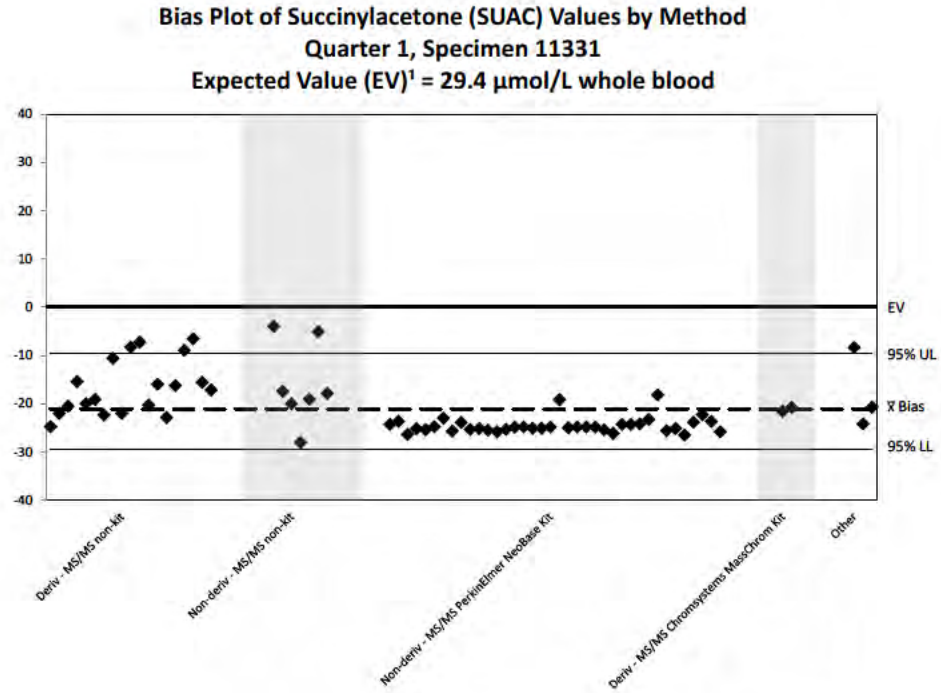
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Arginine (Arg) and Succinylacetone (SUAC)

Quarter 1	
Specimen 5	
Enriched	400.0
CDC Assayed	336.8
Participant Mean	239.7
Participant Bias[2]	-174.9



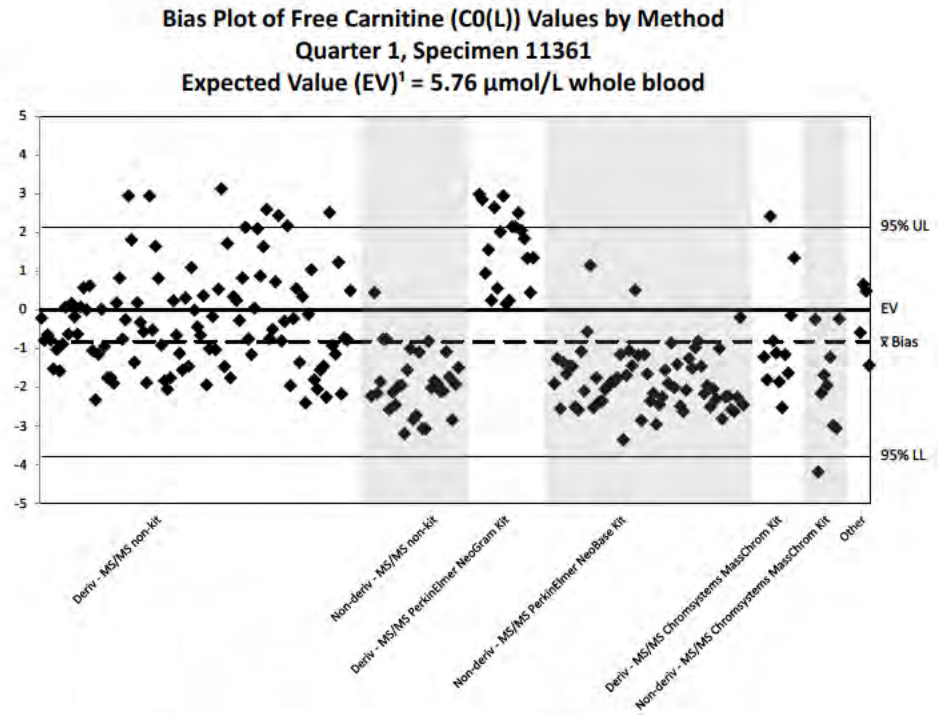
Quarter 1	
Specimen 1	
Enriched	29.0
CDC Assayed	9.5
Participant Mean	8.3
Participant Bias[2]	-21.1



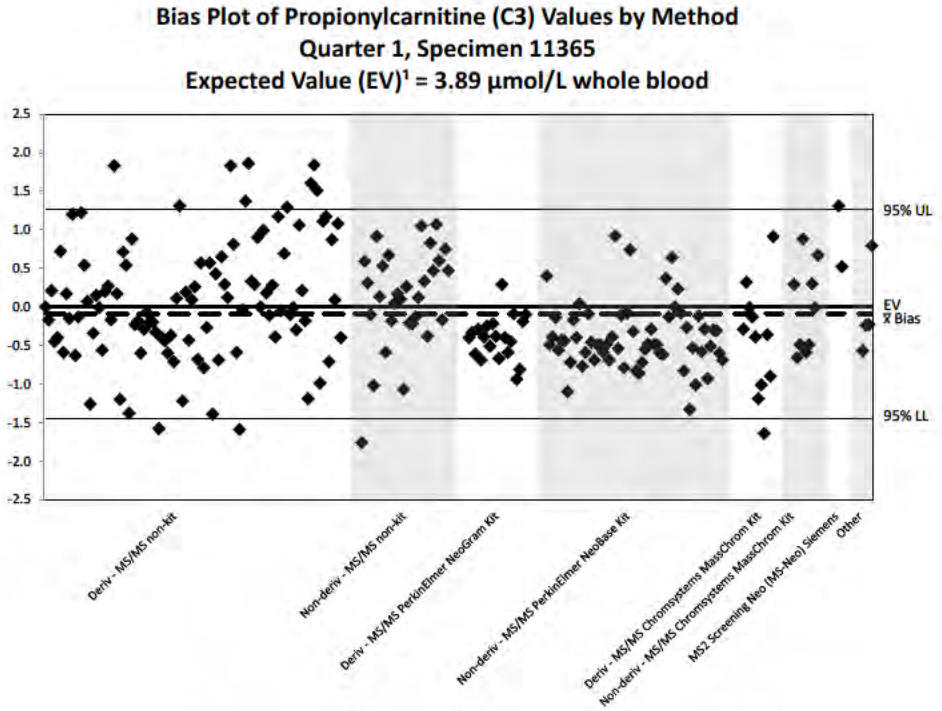
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Free Carnitine (C0(L)) and Propionylcarnitine (C3)

Quarter 1	
Specimen 1	
Enriched	0.00
CDC Assayed	5.76
Participant Mean	4.94
Participant Bias[2]	-0.82



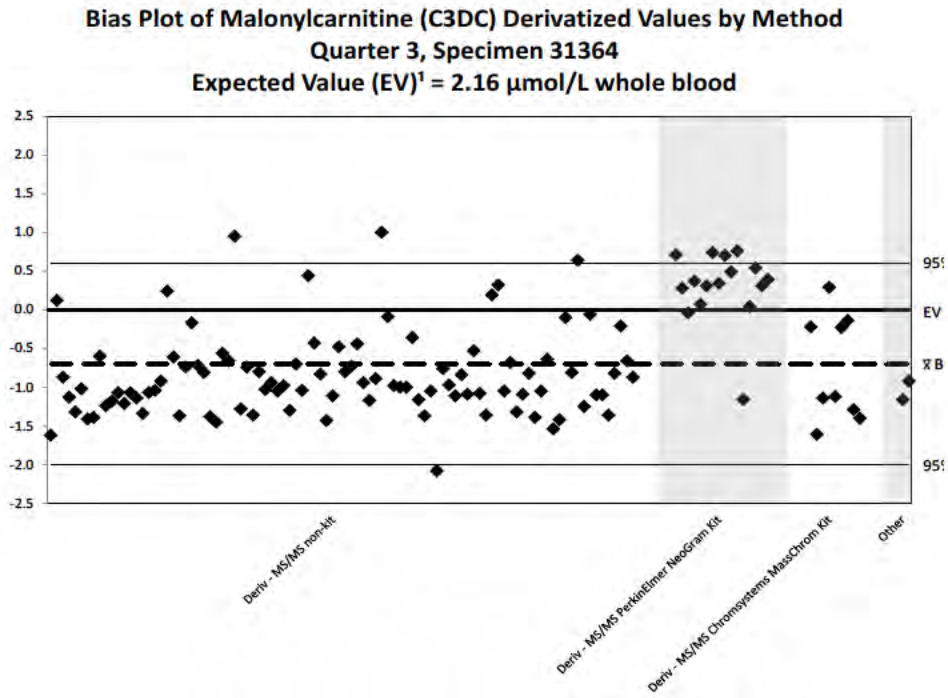
Quarter 1	
Specimen 5	
Enriched	0.00
CDC Assayed	3.75
Participant Mean	3.80
Participant Bias[2]	-0.09



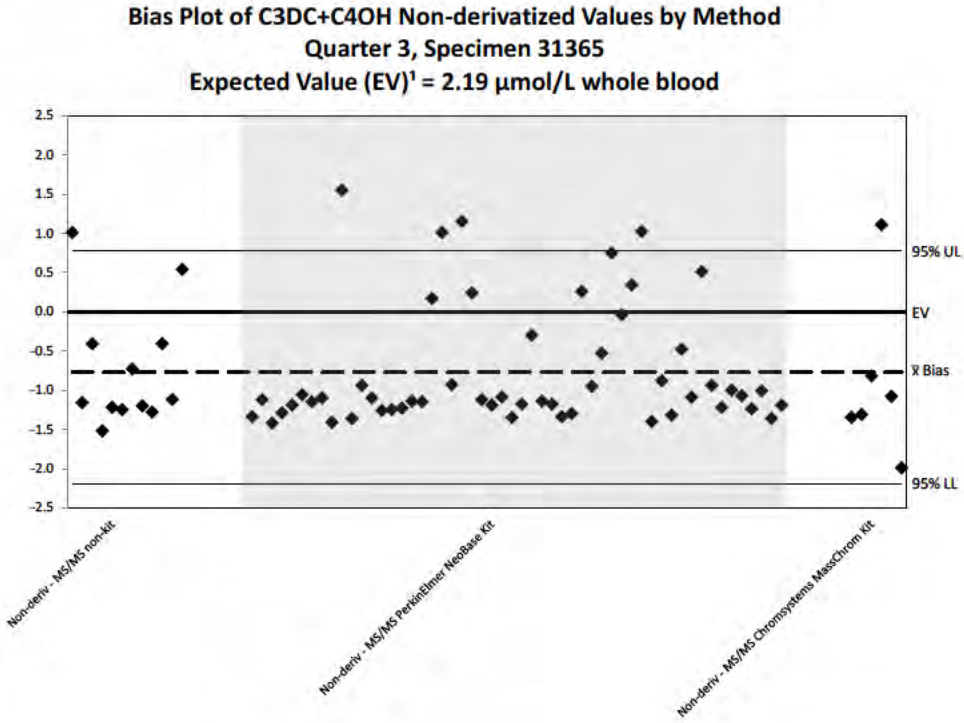
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Malonylcarnitine (C3DC) Derivatized and C3DC+C4OH Non-derivatized

Quarter 3	
Specimen 4	
Enriched	2.00
CDC Assayed	1.29
Participant Mean	1.46
Participant Bias[2]	-0.70



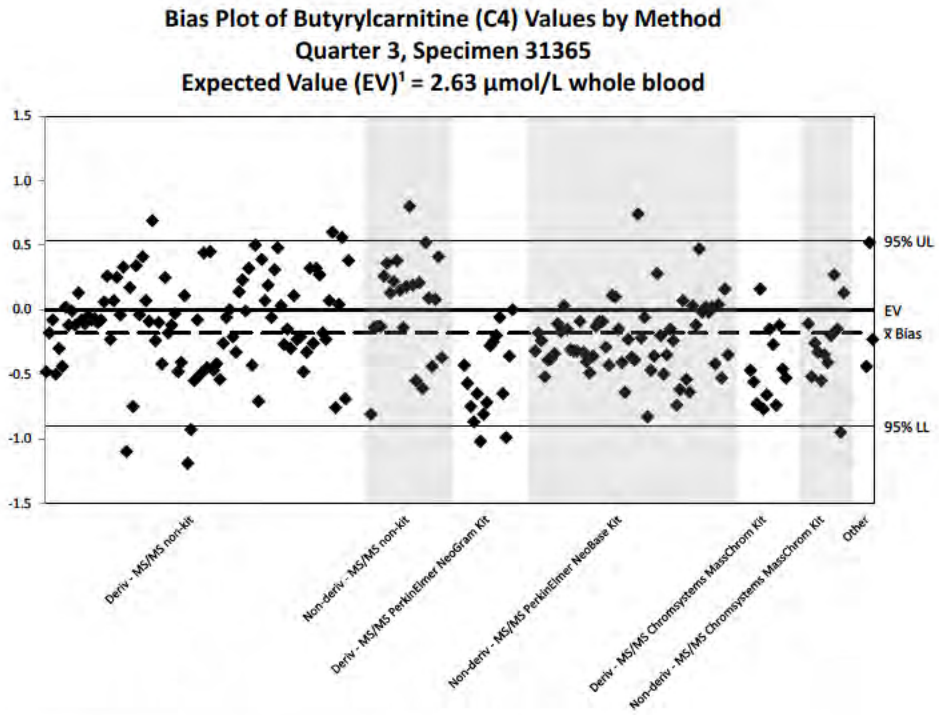
Quarter 3	
Specimen 5	
Enriched	2.00
CDC Assayed	3.44
Participant Mean	1.42
Participant Bias[2]	-0.77



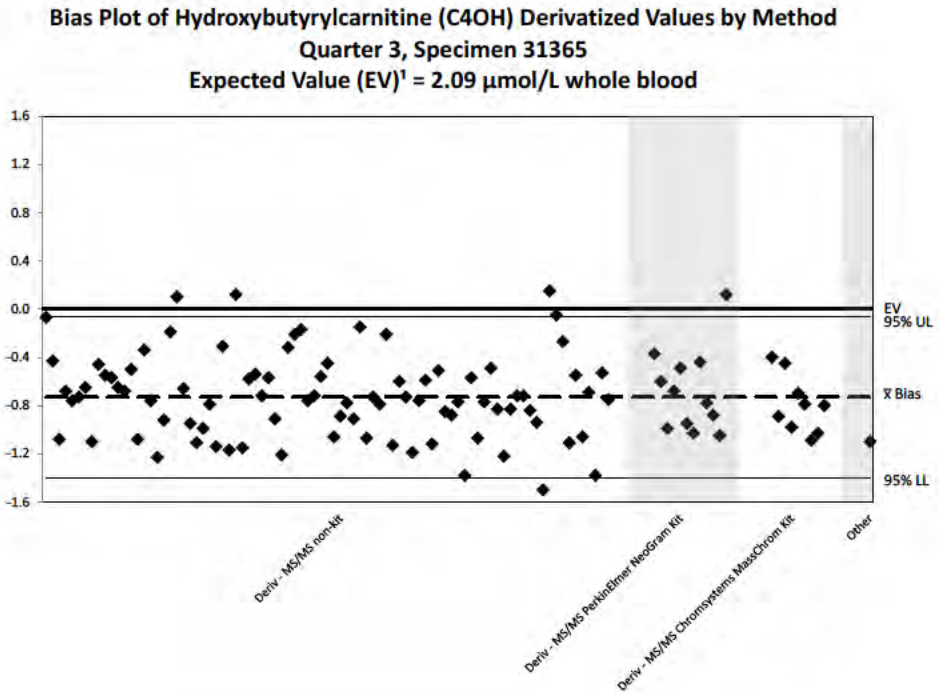
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method
Butyrylcarnitine (C4) and Hydroxybutyrylcarnitine (C4OH) Derivatized

Quarter 3	
Specimen 5	
Enriched	2.50
CDC Assayed	2.28
Participant Mean	2.45
Participant Bias[2]	-0.18



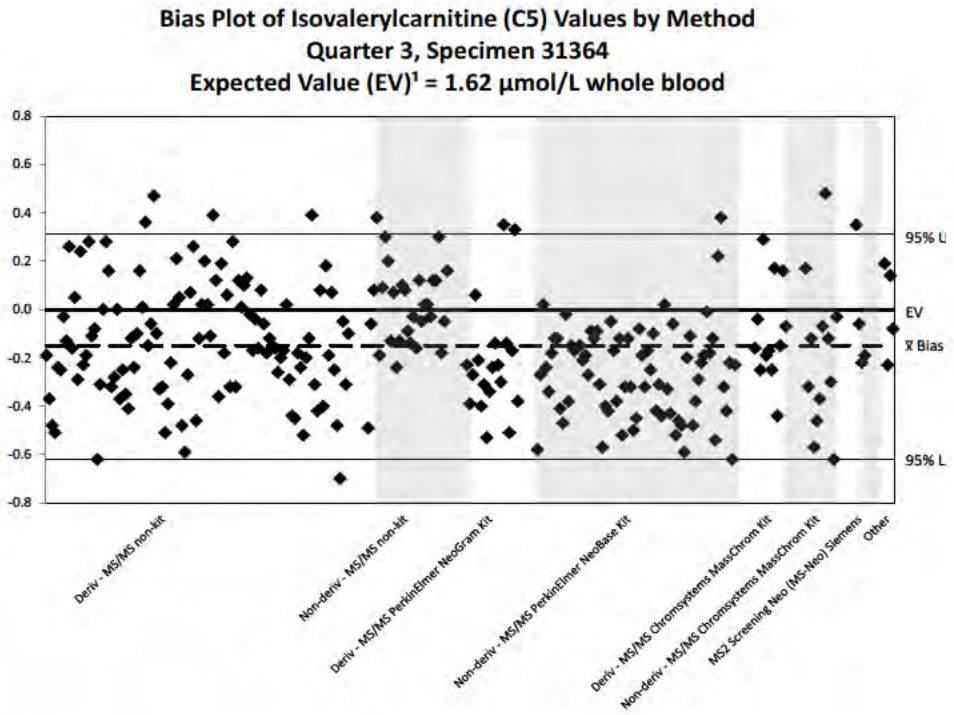
Quarter 3	
Specimen 5	
Enriched	2.00
CDC Assayed	1.23
Participant Mean	1.36
Participant Bias[2]	-0.73



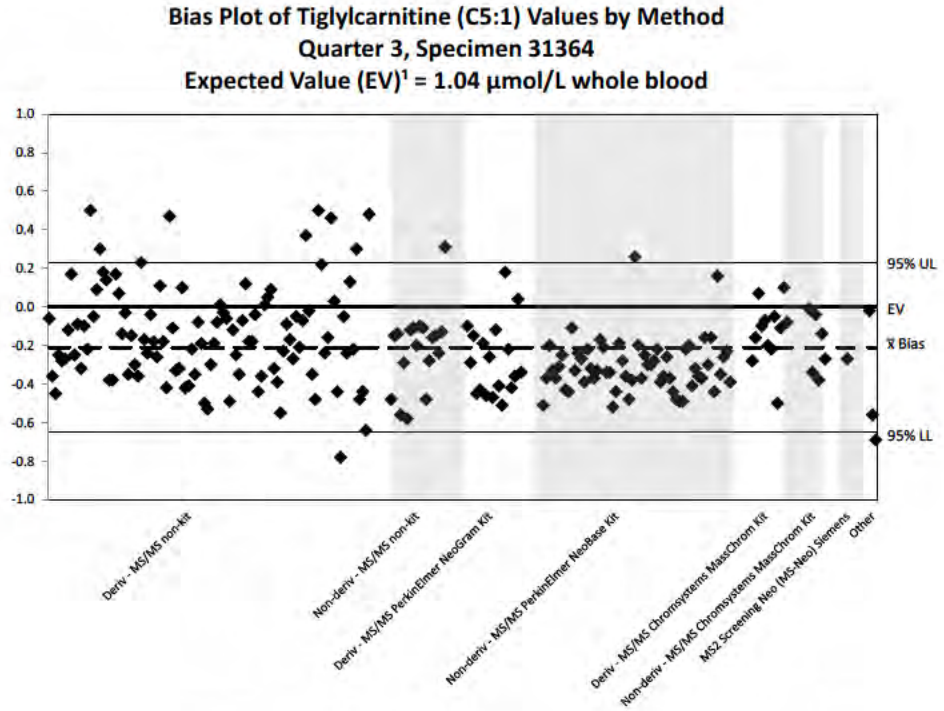
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\overline{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\overline{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Isovalerylcarnitine (C5) and Tigylcarnitine (C5:1)

Quarter 3	
Specimen 4	
Enriched	1.50
CDC Assayed	1.43
Participant Mean	1.47
Participant Bias[2]	-0.15



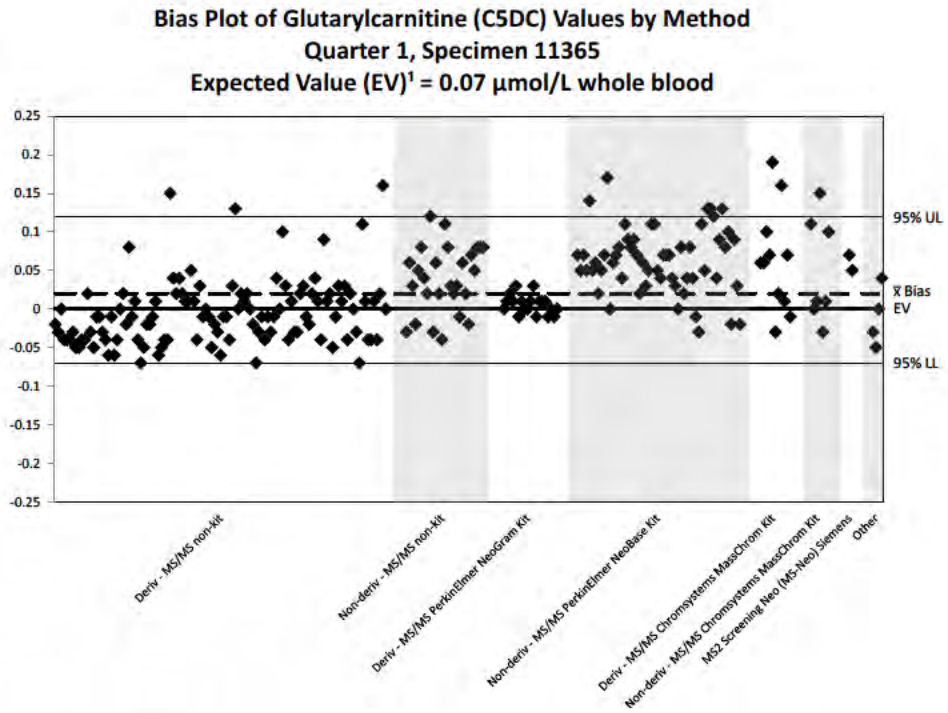
Quarter 3	
Specimen 4	
Enriched	1.00
CDC Assayed	0.84
Participant Mean	0.83
Participant Bias[2]	-0.21



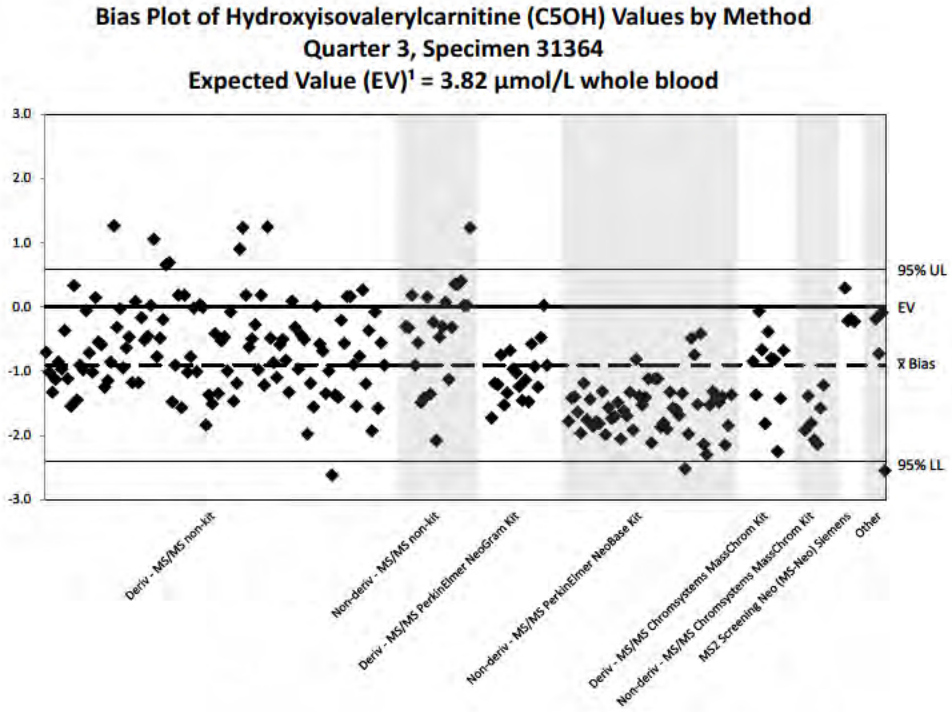
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Glutarylcarnitine (C5DC) and Hydroxyisovalerylcarnitine (C5OH)

Quarter 1	
Specimen 5	
Enriched	0.00
CDC Assayed	0.07
Participant Mean	0.09
Participant Bias[2]	0.02



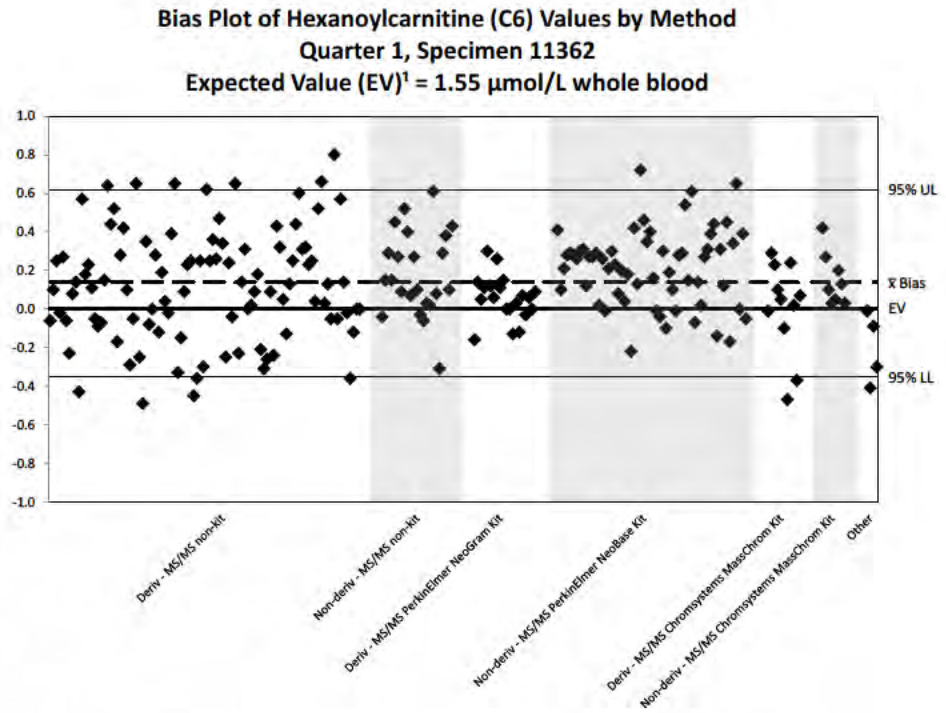
Quarter 3	
Specimen 4	
Enriched	3.00
CDC Assayed	3.18
Participant Mean	2.91
Participant Bias[2]	-0.91



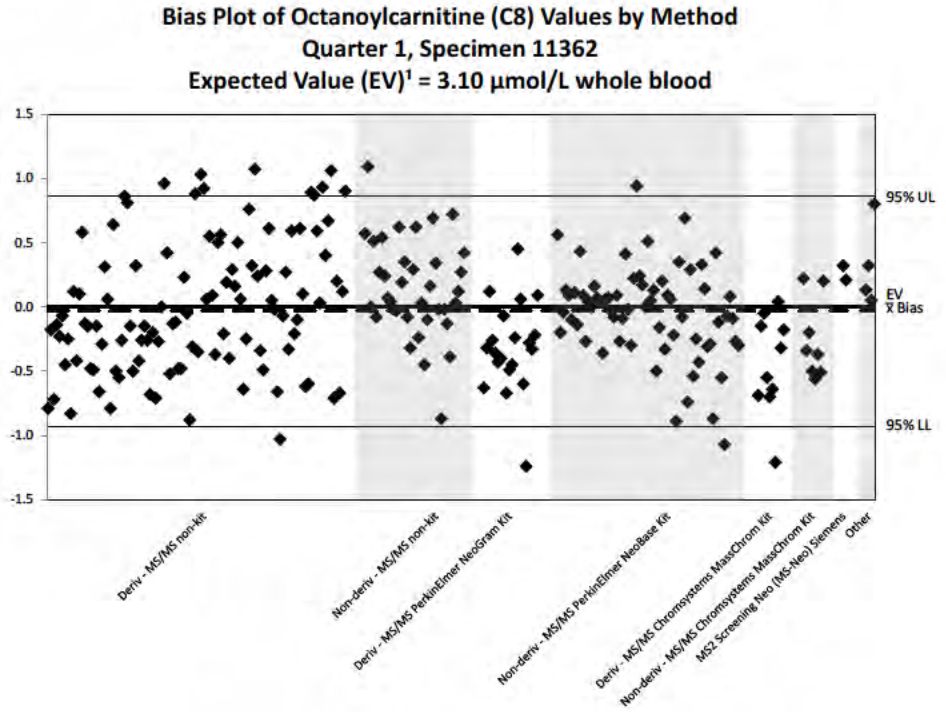
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Hexanoylcarnitine (C6) and Octanoylcarnitine (C8)

Quarter 1	
Specimen 2	
Enriched	1.50
CDC Assayed	1.42
Participant Mean	1.69
Participant Bias[2]	0.14



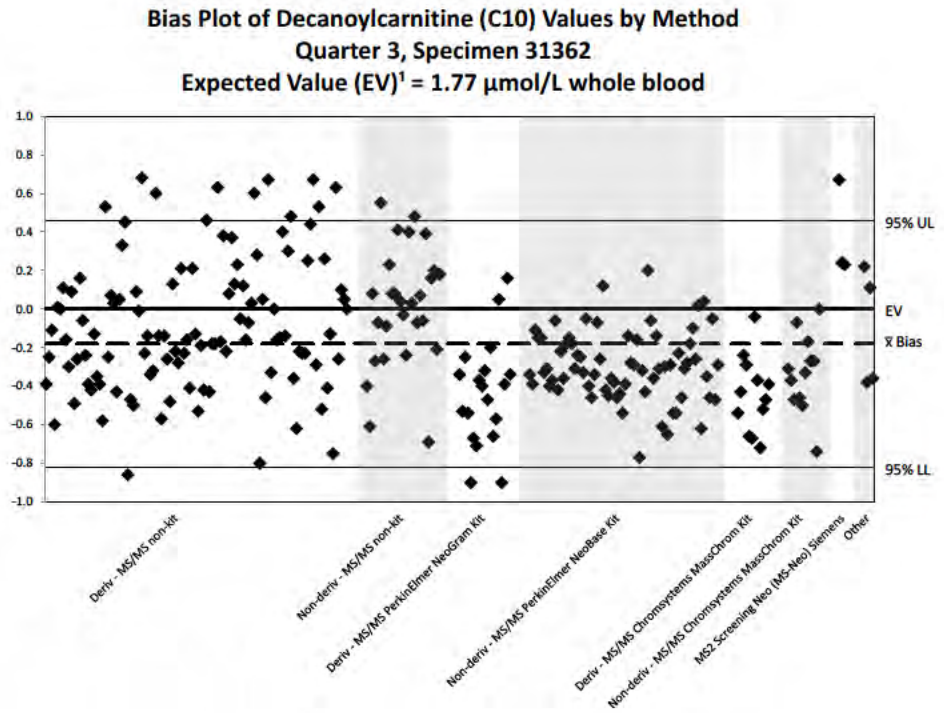
Quarter 1	
Specimen 2	
Enriched	3.00
CDC Assayed	3.19
Participant Mean	3.07
Participant Bias[2]	-0.03



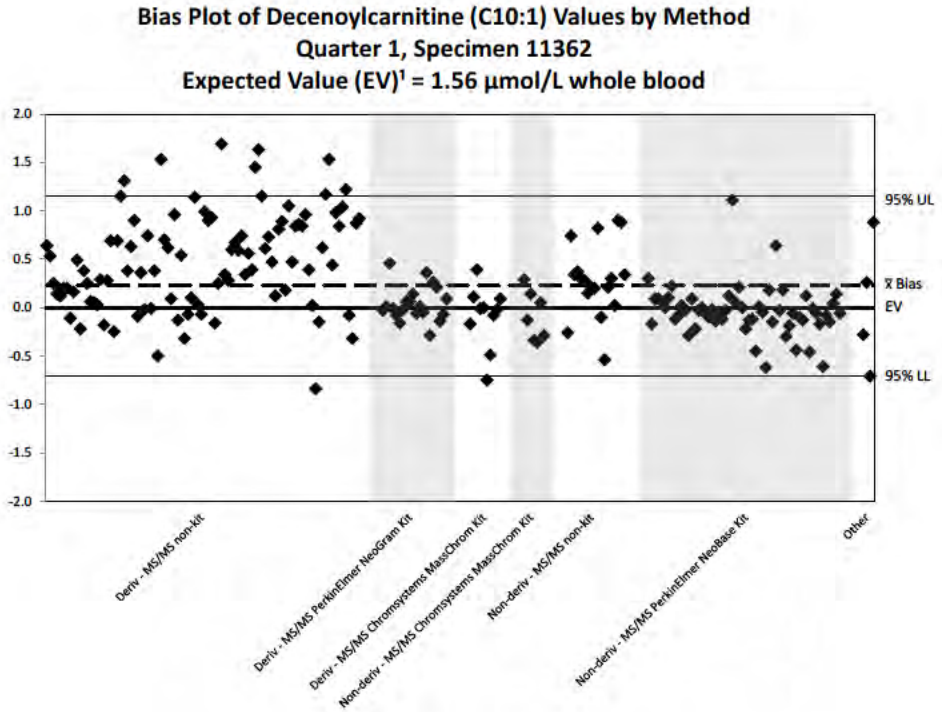
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Decanoylcarnitine (C10) and Decenoylcarnitine (C10:1)

Quarter 3	
Specimen 2	
Enriched	1.75
CDC Assayed	1.74
Participant Mean	1.59
Participant Bias[2]	-0.18



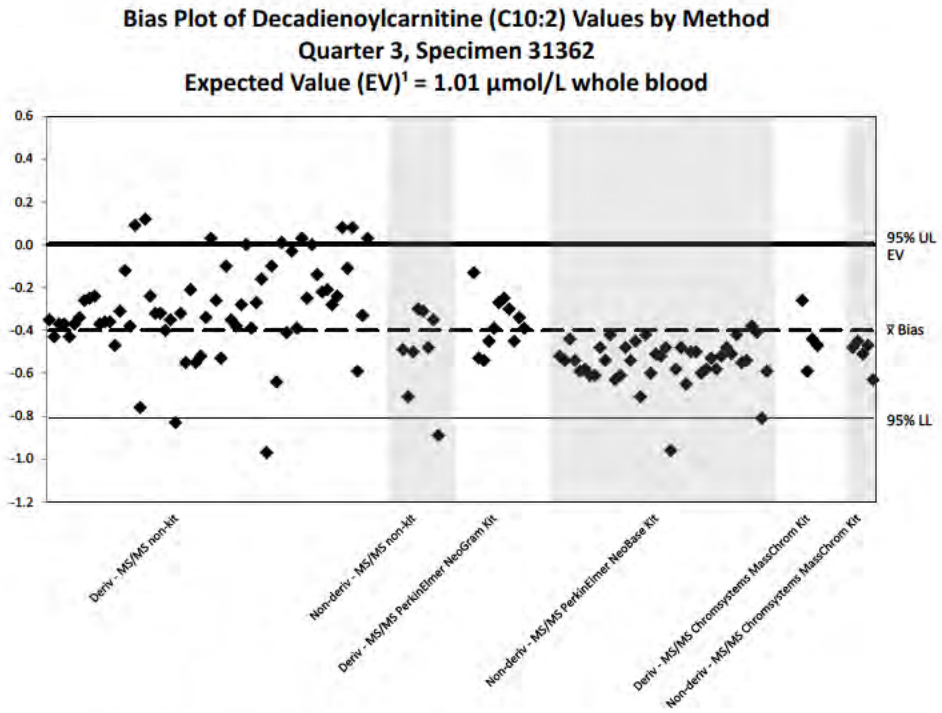
Quarter 1	
Specimen 2	
Enriched	1.50
CDC Assayed	2.09
Participant Mean	1.79
Participant Bias[2]	0.23



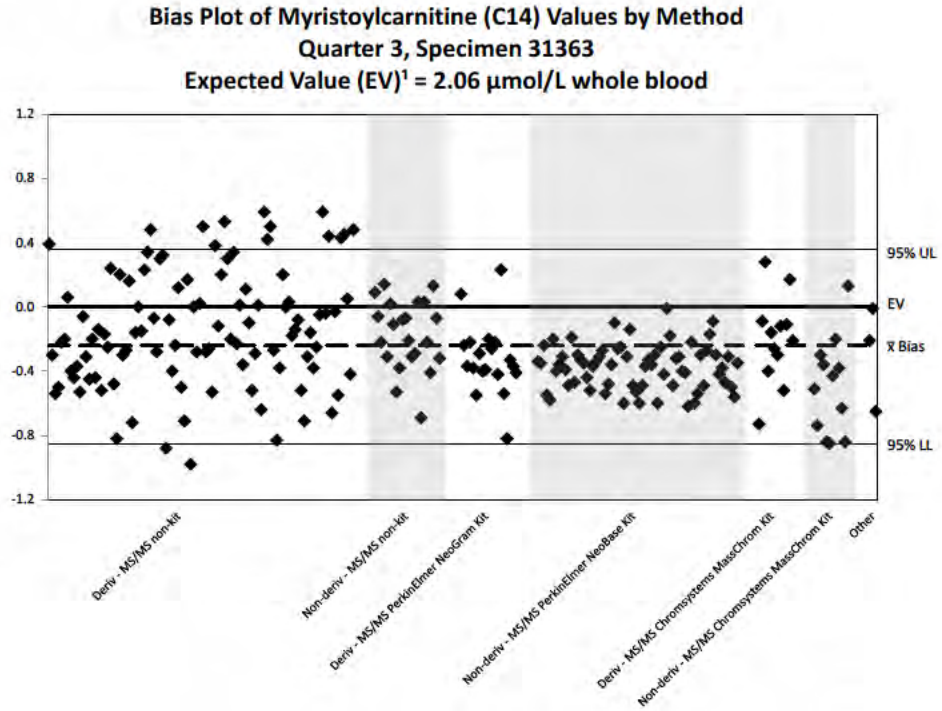
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Decadienoylcarnitine (C10:2) and Myristoylcarnitine (C14)

Quarter 3	
Specimen 2	
Enriched	1.00
CDC Assayed	0.76
Participant Mean	0.61
Participant Bias[2]	-0.40



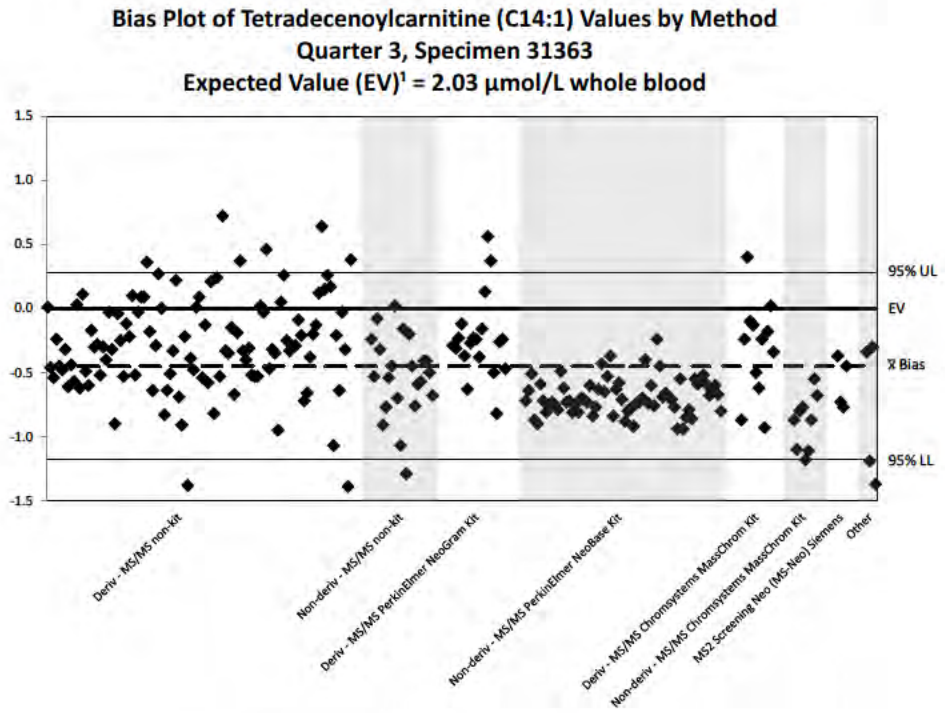
Quarter 3	
Specimen 3	
Enriched	2.00
CDC Assayed	1.83
Participant Mean	1.82
Participant Bias[2]	-0.24



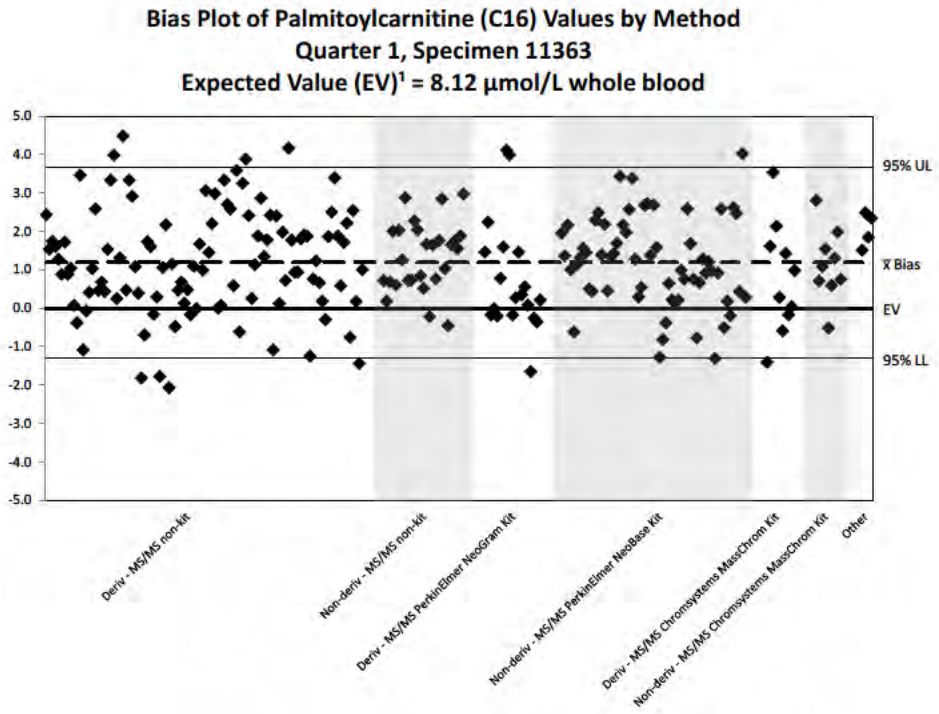
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Tetradecenoylcarnitine (C14:1) and Palmitoylcarnitine (C16)

Quarter 3	
Specimen 3	
Enriched	2.00
CDC Assayed	1.64
Participant Mean	1.58
Participant Bias[2]	-0.45



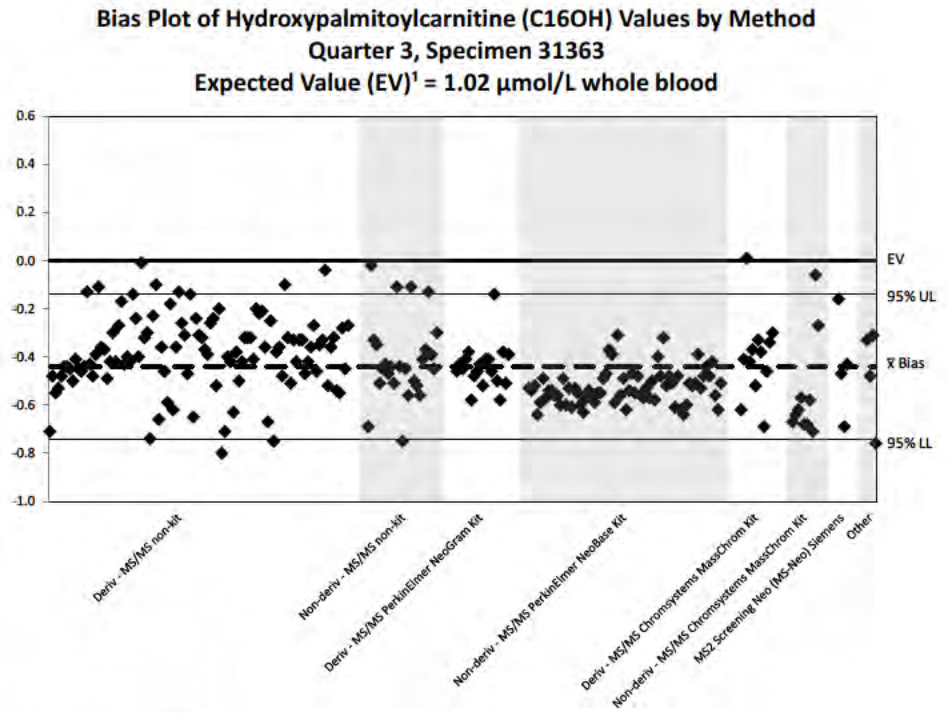
Quarter 1	
Specimen 3	
Enriched	7.50
CDC Assayed	7.85
Participant Mean	9.31
Participant Bias[2]	1.19



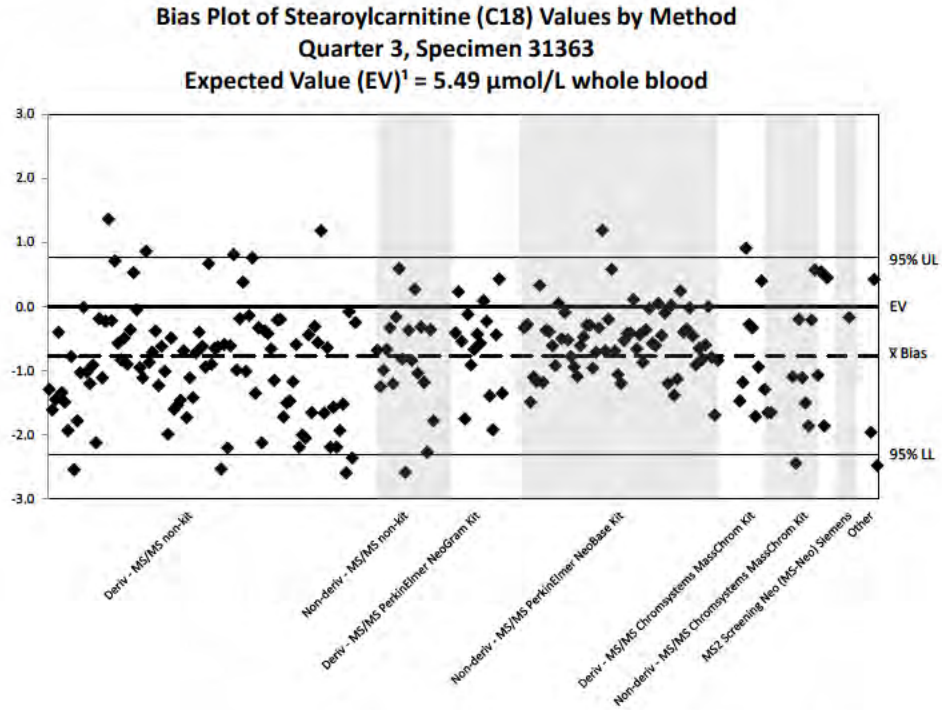
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Hydroxypalmitoylcarnitine (C16OH) and Stearoylcarnitine (C18)

Quarter 3	
Specimen 3	
Enriched	1.00
CDC Assayed	0.73
Participant Mean	0.58
Participant Bias[2]	-0.44



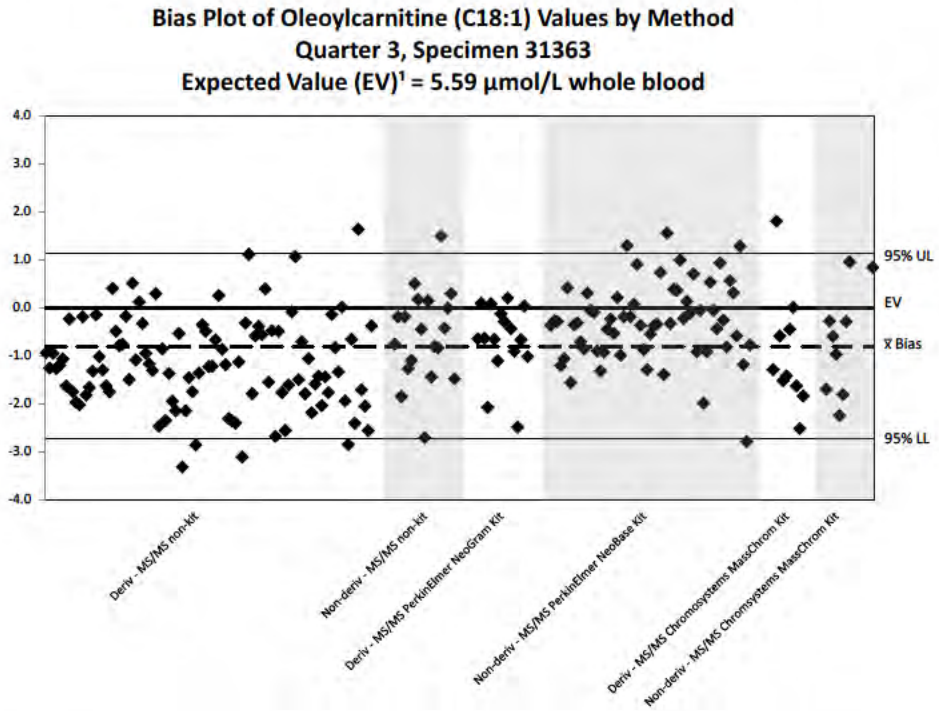
Quarter 3	
Specimen 3	
Enriched	5.00
CDC Assayed	4.56
Participant Mean	4.72
Participant Bias[2]	-0.77



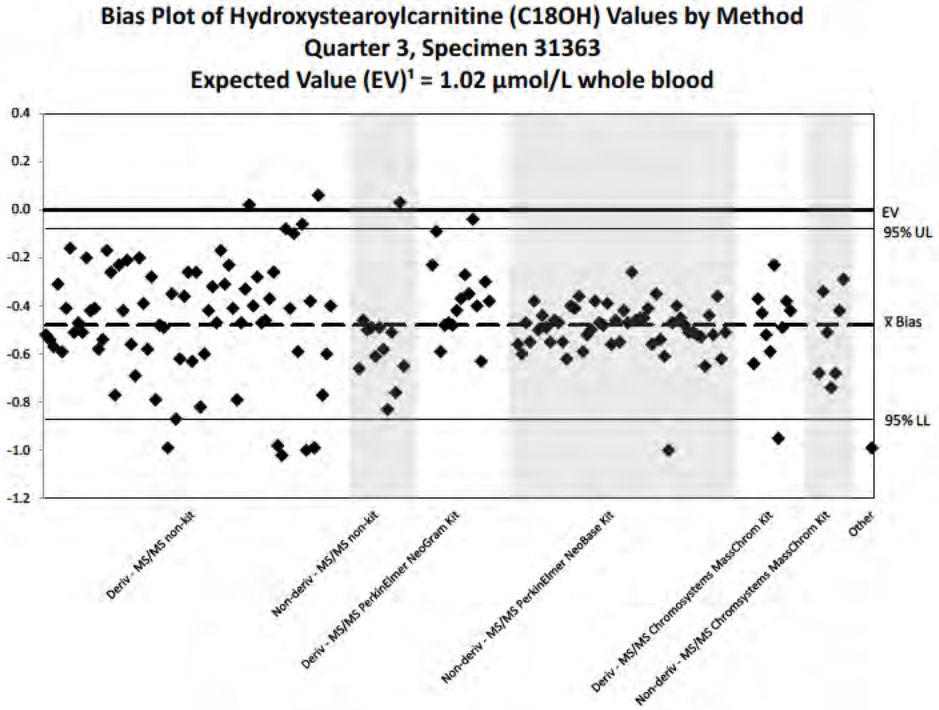
[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier values. The 95% confidence interval is shown.
[3]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 Method Oleoylcarnitine (C18:1) and Hydroxystearoylcarnitine (C18OH)

Quarter 3	
Specimen 3	
Enriched	5.00
CDC Assayed	4.77
Participant Mean	4.78
Participant Bias[2]	-0.81



Quarter 3	
Specimen 3	
Enriched	1.00
CDC Assayed	0.68
Participant Mean	0.54
Participant Bias[2]	-0.48



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]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.
[3]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

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Table 17a. 2013 Quality Control Data
Summaries of Statistical Analyses

THYROXINE (μg T4/dL serum)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 101 - Assayed 1.8 μg/dL serum						
Siemens Healthcare Diagnostics	19	2.0	0.3	0.4	0.4	0.9
Neo-Genesis Accuwell	20	1.6	0.2	0.2	-0.5	1.0
Delfia	68	1.8	0.3	0.4	0.2	0.9
AutoDelfia	254	1.6	0.3	0.3	0.1	0.8
Interscientific NeoMAP Multiplex	40	1.9	0.4	0.4	0.4	0.9
PerkinElmer GSP Neonatal	80	1.5	0.3	0.3	0.1	0.8
Lot 102 - Assayed 7.1 μg/dL serum						
Siemens Healthcare Diagnostics	20	7.0	0.8	0.8	0.4	0.9
Neo-Genesis Accuwell	20	6.0	0.5	0.6	-0.5	1.0
Delfia	70	6.6	0.7	1.1	0.2	0.9
AutoDelfia	254	5.9	0.5	0.6	0.1	0.8
Interscientific NeoMAP Multiplex	40	7.0	0.7	0.8	0.4	0.9
PerkinElmer GSP Neonatal	79	5.7	0.5	0.6	0.1	0.8
Lot 103 - Assayed 11.2 μg/dL serum						
Siemens Healthcare Diagnostics	20	10.7	1.4	1.4	0.4	0.9
Neo-Genesis Accuwell	20	11.0	0.5	4.3	-0.5	1.0
Delfia	70	10.3	1.1	1.6	0.2	0.9
AutoDelfia	254	9.3	0.8	0.9	0.1	0.8
Interscientific NeoMAP Multiplex	40	10.2	0.9	1.0	0.4	0.9
PerkinElmer GSP Neonatal	79	9.1	0.8	1.2	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.

THYROXINE (μg T4/dL serum)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1301 - Assayed 1.6 μg/dL serum						
Siemens Healthcare Diagnostics	20	2.2	0.4	0.4	0.2	1.2
Neo-Genesis Accuwell	20	1.3	0.3	0.4	-0.0	0.9
Delfia	87	1.9	0.2	0.2	0.5	0.9
AutoDelfia	246	1.7	0.3	0.4	0.2	1.0
Interscientific NeoMAP Multiplex	40	1.6	0.5	0.5	-0.2	1.0
PerkinElmer GSP Neonatal	127	1.7	0.2	0.3	0.2	1.0
Lot 1302 - Assayed 6.1 μg/dL serum						
Siemens Healthcare Diagnostics	20	7.3	0.8	0.8	0.2	1.2
Neo-Genesis Accuwell	20	6.0	0.7	0.9	-0.0	0.9
Delfia	88	6.4	0.6	0.7	0.5	0.9
AutoDelfia	241	5.9	0.5	0.6	0.2	1.0
Interscientific NeoMAP Multiplex	40	6.0	0.7	0.7	-0.2	1.0
PerkinElmer GSP Neonatal	126	6.2	0.6	0.6	0.2	1.0
Lot 1303 - Assayed 9.5 μg/dL serum						
Siemens Healthcare Diagnostics	20	11.7	1.2	1.2	0.2	1.2
Neo-Genesis Accuwell	20	8.7	0.7	1.4	-0.0	0.9
Delfia	87	9.2	1.2	1.2	0.5	0.9
AutoDelfia	246	9.3	0.8	1.1	0.2	1.0
Interscientific NeoMAP Multiplex	40	9.8	1.4	1.5	-0.2	1.0
PerkinElmer GSP Neonatal	126	9.5	0.8	1.0	0.2	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 17b. 2013 Quality Control Data
Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE (μIU TSH/mL serum)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 211 - Enriched 25 μIU/mL serum						
Siemens Healthcare Diagnostics	40	31.7	2.4	4.9	8.7	1.0
Neo-Genesis Accuwell	30	24.9	5.6	6.3	5.9	0.9
Delfia	509	26.7	2.6	3.5	7.5	0.8
AutoDelfia	836	28.4	2.2	3.5	8.6	0.8
Ani Labsystems	88	27.6	2.5	4.9	4.7	1.0
Bio-Rad Quantase	90	32.9	3.2	9.8	14.7	0.8
TecnoSuma UMELISA	40	24.2	3.1	6.1	2.8	0.9
DiaSorin	90	26.6	2.4	3.5	9.3	0.7
Interscientific NeoMAP Multiplex	30	23.7	2.3	3.7	5.2	0.8
PerkinElmer GSP Neonatal	188	26.1	2.2	5.0	6.6	0.8
In House	30	27.8	2.6	4.3	4.4	1.1
Lot 212 - Enriched 40 μIU/mL serum						
Siemens Healthcare Diagnostics	40	52.8	8.1	12.2	8.7	1.0
Neo-Genesis Accuwell	30	45.0	5.7	11.8	5.9	0.9
Delfia	515	41.5	4.2	5.8	7.5	0.8
AutoDelfia	828	43.4	3.0	4.2	8.6	0.8
Ani Labsystems	90	45.9	3.7	6.5	4.7	1.0
Bio-Rad Quantase	87	45.9	4.6	11.4	14.7	0.8
TecnoSuma UMELISA	40	40.0	5.7	9.4	2.8	0.9
DiaSorin	89	38.7	3.8	6.8	9.3	0.7
Interscientific NeoMAP Multiplex	30	40.6	3.1	3.4	5.2	0.8
PerkinElmer GSP Neonatal	190	40.4	4.0	7.8	6.6	0.8
In House	30	51.1	6.8	7.3	4.4	1.1
Lot 213 - Enriched 80 μIU/mL serum						
Siemens Healthcare Diagnostics	39	89.2	11.1	13.7	8.7	1.0
Neo-Genesis Accuwell	30	74.9	9.0	17.4	5.9	0.9
Delfia	506	72.2	6.7	9.3	7.5	0.8
AutoDelfia	821	75.0	5.4	7.4	8.6	0.8
Ani Labsystems	90	82.3	5.4	10.2	4.7	1.0
Bio-Rad Quantase	84	74.9	6.5	17.2	14.7	0.8
TecnoSuma UMELISA	40	74.2	9.7	21.8	2.8	0.9
DiaSorin	88	66.3	5.0	9.3	9.3	0.7
Interscientific NeoMAP Multiplex	30	70.0	5.3	6.6	5.2	0.8
PerkinElmer GSP Neonatal	191	71.5	6.3	13.7	6.6	0.8
In House	30	88.0	10.6	12.1	4.4	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 -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1311 - Enriched 25 µIU/mL serum						
Siemens Healthcare Diagnostics	40	31.5	2.6	4.0	-2.0	1.3
Neo-Genesis Accuwell	39	19.4	2.3	8.3	-3.8	0.9
Delfia	501	24.9	2.8	4.8	1.5	1.0
AutoDelfia	859	26.0	2.2	3.7	0.9	1.0
Ani Labsystems	110	22.7	2.6	3.9	-2.8	1.0
Bio-Rad Quantase	89	24.7	3.3	6.9	1.4	0.9
TecnoSuma UMELISA	20	27.2	3.0	3.0	-2.2	1.2
Bioclone ELISA	20	18.9	1.5	7.8	0.5	0.8
DiaSorin	88	25.3	3.1	4.4	1.0	1.0
Interscientific NeoMAP Multiplex	30	22.1	2.0	2.2	-2.4	1.0
PerkinElmer GSP Neonatal	202	23.8	2.2	2.7	-1.4	1.0
In House	47	23.1	2.9	6.2	0.3	1.0
Lot 1312 - Enriched 40 µIU/mL serum						
Siemens Healthcare Diagnostics	40	50.0	5.2	6.8	-2.0	1.3
Neo-Genesis Accuwell	40	33.3	4.7	11.5	-3.8	0.9
Delfia	490	40.1	4.2	6.4	1.5	1.0
AutoDelfia	858	41.7	3.5	4.8	0.9	1.0
Ani Labsystems	106	39.0	4.0	7.0	-2.8	1.0
Bio-Rad Quantase	89	37.4	4.2	8.7	1.4	0.9
TecnoSuma UMELISA	20	45.7	5.1	5.8	-2.2	1.2
Bioclone ELISA	20	30.8	2.5	10.2	0.5	0.8
DiaSorin	89	41.5	4.2	6.1	1.0	1.0
Interscientific NeoMAP Multiplex	30	36.1	4.2	4.3	-2.4	1.0
PerkinElmer GSP Neonatal	205	38.5	3.6	4.8	-1.4	1.0
In House	50	39.7	4.6	12.8	0.3	1.0
Lot 1313 - Enriched 80 µIU/mL serum						
Siemens Healthcare Diagnostics	40	103.6	10.2	12.7	-2.0	1.3
Neo-Genesis Accuwell	40	70.3	9.0	20.5	-3.8	0.9
Delfia	492	77.4	8.6	15.2	1.5	1.0
AutoDelfia	843	81.8	6.6	8.5	0.9	1.0
Ani Labsystems	106	79.7	6.8	13.8	-2.8	1.0
Bio-Rad Quantase	91	74.7	12.0	22.4	1.4	0.9
TecnoSuma UMELISA	20	92.7	8.1	20.7	-2.2	1.2
Bioclone ELISA	20	60.2	5.9	27.0	0.5	0.8
DiaSorin	90	80.4	7.4	10.0	1.0	1.0
Interscientific NeoMAP Multiplex	30	75.3	5.3	8.1	-2.4	1.0
PerkinElmer GSP Neonatal	202	78.7	7.2	9.0	-1.4	1.0
In House	50	76.2	11.6	27.1	0.3	1.0

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

Table 17c. 2013 Quality Control Data
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 251 - Enriched 25 ng/mL serum						
Siemens Healthcare Diagnostics	60	25.1	2.2	3.4	8.7	0.6
MP Biomedicals RIA	39	24.6	2.2	2.3	2.2	0.9
Neo-Genesis Accuwell	59	26.6	4.3	5.5	1.8	1.0
Delfia	322	21.9	2.3	3.6	-2.9	0.9
Delfia Neonatal 17-OHP (A024)	129	21.0	2.3	3.2	-0.9	0.8
AutoDelfia	426	23.2	2.4	3.6	0.0	0.9
AutoDelfia Neonatal 17-OHP (B024)	724	21.6	2.2	3.2	0.0	0.8
Bio-Rad Quantase	145	27.3	4.7	7.5	1.5	0.9
TecnoSuma UMELISA	48	27.4	2.7	4.6	-2.4	1.2
LC-MS/MS	19	24.8	4.7	4.7	1.4	0.9
PerkinElmer GSP Neonatal	317	23.5	2.0	2.6	0.1	0.9
In House	39	26.1	5.3	5.5	4.0	0.9
Lot 252 - Enriched 50 ng/mL serum						
Siemens Healthcare Diagnostics	60	40.5	3.4	5.8	8.7	0.6
MP Biomedicals RIA	40	47.6	4.7	5.4	2.2	0.9
Neo-Genesis Accuwell	59	49.5	10.0	12.4	1.8	1.0
Delfia	318	39.6	3.6	5.4	-2.9	0.9
Delfia Neonatal 17-OHP (A024)	126	38.0	3.8	5.8	-0.9	0.8
AutoDelfia	426	42.5	3.7	6.9	0.0	0.9
AutoDelfia Neonatal 17-OHP (B024)	732	39.4	3.7	5.2	0.0	0.8
Bio-Rad Quantase	146	44.9	8.2	13.8	1.5	0.9
TecnoSuma UMELISA	50	57.7	7.4	11.4	-2.4	1.2
LC-MS/MS	19	44.5	9.8	9.8	1.4	0.9
PerkinElmer GSP Neonatal	316	42.6	3.0	3.6	0.1	0.9
In House	40	47.7	10.0	10.0	4.0	0.9
Lot 253 - Enriched 100 ng/mL serum						
Siemens Healthcare Diagnostics	60	73.3	7.2	16.6	8.7	0.6
MP Biomedicals RIA	39	92.4	7.3	7.4	2.2	0.9
Neo-Genesis Accuwell	60	99.1	19.1	28.1	1.8	1.0
Delfia	326	89.2	8.9	18.3	-2.9	0.9
Delfia Neonatal 17-OHP (A024)	130	81.8	9.4	19.3	-0.9	0.8
AutoDelfia	423	88.9	8.2	14.3	0.0	0.9
AutoDelfia Neonatal 17-OHP (B024)	729	82.6	8.8	12.1	0.0	0.8
Bio-Rad Quantase	142	96.6	17.9	32.3	1.5	0.9
TecnoSuma UMELISA	50	117.4	12.8	25.0	-2.4	1.2
LC-MS/MS	18	91.3	15.8	15.8	1.4	0.9
PerkinElmer GSP Neonatal	318	89.5	7.9	9.1	0.1	0.9
In House	37	91.9	14.0	15.6	4.0	0.9

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

Table 17d. 2013 Quality Control Data
Summaries of Statistical Analyses

IMMUNOREACTIVE TRYPSINOGEN (ng IRT/mL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1391 - Assayed 16.9 ng/mL whole blood						
MP Biomedicals ELISA	121	21.1	3.5	7.1	7.7	1.4
Delfia	414	15.0	1.9	2.5	0.1	0.9
AutoDelfia	1377	14.9	1.4	1.8	-0.6	0.9
Bio-Rad Quantase	20	24.5	2.4	18.4	9.4	1.3
PerkinElmer GSP Neonatal	263	15.9	1.2	1.5	-0.6	1.0
Lot 1392 - Assayed 54.4 ng/mL whole blood						
MP Biomedicals ELISA	127	80.8	12.3	26.1	7.7	1.4
Delfia	410	46.2	4.9	5.8	0.1	0.9
AutoDelfia	1385	48.3	4.2	4.9	-0.6	0.9
Bio-Rad Quantase	20	71.5	10.6	16.4	9.4	1.3
PerkinElmer GSP Neonatal	257	50.4	3.5	3.7	-0.6	1.0
Lot 1393 - Assayed 107.3 ng/mL whole blood						
MP Biomedicals ELISA	120	178.6	27.4	68.9	7.7	1.4
Delfia	409	93.5	9.9	11.5	0.1	0.9
AutoDelfia	1379	100.6	8.0	9.9	-0.6	0.9
Bio-Rad Quantase	20	171.0	46.5	46.5	9.4	1.3
PerkinElmer GSP Neonatal	261	106.3	8.1	9.6	-0.6	1.0
Lot 1394 - Assayed 188.6 ng/mL whole blood						
MP Biomedicals ELISA	118	254.4	36.6	89.8	7.7	1.4
Delfia	413	162.8	16.4	19.9	0.1	0.9
AutoDelfia	1380	172.2	13.1	15.6	-0.6	0.9
Bio-Rad Quantase	20	237.4	94.1	105.9	9.4	1.3
PerkinElmer GSP Neonatal	263	181.6	13.2	16.2	-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 17e. 2013 Quality Control Data
Summaries of Statistical Analyses

TOTAL GALACTOSE (mg TGal/dL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1225 - Enriched 5 mg/dL whole blood						
Siemens Healthcare Diagnostics	38	5.5	0.4	0.4	1.6	0.9
Colorimetric	50	6.2	1.0	1.5	0.1	1.2
PerkinElmer Neonatal Kit	256	5.4	0.5	0.7	1.4	0.9
Fluorometric Manual	119	4.8	0.7	1.2	-0.6	1.1
Neo-Genesis Accuwell	39	5.7	0.5	0.5	0.8	1.0
Bio-Rad Quantase	137	5.9	1.0	1.9	-0.0	1.1
MP Biomedicals Enzyme Assay	20	10.3	1.5	2.0	0.7	1.8
Interscientific Enzyme	30	4.9	0.5	0.8	-0.5	1.0
Astoria-Pacific	100	6.5	0.6	1.0	1.1	1.1
TecnoSuma UMTEST	30	5.7	1.1	3.0	-0.8	1.4
R&D Diagnostics Greece	20	5.1	0.8	0.8	1.3	0.8
Lot 1226 - Enriched 10 mg/dL whole blood						
Siemens Healthcare Diagnostics	38	10.7	0.7	0.9	1.6	0.9
Colorimetric	48	11.8	1.3	1.4	0.1	1.2
PerkinElmer Neonatal Kit	261	9.8	0.8	1.0	1.4	0.9
Fluorometric Manual	106	10.2	1.2	1.5	-0.6	1.1
Neo-Genesis Accuwell	40	10.0	1.1	1.4	0.8	1.0
Bio-Rad Quantase	132	11.2	1.6	2.4	-0.0	1.1
MP Biomedicals Enzyme Assay	20	17.8	2.2	2.6	0.7	1.8
Interscientific Enzyme	30	8.6	1.0	1.3	-0.5	1.0
Astoria-Pacific	99	12.0	0.9	1.4	1.1	1.1
TecnoSuma UMTEST	30	12.5	1.6	4.8	-0.8	1.4
R&D Diagnostics Greece	20	9.5	1.2	1.7	1.3	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.

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1227 - Enriched 15 mg/dL whole blood						
Siemens Healthcare Diagnostics	38	16.0	1.2	1.5	1.6	0.9
Colorimetric	47	18.1	1.5	1.7	0.1	1.2
PerkinElmer Neonatal Kit	252	14.5	1.1	1.7	1.4	0.9
Fluorometric Manual	113	15.8	1.4	2.9	-0.6	1.1
Neo-Genesis Accuwell	40	15.4	1.5	2.1	0.8	1.0
Bio-Rad Quantase	133	17.1	2.2	3.8	-0.0	1.1
MP Biomedicals Enzyme Assay	20	29.1	4.0	4.9	0.7	1.8
Interscientific Enzyme	30	15.9	1.5	1.5	-0.5	1.0
Astoria-Pacific	100	17.7	1.3	2.0	1.1	1.1
TecnoSuma UMTEST	29	22.1	1.8	6.3	-0.8	1.4
R&D Diagnostics Greece	20	14.4	1.5	1.5	1.3	0.8
Lot 1228 - Enriched 30 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	28.2	3.0	7.3	1.6	0.9
Colorimetric	50	36.1	3.4	5.6	0.1	1.2
PerkinElmer Neonatal Kit	263	26.7	1.8	2.4	1.4	0.9
Fluorometric Manual	110	31.9	2.3	4.6	-0.6	1.1
Neo-Genesis Accuwell	40	29.5	3.3	4.0	0.8	1.0
Bio-Rad Quantase	136	34.4	4.9	7.9	-0.0	1.1
MP Biomedicals Enzyme Assay	20	55.5	5.5	9.0	0.7	1.8
Interscientific Enzyme	29	30.1	1.8	1.8	-0.5	1.0
Astoria-Pacific	97	33.8	2.1	3.8	1.1	1.1
TecnoSuma UMTEST	29	40.6	4.1	10.1	-0.8	1.4
R&D Diagnostics Greece	20	25.9	2.3	6.0	1.3	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.

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Enriched 5 mg/dL whole blood						
Siemens Healthcare Diagnostics	38	5.3	0.2	0.3	1.2	0.9
Colorimetric	40	5.9	1.7	1.7	-0.5	1.3
PerkinElmer Neonatal Kit	259	5.2	0.5	1.0	1.1	0.8
Fluorometric Manual	139	5.2	0.9	1.3	0.0	1.1
Neo-Genesis Accuwell	40	5.9	0.6	0.7	0.0	1.2
Bio-Rad Quantase	143	6.0	0.9	1.3	-1.9	1.5
MP Biomedicals Enzyme Assay	10	7.4	1.7	1.7	-3.4	2.1
Interscientific Enzyme	30	5.6	0.6	0.6	-0.1	1.1
Astoria-Pacific	110	6.7	0.6	1.0	1.4	1.1
TecnoSuma UMTEST	20	6.5	1.0	1.0	0.0	1.2
R&D Diagnostics Greece	30	5.3	1.0	1.2	0.7	1.0
Lot 1322 - Enriched 10 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	9.9	0.6	0.7	1.2	0.9
Colorimetric	38	12.3	1.6	1.8	-0.5	1.3
PerkinElmer Neonatal Kit	259	8.5	0.8	1.4	1.1	0.8
Fluorometric Manual	129	10.5	1.2	1.7	0.0	1.1
Neo-Genesis Accuwell	40	11.9	0.7	0.9	0.0	1.2
Bio-Rad Quantase	142	12.5	1.7	2.3	-1.9	1.5
MP Biomedicals Enzyme Assay	10	17.5	1.1	1.1	-3.4	2.1
Interscientific Enzyme	30	10.3	0.8	0.8	-0.1	1.1
Astoria-Pacific	108	11.7	0.8	1.4	1.4	1.1
TecnoSuma UMTEST	20	11.5	1.0	1.7	0.0	1.2
R&D Diagnostics Greece	30	10.8	1.3	1.5	0.7	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 TGal/dL whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1323 - Enriched 15 mg/dL whole blood						
Siemens Healthcare Diagnostics	39	15.0	0.9	1.1	1.2	0.9
Colorimetric	39	18.8	2.4	3.1	-0.5	1.3
PerkinElmer Neonatal Kit	260	12.8	1.0	1.9	1.1	0.8
Fluorometric Manual	129	16.1	1.5	2.0	0.0	1.1
Neo-Genesis Accuwell	40	18.9	1.1	1.7	0.0	1.2
Bio-Rad Quantase	150	19.8	2.4	3.8	-1.9	1.5
MP Biomedicals Enzyme Assay	10	28.9	3.2	3.2	-3.4	2.1
Interscientific Enzyme	30	16.0	1.6	1.6	-0.1	1.1
Astoria-Pacific	110	17.7	1.2	2.1	1.4	1.1
TecnoSuma UMTEST	20	19.4	2.1	3.5	0.0	1.2
R&D Diagnostics Greece	30	16.8	1.4	2.2	0.7	1.0
Lot 1324 - Enriched 30 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	27.4	1.5	6.3	1.2	0.9
Colorimetric	40	38.1	3.8	7.5	-0.5	1.3
PerkinElmer Neonatal Kit	253	24.4	1.7	3.8	1.1	0.8
Fluorometric Manual	130	31.6	2.4	3.6	0.0	1.1
Neo-Genesis Accuwell	39	36.1	2.0	3.2	0.0	1.2
Bio-Rad Quantase	148	42.5	4.8	8.5	-1.9	1.5
MP Biomedicals Enzyme Assay	10	60.5	4.7	4.7	-3.4	2.1
Interscientific Enzyme	30	32.4	3.1	3.2	-0.1	1.1
Astoria-Pacific	110	33.3	2.3	3.5	1.4	1.1
TecnoSuma UMTEST	20	37.1	2.6	9.1	0.0	1.2
R&D Diagnostics Greece	29	30.9	2.4	4.6	0.7	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 17f. 2013 Quality Control Data
Summaries of Statistical Analyses

PHENYLALANINE (μmol Phe/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1225 - Nonenriched 0.0 μmol/L whole blood						
PerkinElmer Neonatal Kit	283	79.54	10.63	14.25	79.67	1.0
Fluorometric Manual	90	101.59	16.50	48.46	112.74	1.0
Neo-Genesis Accuwell	20	62.99	12.42	12.42	64.11	1.1
Ani Labsystems	117	82.27	11.58	23.95	81.93	1.4
Bio-Rad Quantase	39	82.50	18.96	18.96	91.23	1.0
MP Biomedicals Enzyme Assay	10	22.80	6.20	6.20	16.14	1.7
Interscientific Enzyme	55	63.73	7.69	7.69	63.43	0.9
IBL International Neonatal Screening Kit	69	86.03	12.54	18.56	81.86	1.3
Astoria-Pacific	20	89.02	2.20	23.58	90.23	1.0
HPLC	20	75.49	4.40	7.76	74.54	1.0
Derivatized - MS/MS non-kit	808	67.20	4.89	9.80	68.11	0.9
Non-derivatized - MS/MS non-kit	312	72.54	5.27	10.61	72.09	1.0
Derivatized - MS/MS PE NeoGram Kit	179	71.06	5.54	9.63	71.35	1.0
Non-derivatized - MS/MS PE NeoBase Kit	432	69.14	4.70	7.63	70.28	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	78	71.56	5.79	8.21	71.15	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	83.33	6.86	9.02	83.42	1.1
TecnoSuma UMTEST	38	118.72	17.88	28.11	102.38	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	71.14	3.94	3.94	72.88	0.9
Lot 1226 - Enriched 100.0 μmol/L whole blood						
PerkinElmer Neonatal Kit	285	173.94	17.22	27.35	79.67	1.0
Fluorometric Manual	100	224.16	26.90	94.35	112.74	1.0
Neo-Genesis Accuwell	20	166.46	17.48	24.90	64.11	1.1
Ani Labsystems	120	217.93	16.12	42.24	81.93	1.4
Bio-Rad Quantase	40	194.57	36.01	40.34	91.23	1.0
MP Biomedicals Enzyme Assay	10	163.20	23.63	23.63	16.14	1.7
Interscientific Enzyme	59	150.13	12.70	16.07	63.43	0.9
IBL International Neonatal Screening Kit	69	206.55	15.96	30.45	81.86	1.3
Astoria-Pacific	20	185.50	8.26	46.41	90.23	1.0
HPLC	20	170.79	7.22	16.77	74.54	1.0
Derivatized - MS/MS non-kit	811	157.03	11.43	21.12	68.11	0.9
Non-derivatized - MS/MS non-kit	316	167.88	11.51	29.14	72.09	1.0
Derivatized - MS/MS PE NeoGram Kit	174	165.35	11.71	23.03	71.35	1.0
Non-derivatized - MS/MS PE NeoBase Kit	426	160.70	9.56	17.94	70.28	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	80	166.14	13.37	24.26	71.15	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	195.31	13.31	21.39	83.42	1.1
TecnoSuma UMTEST	38	193.46	30.21	39.02	102.38	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	163.84	7.91	11.70	72.88	0.9

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

PHENYLALANINE (µmol Phe/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1227 - Enriched 200.0 µmol/L whole blood						
PerkinElmer Neonatal Kit	287	272.64	23.68	42.48	79.67	1.0
Fluorometric Manual	100	321.60	28.26	138.76	112.74	1.0
Neo-Genesis Accuwell	20	283.97	19.53	43.25	64.11	1.1
Ani Labsystems	120	360.44	26.49	58.83	81.93	1.4
Bio-Rad Quantase	40	304.82	41.31	57.34	91.23	1.0
MP Biomedicals Enzyme Assay	10	384.60	41.52	41.52	16.14	1.7
Interscientific Enzyme	57	241.80	15.54	18.19	63.43	0.9
IBL International Neonatal Screening Kit	69	325.36	20.33	56.17	81.86	1.3
Astoria-Pacific	20	297.71	11.95	54.71	90.23	1.0
HPLC	19	269.81	13.75	19.05	74.54	1.0
Derivatized - MS/MS non-kit	814	253.77	18.79	39.71	68.11	0.9
Non-derivatized - MS/MS non-kit	312	267.56	18.95	42.97	72.09	1.0
Derivatized - MS/MS PE NeoGram Kit	178	263.94	17.15	34.22	71.35	1.0
Non-derivatized - MS/MS PE NeoBase Kit	422	256.66	15.24	25.79	70.28	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	80	271.65	17.91	41.94	71.15	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	316.15	22.46	37.17	83.42	1.1
TecnoSuma UMTEST	40	351.22	50.09	82.53	102.38	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	264.91	12.17	15.27	72.88	0.9
Lot 1228 - Enriched 300.0 µmol/L whole blood						
PerkinElmer Neonatal Kit	289	364.28	35.49	59.20	79.67	1.0
Fluorometric Manual	100	404.89	29.24	203.71	112.74	1.0
Neo-Genesis Accuwell	20	374.83	32.91	37.63	64.11	1.1
Ani Labsystems	120	494.31	36.94	94.13	81.93	1.4
Bio-Rad Quantase	40	374.89	38.18	42.82	91.23	1.0
MP Biomedicals Enzyme Assay	10	517.80	48.67	48.67	16.14	1.7
Interscientific Enzyme	57	326.96	19.66	20.90	63.43	0.9
IBL International Neonatal Screening Kit	70	467.51	33.75	77.65	81.86	1.3
Astoria-Pacific	20	380.26	24.68	106.04	90.23	1.0
HPLC	20	368.00	19.33	24.18	74.54	1.0
Derivatized - MS/MS non-kit	820	335.62	25.21	49.25	68.11	0.9
Non-derivatized - MS/MS non-kit	316	362.98	27.04	60.69	72.09	1.0
Derivatized - MS/MS PE NeoGram Kit	176	354.65	24.49	45.68	71.35	1.0
Non-derivatized - MS/MS PE NeoBase Kit	419	340.21	21.74	37.32	70.28	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	80	362.78	26.54	42.41	71.15	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	423.26	25.53	47.52	83.42	1.1
TecnoSuma UMTEST	39	466.27	42.25	74.00	102.38	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	19	344.46	14.11	14.11	72.88	0.9

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

PHENYLALANINE (μmol Phe/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Nonenriched 0.0 μmol/L whole blood						
PerkinElmer Neonatal Kit	232	74.20	9.19	11.34	74.63	0.9
Fluorometric Manual	80	159.97	13.94	102.17	159.60	0.6
Neo-Genesis Accuwell	20	63.86	11.30	11.30	69.56	1.1
Ani Labsystems	110	84.37	11.38	20.72	83.01	1.3
Bio-Rad Quantase	38	86.01	8.65	11.19	93.99	1.2
MP Biomedicals Enzyme Assay	20	83.38	24.04	75.88	84.56	1.1
Interscientific Enzyme	50	66.12	4.82	5.12	68.01	0.9
IBL International Neonatal Screening Kit	79	88.23	12.93	15.74	85.15	1.5
Astoria-Pacific	20	83.52	4.13	25.64	79.40	1.0
HPLC	10	71.31	6.09	6.09	76.19	0.9
Derivatized - MS/MS non-kit	803	65.13	5.32	9.84	66.29	0.9
Non-derivatized - MS/MS non-kit	324	69.16	5.17	8.67	68.27	0.9
Derivatized - MS/MS PE NeoGram Kit	158	65.09	5.81	7.78	65.99	0.9
Non-derivatized - MS/MS PE NeoBase Kit	513	64.82	4.75	7.65	64.48	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	76	64.75	5.85	8.27	63.38	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	75.94	4.39	9.16	77.42	1.0
TecnoSuma UMTEST	20	115.03	10.71	55.45	112.05	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	69.48	4.56	5.86	70.42	0.9
Lot 1322 - Enriched 100.0 μmol/L whole blood						
PerkinElmer Neonatal Kit	230	167.70	14.09	20.27	74.63	0.9
Fluorometric Manual	80	218.09	27.06	55.41	159.60	0.6
Neo-Genesis Accuwell	20	173.03	19.28	19.28	69.56	1.1
Ani Labsystems	110	210.88	19.44	35.94	83.01	1.3
Bio-Rad Quantase	40	221.18	19.30	39.81	93.99	1.2
MP Biomedicals Enzyme Assay	20	195.28	33.75	91.46	84.56	1.1
Interscientific Enzyme	50	159.13	8.29	9.10	68.01	0.9
IBL International Neonatal Screening Kit	79	227.62	18.11	33.87	85.15	1.5
Astoria-Pacific	20	175.41	7.02	38.07	79.40	1.0
HPLC	10	167.18	9.43	9.43	76.19	0.9
Derivatized - MS/MS non-kit	809	155.45	13.41	23.91	66.29	0.9
Non-derivatized - MS/MS non-kit	320	160.78	10.57	19.92	68.27	0.9
Derivatized - MS/MS PE NeoGram Kit	160	155.42	13.70	19.09	65.99	0.9
Non-derivatized - MS/MS PE NeoBase Kit	510	152.66	10.85	19.20	64.48	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	78	149.93	10.88	18.34	63.38	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	180.32	16.02	24.67	77.42	1.0
TecnoSuma UMTEST	20	218.75	26.31	65.19	112.05	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	162.06	6.30	9.73	70.42	0.9

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

PHENYLALANINE (μmol Phe/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1323 - Enriched 200.0 μmol/L whole blood						
PerkinElmer Neonatal Kit	233	255.38	19.56	31.54	74.63	0.9
Fluorometric Manual	80	276.86	30.93	79.65	159.60	0.6
Neo-Genesis Accuwell	20	300.57	12.59	25.27	69.56	1.1
Ani Labsystems	110	332.12	28.17	62.68	83.01	1.3
Bio-Rad Quantase	38	330.85	21.65	45.89	93.99	1.2
MP Biomedicals Enzyme Assay	20	299.14	38.48	117.73	84.56	1.1
Interscientific Enzyme	50	244.80	16.32	16.32	68.01	0.9
IBL International Neonatal Screening Kit	79	371.05	24.64	50.85	85.15	1.5
Astoria-Pacific	20	275.64	11.49	36.35	79.40	1.0
HPLC	10	258.20	14.67	14.67	76.19	0.9
Derivatized - MS/MS non-kit	819	236.82	19.03	36.90	66.29	0.9
Non-derivatized - MS/MS non-kit	318	248.07	17.32	29.32	68.27	0.9
Derivatized - MS/MS PE NeoGram Kit	160	240.87	18.38	27.23	65.99	0.9
Non-derivatized - MS/MS PE NeoBase Kit	504	236.04	16.31	27.37	64.48	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	79	235.66	16.26	29.27	63.38	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	278.34	18.98	33.49	77.42	1.0
TecnoSuma UMTEST	20	383.00	24.96	122.50	112.05	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	262.90	17.60	30.63	70.42	0.9
Lot 1324 - Enriched 300.0 μmol/L whole blood						
PerkinElmer Neonatal Kit	229	349.63	21.63	43.17	74.63	0.9
Fluorometric Manual	80	336.51	34.34	150.55	159.60	0.6
Neo-Genesis Accuwell	20	372.05	27.05	27.05	69.56	1.1
Ani Labsystems	109	468.10	38.50	88.58	83.01	1.3
Bio-Rad Quantase	39	440.06	32.68	57.61	93.99	1.2
MP Biomedicals Enzyme Assay	20	409.14	42.87	150.89	84.56	1.1
Interscientific Enzyme	50	332.01	25.92	25.92	68.01	0.9
IBL International Neonatal Screening Kit	80	523.79	38.66	80.96	85.15	1.5
Astoria-Pacific	20	383.92	21.57	57.93	79.40	1.0
HPLC	10	332.12	23.69	23.69	76.19	0.9
Derivatized - MS/MS non-kit	821	325.84	28.34	55.86	66.29	0.9
Non-derivatized - MS/MS non-kit	324	346.35	23.77	42.35	68.27	0.9
Derivatized - MS/MS PE NeoGram Kit	158	329.15	25.55	37.46	65.99	0.9
Non-derivatized - MS/MS PE NeoBase Kit	508	327.86	21.96	38.94	64.48	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	78	327.27	24.26	35.68	63.38	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	378.43	27.82	46.10	77.42	1.0
TecnoSuma UMTEST	20	471.36	24.07	125.85	112.05	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	346.90	16.39	27.84	70.42	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 17g. 2013 Quality Control Data
Summaries of Statistical Analyses

LEUCINE (μmol Leu/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1225 - Nonenriched 0.0 μmol/L whole blood						
Interscientific Enzyme	20	153.23	12.05	12.05	134.62	0.9
HPLC	10	108.77	5.45	5.45	90.60	1.0
Derivatized - MS/MS non-kit	817	148.21	12.99	26.94	136.07	0.9
Non-derivatized - MS/MS non-kit	230	177.43	12.93	21.13	162.51	1.0
Derivatized - MS/MS PE NeoGram Kit	169	142.41	9.98	12.89	128.20	1.0
Non-derivatized - MS/MS PE NeoBase Kit	422	168.68	10.41	16.66	156.62	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	88	145.30	13.80	17.99	130.74	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	168.51	12.81	23.11	158.47	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	183.82	11.54	11.96	178.28	1.0
Lot 1226 - Enriched 150.0 μmol/L whole blood						
Interscientific Enzyme	20	232.40	21.49	21.49	134.62	0.9
HPLC	10	200.60	10.78	10.78	90.60	1.0
Derivatized - MS/MS non-kit	818	239.54	20.19	39.20	136.07	0.9
Non-derivatized - MS/MS non-kit	231	272.52	17.94	35.49	162.51	1.0
Derivatized - MS/MS PE NeoGram Kit	167	239.03	17.19	24.48	128.20	1.0
Non-derivatized - MS/MS PE NeoBase Kit	424	265.06	15.31	29.91	156.62	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	228.26	15.95	27.83	130.74	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	269.89	12.67	33.53	158.47	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	285.38	14.05	24.05	178.28	1.0
Lot 1227 - Enriched 250.0 μmol/L whole blood						
Interscientific Enzyme	19	372.45	15.76	15.76	134.62	0.9
HPLC	10	351.43	16.52	16.52	90.60	1.0
Derivatized - MS/MS non-kit	809	388.72	30.38	58.99	136.07	0.9
Non-derivatized - MS/MS non-kit	232	424.40	29.28	59.11	162.51	1.0
Derivatized - MS/MS PE NeoGram Kit	170	394.08	27.16	41.65	128.20	1.0
Non-derivatized - MS/MS PE NeoBase Kit	419	411.60	22.43	41.16	156.62	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	85	358.23	21.64	41.81	130.74	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	424.00	23.69	72.16	158.47	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	453.65	20.15	37.51	178.28	1.0
Lot 1228 - Enriched 500.0 μmol/L whole blood						
Interscientific Enzyme	20	585.68	34.06	34.06	134.62	0.9
HPLC	10	584.31	34.26	34.26	90.60	1.0
Derivatized - MS/MS non-kit	799	592.72	45.01	85.27	136.07	0.9
Non-derivatized - MS/MS non-kit	232	647.66	52.84	95.44	162.51	1.0
Derivatized - MS/MS PE NeoGram Kit	168	617.51	42.57	74.78	128.20	1.0
Non-derivatized - MS/MS PE NeoBase Kit	429	623.85	37.60	66.34	156.62	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	560.53	37.85	58.87	130.74	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	635.49	44.49	79.14	158.47	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	644.09	38.56	64.80	178.28	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.

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Nonenriched 0.0 µmol/L whole blood						
Interscientific Enzyme	20	130.19	9.11	9.11	136.18	0.8
Derivatized - MS/MS non-kit	766	139.46	12.77	25.08	142.75	0.8
Non-derivatized - MS/MS non-kit	256	169.99	14.85	30.29	171.11	0.9
Derivatized - MS/MS PE NeoGram Kit	158	135.33	11.51	14.13	137.74	0.9
Non-derivatized - MS/MS PE NeoBase Kit	501	163.50	11.07	19.08	162.18	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	93	132.98	16.34	21.61	133.44	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	159.72	8.82	22.38	165.19	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	182.12	12.69	24.82	187.90	0.9
Lot 1322 - Enriched 100.0 µmol/L whole blood						
Interscientific Enzyme	20	225.08	16.20	16.20	136.18	0.8
Derivatized - MS/MS non-kit	764	231.30	21.51	37.13	142.75	0.8
Non-derivatized - MS/MS non-kit	257	263.48	21.90	41.89	171.11	0.9
Derivatized - MS/MS PE NeoGram Kit	159	229.15	17.10	24.67	137.74	0.9
Non-derivatized - MS/MS PE NeoBase Kit	494	252.49	17.52	26.17	162.18	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	83	210.29	19.44	29.98	133.44	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	255.91	16.62	33.33	165.19	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	283.22	14.11	36.62	187.90	0.9
Lot 1323 - Enriched 250.0 µmol/L whole blood						
Interscientific Enzyme	20	324.64	30.13	34.35	136.18	0.8
Derivatized - MS/MS non-kit	758	347.25	29.24	51.72	142.75	0.8
Non-derivatized - MS/MS non-kit	256	386.16	27.77	53.37	171.11	0.9
Derivatized - MS/MS PE NeoGram Kit	156	354.56	26.88	32.50	137.74	0.9
Non-derivatized - MS/MS PE NeoBase Kit	498	376.08	26.04	37.06	162.18	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	86	321.09	21.02	35.93	133.44	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	376.37	24.09	56.46	165.19	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	431.21	30.14	66.49	187.90	0.9
Lot 1324 - Enriched 500.0 µmol/L whole blood						
Interscientific Enzyme	20	525.54	43.75	53.43	136.18	0.8
Derivatized - MS/MS non-kit	761	557.02	46.10	90.73	142.75	0.8
Non-derivatized - MS/MS non-kit	259	612.45	47.94	92.29	171.11	0.9
Derivatized - MS/MS PE NeoGram Kit	155	574.75	37.50	44.72	137.74	0.9
Non-derivatized - MS/MS PE NeoBase Kit	506	605.07	42.12	67.59	162.18	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	511.19	40.14	57.89	133.44	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	584.79	42.70	84.18	165.19	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	651.68	34.79	77.60	187.90	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 17h. 2013 Quality Control Data
Summaries of Statistical Analyses

METHIONINE (μmol Met/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1225 - Nonenriched 0.0 μmol/L whole blood						
HPLC	10	14.76	1.16	1.16	12.07	0.7
Derivatized - MS/MS non-kit	843	21.02	2.95	4.40	20.39	0.8
Non-derivatized - MS/MS non-kit	231	19.54	1.40	2.63	16.40	0.9
Derivatized - MS/MS PE NeoGram Kit	157	23.36	2.58	3.45	22.82	0.9
Non-derivatized - MS/MS PE NeoBase Kit	429	18.67	1.54	2.19	16.91	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	75	17.28	2.56	6.30	16.42	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	17.62	1.76	2.90	14.53	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	19.29	1.17	1.59	18.63	0.8
Lot 1226 - Enriched 50.0 μmol/L whole blood						
HPLC	10	45.78	3.23	3.23	12.07	0.7
Derivatized - MS/MS non-kit	844	59.02	6.35	10.95	20.39	0.8
Non-derivatized - MS/MS non-kit	237	56.36	4.46	8.94	16.40	0.9
Derivatized - MS/MS PE NeoGram Kit	159	67.68	5.97	9.92	22.82	0.9
Non-derivatized - MS/MS PE NeoBase Kit	418	53.24	3.60	5.64	16.91	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	80	46.16	5.65	18.48	16.42	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	38	50.68	3.42	7.15	14.53	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	56.16	3.02	5.24	18.63	0.8
Lot 1227 - Enriched 150.0 μmol/L whole blood						
HPLC	10	121.24	5.09	5.09	12.07	0.7
Derivatized - MS/MS non-kit	825	141.42	11.70	23.52	20.39	0.8
Non-derivatized - MS/MS non-kit	239	140.15	13.38	22.07	16.40	0.9
Derivatized - MS/MS PE NeoGram Kit	160	161.19	14.26	22.52	22.82	0.9
Non-derivatized - MS/MS PE NeoBase Kit	421	131.90	7.75	12.35	16.91	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	80	111.14	13.73	48.79	16.42	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	135.43	7.90	25.51	14.53	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	144.55	8.05	12.22	18.63	0.8
Lot 1228 - Enriched 250.0 μmol/L whole blood						
HPLC	10	196.48	15.75	15.75	12.07	0.7
Derivatized - MS/MS non-kit	822	219.85	18.70	37.70	20.39	0.8
Non-derivatized - MS/MS non-kit	237	230.01	17.36	32.83	16.40	0.9
Derivatized - MS/MS PE NeoGram Kit	160	252.00	23.09	38.26	22.82	0.9
Non-derivatized - MS/MS PE NeoBase Kit	424	209.68	13.49	22.73	16.91	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	80	172.33	26.05	68.69	16.42	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	216.57	13.26	34.18	14.53	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	19	219.09	10.10	14.60	18.63	0.8

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

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	778	19.55	2.38	4.33	20.00	0.8
Non-derivatized - MS/MS non-kit	261	19.42	1.67	3.08	20.43	0.9
Derivatized - MS/MS PE NeoGram Kit	146	20.23	2.50	3.04	20.31	0.8
Non-derivatized - MS/MS PE NeoBase Kit	496	17.67	1.61	3.00	17.99	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	15.33	2.42	3.78	15.12	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	13.88	1.78	2.40	14.91	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	20.06	1.74	2.44	21.38	1.0
Lot 1322 - Enriched 50.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	776	59.68	5.77	9.54	20.00	0.8
Non-derivatized - MS/MS non-kit	257	65.61	5.82	8.92	20.43	0.9
Derivatized - MS/MS PE NeoGram Kit	148	62.04	6.00	8.78	20.31	0.8
Non-derivatized - MS/MS PE NeoBase Kit	507	60.60	4.70	8.68	17.99	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	41.22	6.32	10.34	15.12	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	54.99	4.74	7.22	14.91	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	68.39	3.49	7.88	21.38	1.0
Lot 1323 - Enriched 150.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	762	135.68	11.87	21.78	20.00	0.8
Non-derivatized - MS/MS non-kit	258	154.72	12.82	19.62	20.43	0.9
Derivatized - MS/MS PE NeoGram Kit	148	145.73	11.69	19.17	20.31	0.8
Non-derivatized - MS/MS PE NeoBase Kit	506	143.21	10.29	19.86	17.99	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	97.95	14.11	24.32	15.12	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	126.64	9.92	13.55	14.91	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	169.34	10.19	23.37	21.38	1.0
Lot 1324 - Enriched 250.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	761	214.18	18.81	33.89	20.00	0.8
Non-derivatized - MS/MS non-kit	254	241.75	20.21	30.63	20.43	0.9
Derivatized - MS/MS PE NeoGram Kit	148	228.82	20.73	33.30	20.31	0.8
Non-derivatized - MS/MS PE NeoBase Kit	509	227.90	17.93	31.59	17.99	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	150.10	17.82	36.01	15.12	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	204.93	18.94	26.72	14.91	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	257.42	14.96	33.30	21.38	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 17i. 2013 Quality Control Data
Summaries of Statistical Analyses

TYROSINE (μmol Tyr/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1225 - Nonenriched 0.0 μmol/L whole blood						
HPLC	20	61.93	3.16	8.39	60.69	1.0
Derivatized - MS/MS non-kit	821	51.10	4.35	8.32	51.77	0.8
Non-derivatized - MS/MS non-kit	276	54.29	4.52	9.02	53.28	0.9
Derivatized - MS/MS PE NeoGram Kit	169	51.23	3.92	4.95	51.76	0.8
Non-derivatized - MS/MS PE NeoBase Kit	434	55.60	4.43	8.05	57.49	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	60.16	7.17	10.39	61.85	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	37	65.52	5.22	5.22	61.53	1.1
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	19	52.75	2.28	2.75	56.61	0.8
Lot 1226 - Enriched 200.0 μmol/L whole blood						
HPLC	20	251.43	11.38	27.87	60.69	1.0
Derivatized - MS/MS non-kit	826	211.48	17.27	30.51	51.77	0.8
Non-derivatized - MS/MS non-kit	288	225.67	17.12	42.20	53.28	0.9
Derivatized - MS/MS PE NeoGram Kit	166	213.40	14.80	18.47	51.76	0.8
Non-derivatized - MS/MS PE NeoBase Kit	437	232.76	16.31	32.47	57.49	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	249.08	17.86	40.13	61.85	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	266.69	17.88	22.92	61.53	1.1
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	217.17	17.54	24.51	56.61	0.8
Lot 1227 - Enriched 400.0 μmol/L whole blood						
HPLC	20	450.56	21.49	32.55	60.69	1.0
Derivatized - MS/MS non-kit	825	380.98	29.48	54.36	51.77	0.8
Non-derivatized - MS/MS non-kit	285	409.14	30.22	71.27	53.28	0.9
Derivatized - MS/MS PE NeoGram Kit	165	379.48	25.81	36.33	51.76	0.8
Non-derivatized - MS/MS PE NeoBase Kit	434	419.19	27.52	52.97	57.49	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	90	456.91	44.38	93.57	61.85	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	487.66	36.19	49.67	61.53	1.1
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	393.95	30.42	35.54	56.61	0.8
Lot 1228 - Enriched 600.0 μmol/L whole blood						
HPLC	20	641.45	34.36	48.22	60.69	1.0
Derivatized - MS/MS non-kit	831	533.48	40.21	76.63	51.77	0.8
Non-derivatized - MS/MS non-kit	284	579.33	51.77	105.09	53.28	0.9
Derivatized - MS/MS PE NeoGram Kit	167	537.01	42.08	53.22	51.76	0.8
Non-derivatized - MS/MS PE NeoBase Kit	434	582.26	37.69	75.03	57.49	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	90	628.07	54.48	114.91	61.85	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	37	697.91	38.66	48.79	61.53	1.1
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	533.56	40.57	47.66	56.61	0.8

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

TYROSINE (µmol Tyr/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Nonenriched 0.0 µmol/L whole blood						
HPLC	10	76.88	6.64	6.64	85.18	0.9
Derivatized - MS/MS non-kit	786	50.77	4.45	7.96	52.15	0.8
Non-derivatized - MS/MS non-kit	309	53.72	4.89	7.55	52.46	0.9
Derivatized - MS/MS PE NeoGram Kit	155	49.49	4.69	5.66	49.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	503	54.11	4.13	7.00	52.25	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	93	56.68	5.47	8.61	57.19	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	56.48	4.44	9.27	57.27	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	56.37	4.22	5.65	55.96	0.9
Lot 1322 - Enriched 200.0 µmol/L whole blood						
HPLC	10	265.44	11.17	11.17	85.18	0.9
Derivatized - MS/MS non-kit	788	215.23	18.53	31.92	52.15	0.8
Non-derivatized - MS/MS non-kit	311	224.56	16.71	28.55	52.46	0.9
Derivatized - MS/MS PE NeoGram Kit	154	207.15	17.40	20.04	49.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	504	225.97	16.29	30.02	52.25	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	233.77	18.80	28.10	57.19	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	240.81	21.38	40.05	57.27	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	235.22	9.12	16.47	55.96	0.9
Lot 1323 - Enriched 400.0 µmol/L whole blood						
HPLC	10	454.27	20.53	20.53	85.18	0.9
Derivatized - MS/MS non-kit	795	375.49	30.70	54.31	52.15	0.8
Non-derivatized - MS/MS non-kit	308	391.58	28.42	49.31	52.46	0.9
Derivatized - MS/MS PE NeoGram Kit	157	370.02	31.08	37.48	49.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	505	396.77	28.91	51.74	52.25	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	422.84	35.03	58.02	57.19	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	424.99	39.86	84.00	57.27	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	425.91	26.54	44.15	55.96	0.9
Lot 1324 - Enriched 600.0 µmol/L whole blood						
HPLC	10	601.21	36.57	36.57	85.18	0.9
Derivatized - MS/MS non-kit	792	535.18	45.40	81.76	52.15	0.8
Non-derivatized - MS/MS non-kit	314	570.60	40.42	73.65	52.46	0.9
Derivatized - MS/MS PE NeoGram Kit	155	527.39	41.74	50.43	49.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	499	578.45	41.88	73.24	52.25	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	591.25	54.31	85.31	57.19	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	605.44	61.85	112.49	57.27	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	600.93	31.67	60.97	55.96	0.9

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

Table 17j. 2013 Quality Control Data
Summaries of Statistical Analyses

VALINE (μmol Val/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1225 - Nonenriched 0.0 μmol/L whole blood						
HPLC	10	163.07	7.87	7.87	147.06	1.0
Derivatized - MS/MS non-kit	748	149.03	14.63	29.77	136.69	0.8
Non-derivatized - MS/MS non-kit	209	146.11	13.97	24.11	131.88	0.8
Derivatized - MS/MS PE NeoGram Kit	164	153.69	14.08	21.60	138.91	0.8
Non-derivatized - MS/MS PE NeoBase Kit	413	160.59	14.30	26.52	148.77	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	86	134.77	13.64	15.85	123.52	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	120.82	8.38	30.30	110.43	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	172.83	13.70	22.09	163.59	1.0
Lot 1226 - Enriched 250.0 μmol/L whole blood						
HPLC	10	349.58	16.79	16.79	147.06	1.0
Derivatized - MS/MS non-kit	759	295.83	27.18	56.34	136.69	0.8
Non-derivatized - MS/MS non-kit	209	302.73	29.45	58.86	131.88	0.8
Derivatized - MS/MS PE NeoGram Kit	166	309.82	32.11	51.89	138.91	0.8
Non-derivatized - MS/MS PE NeoBase Kit	417	342.95	30.31	61.83	148.77	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	85	262.76	19.19	34.54	123.52	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	254.53	16.82	58.10	110.43	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	363.38	17.50	54.56	163.59	1.0
Lot 1227 - Enriched 350.0 μmol/L whole blood						
HPLC	10	497.51	22.82	22.82	147.06	1.0
Derivatized - MS/MS non-kit	733	416.50	37.95	76.08	136.69	0.8
Non-derivatized - MS/MS non-kit	209	423.28	40.93	78.42	131.88	0.8
Derivatized - MS/MS PE NeoGram Kit	169	432.88	45.93	67.79	138.91	0.8
Non-derivatized - MS/MS PE NeoBase Kit	410	486.94	41.87	85.56	148.77	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	365.93	30.61	53.82	123.52	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	360.18	22.53	73.71	110.43	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	527.65	31.46	73.87	163.59	1.0
Lot 1228 - Enriched 500.0 μmol/L whole blood						
HPLC	10	641.75	35.17	35.17	147.06	1.0
Derivatized - MS/MS non-kit	736	525.79	46.63	100.62	136.69	0.8
Non-derivatized - MS/MS non-kit	207	550.20	54.91	105.68	131.88	0.8
Derivatized - MS/MS PE NeoGram Kit	167	559.73	55.64	84.56	138.91	0.8
Non-derivatized - MS/MS PE NeoBase Kit	413	610.16	53.82	103.88	148.77	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	88	465.58	40.68	56.09	123.52	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	458.80	30.97	108.08	110.43	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	634.81	40.96	77.69	163.59	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.

VALINE (μmol Val/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	721	148.73	14.33	30.46	150.33	0.7
Non-derivatized - MS/MS non-kit	239	147.72	14.67	28.16	146.51	0.8
Derivatized - MS/MS PE NeoGram Kit	153	167.82	21.08	29.31	167.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	486	154.06	12.87	26.14	152.73	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	96	124.89	17.03	19.15	123.33	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	119.89	7.78	22.14	122.46	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	170.99	12.67	28.50	171.81	0.9
Lot 1322 - Enriched 200.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	719	291.56	27.93	52.02	150.33	0.7
Non-derivatized - MS/MS non-kit	236	299.81	27.52	53.77	146.51	0.8
Derivatized - MS/MS PE NeoGram Kit	157	323.61	37.00	49.39	167.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	487	322.79	27.92	53.26	152.73	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	239.75	25.56	32.47	123.33	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	253.94	16.51	51.53	122.46	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	346.75	14.01	51.95	171.81	0.9
Lot 1323 - Enriched 350.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	718	392.31	34.23	67.01	150.33	0.7
Non-derivatized - MS/MS non-kit	238	413.44	37.37	76.21	146.51	0.8
Derivatized - MS/MS PE NeoGram Kit	156	445.47	38.92	59.16	167.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	476	446.52	36.72	68.23	152.73	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	331.61	26.16	40.79	123.33	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	348.02	23.49	67.28	122.46	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	501.95	36.13	79.60	171.81	0.9
Lot 1324 - Enriched 500.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	711	495.47	44.78	81.53	150.33	0.7
Non-derivatized - MS/MS non-kit	234	533.72	46.96	98.69	146.51	0.8
Derivatized - MS/MS PE NeoGram Kit	157	562.87	60.73	80.30	167.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	483	581.26	50.18	94.29	152.73	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	422.49	45.32	59.53	123.33	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	439.91	29.68	89.85	122.46	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	615.84	32.19	84.86	171.81	0.9

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

Table 17k. 2013 Quality Control Data
Summaries of Statistical Analyses

CITRULLINE (μmol Cit/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1225 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	806	24.43	2.62	5.81	25.79	0.8
Non-derivatized - MS/MS non-kit	209	27.31	2.68	3.10	27.46	0.9
Derivatized - MS/MS PE NeoGram Kit	169	27.18	1.70	3.04	28.27	0.9
Non-derivatized - MS/MS PE NeoBase Kit	400	27.65	2.34	2.98	29.50	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	76	28.66	2.31	3.65	29.16	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	25.01	2.41	6.55	25.10	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	28.09	2.06	3.26	29.57	0.8
Lot 1226 - Enriched 25.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	793	44.55	4.51	9.86	25.79	0.8
Non-derivatized - MS/MS non-kit	207	48.32	4.23	6.37	27.46	0.9
Derivatized - MS/MS PE NeoGram Kit	170	50.12	3.37	6.59	28.27	0.9
Non-derivatized - MS/MS PE NeoBase Kit	407	51.32	3.63	5.80	29.50	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	80	51.39	4.61	7.20	29.16	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	45.01	4.81	11.96	25.10	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	49.79	3.27	8.43	29.57	0.8
Lot 1227 - Enriched 100.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	790	103.16	9.39	22.71	25.79	0.8
Non-derivatized - MS/MS non-kit	211	113.39	9.99	15.14	27.46	0.9
Derivatized - MS/MS PE NeoGram Kit	170	113.89	7.90	13.48	28.27	0.9
Non-derivatized - MS/MS PE NeoBase Kit	406	116.93	7.68	12.61	29.50	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	80	121.15	9.52	15.27	29.16	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	102.54	10.30	30.10	25.10	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	116.84	7.56	18.46	29.57	0.8
Lot 1228 - Enriched 250.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	800	212.49	19.12	48.79	25.79	0.8
Non-derivatized - MS/MS non-kit	212	239.83	22.73	32.09	27.46	0.9
Derivatized - MS/MS PE NeoGram Kit	169	239.81	14.07	25.76	28.27	0.9
Non-derivatized - MS/MS PE NeoBase Kit	407	241.50	16.40	26.86	29.50	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	79	255.05	23.27	32.16	29.16	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	220.07	14.62	60.88	25.10	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	237.58	11.36	35.74	29.57	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 -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	764	23.40	2.64	5.30	24.90	0.7
Non-derivatized - MS/MS non-kit	243	26.14	3.16	4.10	26.91	0.8
Derivatized - MS/MS PE NeoGram Kit	164	26.82	2.34	3.05	28.13	0.8
Non-derivatized - MS/MS PE NeoBase Kit	480	26.47	2.83	3.98	27.90	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	92	26.68	2.16	2.55	28.72	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	28.87	4.24	9.24	29.53	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	25.63	2.41	2.85	26.42	0.8
Lot 1322 - Enriched 25.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	764	44.61	5.32	10.34	24.90	0.7
Non-derivatized - MS/MS non-kit	237	48.61	5.17	7.91	26.91	0.8
Derivatized - MS/MS PE NeoGram Kit	166	49.34	3.27	4.77	28.13	0.8
Non-derivatized - MS/MS PE NeoBase Kit	481	49.48	4.52	6.95	27.90	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	48.65	3.92	6.11	28.72	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	56	51.93	4.40	7.75	29.53	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	46.57	2.41	3.67	26.42	0.8
Lot 1323 - Enriched 100.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	759	100.19	10.62	22.30	24.90	0.7
Non-derivatized - MS/MS non-kit	241	111.37	10.79	16.57	26.91	0.8
Derivatized - MS/MS PE NeoGram Kit	170	113.97	7.58	12.61	28.13	0.8
Non-derivatized - MS/MS PE NeoBase Kit	482	115.71	9.58	15.94	27.90	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	87	112.27	9.97	12.28	28.72	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	115.63	12.09	14.40	29.53	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	108.63	7.64	11.45	26.42	0.8
Lot 1324 - Enriched 250.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	746	210.52	19.27	43.03	24.90	0.7
Non-derivatized - MS/MS non-kit	241	237.08	21.90	37.73	26.91	0.8
Derivatized - MS/MS PE NeoGram Kit	165	237.42	15.32	23.43	28.13	0.8
Non-derivatized - MS/MS PE NeoBase Kit	482	241.23	19.18	30.50	27.90	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	86	227.01	18.60	22.49	28.72	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	244.95	27.28	34.67	29.53	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	227.95	11.95	20.16	26.42	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 17l. 2013 Quality Control Data
Summaries of Statistical Analyses

ARGININE (μmol Arg/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1225 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	593	7.96	1.58	3.86	5.28	0.3
Non-derivatized - MS/MS non-kit	112	7.14	1.18	2.68	1.52	0.4
Derivatized - MS/MS PE NeoGram Kit	155	8.75	0.95	1.95	4.00	0.4
Non-derivatized - MS/MS PE NeoBase Kit	324	7.53	0.92	1.81	3.60	0.4
Derivatized - MS/MS Chromsystems MassChrom Kit	73	10.44	1.88	4.86	3.82	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	6.75	0.85	2.53	3.23	0.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	5.96	0.41	0.86	1.99	0.3
Lot 1226 - Enriched 100.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	590	29.45	3.98	13.04	5.28	0.3
Non-derivatized - MS/MS non-kit	118	31.27	3.26	6.20	1.52	0.4
Derivatized - MS/MS PE NeoGram Kit	159	41.30	3.91	11.66	4.00	0.4
Non-derivatized - MS/MS PE NeoBase Kit	320	40.97	3.11	11.01	3.60	0.4
Derivatized - MS/MS Chromsystems MassChrom Kit	79	43.17	3.74	18.51	3.82	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	32.63	4.13	9.81	3.23	0.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	27.24	1.27	8.21	1.99	0.3
Lot 1227 - Enriched 200.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	589	64.56	7.83	28.08	5.28	0.3
Non-derivatized - MS/MS non-kit	118	72.95	7.30	17.22	1.52	0.4
Derivatized - MS/MS PE NeoGram Kit	160	91.57	11.80	25.37	4.00	0.4
Non-derivatized - MS/MS PE NeoBase Kit	328	81.83	6.85	22.32	3.60	0.4
Derivatized - MS/MS Chromsystems MassChrom Kit	80	97.48	9.32	43.64	3.82	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	73.55	8.62	22.89	3.23	0.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	59.08	3.79	4.98	1.99	0.3
Lot 1228 - Enriched 300.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	593	92.68	11.22	41.67	5.28	0.3
Non-derivatized - MS/MS non-kit	119	115.39	12.38	27.26	1.52	0.4
Derivatized - MS/MS PE NeoGram Kit	159	138.61	16.00	37.58	4.00	0.4
Non-derivatized - MS/MS PE NeoBase Kit	329	131.23	10.03	32.12	3.60	0.4
Derivatized - MS/MS Chromsystems MassChrom Kit	80	150.66	15.35	41.57	3.82	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	109.52	13.94	20.25	3.23	0.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	94.94	5.38	6.75	1.99	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.

ARGININE (µmol Arg/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	623	7.91	1.56	4.68	8.53	0.6
Non-derivatized - MS/MS non-kit	123	5.98	0.85	1.90	6.20	0.6
Derivatized - MS/MS PE NeoGram Kit	122	8.47	0.84	1.73	8.66	0.8
Non-derivatized - MS/MS PE NeoBase Kit	409	6.83	0.73	1.49	5.62	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	95	8.85	1.39	2.12	10.88	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	8.05	1.34	1.90	11.96	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	5.08	0.53	2.63	4.75	0.4
Lot 1322 - Enriched 100.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	646	64.63	7.14	29.86	8.53	0.6
Non-derivatized - MS/MS non-kit	129	70.60	6.64	18.82	6.20	0.6
Derivatized - MS/MS PE NeoGram Kit	122	87.40	6.38	14.08	8.66	0.8
Non-derivatized - MS/MS PE NeoBase Kit	415	85.78	5.59	11.51	5.62	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	89.07	12.07	18.63	10.88	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	83.21	7.29	14.81	11.96	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	43.11	3.92	5.96	4.75	0.4
Lot 1323 - Enriched 200.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	640	120.14	13.48	56.55	8.53	0.6
Non-derivatized - MS/MS non-kit	129	134.11	14.20	31.75	6.20	0.6
Derivatized - MS/MS PE NeoGram Kit	121	164.61	10.70	28.26	8.66	0.8
Non-derivatized - MS/MS PE NeoBase Kit	416	167.19	11.11	22.29	5.62	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	173.09	16.06	36.75	10.88	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	152.25	12.65	30.07	11.96	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	80.70	7.01	12.69	4.75	0.4
Lot 1324 - Enriched 300.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	637	174.40	19.76	82.11	8.53	0.6
Non-derivatized - MS/MS non-kit	128	198.24	22.38	53.45	6.20	0.6
Derivatized - MS/MS PE NeoGram Kit	122	243.43	16.84	44.54	8.66	0.8
Non-derivatized - MS/MS PE NeoBase Kit	415	250.90	17.79	31.17	5.62	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	240.70	24.68	54.66	10.88	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	211.22	19.53	45.94	11.96	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	120.61	7.94	15.90	4.75	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 17m. 2013 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 1225 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	558	281.19	26.02	85.58	283.23	0.6
Non-derivatized - MS/MS non-kit	102	333.60	25.15	64.27	333.29	0.7
Derivatized - MS/MS PE NeoGram Kit	115	383.17	42.00	80.27	396.36	0.8
Non-derivatized - MS/MS PE NeoBase Kit	290	380.73	33.30	80.44	390.16	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	80	317.18	27.89	47.57	316.35	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	290.65	23.12	38.83	294.93	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	302.81	19.90	19.90	309.65	0.7
Lot 1226 - Enriched 200.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	565	404.44	39.50	119.07	283.23	0.6
Non-derivatized - MS/MS non-kit	102	467.99	29.13	88.45	333.29	0.7
Derivatized - MS/MS PE NeoGram Kit	110	563.73	46.40	68.39	396.36	0.8
Non-derivatized - MS/MS PE NeoBase Kit	299	557.47	42.06	110.48	390.16	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	78	456.28	37.59	71.89	316.35	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	427.62	27.80	55.31	294.93	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	434.89	21.75	21.75	309.65	0.7
Lot 1227 - Enriched 400.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	564	552.93	54.89	168.48	283.23	0.6
Non-derivatized - MS/MS non-kit	101	618.67	45.65	111.66	333.29	0.7
Derivatized - MS/MS PE NeoGram Kit	110	765.21	67.21	106.37	396.36	0.8
Non-derivatized - MS/MS PE NeoBase Kit	297	743.93	51.90	138.70	390.16	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	80	638.11	47.98	108.82	316.35	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	585.63	32.75	86.62	294.93	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	605.83	29.86	29.86	309.65	0.7
Lot 1228 - Enriched 600.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	563	653.40	61.18	202.35	283.23	0.6
Non-derivatized - MS/MS non-kit	100	746.39	50.15	107.39	333.29	0.7
Derivatized - MS/MS PE NeoGram Kit	120	869.42	88.55	195.10	396.36	0.8
Non-derivatized - MS/MS PE NeoBase Kit	297	869.47	66.81	159.91	390.16	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	80	760.54	52.48	118.78	316.35	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	690.67	38.91	74.66	294.93	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	684.31	41.70	45.10	309.65	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.

ALANINE (μmol Ala/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	606	263.90	26.57	80.91	269.22	0.6
Non-derivatized - MS/MS non-kit	119	313.98	30.38	67.42	314.71	0.7
Derivatized - MS/MS PE NeoGram Kit	117	333.26	38.24	71.85	331.79	0.8
Non-derivatized - MS/MS PE NeoBase Kit	369	339.51	26.19	62.45	339.60	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	254.26	25.26	53.70	251.28	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	286.91	23.12	57.71	294.13	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	10	383.21	40.38	40.38	383.29	0.9
Lot 1322 - Enriched 200.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	619	395.00	40.79	124.84	269.22	0.6
Non-derivatized - MS/MS non-kit	119	446.31	41.22	93.75	314.71	0.7
Derivatized - MS/MS PE NeoGram Kit	117	496.93	61.80	115.11	331.79	0.8
Non-derivatized - MS/MS PE NeoBase Kit	372	503.83	40.80	86.36	339.60	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	359.14	45.35	70.81	251.28	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	432.39	31.71	89.34	294.13	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	10	549.53	57.59	57.59	383.29	0.9
Lot 1323 - Enriched 400.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	609	490.74	48.40	145.58	269.22	0.6
Non-derivatized - MS/MS non-kit	120	578.04	47.88	130.92	314.71	0.7
Derivatized - MS/MS PE NeoGram Kit	116	643.10	71.70	142.82	331.79	0.8
Non-derivatized - MS/MS PE NeoBase Kit	376	640.34	48.14	111.30	339.60	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	473.03	39.97	62.44	251.28	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	543.29	51.57	110.08	294.13	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	10	728.99	40.44	40.44	383.29	0.9
Lot 1324 - Enriched 600.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	610	613.38	59.82	179.58	269.22	0.6
Non-derivatized - MS/MS non-kit	120	707.06	54.21	163.49	314.71	0.7
Derivatized - MS/MS PE NeoGram Kit	114	823.06	84.42	167.76	331.79	0.8
Non-derivatized - MS/MS PE NeoBase Kit	378	817.97	62.44	139.44	339.60	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	589.42	47.82	72.62	251.28	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	669.95	66.57	142.55	294.13	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	10	888.33	67.22	67.22	383.29	0.9

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

Table 17n. 2013 Quality Control Data
Summaries of Statistical Analyses

SUCCINYLACETONE (μmol SUAC/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1225 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	198	0.80	0.31	0.55	0.80	0.5
Non-derivatized - MS/MS non-kit	48	0.83	0.37	0.46	1.10	0.4
Derivatized - MS/MS PE NeoGram Kit	10	0.19	0.07	0.07	0.00	0.7
Non-derivatized - MS/MS PE NeoBase Kit	246	0.45	0.14	0.25	0.45	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	30	0.49	0.22	0.44	0.51	0.4
Lot 1226 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	189	2.22	0.34	1.12	0.80	0.5
Non-derivatized - MS/MS non-kit	50	2.28	0.40	1.13	1.10	0.4
Derivatized - MS/MS PE NeoGram Kit	10	1.64	0.33	0.33	0.00	0.7
Non-derivatized - MS/MS PE NeoBase Kit	245	0.87	0.18	0.28	0.45	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	30	1.54	0.17	0.22	0.51	0.4
Lot 1227 - Enriched 7.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	187	4.77	0.48	2.41	0.80	0.5
Non-derivatized - MS/MS non-kit	50	4.78	0.56	3.24	1.10	0.4
Derivatized - MS/MS PE NeoGram Kit	10	4.97	0.79	0.79	0.00	0.7
Non-derivatized - MS/MS PE NeoBase Kit	245	1.74	0.29	0.55	0.45	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	30	3.55	0.30	0.92	0.51	0.4
Lot 1228 - Enriched 15.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	190	8.99	0.72	4.62	0.80	0.5
Non-derivatized - MS/MS non-kit	48	7.43	0.74	5.58	1.10	0.4
Derivatized - MS/MS PE NeoGram Kit	10	10.50	1.58	1.58	0.00	0.7
Non-derivatized - MS/MS PE NeoBase Kit	243	3.02	0.32	0.91	0.45	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	30	6.57	0.66	2.71	0.51	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.

SUCCINYLACETONE (μmol SUAC/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1321 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	189	0.80	0.17	0.69	0.88	0.7
Non-derivatized - MS/MS non-kit	50	1.47	0.23	1.36	1.52	0.8
Non-derivatized - MS/MS PE NeoBase Kit	270	0.39	0.14	0.24	0.34	0.3
Derivatized - MS/MS Chromsystems MassChrom Kit	39	0.49	0.22	0.39	0.51	0.4
Lot 1322 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	189	2.67	0.40	1.58	0.88	0.7
Non-derivatized - MS/MS non-kit	50	3.77	0.71	1.63	1.52	0.8
Non-derivatized - MS/MS PE NeoBase Kit	287	1.02	0.19	0.45	0.34	0.3
Derivatized - MS/MS Chromsystems MassChrom Kit	40	1.50	0.33	0.57	0.51	0.4
Lot 1323 - Enriched 7.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	190	5.84	0.73	3.48	0.88	0.7
Non-derivatized - MS/MS non-kit	48	7.56	0.96	1.98	1.52	0.8
Non-derivatized - MS/MS PE NeoBase Kit	290	2.44	0.32	0.95	0.34	0.3
Derivatized - MS/MS Chromsystems MassChrom Kit	40	3.39	0.51	0.99	0.51	0.4
Lot 1324 - Enriched 15.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	189	10.88	1.21	6.77	0.88	0.7
Non-derivatized - MS/MS non-kit	49	14.05	2.36	3.58	1.52	0.8
Non-derivatized - MS/MS PE NeoBase Kit	290	4.62	0.53	1.89	0.34	0.3
Derivatized - MS/MS Chromsystems MassChrom Kit	40	6.27	0.79	1.71	0.51	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 17o. 2013 Quality Control Data
Summaries of Statistical Analyses

FREE CARNITINE (μmol C0/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	835	14.34	1.45	2.52	14.11	1.4
Non-derivatized - MS/MS non-kit	230	12.79	1.56	2.65	12.77	1.1
Derivatized - MS/MS PE NeoGram Kit	168	17.80	1.48	2.67	17.33	1.8
Non-derivatized - MS/MS PE NeoBase Kit	427	12.75	1.01	1.82	12.78	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	97	13.08	1.44	2.74	13.54	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	11.38	0.74	3.21	11.35	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	14.23	0.79	2.10	13.99	1.2
Lot 1266 - Enriched 10.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	845	27.81	2.68	4.96	14.11	1.4
Non-derivatized - MS/MS non-kit	228	24.15	2.25	4.64	12.77	1.1
Derivatized - MS/MS PE NeoGram Kit	166	34.56	2.57	4.92	17.33	1.8
Non-derivatized - MS/MS PE NeoBase Kit	422	23.81	1.88	3.68	12.78	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	99	26.29	3.66	6.19	13.54	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	20.75	1.09	5.96	11.35	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	25.99	1.70	3.46	13.99	1.2
Lot 1267 - Enriched 20.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	853	41.29	3.68	7.21	14.11	1.4
Non-derivatized - MS/MS non-kit	227	35.11	3.67	6.91	12.77	1.1
Derivatized - MS/MS PE NeoGram Kit	167	53.07	3.89	8.07	17.33	1.8
Non-derivatized - MS/MS PE NeoBase Kit	423	34.32	2.78	4.76	12.78	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	99	39.58	4.50	12.02	13.54	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	29.64	1.74	9.61	11.35	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	38.02	1.36	5.85	13.99	1.2
Lot 1268 - Enriched 30.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	866	55.90	4.97	10.13	14.11	1.4
Non-derivatized - MS/MS non-kit	230	46.75	5.33	9.20	12.77	1.1
Derivatized - MS/MS PE NeoGram Kit	165	71.31	5.94	11.15	17.33	1.8
Non-derivatized - MS/MS PE NeoBase Kit	426	45.50	3.58	6.98	12.78	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	90	50.41	6.15	16.73	13.54	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	39.42	2.24	13.18	11.35	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	50.82	2.36	5.10	13.99	1.2

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

FREE CARNITINE (μmol C0/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	851	17.51	1.57	2.99	16.84	1.3
Non-derivatized - MS/MS non-kit	246	16.37	1.37	2.86	16.27	1.0
Derivatized - MS/MS PE NeoGram Kit	160	22.30	1.78	3.51	21.72	1.8
Non-derivatized - MS/MS PE NeoBase Kit	487	15.70	1.26	2.27	15.39	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	103	16.63	1.79	3.06	16.45	1.1
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	14.41	1.47	2.94	14.23	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	17.13	1.48	3.32	17.11	1.0
Lot 1362 - Enriched 10.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	853	29.08	2.45	4.86	16.84	1.3
Non-derivatized - MS/MS non-kit	249	26.67	2.72	4.97	16.27	1.0
Derivatized - MS/MS PE NeoGram Kit	159	39.29	3.15	6.30	21.72	1.8
Non-derivatized - MS/MS PE NeoBase Kit	488	25.10	1.96	3.36	15.39	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	97	27.26	3.11	4.75	16.45	1.1
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	23.51	2.74	4.71	14.23	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	27.17	1.77	5.07	17.11	1.0
Lot 1363 - Enriched 20.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	874	41.88	3.76	7.00	16.84	1.3
Non-derivatized - MS/MS non-kit	249	36.95	3.22	7.33	16.27	1.0
Derivatized - MS/MS PE NeoGram Kit	159	56.34	4.40	9.23	21.72	1.8
Non-derivatized - MS/MS PE NeoBase Kit	491	34.76	2.62	4.76	15.39	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	96	39.21	3.90	5.94	16.45	1.1
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	31.10	3.58	4.69	14.23	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	37.60	2.42	6.82	17.11	1.0
Lot 1364 - Enriched 30.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	867	56.17	4.97	9.51	16.84	1.3
Non-derivatized - MS/MS non-kit	249	47.75	3.55	9.37	16.27	1.0
Derivatized - MS/MS PE NeoGram Kit	160	76.20	6.00	13.78	21.72	1.8
Non-derivatized - MS/MS PE NeoBase Kit	488	45.56	3.54	6.21	15.39	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	94	50.09	4.93	6.40	16.45	1.1
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	41.82	5.09	7.12	14.23	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	47.55	2.33	7.87	17.11	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 17p. 2013 Quality Control Data
Summaries of Statistical Analyses

ACETYLCARNITINE (μmol C2/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	842	10.49	1.04	2.82	10.58	0.9
Non-derivatized - MS/MS non-kit	227	8.48	0.71	1.07	8.56	1.0
Derivatized - MS/MS PE NeoGram Kit	159	13.39	0.93	1.69	13.36	0.7
Non-derivatized - MS/MS PE NeoBase Kit	418	7.45	0.52	0.82	7.48	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	99	10.41	1.15	3.80	10.15	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	7.57	0.45	1.38	7.73	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	9.87	0.60	3.16	9.81	1.1
Lot 1266 - Enriched 10.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	854	19.53	1.90	4.52	10.58	0.9
Non-derivatized - MS/MS non-kit	223	18.05	1.43	2.62	8.56	1.0
Derivatized - MS/MS PE NeoGram Kit	160	20.07	1.16	2.47	13.36	0.7
Non-derivatized - MS/MS PE NeoBase Kit	405	15.82	1.02	1.50	7.48	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	98	19.20	1.50	5.20	10.15	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	15.98	0.83	3.12	7.73	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	20.16	1.25	5.92	9.81	1.1
Lot 1267 - Enriched 20.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	850	28.30	2.50	6.27	10.58	0.9
Non-derivatized - MS/MS non-kit	225	27.81	2.29	4.00	8.56	1.0
Derivatized - MS/MS PE NeoGram Kit	157	26.49	1.39	2.45	13.36	0.7
Non-derivatized - MS/MS PE NeoBase Kit	410	24.03	1.52	1.98	7.48	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	100	29.44	2.68	8.23	10.15	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	24.02	1.48	5.78	7.73	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	31.12	1.54	9.67	9.81	1.1
Lot 1268 - Enriched 30.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	851	37.04	3.20	8.30	10.58	0.9
Non-derivatized - MS/MS non-kit	223	36.90	3.04	5.24	8.56	1.0
Derivatized - MS/MS PE NeoGram Kit	158	33.48	1.98	2.81	13.36	0.7
Non-derivatized - MS/MS PE NeoBase Kit	412	32.28	2.07	3.11	7.48	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	38.81	3.38	10.65	10.15	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	31.80	1.33	5.42	7.73	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	41.38	2.22	10.17	9.81	1.1

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

ACETYLCARNITINE (µmol C2/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	810	14.30	1.49	3.92	14.14	0.9
Non-derivatized - MS/MS non-kit	221	11.51	0.73	1.48	11.52	1.0
Derivatized - MS/MS PE NeoGram Kit	159	18.43	1.35	2.42	18.06	0.6
Non-derivatized - MS/MS PE NeoBase Kit	477	10.44	0.70	1.21	10.39	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	102	13.88	2.06	5.57	13.44	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	10.59	0.87	1.04	10.79	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	12.84	0.76	1.92	12.85	1.1
Lot 1362 - Enriched 10.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	809	22.56	2.05	4.75	14.14	0.9
Non-derivatized - MS/MS non-kit	229	21.17	1.40	2.68	11.52	1.0
Derivatized - MS/MS PE NeoGram Kit	158	23.28	1.45	2.64	18.06	0.6
Non-derivatized - MS/MS PE NeoBase Kit	479	19.28	1.26	2.19	10.39	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	93	21.31	1.78	3.61	13.44	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	20.31	1.81	2.39	10.79	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	23.50	1.54	3.35	12.85	1.1
Lot 1363 - Enriched 20.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	815	31.42	2.78	6.75	14.14	0.9
Non-derivatized - MS/MS non-kit	230	31.12	2.24	3.93	11.52	1.0
Derivatized - MS/MS PE NeoGram Kit	156	29.53	2.00	2.85	18.06	0.6
Non-derivatized - MS/MS PE NeoBase Kit	480	28.49	1.84	3.44	10.39	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	94	29.73	2.74	4.90	13.44	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	29.11	1.94	2.61	10.79	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	34.46	1.72	5.06	12.85	1.1
Lot 1364 - Enriched 30.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	811	40.22	3.51	8.17	14.14	0.9
Non-derivatized - MS/MS non-kit	229	40.60	2.49	4.90	11.52	1.0
Derivatized - MS/MS PE NeoGram Kit	159	35.53	2.00	3.23	18.06	0.6
Non-derivatized - MS/MS PE NeoBase Kit	473	37.39	2.52	4.45	10.39	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	97	38.98	3.23	5.97	13.44	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	38.29	2.81	3.54	10.79	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	44.92	3.38	6.16	12.85	1.1

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

Table 17q. 2013 Quality Control Data
Summaries of Statistical Analyses

PROPIONYLCARNITINE (μmol C3/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	856	0.84	0.12	0.19	0.86	0.9
Non-derivatized - MS/MS non-kit	216	0.79	0.08	0.13	0.80	1.0
Derivatized - MS/MS PE NeoGram Kit	158	0.68	0.06	0.08	0.69	0.8
Non-derivatized - MS/MS PE NeoBase Kit	408	0.66	0.05	0.08	0.65	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	0.70	0.14	0.20	0.68	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.72	0.06	0.08	0.75	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.82	0.05	0.18	0.81	1.0
Lot 1266 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	858	3.69	0.41	0.68	0.86	0.9
Non-derivatized - MS/MS non-kit	218	3.74	0.34	0.49	0.80	1.0
Derivatized - MS/MS PE NeoGram Kit	168	3.10	0.21	0.33	0.69	0.8
Non-derivatized - MS/MS PE NeoBase Kit	418	3.12	0.22	0.36	0.65	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	3.28	0.38	0.57	0.68	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	3.29	0.20	0.41	0.75	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	3.76	0.20	0.64	0.81	1.0
Lot 1267 - Enriched 7.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	860	7.82	0.80	1.53	0.86	0.9
Non-derivatized - MS/MS non-kit	218	7.97	0.59	0.99	0.80	1.0
Derivatized - MS/MS PE NeoGram Kit	166	6.74	0.40	0.69	0.69	0.8
Non-derivatized - MS/MS PE NeoBase Kit	421	6.57	0.41	0.66	0.65	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	85	6.95	0.77	1.16	0.68	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	6.88	0.58	1.15	0.75	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	7.99	0.34	1.54	0.81	1.0
Lot 1268 - Enriched 12.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	865	11.99	1.25	2.30	0.86	0.9
Non-derivatized - MS/MS non-kit	219	12.42	1.14	1.57	0.80	1.0
Derivatized - MS/MS PE NeoGram Kit	166	10.30	0.68	1.00	0.69	0.8
Non-derivatized - MS/MS PE NeoBase Kit	421	10.37	0.72	1.12	0.65	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	85	10.98	1.21	1.80	0.68	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	10.64	0.67	1.17	0.75	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	12.54	0.69	1.58	0.81	1.0

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

PROPIONYLCARNITINE (µmol C3/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	839	1.30	0.16	0.26	1.15	1.1
Non-derivatized - MS/MS non-kit	238	1.28	0.11	0.18	1.10	1.1
Derivatized - MS/MS PE NeoGram Kit	153	1.09	0.08	0.10	0.92	0.9
Non-derivatized - MS/MS PE NeoBase Kit	492	1.08	0.09	0.13	0.89	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	105	1.19	0.16	0.20	0.99	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	1.14	0.12	0.14	0.97	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	1.33	0.10	0.16	1.14	1.1
Lot 1362 - Enriched 3.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	843	4.28	0.47	0.82	1.15	1.1
Non-derivatized - MS/MS non-kit	235	4.37	0.36	0.61	1.10	1.1
Derivatized - MS/MS PE NeoGram Kit	156	3.60	0.24	0.34	0.92	0.9
Non-derivatized - MS/MS PE NeoBase Kit	496	3.67	0.27	0.41	0.89	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	99	3.76	0.39	0.59	0.99	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	3.94	0.36	0.52	0.97	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	4.45	0.35	0.52	1.14	1.1
Lot 1363 - Enriched 7.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	842	8.71	0.90	1.67	1.15	1.1
Non-derivatized - MS/MS non-kit	240	9.17	0.75	1.35	1.10	1.1
Derivatized - MS/MS PE NeoGram Kit	151	7.42	0.49	0.69	0.92	0.9
Non-derivatized - MS/MS PE NeoBase Kit	492	7.51	0.50	0.84	0.89	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	95	7.81	0.65	1.09	0.99	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	8.18	0.69	0.96	0.97	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	9.07	0.55	1.04	1.14	1.1
Lot 1364 - Enriched 12.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	829	14.00	1.49	2.75	1.15	1.1
Non-derivatized - MS/MS non-kit	238	14.75	1.11	1.88	1.10	1.1
Derivatized - MS/MS PE NeoGram Kit	154	12.12	0.68	0.97	0.92	0.9
Non-derivatized - MS/MS PE NeoBase Kit	494	12.42	0.86	1.44	0.89	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	96	12.73	1.06	1.85	0.99	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	13.32	0.96	1.57	0.97	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	14.77	0.96	1.30	1.14	1.1

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

Table 17r. 2013 Quality Control Data
Summaries of Statistical Analyses

MALONYLCARNITINE (μmol C3DC/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	710	0.03	0.02	0.03	0.04	0.5
Derivatized - MS/MS PE NeoGram Kit	126	0.03	0.01	0.01	0.04	1.3
Derivatized - MS/MS Chromsystems MassChrom Kit	80	0.03	0.02	0.03	0.04	0.9
Lot 1266 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	717	0.29	0.05	0.11	0.04	0.5
Derivatized - MS/MS PE NeoGram Kit	120	0.69	0.06	0.10	0.04	1.3
Derivatized - MS/MS Chromsystems MassChrom Kit	80	0.44	0.13	0.28	0.04	0.9
Lot 1267 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	717	0.78	0.12	0.27	0.04	0.5
Derivatized - MS/MS PE NeoGram Kit	120	2.07	0.17	0.31	0.04	1.3
Derivatized - MS/MS Chromsystems MassChrom Kit	82	1.36	0.20	1.40	0.04	0.9
Lot 1268 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	717	1.51	0.23	0.54	0.04	0.5
Derivatized - MS/MS PE NeoGram Kit	119	4.02	0.32	0.60	0.04	1.3
Derivatized - MS/MS Chromsystems MassChrom Kit	79	2.56	0.46	1.68	0.04	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.

MALONYLCARNITINE (µmol C3DC/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	735	0.03	0.02	0.03	0.03	0.5
Derivatized - MS/MS PE NeoGram Kit	133	0.03	0.01	0.02	0.03	1.2
Derivatized - MS/MS Chromsystems MassChrom Kit	86	0.05	0.02	0.03	0.05	0.7
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	729	0.27	0.05	0.10	0.03	0.5
Derivatized - MS/MS PE NeoGram Kit	126	0.64	0.06	0.13	0.03	1.2
Derivatized - MS/MS Chromsystems MassChrom Kit	79	0.36	0.08	0.11	0.05	0.7
Lot 1363 - Enriched 1.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	731	0.75	0.12	0.27	0.03	0.5
Derivatized - MS/MS PE NeoGram Kit	124	1.82	0.16	0.38	0.03	1.2
Derivatized - MS/MS Chromsystems MassChrom Kit	79	1.07	0.19	0.31	0.05	0.7
Lot 1364 - Enriched 3.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	739	1.48	0.24	0.51	0.03	0.5
Derivatized - MS/MS PE NeoGram Kit	124	3.64	0.29	0.81	0.03	1.2
Derivatized - MS/MS Chromsystems MassChrom Kit	79	2.03	0.24	0.54	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 17s. 2013 Quality Control Data
Summaries of Statistical Analyses

MALONYLCARNITINE + HYDROXYBUTYRYLCARNITINE
(μmol C3DC+C4OH/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Non-derivatized - MS/MS non-kit	105	0.07	0.02	0.04	0.03	0.5
Non-derivatized - MS/MS PE NeoBase Kit	293	0.07	0.02	0.04	0.03	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.04	0.01	0.01	0.02	0.2
Lot 1266 - Enriched 1.0 μmol/L whole blood						
Non-derivatized - MS/MS non-kit	102	0.58	0.07	0.25	0.03	0.5
Non-derivatized - MS/MS PE NeoBase Kit	285	0.47	0.05	0.19	0.03	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.28	0.02	0.05	0.02	0.2
Lot 1267 - Enriched 2.5 μmol/L whole blood						
Non-derivatized - MS/MS non-kit	104	1.20	0.18	0.52	0.03	0.5
Non-derivatized - MS/MS PE NeoBase Kit	283	0.94	0.09	0.38	0.03	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.53	0.05	0.10	0.02	0.2
Lot 1268 - Enriched 5.5 μmol/L whole blood						
Non-derivatized - MS/MS non-kit	103	2.92	0.50	1.33	0.03	0.5
Non-derivatized - MS/MS PE NeoBase Kit	289	2.35	0.27	1.01	0.03	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	1.32	0.09	0.17	0.02	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.

MALONYLCARNITINE + HYDROXYBUTYRYLCARNITINE

(µmol C3DC+C4OH/L whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Non-derivatized - MS/MS non-kit	77	0.12	0.03	0.05	0.14	0.6
Non-derivatized - MS/MS PE NeoBase Kit	387	0.07	0.01	0.04	0.05	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.19	0.03	0.24	0.24	0.9
Lot 1362 - Enriched 1.0 µmol/L whole blood						
Non-derivatized - MS/MS non-kit	77	0.78	0.11	0.24	0.14	0.6
Non-derivatized - MS/MS PE NeoBase Kit	383	0.43	0.05	0.21	0.05	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.23	0.15	1.58	0.24	0.9
Lot 1363 - Enriched 2.5 µmol/L whole blood						
Non-derivatized - MS/MS non-kit	75	1.53	0.18	0.42	0.14	0.6
Non-derivatized - MS/MS PE NeoBase Kit	388	0.91	0.09	0.50	0.05	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.31	0.25	2.90	0.24	0.9
Lot 1364 - Enriched 5.5 µmol/L whole blood						
Non-derivatized - MS/MS non-kit	77	3.35	0.41	1.10	0.14	0.6
Non-derivatized - MS/MS PE NeoBase Kit	398	2.08	0.23	1.14	0.05	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	5.04	0.44	6.32	0.24	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 17t. 2013 Quality Control Data
Summaries of Statistical Analyses

BUTYRYLCARNITINE (μmol C4/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	806	0.13	0.04	0.07	0.10	0.8
Non-derivatized - MS/MS non-kit	190	0.08	0.01	0.02	0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	149	0.11	0.04	0.05	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	405	0.10	0.02	0.03	0.06	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	0.10	0.04	0.05	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.09	0.01	0.02	0.08	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.09	0.01	0.01	0.05	0.8
Lot 1266 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	804	0.91	0.12	0.18	0.10	0.8
Non-derivatized - MS/MS non-kit	197	0.93	0.08	0.15	0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	156	0.79	0.12	0.13	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	404	0.84	0.06	0.10	0.06	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	86	0.84	0.11	0.16	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.83	0.05	0.08	0.08	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.89	0.05	0.10	0.05	0.8
Lot 1267 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	812	2.08	0.22	0.38	0.10	0.8
Non-derivatized - MS/MS non-kit	198	2.15	0.18	0.30	0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	158	1.89	0.28	0.34	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	409	1.91	0.12	0.22	0.06	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	1.88	0.25	0.31	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.83	0.14	0.34	0.08	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	2.07	0.10	0.17	0.05	0.8
Lot 1268 - Enriched 5.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	811	4.19	0.45	0.74	0.10	0.8
Non-derivatized - MS/MS non-kit	199	4.49	0.41	0.59	0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	156	3.81	0.50	0.60	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	400	3.95	0.24	0.55	0.06	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	84	3.96	0.47	0.60	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	3.75	0.20	0.39	0.08	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	4.30	0.25	0.25	0.05	0.8

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

BUTYRYLCARNITINE (µmol C4/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	808	0.14	0.04	0.05	0.14	0.9
Non-derivatized - MS/MS non-kit	205	0.11	0.02	0.03	0.11	0.9
Derivatized - MS/MS PE NeoGram Kit	147	0.13	0.05	0.05	0.15	0.7
Non-derivatized - MS/MS PE NeoBase Kit	471	0.12	0.02	0.03	0.12	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	103	0.15	0.04	0.04	0.13	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.10	0.02	0.02	0.12	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	0.11	0.01	0.01	0.08	0.9
Lot 1362 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	812	0.99	0.13	0.19	0.14	0.9
Non-derivatized - MS/MS non-kit	216	1.01	0.09	0.14	0.11	0.9
Derivatized - MS/MS PE NeoGram Kit	148	0.85	0.16	0.19	0.15	0.7
Non-derivatized - MS/MS PE NeoBase Kit	469	0.92	0.07	0.11	0.12	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	94	0.90	0.13	0.16	0.13	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	0.92	0.09	0.10	0.12	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.98	0.07	0.11	0.08	0.9
Lot 1363 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	822	2.30	0.25	0.40	0.14	0.9
Non-derivatized - MS/MS non-kit	213	2.38	0.20	0.31	0.11	0.9
Derivatized - MS/MS PE NeoGram Kit	150	2.00	0.38	0.45	0.15	0.7
Non-derivatized - MS/MS PE NeoBase Kit	466	2.12	0.14	0.22	0.12	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	96	2.05	0.21	0.29	0.13	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	2.15	0.21	0.22	0.12	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	2.35	0.12	0.28	0.08	0.9
Lot 1364 - Enriched 5.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	818	4.44	0.48	0.75	0.14	0.9
Non-derivatized - MS/MS non-kit	214	4.61	0.31	0.49	0.11	0.9
Derivatized - MS/MS PE NeoGram Kit	147	3.68	0.54	0.67	0.15	0.7
Non-derivatized - MS/MS PE NeoBase Kit	462	4.12	0.33	0.44	0.12	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	96	4.01	0.46	0.54	0.13	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	4.07	0.30	0.40	0.12	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	4.70	0.36	0.65	0.08	0.9

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

Table 17u. 2013 Quality Control Data
Summaries of Statistical Analyses

HYDROXYBUTYRYLCARNITINE (μmol C4OH/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	577	0.07	0.02	0.03	0.05	0.7
Derivatized - MS/MS PE NeoGram Kit	118	0.08	0.03	0.04	0.05	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	76	0.06	0.02	0.02	0.04	0.6
Lot 1266 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	570	0.37	0.06	0.11	0.05	0.7
Derivatized - MS/MS PE NeoGram Kit	120	0.40	0.08	0.13	0.05	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	76	0.34	0.05	0.07	0.04	0.6
Lot 1267 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	574	0.69	0.09	0.18	0.05	0.7
Derivatized - MS/MS PE NeoGram Kit	118	0.76	0.13	0.22	0.05	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	75	0.67	0.11	0.13	0.04	0.6
Lot 1268 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	581	1.73	0.20	0.48	0.05	0.7
Derivatized - MS/MS PE NeoGram Kit	116	1.92	0.27	0.48	0.05	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	77	1.63	0.21	0.30	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.

HYDROXYBUTYRYLCARNITINE (µmol C4OH/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	650	0.08	0.03	0.04	0.10	0.6
Derivatized - MS/MS PE NeoGram Kit	108	0.09	0.03	0.05	0.11	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.09	0.02	0.03	0.12	0.6
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	651	0.40	0.06	0.10	0.10	0.6
Derivatized - MS/MS PE NeoGram Kit	109	0.50	0.10	0.19	0.11	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	66	0.43	0.05	0.07	0.12	0.6
Lot 1363 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	654	0.74	0.10	0.19	0.10	0.6
Derivatized - MS/MS PE NeoGram Kit	100	0.82	0.16	0.27	0.11	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.80	0.12	0.16	0.12	0.6
Lot 1364 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	650	1.62	0.20	0.39	0.10	0.6
Derivatized - MS/MS PE NeoGram Kit	105	1.89	0.28	0.72	0.11	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	66	1.68	0.18	0.24	0.12	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 17v. 2013 Quality Control Data
Summaries of Statistical Analyses

ISOVALERYLCARNITINE (μmol C5/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	835	0.07	0.02	0.03	0.04	0.9
Non-derivatized - MS/MS non-kit	248	0.05	0.01	0.01	0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	161	0.07	0.02	0.02	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	420	0.06	0.01	0.02	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	94	0.07	0.02	0.03	0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.06	0.01	0.02	0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.06	0.01	0.01	0.01	1.0
Lot 1266 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	849	0.47	0.06	0.08	0.04	0.9
Non-derivatized - MS/MS non-kit	256	0.49	0.04	0.06	0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	168	0.47	0.07	0.09	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	418	0.46	0.04	0.06	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.48	0.08	0.10	0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.43	0.02	0.10	0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.49	0.02	0.05	0.01	1.0
Lot 1267 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	857	1.26	0.13	0.19	0.04	0.9
Non-derivatized - MS/MS non-kit	254	1.33	0.11	0.15	0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	170	1.25	0.17	0.21	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	422	1.22	0.08	0.17	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	98	1.35	0.18	0.25	0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.15	0.07	0.27	0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	1.33	0.06	0.13	0.01	1.0
Lot 1268 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	860	2.67	0.27	0.40	0.04	0.9
Non-derivatized - MS/MS non-kit	257	2.89	0.25	0.35	0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	168	2.56	0.31	0.40	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	424	2.66	0.24	0.40	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	97	2.82	0.27	0.47	0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.55	0.16	0.57	0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	2.94	0.14	0.16	0.01	1.0

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

ISOVALERYLCARNITINE (µmol C5/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	853	0.09	0.02	0.03	0.09	0.9
Non-derivatized - MS/MS non-kit	248	0.07	0.01	0.02	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	150	0.08	0.02	0.03	0.09	0.8
Non-derivatized - MS/MS PE NeoBase Kit	497	0.07	0.01	0.02	0.07	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	103	0.11	0.04	0.05	0.10	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	0.07	0.02	0.03	0.08	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.09	0.01	0.03	0.08	1.0
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	868	0.52	0.07	0.09	0.09	0.9
Non-derivatized - MS/MS non-kit	254	0.54	0.05	0.07	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	159	0.48	0.08	0.10	0.09	0.8
Non-derivatized - MS/MS PE NeoBase Kit	507	0.47	0.04	0.07	0.07	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.52	0.07	0.08	0.10	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.51	0.06	0.11	0.08	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.57	0.04	0.10	0.08	1.0
Lot 1363 - Enriched 1.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	857	1.37	0.15	0.20	0.09	0.9
Non-derivatized - MS/MS non-kit	252	1.49	0.11	0.17	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	153	1.30	0.19	0.21	0.09	0.8
Non-derivatized - MS/MS PE NeoBase Kit	494	1.27	0.09	0.16	0.07	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	93	1.38	0.14	0.16	0.10	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	1.31	0.14	0.28	0.08	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.56	0.10	0.26	0.08	1.0
Lot 1364 - Enriched 3.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	856	2.66	0.27	0.40	0.09	0.9
Non-derivatized - MS/MS non-kit	253	2.90	0.19	0.33	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	156	2.47	0.27	0.33	0.09	0.8
Non-derivatized - MS/MS PE NeoBase Kit	501	2.49	0.19	0.37	0.07	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	96	2.70	0.27	0.38	0.10	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	2.58	0.22	0.53	0.08	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	3.05	0.19	0.45	0.08	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 17w. 2013 Quality Control Data
Summaries of Statistical Analyses

GLUTARYLCARNITINE (μmol C5DC/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	836	0.03	0.01	0.02	0.00	0.6
Non-derivatized - MS/MS non-kit	214	0.03	0.01	0.02	-0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	160	0.03	0.01	0.01	-0.01	1.1
Non-derivatized - MS/MS PE NeoBase Kit	352	0.04	0.01	0.03	-0.01	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	96	0.05	0.03	0.03	0.00	1.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	0.06	0.01	0.03	0.01	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.06	0.01	0.02	0.01	1.1
Lot 1266 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	821	0.28	0.05	0.10	0.00	0.6
Non-derivatized - MS/MS non-kit	228	0.45	0.07	0.17	-0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	164	0.51	0.04	0.08	-0.01	1.1
Non-derivatized - MS/MS PE NeoBase Kit	364	0.52	0.05	0.08	-0.01	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	98	0.68	0.17	0.24	0.00	1.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.72	0.10	0.28	0.01	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.57	0.05	0.15	0.01	1.1
Lot 1267 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	815	0.53	0.08	0.19	0.00	0.6
Non-derivatized - MS/MS non-kit	230	0.88	0.11	0.31	-0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	164	1.03	0.06	0.14	-0.01	1.1
Non-derivatized - MS/MS PE NeoBase Kit	367	0.99	0.08	0.16	-0.01	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	99	1.33	0.31	0.41	0.00	1.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.34	0.18	0.61	0.01	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	1.11	0.07	0.31	0.01	1.1
Lot 1268 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	821	1.41	0.19	0.47	0.00	0.6
Non-derivatized - MS/MS non-kit	230	2.35	0.26	0.83	-0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	165	2.73	0.18	0.34	-0.01	1.1
Non-derivatized - MS/MS PE NeoBase Kit	355	2.70	0.23	0.40	-0.01	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	97	3.48	0.69	0.97	0.00	1.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	3.58	0.51	1.52	0.01	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	2.90	0.17	0.67	0.01	1.1

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

GLUTARYLCARNITINE (µmol C5DC/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	839	0.02	0.01	0.02	0.04	0.5
Non-derivatized - MS/MS non-kit	235	0.06	0.02	0.03	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	154	0.03	0.01	0.02	0.05	1.0
Non-derivatized - MS/MS PE NeoBase Kit	421	0.07	0.02	0.03	0.08	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	104	0.07	0.04	0.05	0.10	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.09	0.04	0.05	0.07	1.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.08	0.01	0.02	0.08	1.0
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	849	0.31	0.05	0.13	0.04	0.5
Non-derivatized - MS/MS non-kit	237	0.50	0.06	0.14	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	153	0.57	0.04	0.07	0.05	1.0
Non-derivatized - MS/MS PE NeoBase Kit	438	0.55	0.05	0.09	0.08	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	95	0.77	0.18	0.24	0.10	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	0.82	0.19	0.33	0.07	1.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.57	0.05	0.07	0.08	1.0
Lot 1363 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	839	0.60	0.09	0.24	0.04	0.5
Non-derivatized - MS/MS non-kit	238	0.95	0.09	0.27	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	150	1.10	0.08	0.12	0.05	1.0
Non-derivatized - MS/MS PE NeoBase Kit	438	1.04	0.08	0.16	0.08	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	96	1.47	0.29	0.33	0.10	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	1.50	0.31	0.55	0.07	1.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.09	0.06	0.14	0.08	1.0
Lot 1364 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	836	1.38	0.20	0.54	0.04	0.5
Non-derivatized - MS/MS non-kit	239	2.23	0.21	0.62	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	153	2.59	0.15	0.32	0.05	1.0
Non-derivatized - MS/MS PE NeoBase Kit	437	2.43	0.19	0.36	0.08	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	96	3.41	0.64	0.82	0.10	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	3.79	0.89	1.34	0.07	1.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.58	0.18	0.34	0.08	1.0

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

Table 17x. 2013 Quality Control Data
Summaries of Statistical Analyses

HYDROXYISOVALERYLCARNITINE (μmol C5OH/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	829	0.42	0.06	0.09	0.40	0.7
Non-derivatized - MS/MS non-kit	197	0.57	0.06	0.09	0.54	0.8
Derivatized - MS/MS PE NeoGram Kit	169	0.40	0.08	0.09	0.39	0.7
Non-derivatized - MS/MS PE NeoBase Kit	309	0.48	0.05	0.11	0.46	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	79	0.36	0.06	0.09	0.34	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.35	0.02	0.03	0.33	0.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.64	0.03	0.07	0.59	0.9
Lot 1266 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	810	0.75	0.09	0.15	0.40	0.7
Non-derivatized - MS/MS non-kit	198	0.92	0.07	0.13	0.54	0.8
Derivatized - MS/MS PE NeoGram Kit	165	0.71	0.10	0.14	0.39	0.7
Non-derivatized - MS/MS PE NeoBase Kit	310	0.74	0.06	0.19	0.46	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	80	0.66	0.10	0.13	0.34	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.53	0.03	0.06	0.33	0.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	1.01	0.05	0.09	0.59	0.9
Lot 1267 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	828	1.41	0.15	0.27	0.40	0.7
Non-derivatized - MS/MS non-kit	200	1.60	0.12	0.27	0.54	0.8
Derivatized - MS/MS PE NeoGram Kit	167	1.33	0.19	0.26	0.39	0.7
Non-derivatized - MS/MS PE NeoBase Kit	310	1.22	0.09	0.31	0.46	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	75	1.23	0.18	0.22	0.34	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.87	0.06	0.10	0.33	0.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	1.78	0.07	0.20	0.59	0.9
Lot 1268 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	826	2.18	0.23	0.42	0.40	0.7
Non-derivatized - MS/MS non-kit	200	2.46	0.23	0.44	0.54	0.8
Derivatized - MS/MS PE NeoGram Kit	166	2.04	0.29	0.36	0.39	0.7
Non-derivatized - MS/MS PE NeoBase Kit	320	1.89	0.16	0.58	0.46	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	78	1.96	0.24	0.39	0.34	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.35	0.07	0.21	0.33	0.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	2.79	0.13	0.18	0.59	0.9

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

HYDROXYISOVALERYLCARNITINE (µmol C5OH/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	835	0.55	0.07	0.11	0.55	0.8
Non-derivatized - MS/MS non-kit	219	0.72	0.06	0.15	0.73	0.8
Derivatized - MS/MS PE NeoGram Kit	154	0.55	0.08	0.11	0.54	0.7
Non-derivatized - MS/MS PE NeoBase Kit	318	0.55	0.05	0.13	0.54	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	106	0.55	0.10	0.14	0.55	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.44	0.06	0.09	0.45	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	0.80	0.07	0.10	0.81	0.9
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	827	0.93	0.12	0.18	0.55	0.8
Non-derivatized - MS/MS non-kit	220	1.14	0.10	0.21	0.73	0.8
Derivatized - MS/MS PE NeoGram Kit	157	0.90	0.12	0.16	0.54	0.7
Non-derivatized - MS/MS PE NeoBase Kit	322	0.81	0.06	0.16	0.54	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	91	0.91	0.13	0.22	0.55	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	0.70	0.15	0.18	0.45	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	29	1.27	0.09	0.14	0.81	0.9
Lot 1363 - Enriched 1.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	831	1.68	0.20	0.32	0.55	0.8
Non-derivatized - MS/MS non-kit	220	1.94	0.16	0.35	0.73	0.8
Derivatized - MS/MS PE NeoGram Kit	156	1.65	0.21	0.25	0.54	0.7
Non-derivatized - MS/MS PE NeoBase Kit	317	1.28	0.11	0.26	0.54	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	94	1.57	0.19	0.38	0.55	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	1.12	0.15	0.22	0.45	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	29	2.22	0.12	0.21	0.81	0.9
Lot 1364 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	823	2.45	0.27	0.43	0.55	0.8
Non-derivatized - MS/MS non-kit	220	2.74	0.23	0.50	0.73	0.8
Derivatized - MS/MS PE NeoGram Kit	158	2.39	0.28	0.37	0.54	0.7
Non-derivatized - MS/MS PE NeoBase Kit	331	1.84	0.13	0.45	0.54	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	96	2.27	0.31	0.58	0.55	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	55	1.60	0.22	0.30	0.45	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	3.11	0.17	0.24	0.81	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 17y. 2013 Quality Control Data
Summaries of Statistical Analyses

HEXANOYLCARNITINE (μmol C6/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	807	0.04	0.02	0.03	0.00	0.8
Non-derivatized - MS/MS non-kit	207	0.01	0.01	0.01	-0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	166	0.03	0.02	0.02	0.03	0.7
Non-derivatized - MS/MS PE NeoBase Kit	405	0.02	0.01	0.01	-0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	83	0.04	0.02	0.02	0.04	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.02	0.00	0.01	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.01	0.00	0.00	-0.07	0.8
Lot 1266 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	813	0.41	0.06	0.09	0.00	0.8
Non-derivatized - MS/MS non-kit	210	0.41	0.04	0.08	-0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	166	0.39	0.07	0.08	0.03	0.7
Non-derivatized - MS/MS PE NeoBase Kit	421	0.42	0.04	0.05	-0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	88	0.39	0.07	0.08	0.04	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.41	0.03	0.05	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.34	0.02	0.03	-0.07	0.8
Lot 1267 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	807	0.78	0.09	0.15	0.00	0.8
Non-derivatized - MS/MS non-kit	210	0.79	0.07	0.15	-0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	168	0.69	0.09	0.10	0.03	0.7
Non-derivatized - MS/MS PE NeoBase Kit	408	0.78	0.06	0.09	-0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	88	0.66	0.09	0.14	0.04	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.77	0.05	0.10	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.66	0.04	0.06	-0.07	0.8
Lot 1268 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	818	2.09	0.22	0.41	0.00	0.8
Non-derivatized - MS/MS non-kit	208	2.21	0.17	0.36	-0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	168	1.73	0.16	0.21	0.03	0.7
Non-derivatized - MS/MS PE NeoBase Kit	405	2.15	0.16	0.27	-0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	88	1.64	0.24	0.48	0.04	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.06	0.08	0.10	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	1.83	0.12	0.12	-0.07	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.

HEXANOYLCARNITINE (µmol C6/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	804	0.03	0.02	0.03	0.05	0.8
Non-derivatized - MS/MS non-kit	212	0.01	0.00	0.01	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	160	0.03	0.02	0.03	0.09	0.6
Non-derivatized - MS/MS PE NeoBase Kit	478	0.02	0.01	0.01	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	109	0.07	0.03	0.05	0.10	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.01	0.01	0.01	0.04	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	0.01	0.00	0.00	0.02	0.8
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	818	0.42	0.06	0.09	0.05	0.8
Non-derivatized - MS/MS non-kit	225	0.47	0.04	0.09	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	161	0.41	0.07	0.08	0.09	0.6
Non-derivatized - MS/MS PE NeoBase Kit	485	0.43	0.03	0.05	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	94	0.42	0.06	0.07	0.10	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.45	0.04	0.05	0.04	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.39	0.04	0.04	0.02	0.8
Lot 1363 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	820	0.83	0.10	0.17	0.05	0.8
Non-derivatized - MS/MS non-kit	219	0.92	0.08	0.16	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	164	0.73	0.10	0.13	0.09	0.6
Non-derivatized - MS/MS PE NeoBase Kit	487	0.85	0.06	0.10	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.70	0.10	0.12	0.10	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.86	0.07	0.09	0.04	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.78	0.04	0.05	0.02	0.8
Lot 1364 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	817	1.91	0.20	0.40	0.05	0.8
Non-derivatized - MS/MS non-kit	225	2.17	0.18	0.35	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	165	1.53	0.18	0.23	0.09	0.6
Non-derivatized - MS/MS PE NeoBase Kit	488	1.97	0.13	0.24	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	98	1.51	0.17	0.30	0.10	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	1.98	0.18	0.23	0.04	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	1.88	0.12	0.13	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.

Table 17z. 2013 Quality Control Data
Summaries of Statistical Analyses

OCTANOYLCARNITINE (μmol C8/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	849	0.04	0.02	0.03	0.02	0.9
Non-derivatized - MS/MS non-kit	275	0.03	0.01	0.02	0.01	1.0
Derivatized - MS/MS PE NeoGram Kit	164	0.03	0.02	0.02	0.01	0.9
Non-derivatized - MS/MS PE NeoBase Kit	404	0.02	0.01	0.01	-0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	105	0.03	0.01	0.02	0.00	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.02	0.00	0.01	-0.01	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.04	0.01	0.01	0.00	1.0
Lot 1266 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	847	0.47	0.06	0.10	0.02	0.9
Non-derivatized - MS/MS non-kit	282	0.48	0.05	0.07	0.01	1.0
Derivatized - MS/MS PE NeoGram Kit	165	0.46	0.08	0.08	0.01	0.9
Non-derivatized - MS/MS PE NeoBase Kit	416	0.44	0.04	0.06	-0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	104	0.43	0.07	0.09	0.00	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.43	0.03	0.04	-0.01	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.49	0.03	0.06	0.00	1.0
Lot 1267 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	851	0.93	0.11	0.17	0.02	0.9
Non-derivatized - MS/MS non-kit	285	0.93	0.09	0.13	0.01	1.0
Derivatized - MS/MS PE NeoGram Kit	165	0.87	0.12	0.15	0.01	0.9
Non-derivatized - MS/MS PE NeoBase Kit	420	0.86	0.07	0.10	-0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	103	0.82	0.11	0.14	0.00	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.82	0.07	0.10	-0.01	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.93	0.04	0.12	0.00	1.0
Lot 1268 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	855	2.36	0.25	0.39	0.02	0.9
Non-derivatized - MS/MS non-kit	286	2.43	0.20	0.31	0.01	1.0
Derivatized - MS/MS PE NeoGram Kit	165	2.23	0.29	0.32	0.01	0.9
Non-derivatized - MS/MS PE NeoBase Kit	414	2.32	0.16	0.26	-0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	104	2.16	0.21	0.29	0.00	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	2.18	0.13	0.16	-0.01	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	2.49	0.13	0.21	0.00	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.

OCTANOYLCARNITINE (µmol C8/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	860	0.04	0.02	0.03	0.03	1.0
Non-derivatized - MS/MS non-kit	262	0.03	0.01	0.02	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	156	0.03	0.02	0.02	0.03	0.9
Non-derivatized - MS/MS PE NeoBase Kit	497	0.02	0.01	0.01	0.03	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	101	0.04	0.02	0.03	0.05	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	66	0.02	0.01	0.01	0.03	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	0.04	0.01	0.01	0.05	1.0
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	851	0.52	0.07	0.10	0.03	1.0
Non-derivatized - MS/MS non-kit	272	0.54	0.04	0.07	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	156	0.50	0.09	0.10	0.03	0.9
Non-derivatized - MS/MS PE NeoBase Kit	500	0.51	0.04	0.05	0.03	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	94	0.47	0.07	0.08	0.05	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	67	0.46	0.04	0.06	0.03	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.55	0.04	0.07	0.05	1.0
Lot 1363 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	860	1.00	0.11	0.19	0.03	1.0
Non-derivatized - MS/MS non-kit	279	1.05	0.09	0.14	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	156	0.93	0.15	0.16	0.03	0.9
Non-derivatized - MS/MS PE NeoBase Kit	502	1.01	0.07	0.11	0.03	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	94	0.92	0.10	0.11	0.05	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.91	0.07	0.09	0.03	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.06	0.07	0.14	0.05	1.0
Lot 1364 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	856	2.47	0.26	0.43	0.03	1.0
Non-derivatized - MS/MS non-kit	278	2.54	0.21	0.33	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	155	2.29	0.29	0.29	0.03	0.9
Non-derivatized - MS/MS PE NeoBase Kit	496	2.45	0.17	0.25	0.03	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	96	2.18	0.23	0.32	0.05	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	2.20	0.17	0.25	0.03	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	2.55	0.11	0.28	0.05	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 17aa. 2013 Quality Control Data
Summaries of Statistical Analyses

DECANOYLCARNITINE (µmol C10/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	820	0.03	0.01	0.02	0.06	0.9
Non-derivatized - MS/MS non-kit	270	0.03	0.01	0.02	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	159	0.03	0.01	0.02	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	424	0.02	0.01	0.01	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	86	0.03	0.02	0.03	0.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.02	0.01	0.01	0.03	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.02	0.00	0.01	0.02	1.1
Lot 1266 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	842	0.53	0.08	0.12	0.06	0.9
Non-derivatized - MS/MS non-kit	274	0.54	0.06	0.10	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	169	0.40	0.06	0.08	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	426	0.45	0.04	0.06	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	85	0.44	0.06	0.10	0.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.43	0.03	0.06	0.03	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.58	0.04	0.09	0.02	1.1
Lot 1267 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	840	1.02	0.14	0.23	0.06	0.9
Non-derivatized - MS/MS non-kit	277	1.03	0.11	0.20	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	166	0.76	0.11	0.12	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	421	0.85	0.07	0.12	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	84	0.84	0.12	0.18	0.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.79	0.06	0.14	0.03	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	1.08	0.06	0.17	0.02	1.1
Lot 1268 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	833	2.38	0.27	0.47	0.06	0.9
Non-derivatized - MS/MS non-kit	278	2.46	0.24	0.47	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	163	1.82	0.20	0.23	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	428	2.07	0.16	0.29	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	2.07	0.24	0.39	0.03	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.98	0.13	0.26	0.03	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	2.74	0.16	0.32	0.02	1.1

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

DECANOYLCARNITINE (µmol C10/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	830	0.03	0.01	0.02	0.04	1.0
Non-derivatized - MS/MS non-kit	247	0.02	0.01	0.02	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	152	0.03	0.02	0.02	0.05	0.7
Non-derivatized - MS/MS PE NeoBase Kit	505	0.02	0.01	0.01	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	105	0.03	0.02	0.03	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.02	0.01	0.02	0.03	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	0.03	0.01	0.01	0.04	1.1
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	836	0.54	0.07	0.12	0.04	1.0
Non-derivatized - MS/MS non-kit	257	0.56	0.06	0.09	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	159	0.43	0.08	0.08	0.05	0.7
Non-derivatized - MS/MS PE NeoBase Kit	493	0.46	0.04	0.05	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	98	0.47	0.08	0.09	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.48	0.06	0.07	0.03	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.63	0.05	0.13	0.04	1.1
Lot 1363 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	829	1.01	0.13	0.21	0.04	1.0
Non-derivatized - MS/MS non-kit	254	1.04	0.09	0.16	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	158	0.80	0.12	0.14	0.05	0.7
Non-derivatized - MS/MS PE NeoBase Kit	499	0.88	0.06	0.12	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.90	0.11	0.18	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.90	0.07	0.11	0.03	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.18	0.09	0.25	0.04	1.1
Lot 1364 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	842	2.49	0.31	0.51	0.04	1.0
Non-derivatized - MS/MS non-kit	253	2.53	0.24	0.38	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	154	1.89	0.20	0.22	0.05	0.7
Non-derivatized - MS/MS PE NeoBase Kit	505	2.15	0.16	0.28	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	93	2.07	0.21	0.32	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	2.21	0.19	0.32	0.03	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.88	0.29	0.56	0.04	1.1

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

Table 17bb. 2013 Quality Control Data
Summaries of Statistical Analyses

DODECANOYLCARNITINE (μmol C12/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	687	0.03	0.02	0.03	0.04	0.9
Non-derivatized - MS/MS non-kit	171	0.01	0.01	0.01	0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	146	0.03	0.02	0.02	0.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	378	0.01	0.00	0.01	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	85	0.03	0.01	0.02	0.06	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.01	0.00	0.00	-0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.01	0.00	0.00	-0.04	0.9
Lot 1266 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	697	0.47	0.08	0.11	0.04	0.9
Non-derivatized - MS/MS non-kit	166	0.45	0.05	0.10	0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	157	0.45	0.07	0.08	0.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	372	0.42	0.04	0.06	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	0.46	0.07	0.14	0.06	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.40	0.03	0.03	-0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.41	0.03	0.03	-0.04	0.9
Lot 1267 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	686	0.91	0.13	0.20	0.04	0.9
Non-derivatized - MS/MS non-kit	163	0.84	0.09	0.19	0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	156	0.88	0.13	0.15	0.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	369	0.79	0.06	0.10	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	0.96	0.15	0.28	0.06	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.75	0.04	0.08	-0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.78	0.04	0.04	-0.04	0.9
Lot 1268 - Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	688	2.19	0.28	0.43	0.04	0.9
Non-derivatized - MS/MS non-kit	163	2.16	0.24	0.49	0.01	0.9
Derivatized - MS/MS PE NeoGram Kit	154	2.07	0.24	0.26	0.04	0.8
Non-derivatized - MS/MS PE NeoBase Kit	363	2.01	0.14	0.24	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	86	2.16	0.28	0.49	0.06	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.00	0.11	0.14	-0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	19	2.10	0.09	0.09	-0.04	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.

DODECANOYLCARNITINE (µmol C12/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	709	0.04	0.02	0.03	0.07	0.9
Non-derivatized - MS/MS non-kit	176	0.02	0.01	0.01	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	148	0.05	0.03	0.03	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	440	0.01	0.00	0.01	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	93	0.05	0.02	0.04	0.11	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.01	0.00	0.01	0.02	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	0.01	0.00	0.00	0.03	0.9
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	718	0.51	0.08	0.13	0.07	0.9
Non-derivatized - MS/MS non-kit	177	0.51	0.06	0.11	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	146	0.52	0.09	0.10	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	441	0.45	0.03	0.05	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	83	0.51	0.11	0.14	0.11	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.44	0.05	0.07	0.02	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.51	0.03	0.08	0.03	0.9
Lot 1363 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	714	1.00	0.15	0.24	0.07	0.9
Non-derivatized - MS/MS non-kit	177	0.99	0.10	0.23	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	145	1.00	0.14	0.15	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	441	0.89	0.06	0.10	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	82	1.04	0.14	0.27	0.11	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.85	0.07	0.10	0.02	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.99	0.06	0.16	0.03	0.9
Lot 1364 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	725	2.26	0.30	0.48	0.07	0.9
Non-derivatized - MS/MS non-kit	177	2.36	0.23	0.56	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	146	2.23	0.24	0.31	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	443	2.16	0.15	0.25	0.02	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	83	2.09	0.31	0.41	0.11	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	2.07	0.14	0.23	0.02	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	2.38	0.12	0.29	0.03	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 17cc. 2013 Quality Control Data
Summaries of Statistical Analyses

MYRISTOYLCARNITINE (μmol C14/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	809	0.06	0.02	0.03	0.06	0.8
Non-derivatized - MS/MS non-kit	202	0.04	0.01	0.02	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	161	0.06	0.02	0.03	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	404	0.03	0.01	0.01	0.02	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	85	0.07	0.02	0.03	0.08	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	0.03	0.01	0.01	0.02	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.04	0.01	0.01	0.02	0.8
Lot 1266 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	807	0.48	0.07	0.10	0.06	0.8
Non-derivatized - MS/MS non-kit	200	0.46	0.05	0.06	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	165	0.43	0.05	0.07	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	411	0.41	0.03	0.05	0.02	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	86	0.44	0.07	0.12	0.08	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.37	0.03	0.03	0.02	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.43	0.03	0.04	0.02	0.8
Lot 1267 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	809	1.28	0.15	0.22	0.06	0.8
Non-derivatized - MS/MS non-kit	197	1.27	0.12	0.17	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	163	1.21	0.13	0.17	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	412	1.17	0.09	0.13	0.02	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	1.13	0.18	0.29	0.08	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.04	0.07	0.10	0.02	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	1.21	0.06	0.15	0.02	0.8
Lot 1268 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	802	2.53	0.27	0.43	0.06	0.8
Non-derivatized - MS/MS non-kit	201	2.62	0.30	0.43	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	166	2.39	0.31	0.37	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	411	2.40	0.17	0.28	0.02	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	81	2.19	0.26	0.39	0.08	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.12	0.13	0.18	0.02	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	2.50	0.12	0.18	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.

MYRISTOYLCARNITINE (µmol C14/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	811	0.07	0.02	0.03	0.08	0.9
Non-derivatized - MS/MS non-kit	215	0.05	0.01	0.01	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	158	0.07	0.02	0.03	0.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	466	0.05	0.01	0.01	0.05	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	96	0.07	0.03	0.03	0.08	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	0.04	0.01	0.01	0.05	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.05	0.01	0.01	0.06	0.9
Lot 1362 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	817	0.53	0.08	0.11	0.08	0.9
Non-derivatized - MS/MS non-kit	220	0.53	0.05	0.08	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	157	0.48	0.08	0.08	0.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	488	0.47	0.04	0.06	0.05	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	0.47	0.07	0.08	0.08	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	0.44	0.04	0.05	0.05	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.49	0.04	0.09	0.06	0.9
Lot 1363 - Enriched 1.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	835	1.44	0.18	0.28	0.08	0.9
Non-derivatized - MS/MS non-kit	218	1.50	0.11	0.20	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	155	1.28	0.15	0.16	0.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	476	1.34	0.09	0.16	0.05	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	1.16	0.12	0.21	0.08	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	1.22	0.10	0.13	0.05	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.39	0.09	0.27	0.06	0.9
Lot 1364 - Enriched 3.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	831	2.73	0.31	0.51	0.08	0.9
Non-derivatized - MS/MS non-kit	218	2.82	0.24	0.37	0.07	0.9
Derivatized - MS/MS PE NeoGram Kit	155	2.49	0.23	0.25	0.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	486	2.57	0.19	0.29	0.05	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	2.29	0.23	0.37	0.08	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	2.36	0.20	0.29	0.05	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	2.63	0.12	0.42	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.

Table 17dd. 2013 Quality Control Data
Summaries of Statistical Analyses

PALMITOYLCARNITINE (μmol C16/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	820	0.61	0.08	0.13	0.57	0.8
Non-derivatized - MS/MS non-kit	210	0.59	0.06	0.08	0.52	0.8
Derivatized - MS/MS PE NeoGram Kit	156	0.57	0.07	0.08	0.50	0.7
Non-derivatized - MS/MS PE NeoBase Kit	410	0.55	0.05	0.08	0.47	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	98	0.52	0.08	0.10	0.44	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.57	0.04	0.05	0.48	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.65	0.05	0.08	0.55	0.8
Lot 1266 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	822	2.77	0.27	0.46	0.57	0.8
Non-derivatized - MS/MS non-kit	220	2.90	0.25	0.38	0.52	0.8
Derivatized - MS/MS PE NeoGram Kit	161	2.54	0.22	0.29	0.50	0.7
Non-derivatized - MS/MS PE NeoBase Kit	422	2.63	0.21	0.32	0.47	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	95	2.50	0.30	0.42	0.44	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	2.60	0.17	0.18	0.48	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	2.96	0.18	0.29	0.55	0.8
Lot 1267 - Enriched 8.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	827	6.64	0.61	1.02	0.57	0.8
Non-derivatized - MS/MS non-kit	213	7.08	0.48	0.78	0.52	0.8
Derivatized - MS/MS PE NeoGram Kit	165	6.41	0.55	0.84	0.50	0.7
Non-derivatized - MS/MS PE NeoBase Kit	425	6.40	0.50	0.82	0.47	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	99	6.36	0.67	1.14	0.44	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	29	6.39	0.43	0.44	0.48	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	7.21	0.30	0.94	0.55	0.8
Lot 1268 - Enriched 12.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	824	9.65	0.82	1.51	0.57	0.8
Non-derivatized - MS/MS non-kit	214	10.44	0.80	1.21	0.52	0.8
Derivatized - MS/MS PE NeoGram Kit	163	9.19	0.82	1.16	0.50	0.7
Non-derivatized - MS/MS PE NeoBase Kit	426	9.50	0.78	1.31	0.47	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	98	9.23	0.93	1.67	0.44	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	9.45	0.51	0.75	0.48	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	10.65	0.55	0.89	0.55	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.

PALMITOYLCARNITINE (µmol C16/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	852	0.82	0.09	0.14	0.63	0.8
Non-derivatized - MS/MS non-kit	230	0.83	0.08	0.12	0.63	0.9
Derivatized - MS/MS PE NeoGram Kit	156	0.75	0.09	0.10	0.58	0.8
Non-derivatized - MS/MS PE NeoBase Kit	487	0.75	0.05	0.07	0.53	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	105	0.77	0.10	0.15	0.54	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.77	0.09	0.14	0.58	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	37	0.90	0.05	0.08	0.74	0.9
Lot 1362 - Enriched 4.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	863	3.51	0.37	0.51	0.63	0.8
Non-derivatized - MS/MS non-kit	233	3.72	0.30	0.47	0.63	0.9
Derivatized - MS/MS PE NeoGram Kit	158	3.27	0.38	0.48	0.58	0.8
Non-derivatized - MS/MS PE NeoBase Kit	491	3.27	0.23	0.28	0.53	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	95	3.22	0.28	0.45	0.54	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	3.42	0.37	0.58	0.58	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	3.98	0.25	0.41	0.74	0.9
Lot 1363 - Enriched 8.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	870	7.41	0.70	1.14	0.63	0.8
Non-derivatized - MS/MS non-kit	235	7.91	0.61	1.02	0.63	0.9
Derivatized - MS/MS PE NeoGram Kit	157	6.81	0.62	0.75	0.58	0.8
Non-derivatized - MS/MS PE NeoBase Kit	491	7.08	0.46	0.65	0.53	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	95	6.93	0.65	1.13	0.54	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	6.90	0.47	0.91	0.58	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	8.34	0.52	0.98	0.74	0.9
Lot 1364 - Enriched 12.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	844	10.45	0.88	1.48	0.63	0.8
Non-derivatized - MS/MS non-kit	232	11.15	0.77	1.34	0.63	0.9
Derivatized - MS/MS PE NeoGram Kit	156	9.63	0.87	0.98	0.58	0.8
Non-derivatized - MS/MS PE NeoBase Kit	487	10.03	0.71	0.98	0.53	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	9.95	0.90	1.04	0.54	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	10.07	0.63	1.36	0.58	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	11.56	0.50	0.97	0.74	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 17ee. 2013 Quality Control Data
Summaries of Statistical Analyses

HYDROXYPALMITOYLCARNITINE (μmol C16OH/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	819	0.02	0.01	0.01	0.02	0.7
Non-derivatized - MS/MS non-kit	227	0.01	0.00	0.01	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	151	0.01	0.01	0.01	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	401	0.01	0.00	0.01	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	88	0.01	0.01	0.01	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.01	0.00	0.00	0.00	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.00	0.00	0.00	0.00	0.7
Lot 1266 - Enriched 0.1 μmol/L whole blood						
Derivatized - MS/MS non-kit	829	0.09	0.02	0.04	0.02	0.7
Non-derivatized - MS/MS non-kit	231	0.08	0.01	0.02	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	155	0.09	0.02	0.03	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	395	0.07	0.01	0.01	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	87	0.07	0.02	0.03	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.05	0.00	0.00	0.00	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.08	0.01	0.01	0.00	0.7
Lot 1267 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	823	0.35	0.05	0.09	0.02	0.7
Non-derivatized - MS/MS non-kit	236	0.33	0.03	0.07	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	157	0.36	0.06	0.08	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	394	0.28	0.03	0.04	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	87	0.30	0.06	0.08	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.24	0.02	0.02	0.00	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.34	0.02	0.05	0.00	0.7
Lot 1268 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	810	0.70	0.08	0.16	0.02	0.7
Non-derivatized - MS/MS non-kit	237	0.68	0.07	0.13	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	156	0.70	0.09	0.13	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	399	0.58	0.06	0.10	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	87	0.59	0.08	0.11	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	20	0.49	0.03	0.03	0.00	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.71	0.05	0.08	0.00	0.7

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

HYDROXYPALMITOYLCARNITINE (µmol C16OH/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	827	0.02	0.01	0.02	0.02	0.7
Non-derivatized - MS/MS non-kit	193	0.01	0.00	0.01	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	150	0.02	0.01	0.01	0.03	0.6
Non-derivatized - MS/MS PE NeoBase Kit	510	0.01	0.00	0.01	0.01	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	92	0.02	0.01	0.02	0.02	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.01	0.00	0.00	0.01	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.01	0.00	0.00	0.01	0.6
Lot 1362 - Enriched 0.1 µmol/L whole blood						
Derivatized - MS/MS non-kit	840	0.09	0.02	0.03	0.02	0.7
Non-derivatized - MS/MS non-kit	197	0.08	0.01	0.02	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	145	0.10	0.02	0.03	0.03	0.6
Non-derivatized - MS/MS PE NeoBase Kit	494	0.07	0.01	0.02	0.01	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	84	0.08	0.02	0.04	0.02	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.06	0.01	0.01	0.01	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.08	0.01	0.03	0.01	0.6
Lot 1363 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS non-kit	844	0.35	0.05	0.09	0.02	0.7
Non-derivatized - MS/MS non-kit	194	0.32	0.04	0.08	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	147	0.35	0.06	0.07	0.03	0.6
Non-derivatized - MS/MS PE NeoBase Kit	491	0.27	0.03	0.05	0.01	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	84	0.31	0.05	0.08	0.02	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	0.23	0.02	0.03	0.01	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.33	0.02	0.12	0.01	0.6
Lot 1364 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	841	0.67	0.08	0.16	0.02	0.7
Non-derivatized - MS/MS non-kit	200	0.63	0.07	0.14	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	144	0.65	0.09	0.11	0.03	0.6
Non-derivatized - MS/MS PE NeoBase Kit	494	0.53	0.05	0.09	0.01	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	86	0.58	0.08	0.14	0.02	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	0.46	0.05	0.07	0.01	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.64	0.05	0.23	0.01	0.6

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

Table 17ff. 2013 Quality Control Data
Summaries of Statistical Analyses

STEAROYLCARNITINE (μmol C18/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1265 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	776	0.54	0.08	0.14	0.49	0.9
Non-derivatized - MS/MS non-kit	177	0.52	0.05	0.09	0.44	0.9
Derivatized - MS/MS PE NeoGram Kit	156	0.51	0.07	0.09	0.44	0.8
Non-derivatized - MS/MS PE NeoBase Kit	416	0.50	0.05	0.09	0.43	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	88	0.47	0.08	0.11	0.44	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.48	0.04	0.07	0.40	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	0.58	0.03	0.06	0.49	1.0
Lot 1266 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	775	1.34	0.15	0.28	0.49	0.9
Non-derivatized - MS/MS non-kit	179	1.35	0.12	0.23	0.44	0.9
Derivatized - MS/MS PE NeoGram Kit	157	1.23	0.12	0.22	0.44	0.8
Non-derivatized - MS/MS PE NeoBase Kit	413	1.32	0.12	0.21	0.43	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	1.33	0.21	0.36	0.44	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.24	0.08	0.19	0.40	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	1.46	0.11	0.17	0.49	1.0
Lot 1267 - Enriched 2.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	778	2.15	0.24	0.43	0.49	0.9
Non-derivatized - MS/MS non-kit	179	2.14	0.18	0.32	0.44	0.9
Derivatized - MS/MS PE NeoGram Kit	158	2.04	0.19	0.37	0.44	0.8
Non-derivatized - MS/MS PE NeoBase Kit	416	2.08	0.19	0.36	0.43	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	84	2.08	0.29	0.45	0.44	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	1.97	0.17	0.25	0.40	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	2.36	0.11	0.31	0.49	1.0
Lot 1268 - Enriched 5.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	768	4.82	0.50	0.95	0.49	0.9
Non-derivatized - MS/MS non-kit	180	5.04	0.44	0.82	0.44	0.9
Derivatized - MS/MS PE NeoGram Kit	158	4.64	0.46	0.82	0.44	0.8
Non-derivatized - MS/MS PE NeoBase Kit	411	4.89	0.42	0.77	0.43	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	85	4.81	0.64	1.16	0.44	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	4.68	0.25	0.63	0.40	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	20	5.55	0.33	0.46	0.49	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.

STEAROYLCARNITINE (µmol C18/L whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	779	0.67	0.09	0.15	0.68	0.8
Non-derivatized - MS/MS non-kit	184	0.66	0.06	0.11	0.67	0.9
Derivatized - MS/MS PE NeoGram Kit	145	0.67	0.08	0.10	0.69	0.9
Non-derivatized - MS/MS PE NeoBase Kit	486	0.69	0.05	0.08	0.69	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	105	0.67	0.10	0.14	0.62	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	0.63	0.08	0.11	0.64	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.65	0.05	0.14	0.67	0.9
Lot 1362 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	788	1.54	0.18	0.35	0.68	0.8
Non-derivatized - MS/MS non-kit	182	1.58	0.16	0.24	0.67	0.9
Derivatized - MS/MS PE NeoGram Kit	147	1.62	0.18	0.22	0.69	0.9
Non-derivatized - MS/MS PE NeoBase Kit	477	1.66	0.12	0.17	0.69	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	96	1.49	0.22	0.29	0.62	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	1.55	0.22	0.30	0.64	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.60	0.12	0.35	0.67	0.9
Lot 1363 - Enriched 2.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	777	2.30	0.26	0.50	0.68	0.8
Non-derivatized - MS/MS non-kit	180	2.36	0.24	0.34	0.67	0.9
Derivatized - MS/MS PE NeoGram Kit	145	2.38	0.22	0.29	0.69	0.9
Non-derivatized - MS/MS PE NeoBase Kit	495	2.51	0.20	0.29	0.69	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	98	2.17	0.32	0.48	0.62	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	2.29	0.24	0.38	0.64	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.41	0.16	0.50	0.67	0.9
Lot 1364 - Enriched 5.0 µmol/L whole blood						
Derivatized - MS/MS non-kit	781	4.78	0.50	1.08	0.68	0.8
Non-derivatized - MS/MS non-kit	183	5.04	0.48	0.86	0.67	0.9
Derivatized - MS/MS PE NeoGram Kit	150	5.08	0.46	0.61	0.69	0.9
Non-derivatized - MS/MS PE NeoBase Kit	489	5.39	0.41	0.59	0.69	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	95	4.82	0.69	1.05	0.62	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	4.94	0.48	0.72	0.64	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	5.10	0.37	1.08	0.67	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 17gg. 2013 Quality Control Data
Summaries of Statistical Analyses

HYDROXYSTEAROYLCARNITINE (μmol C18OH/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1361 - Nonenriched 0.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	523	0.01	0.01	0.01	0.01	0.6
Non-derivatized - MS/MS non-kit	76	0.01	0.00	0.01	0.01	0.5
Derivatized - MS/MS PE NeoGram Kit	118	0.02	0.01	0.01	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	362	0.00	0.00	0.01	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	106	0.01	0.01	0.01	0.01	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	43	0.00	0.00	0.00	0.00	0.4
Lot 1362 - Enriched 0.1 μmol/L whole blood						
Derivatized - MS/MS non-kit	542	0.08	0.02	0.03	0.01	0.6
Non-derivatized - MS/MS non-kit	73	0.06	0.02	0.06	0.01	0.5
Derivatized - MS/MS PE NeoGram Kit	115	0.09	0.03	0.03	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	348	0.07	0.01	0.02	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	109	0.05	0.02	0.03	0.01	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	46	0.05	0.01	0.01	0.00	0.4
Lot 1363 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS non-kit	547	0.29	0.05	0.12	0.01	0.6
Non-derivatized - MS/MS non-kit	71	0.25	0.05	0.30	0.01	0.5
Derivatized - MS/MS PE NeoGram Kit	119	0.34	0.07	0.08	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	345	0.29	0.03	0.05	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	109	0.19	0.06	0.12	0.01	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	45	0.21	0.02	0.04	0.00	0.4
Lot 1364 - Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS non-kit	546	0.58	0.08	0.24	0.01	0.6
Non-derivatized - MS/MS non-kit	72	0.52	0.08	0.53	0.01	0.5
Derivatized - MS/MS PE NeoGram Kit	115	0.66	0.09	0.13	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	346	0.58	0.06	0.10	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	110	0.37	0.08	0.24	0.01	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	46	0.43	0.04	0.07	0.00	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.

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