Newborn Screening Quality Assurance Program

2009 ANNUAL SUMMARY REPORT

Volume 27 February 2010

INTRODUCTION

The Centers for Disease Control and Prevention's (CDC) Newborn Screening Quality Assurance Program (NSQAP) is designed to help screening laboratories achieve excellent technical proficiency and maintain confidence in their performance while processing large volumes of specimens daily. CDC continually strives to produce certified dried-blood spot (DBS) materials for reference and quality control (QC) analysis, to improve the quality and scope of services, and to provide immediate consultative assistance. By working closely with program participants, we make necessary adjustments to meet their growing and changing needs. CDC always welcomes comments and suggestions about how we may better serve the newborn screening laboratories.

A major public health responsibility, newborn screening for detection of treatable, inherited metabolic diseases is a system consisting of six parts: education, screening, follow-up, diagnosis, management, and evaluation. Effective screening of newborns by use of DBS specimens collected at birth, combined with follow-up diagnostic studies and treatment, helps prevent mental retardation and premature death. These blood specimens are collected routinely from more than 98% of all newborns in the United States. State public health laboratories or their associated laboratories routinely screen DBS specimens for inborn errors of metabolism and other disorders that require intervention. For more than 31 years, the CDC, with its cosponsor, the Association of Public Health Laboratories (APHL), has conducted research on materials development and assisted laboratories with quality assurance (QA) for these DBS screening tests. The QA services primarily support newborn screening tests performed by state laboratories; however, CDC also accepts other laboratories and international participants into the QA program. All laboratories in the United States that test DBS specimens participate voluntarily in NSQAP. The program provides QA services for congenital hypothyroidism, phenylketonuria, galactosemia, congenital adrenal hyperplasia, maple syrup urine disease, homocystinuria, tyrosinemia, citrullinemia, succinylacetone (SUAC), biotinidase deficiency, cystic fibrosis (CF), and hemoglobinopathies. QA services are also provided for urea cycle disorders, fatty acid oxidation disorders, and organic acid metabolic disorders. The QA program consists of two DBS distribution components: QC materials for periodic use and quarterly proficiency testing (PT). The QC program enables laboratories to achieve high levels of technical proficiency and continuity that transcend changes in commercial assay reagents while maintaining the requisite high-volume specimen throughput. The QC materials, which supplement the participants' method- or kit-control materials, allow participants to monitor the long-term stability of their assays. The PT program provides laboratories with quarterly panels of blind-coded DBS specimens and provides an independent external assessment of each laboratory's performance. DBS materials for QC and PT are certified for homogeneity, accuracy, stability, and suitability for all kits manufactured by different commercial sources.

Over the last ten years, NSQAP has grown substantially, both in the number of participants and in the scope of global participation (Figure 1). In 2009, 448 newborn screening laboratories in 61 countries (at least one laboratory per country) were active program participants (Figure 2); of these, 355 participated in the PT component (Figure 3) and 360 in the QC part (Figure 4). Two hundred laboratories reported PT data by use of tandem mass spectrometry (MS/MS). Of these, 61 were

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
and the
Association of Public Health Laboratories

FROM THE

EDITOR

Carla Cuthbert, PhD . . . NSQAP's New Director

We proudly announce the selection of Dr. Carla Cuthbert as the new director of CDC's Newborn Screening Quality Assurance Program (NSQAP). She is the second person to hold that position. Dr. W. Harry Hannon, who created and nurtured the NSQAP to its present status, retired in early 2009 after more than 40 years of dedicated service to CDC and to newborn screening.

Carla is board-certified in Clinical Laboratory Biochemical Genetics from both the American College of Medical Genetics and the Canadian College of Medical Geneticists. She has co-authored a number of book chapters and journal articles and has presented on topics related to newborn screening and clinical chemistry. Carla comes to us from the Department of Pediatrics at the Miller School of Medicine, University of Miami, Florida, where she was Director of Miami's UHealth Biochemical Genetics Laboratory.

She received her Ph.D. in Pathology from Queen's University, Kingston, Ontario, Canada. Her undergraduate degree was in Biochemistry from McMaster University, Hamilton, Ontario, Canada.

We look forward to getting to know Carla, working under her direction, being mentored by her, and supporting her efforts and ideas to meet demands and developments in the worldwide newborn screening community.

Carla, Welcome Aboard!

Carol J Bell

Editor and Program Administrator

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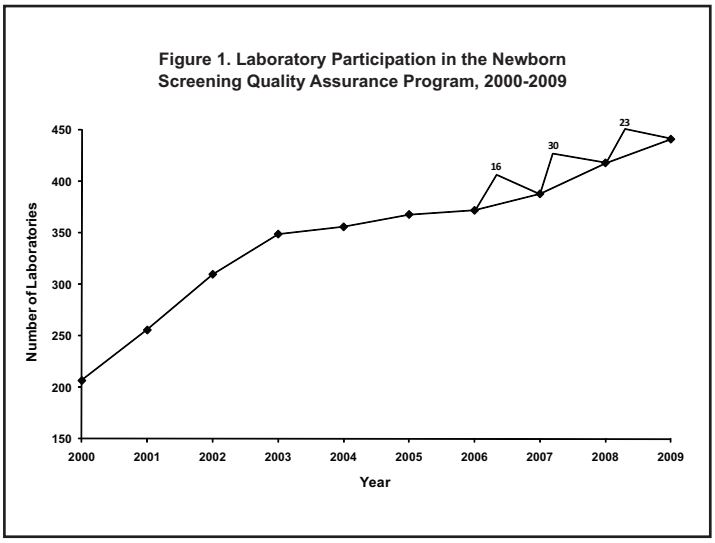
Program Information Web site:
http://www.cdc.gov/labstandards/nsqap.htm

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

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services or the Association of Public Health Laboratories.



domestic laboratories. MS/MS has made a major impact on the data reported to NSQAP. DBS materials for 38 analytes, covering primary markers for 48 disorders, were distributed to participating laboratories (Figures 3–4). This report presents an overview of all phases of the PT program and summarizes all QC data reported in 2009. For biotinidase, galactose-1-phosphate uridyltransferase (GALT) deficiency, and hemoglobins, QC materials were not distributed because of the limited availability of appropriate blood sources.

NEW ACTIVITIES

On January 2, 2009, Dr. Harry Hannon, NSQAP chief, retired after almost 40 years of federal service. Nevertheless, he was contracted to continue his work with us over the last year while a search was undertaken to find his successor. Dr. Carla Cuthbert became NSQAP chief in December.

The NSQAP PT data-reporting Web site was upgraded first in January and again in July with the capability to report results of more acylcarnitines. The latest additions to the acylcarnitines PT panel are C0(Low), C5OH, and C18. These analytes were also added to the UDOT program. Furthermore, NSQAP began evaluating the addition of C5:1, C4OH and C16OH into its PT panels for distribution beginning in January 2010. The inclusion of these six acylcarnitines will result in NSQAP's complete coverage of the 28 primary (core) conditions/analytes included in the American College of Medical Genetics (ACMG) recommended uniform panel for newborn screening programs (hearing tests excluded) and all 25 secondary (target) conditions/analytes upon receipt of C10:2 (currently under synthesis).

In January, NSQAP launched its paperless QC data-reporting system through Excel file or PDF file by e-mail.

Annual Report Dedicated to Laessig and Schmidt

Both men were true friends of the newborn screening community and are greatly missed by all of us. For their outstanding scientific achievements and countless contributions, we dedicate this Newborn Screening Quality Assurance Program Annual Summary Report to them.

Ronald H. Laessig
1940-2009

Benjamin Schmidt
1931-2009

Ronald H. Laessig died March 29, 2009. He was Emeritus Director of the Wisconsin State Laboratory of Hygiene and Emeritus Professor of Population Health Sciences at the University of Wisconsin Medical School. Beginning in 1979 when he inspired colleagues to organize *A National Model for Standardization of Neonatal Hypothyroid Screening Programs*, the first national conference on newborn screening, he worked diligently and tirelessly for over 40 years to advance the quality of laboratory testing, training, and management. He had a unique sense of humor and always enjoyed telling topic-related stories during his presentations.

Benjamin J. Schmidt died June 6, 2009. He was a renowned pediatrician in São Paulo, Brazil, whose interest always focused on inborn errors of metabolism. A 1990 Brazilian federal law, which was the culmination of many years of work dedicated to newborn screening, established mandatory testing and treatment of metabolism anomalies in newborns as idealized by Dr. Schmidt in 1973. In honor of his dedication and commitment to newborn screening in Brazil and Latin America, the Brazilian Society of Newborn Screening has established a prize called the *Benjamin Schmidt – a Pioneer* award for the best submitted work.

2009
NSQAP
BY THE NUMBERS

100 percentage of states covered

61 countries participated

879,790 DBS produced

28 employees

31 new enrollments

14 labs moved to inactive status

448 labs enrolled at year end

441 labs reported data

355 labs participated in PT

360 labs participated in QC

17 reports provided to participants

3 filter paper lots evaluated

31 US labs participated when NSQAP was established in 1978

Source: Newborn Screening Quality Assurance Program, December 2009

We urge everyone to report their QC data by the new e-mail data-reporting system.

In April, UDOT, a special PT panel, replaced one of the PT events within NSQAP's routine quarterly PT program. Seventy-one laboratories in the United States and Canada participated. All interactions between NSQAP and participants were handled completely by e-mail. There was a 16-day time period between shipping day and data deadline. Most participants liked UDOT because the PT simulated screening practice. The report for this program can be found online at http://www.cdc.gov/labstandards/nsqap_reports.htm.

NSQAP continued a PT program for laboratories testing DBS for IgM antibodies to *Toxoplasma gondii*. The program had twelve participants; most were from outside the United States. Quarterly reports for this program can be found online at http://www.cdc.gov/labstandards/nsqap_reports.htm.

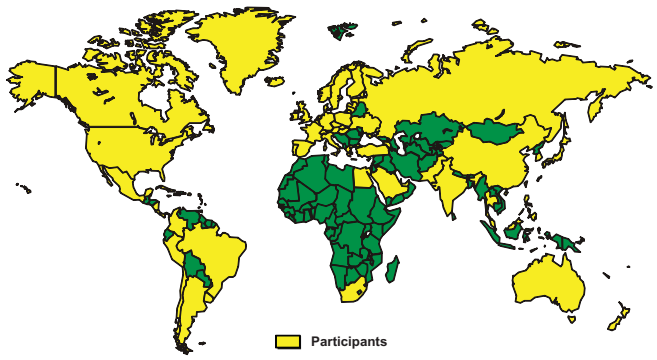
A few years ago APHL organized a subcommittee of the Newborn Screening and Genetics in Public Health Committee. This subcommittee was charged with overseeing quality assurance/quality control/proficiency testing. One mission component of this subcommittee is to provide guidance to the NSQAP on procedures, policies, and activities for the quality assessment of laboratory testing. In March 2009, this subcommittee met in Atlanta, where the members discussed current issues. We believe that input from this subcommittee will enhance our continuing efforts to better serve our participants.

In May, NSQAP cosponsored with APHL the two-part training webcast, *Molecular Testing in Newborn Screening (*www.aphl.org/aphlprograms/nsg/Pages/moleculartesting.aspx). A total of 145 participants from around the world attended.

NSQAP continued the Cystic Fibrosis Mutation Detection PT program for DNA testing (CFDNA). The number of participants grew from 37 in 2008 to 45 by the end of 2009. The quarterly CFDNA data are summarized in reports posted at http://www.cdc.gov/labstandards/nsqap_reports.htm. The CDC Cystic Fibrosis Mutation Dried-Blood Spot Repository now includes all 23 of the ACMG-recommended panel for population screening and 15 other less common mutations.

In October, Tera Mize was presented with the 2009 Friends of Children Award given by the Georgia Chapter of the Academy of Pediatrics. This award was presented for her efforts to raise awareness and improve newborn screening (NBS) through the foundation she started,

FIGURE 2. Sixty-one Countries Participated in the Newborn Screening Quality Assurance Program in 2009



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

One or more laboratories represented for each country listed.

Save Babies Through Screening Foundation. It is a non-profit volunteer organization devoted exclusively to NBS advocacy and is where parents and professionals find and contribute up-to-date NBS information.

In November, the Newborn Screening Translation Research Initiative (NSMBB and CDC Foundation) sponsored a training program, *Newborn Bloodspot Screening for Lysosomal Storage Disorders Workshop*, held in Atlanta, GA. Forty participants attended from seven U.S. states, Europe, and Asia.

NSQAP continued the pilot PT program to investigate materials and clinical interpretations, based on the ratio of 17-OHP, androstenedione, cortisol, 21-deoxycortisol, and 11-deoxycortisol for second tier CAH screening by use of LC-MS/MS. Ten laboratories participated in three quarterly surveys, and two new laboratories will be added in 2010. A presentation, *Proficiency Testing for Second Tier CAH Screening – Towards Harmonization of Results*, was presented at the 6th ISNS European Regional Meeting, held in Prague, Czech Republic, in April 2009.

NEWBORN SCREENING TRANSLATION RESEARCH INITIATIVE

The CDC Newborn Screening Translation Research Initiative (NSTRI) completed its fourth year of operation in 2009. NSTRI is an ongoing collaboration between the CDC Foundation and the CDC Newborn Screening and Molecular Biology Branch. The vision of NSTRI is the methodical expansion of newborn screening to detect more conditions in more infants around the world so that all babies with identified congenital disorders have a better chance for a healthy childhood. The mission of NSTRI is to assemble 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," but a better description for NSTRI would be "from bench to bassinet." One of the most critical processes in translating laboratory research methods to practical newborn screening assays is the integration of quality assurance systems. The ultimate goal of NSTRI is to help transform research methods into routine assays that become part of NSQAP as they are adapted for routine population-based newborn screening. All NSTRI projects include collaboration with public health newborn screening programs.

During its fourth year of operation, NSTRI continued to focus on several disorders and the innovative laboratory methods to detect newborn biomarkers for them. The disorders that were targeted in these projects included lysosomal storage disorders (LSD), severe combined immune deficiency (SCID), and neuromental disorders such as epilepsy and autism. More than a dozen partnerships were involved in these projects, and many of the partners contributed both scientific and financial support. NSTRI co-organized two meetings in 2009, one on LSD and one on SCID, bringing state public health laboratory scientists together with other scientists, federal agency officials, and parent advocates.

For more information about NSTRI or any of its current projects, please contact Dr. Robert Vogt at rvogt@cdc.gov. Ideas for new projects and partnerships are welcomed.

Figure 3. Number of Participants in Proficiency Testing Program, 2009
Total - 355

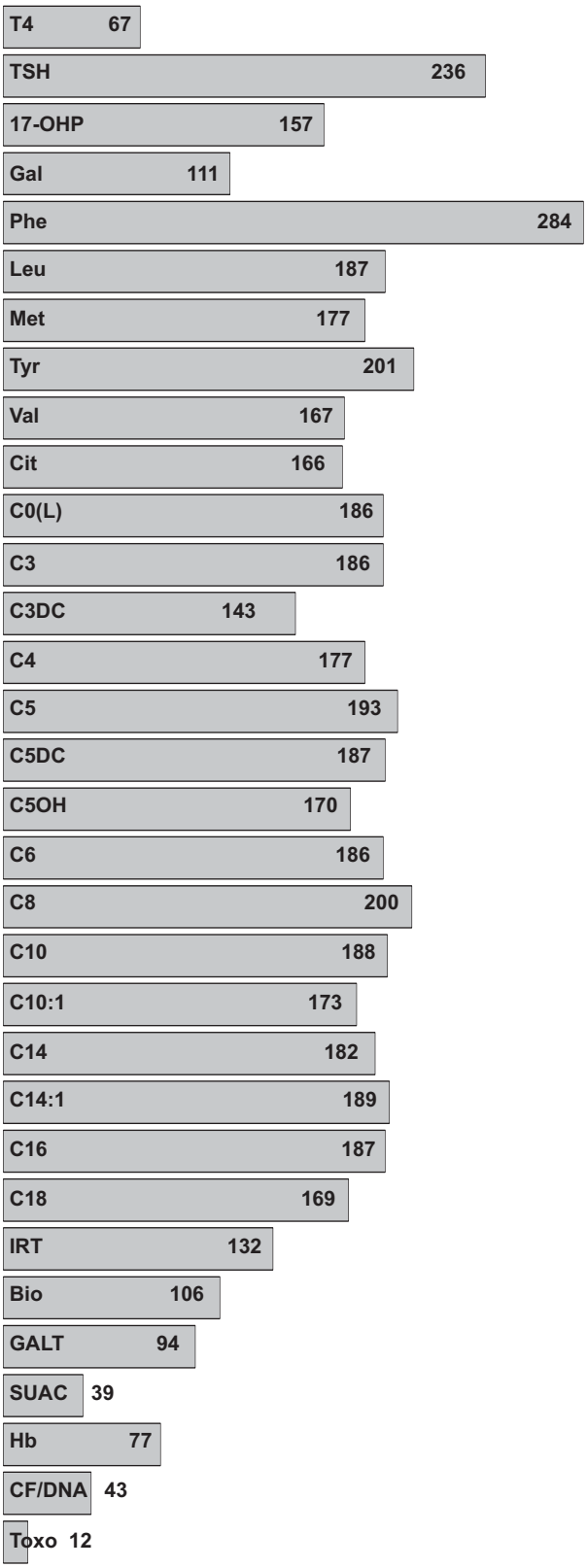
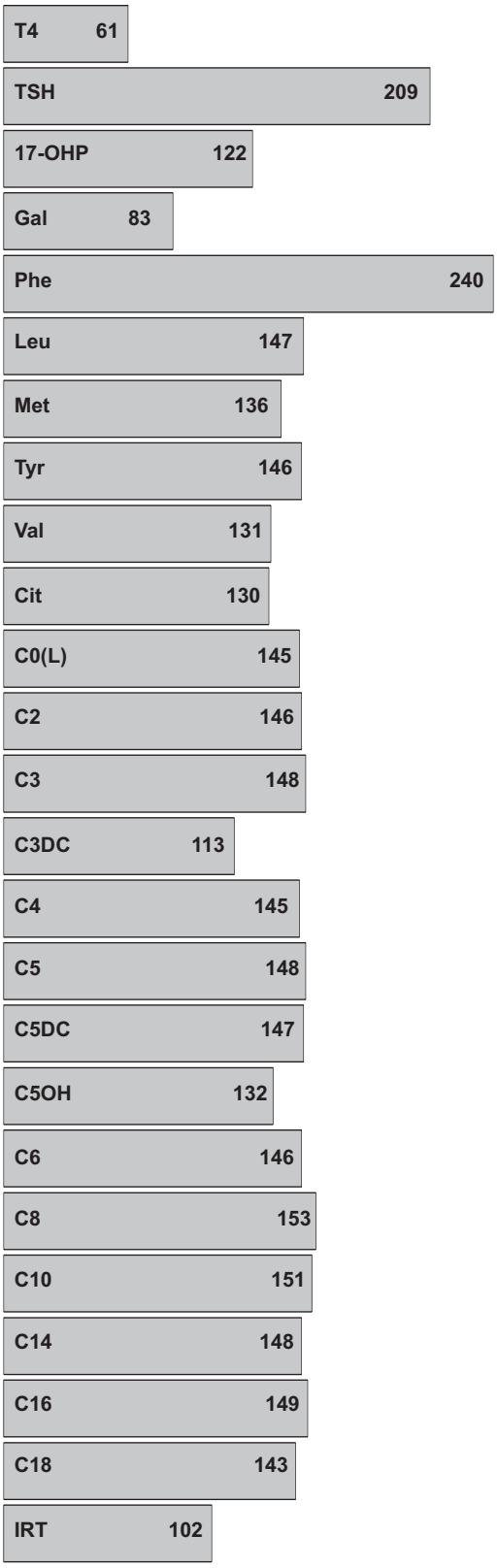


Figure 4. Number of Participants in Quality Control Program, 2009
Total - 360



FILTER PAPER

The paper disk that is punched to aliquot DBS specimens is a volumetric measurement that requires a degree of uniformity among and within production lots. As part of the QA program, we used an isotopic method[1] developed at CDC to evaluate and compare different lots of filter paper. Mean counts per minute of added isotope-labeled thyroxine (T_4) within a 1/8-inch disk were equated with the serum volume of the disks from the dried whole blood specimens. In comparing production lots, we used statistical analyses of the counting data to determine values for homogeneity, absorption time, and serum absorption of the disks. We also measure spot diameters to ensure that they are within acceptable (CLSI) limits.[1] Lysed-cell whole blood was used initially to avoid variability contributed by uncontrolled red blood cell (RBC) lysis during the 4-day QC production span. Results of later studies concluded that RBC lysis occurring during processing of the intact-cell blood pools was not sufficient to contribute substantially to the variance. For historical reference and for maintaining uniformity of testing on all the paper production lots, we have continued using the lysed-cell procedure (Figure 6). We also measure performance with intact-cell preparations (Figures 5 and 7). Intact-cell evaluation studies were confirmed by comparison to data from the lysed-cell evaluation. The published and standardized acceptable serum volumes per 1/8-inch disk are 1.30 ± 0.19 µL (mean value and 95% confidence interval [CI]) for lysed-cell blood and 1.54 ± 0.17 µL for intact-cell blood.[1] The mean serum volume per 1/8-inch disk for lysed-cell blood differs from that of intact-cell blood. The mean values and CIs are the filter-paper evaluation parameters published in the Clinical and Laboratory Standards Institute (CLSI), formerly NCCLS-approved standard.[1] 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.[1] In 2006, the mean value and CI for the intact-cell measurements were examined and discussed during a routinely scheduled review period for revision of the LA4 standard. The CLSI committee retained the original values (not produced at CDC) for intact cells in the revised standard. The mean value and 95% CI for intact cells (Figures 5 and 7) are the values based on CDC data covering more than ten filter paper lots.

2 New countries joined NSQAP: Nicaragua and Slovak Republic

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2009 were W051 and W071 of Grade 903. All filter paper lots were analyzed for agreement with the evaluation parameters according to the CLSI-approved standard.[1]

Each year, with the extensive cooperation of the manufacturers (Whatman Inc., Fairfield, NJ, and Ahlstrom Filtration LLC, Holly Springs, PA) of filter paper approved (cleared) by the Food and Drug Administration (FDA) for blood collection, we have routinely evaluated new lots and compared new lots with previous lots. The criteria for acceptable performance are the limits established in the CLSI standard.[1] A manufacturer also is expected to establish its own testing program using the CLSI standard and to make available to the user its certification data for each distributed lot of paper. The independent evaluations by CDC are an impartial and voluntary service offered as a function of our QA program; they do not constitute preferential endorsement of any product.

The serum-absorbance volumes of 27 lots of Grade 903 filter paper (Whatman Inc.) determined from lysed RBCs (Figure 6) and for 17 lots determined from intact RBCs (Figure 7) are shown in chronological order. For W091, the most recent production lot of Grade 903 filter paper, we found the mean serum-absorbance volume was 1.35 µL for a 1/8-inch disk for lysed-cell blood and 1.46 µL per 1/8-inch disk for intact-cell blood. Each mean value is within the acceptable range for the matrix

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2009 were W051 and W071 of Grade 903.

used. Lot W091 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within the acceptable limits). Our data for a production lot depend on the filter paper sample provided by the manufacturer as being representative of the entire production batch—i.e., statistically valid sampling.

In 2008, the FDA approved the filter paper, Grade 226, produced by Ahlstrom Filtration LLC (Holly Springs, PA) as a blood collection device. CDC evaluated Grade 226 according to the criteria previously described.[1] The serum-absorbance volumes for six lots of Grade 226 filter paper determined from intact RBCs are shown in chronological order (Figure 5). Data and plot are not currently available for the lysed-cell preparations on the Ahlstrom filter paper; only intact-cell data are shown. For 8040201, the most recent production lot of Grade 226 filter paper, we found the mean serum-absorbance volume was 1.60 µL for a 1/8-inch disk for intact-cell blood. Each mean value was within the acceptable range for the matrix used. Lot 8040201 was homogeneous (i.e., the measured variance was within the acceptable limits).

SPECIMEN PREPARATION AND DATA HANDLING

Tables and figures show the enriched concentrations of PT specimens and QC lots as well as the summarized quantitative data. The total concentration of each specimen or lot equaled the sum of the enriched concentration and the endogenous concentration (nonenriched). For T_4 PT specimens, the CDC assayed values were reported because of differences in the blood sources used for DBS production. Some specimens were enriched above the endogenous T_4 concentration, and some were enriched with T_4 after T_4 depletion of the base serum. The majority of DBS specimens in the amino acids and acylcarnitines PT panels were prepared from whole blood of 50% hematocrit, but a few were from our 55% hematocrit specimen stock. All other PT specimens were prepared from whole blood of 50% hematocrit. All QC lots were prepared from whole blood of 50% hematocrit. Purified analytes or natural donor blood, except for thyroid-stimulating hormone (TSH) which used the Third International Reference Preparation (81/565), were used for all enrichments. For galactosemia, enrichments were made with galactose and galactose-1-phosphate so that both free galactose (galactose alone) and total galactose (free galactose plus galactose present as galactose-1-phosphate) could be measured. For biotinidase, GALT, and CFDNA, individual donor blood from adults with these disorders was used, with the hematocrit adjusted to 50%. CDC assayed values were used as PT expected values for T_4, immunoreactive trypsinogen (IRT), GALT, C3DC, C5DC, C5OH, C10:1, C14:1, and C18. All reported analytic values outside the 99% CI were excluded from the summaries of quantitative results.

For obtaining data on the QC materials, we estimated the method response to endogenous materials by performing weighted linear regression analyses for mean-reported concentrations versus enriched concentrations. We then extrapolated the regression lines to the Y-axis (intercept) to obtain an estimate of the observed endogenous analyte concentration for each method category. These estimates are reliable when (1) enrichments are accurate, (2) the analytic method gives a linear response across the range of the measurements, and (3) the slopes for regression lines are approximately equal to one. In 2009, we applied the laboratory-reported specific cutoff values, when available, to our grading algorithm for clinical assessments; if no cutoff was reported, we used the NSQAP-assigned working cutoff values based on the national mean value for this assessment.

MASS SPECTROMETRY WORKGROUP

NSQAP's Mass Spectrometry Workgroup serves as a clearinghouse for MS/MS services and research for its participants. The workgroup is comprised of nine members tasked with providing NSQAP participants with QC and PT materials for amino acids, acylcarnitines, second-tier CAH testing, and LSDs. In addition, workgroup members are conducting research to expand NSQAP's analyte offerings in our MS/MS panels in order to include all primary and secondary biomarkers for the ACMG-recommended uniform panel for newborn screening programs.

Acylcarnitine PT panels shipped in January 2010 contain three additional acylcarnitines: tiglylcarnitine (C5:1), 3-hydroxybutyrylcarnitine (C4OH), and 3-hydroxypalmitoylcarnitine (C16OH). Furthermore, the workgroup has added arginine (Arg) to its 2010 amino acid PT panels. In July 2010, amino acid QC panels will contain Arg and SUAC. By adding these markers to the amino acids and acylcarnitine panels, NSQAP now covers 13 of the 14 primary and 7 of the 10 secondary/other MS/MS-detectable biomarkers listed to cover the ACMG-recommended disorders/analytes. The workgroup has commissioned the synthesis of 2,4-decadienoylcarnitine (C10:2) in order to complete our coverage of ACMG-recommended primary markers for both primary and secondary disorder targets.

While separate amino acid and acylcarnitine panels have been traditionally offered by NSQAP, workgroup members developed blood pools that contain amino acids

and acylcarnitines together in a single blood spot. We have a limited quantity of cards to distribute to interested NSQAP participants.

Workgroup members welcome the opportunity to investigate new analytes and mass spectrometry-based methods to better serve the needs of our participants. For more information about NSQAP's Mass Spectrometry Workgroup or any of its current projects, please contact Dr. Victor R. De Jesus at vdejesus@cdc.gov.

CUTOFFS

When reporting cutoff values, we requested the decision level for sorting test results reported as presumptive positive (outside limits) from results reported as negative (within limits). The reported cutoff values are summarized in Tables 1 and 2 for domestic and foreign laboratories. The values for mean (arithmetic average), median (middle value), and mode (most frequent value) are shown for each analyte. The mean cutoff values for domestic and foreign laboratories are similar except for 17-OHP, which is twice as high for domestic laboratories, and for non-MS/MS Tyr, which is 33% higher for foreign laboratories. The range (min/max) of cutoff values is large for TSH, 17-OHP, total galactose (Gal), IRT, Val, Leu, C3, C3DC, C5, and C14:1 for both domestic and foreign laboratories. The mean and median cutoff values for the MS/MS amino acids are similar for domestic and foreign laboratories; however, the range is larger for foreign laboratories. Mean cutoff values for Phe, C5DC, C10:1, and C14:1 are almost identical for domestic and foreign laboratories.

PROFICIENCY TESTING

All PT panels contained five blind-coded 75-µL DBS specimens. Specimens in the PT panels either contained endogenous levels or were enriched with predetermined levels of T_4, TSH, 17-OHP, Gal, IRT, Phe, leucine (Leu), methionine (Met), tyrosine (Tyr), valine (Val), citrulline (Cit), SUAC, and acylcarnitines (C0[L], C3, C3DC, C4, C5, C5DC, C5OH, C6, C8, C10, C10:1, C14, C14:1, C16, C18). CFDNA panels were made from the blood of either an adult or an adolescent CF donor. Separate panels for biotinidase deficiency and

Ahlstrom

FIGURE 5. Ahlstrom Grade 226 Specimen Collection Paper Serum Volume by Lot Number - Intact Red Blood Cells

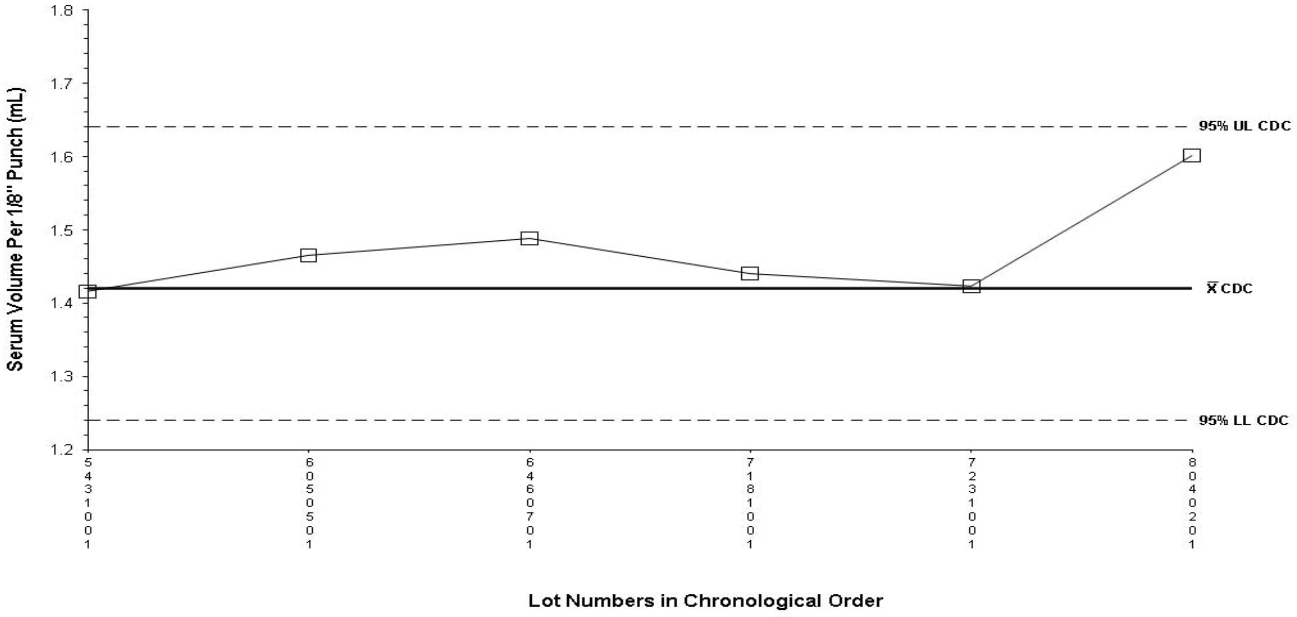
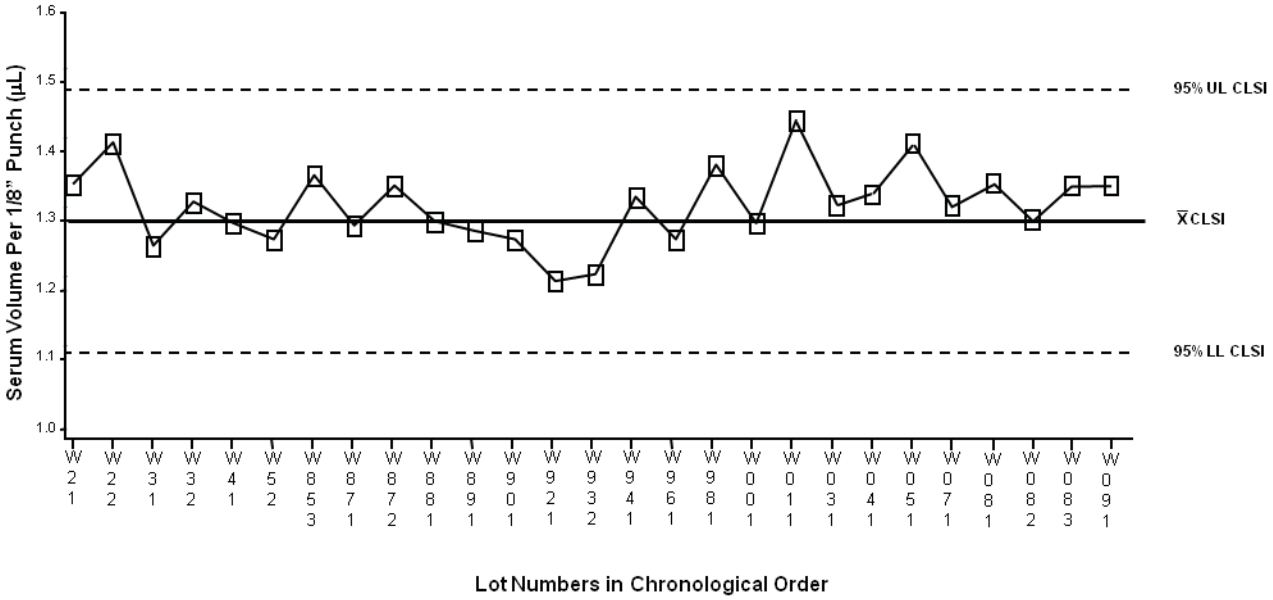


FIGURE 6. Whatman 903® Specimen Collection Paper
Serum Volume by Lot Number - Lysed Red Blood Cells



Whatman Inc.

FIGURE 7. Whatman 903® Specimen Collection Paper
Serum Volume by Lot Number - Intact Red Blood Cells

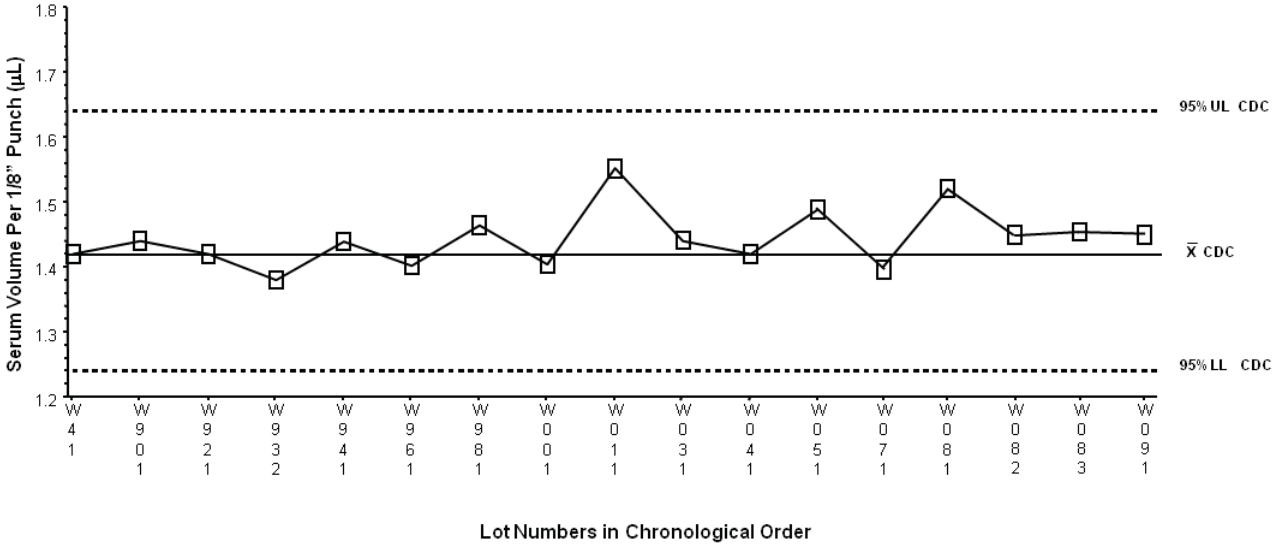


TABLE 1. 2009 Summary of Non-MS/MS Cutoff Values of Domestic and Foreign Laboratories

Domestic

Analyte	N	Mean	Median	Mode	Min/Max
T4	25	5.9	6.0	6.0	3.5-8.0
TSH	44	33.5	26.8	20.0	19.4-61.0
17-OHP	44	68.5	67.3	87.6	25-105
Galactose	21	11.6	10.0	10.0	6.5-20.0
Phenylalanine	9	153.89	151.50	181.80	121-206
Tyrosine	3	237.33	160.00	---	138-414
IRT	42	79.9	65.0	62.0	39.6-170
GALT	20	3.0	3.1	3.1	0.7-4.0

Foreign

Analyte	N	Mean	Median	Mode	Min/Max
T4	28	5.7	6.0	6.0	4.0-9.3
TSH	165	24.9	22.0	20.0	7.5-50.0
17-OHP	98	32.4	26.3	50.0	2.5-199.8
Galactose	74	11.6	10.0	10.0	3.0-30.0
Phenylalanine	67	164.61	151.50	121.20	61-242
Leucine	7	297.97	305.00	228.90	229-382
Tyrosine	6	356.43	398.50	200.00	200-500
IRT	81	68.9	70.0	70.0	40-150
GALT	30	2.9	3.1	3.5	1.2-5.0

for GALT deficiency were prepared with purchased blood from donors with enzyme deficiencies. Specimens for the hemoglobinopathies panel were prepared from umbilical cord blood. Specimen sets were packaged in a zip-close metallized plastic bag with desiccant, instructions for analysis, and data-report forms for laboratories that did not report data by Internet. We prepared and distributed quarterly reports of all results that had been received by the deadline dates. In this annual report, the comparisons of results by different methods (Figures 9–36) are illustrated with the participants' reported PT data for one selected challenge for each analyte during the year. These are compared by use of bias plots that show the difference (positive or negative) by laboratory and method of the reported value subtracted from the expected value, i.e., CDC-measured endogenous level plus enrichment; for T_4, IRT, GALT, C3DC, C5DC, C10:1, and C14:1 the reported value has been subtracted from the CDC assayed value. As you examine the bias plots, note the scale-changes of the Y-axis relative to the expected value for each plot. A reported value matching the expected value will show the illustrated value as falling on the "0" line of the plot. A reasonable bias is less than ± 20% of the expected value or within the 95% confidence interval (CI) for Figures 9–36. A summary of the specimen data for the selected-quarter PT challenge in 2009 is tabulated in the left margin for each figure.

The representative PT challenge specimens selected for the bias plots (Figures 9–36) were either above or below the cutoff value for the analyte. When comparing data scatter among figures, note that the scale (Y-axis) may differ. We included the 95% CI for the mean participant bias. Good performance of a method or group of methods is indicated by a tight scatter within this interval. In general, the quantitative comparisons (Figures 9–36) for PT challenges are reasonable within a method but they vary among methods. The PT quantitative results are grouped by kit or method to illustrate any method-related differences in analyte recoveries. Because some of the pools in a routine PT survey represent a unique donor specimen, differences in endogenous materials in the donor specimens may influence method-related differences.

Representative bias plots are shown for all analytes distributed in PT challenges during 2009 that required a quantitative measurement to determine the presumptive "clinical" assessments. The bias scatter plots for T_4 and TSH (Figures 9 and 10) indicate reasonable performance among all the users. Over the years, the number of T_4 users appears to be diminishing as more laboratories shift to TSH only as the primary screening method for CH. Most of the T_4 and TSH methods show good agreement among users with a tight scatter of values. The recovery

TABLE 2. 2009 Summary of MS/MS Cutoff Values of Domestic and Foreign Laboratories

Domestic

Analyte	N	Mean	Median	Mode	Min/Max
Phenylalanine	48	147.22	140.00	140.00	97.00-220.00
Leucine	46	276.15	300.00	300.00	200.00-400.00
Methionine	45	84.00	90.00	100.00	45.00-134.20
Tyrosine	47	390.41	363.50	400.00	88.00-700.00
Valine	38	282.33	275.00	275.00	175.00-444.60
Citrulline	45	60.51	60.00	75.00	27.00-100.00
SUAC	8	2.94	3.13	---	0.50-5.40
C0(L)	49	10.15	10.00	12.00	3.80-17.00
C3	50	5.87	6.00	6.50	1.20-10.0
C3DC	39	0.27	0.30	0.30	0.10-0.50
C4	45	1.41	1.40	1.80	0.49-2.14
C5	50	0.77	0.70	1.20	0.32-1.20
C5DC	50	0.28	0.32	0.35	0.05-0.53
C5OH	49	0.87	0.80	1.20	0.12-1.70
C6	47	0.44	0.39	0.70	0.16-0.88
C8	50	0.45	0.46	0.50	0.22-0.80
C10	47	0.48	0.45	0.60	0.22-1.17
C10:1	45	0.34	0.32	0.45	0.15-0.56
C14	45	0.78	0.77	0.70	0.17-1.18
C14:1	50	0.62	0.65	0.80	0.17-0.80
C16	49	7.49	8.00	9.00	0.30-10.00
C18	41	2.36	2.27	3.50	0.22-3.50

Foreign

Analyte	N	Mean	Median	Mode	Min/Max
Phenylalanine	130	148.98	142.00	150.00	49.10-400.00
Leucine	113	320.33	300.00	400.00	163.00-600.00
Methionine	111	61.30	59.00	80.00	20.50-101.00
Tyrosine	123	314.15	292.42	250.00	73.60-800.00
Valine	108	277.97	280.00	250.00	112.00-428.00
Citrulline	100	55.45	50.00	40.00	19.38-200.00
SUAC	25	3.58	3.50	1.20	0.98-10.00
C0(L)	93	8.89	10.00	10.00	3.00-15.00
C3	115	5.57	5.50	5.00	1.94-10.00
C3DC	87	0.49	0.30	0.25	0.08-5.62
C4	111	1.16	1.00	1.00	0.35-4.00
C5	121	0.74	0.67	1.00	0.06-2.00
C5DC	120	0.27	0.25	0.35	0.08-0.94
C5OH	106	0.83	0.88	1.00	0.07-3.50
C6	115	0.38	0.30	0.20	0.07-1.70
C8	127	0.40	0.38	0.50	0.11-1.00
C10	116	0.41	0.40	0.50	0.13-1.00
C10:1	106	0.33	0.30	0.30	0.10-1.00
C14	112	0.66	0.64	0.50	0.11-1.50
C14:1	119	0.61	0.44	0.40	0.11-11.00
C16	115	7.21	7.50	8.00	0.25-14.00
C18	105	2.23	2.00	1.80	0.10-9.00

TABLE 3. 2009 Summary of Proficiency Testing Errors by Domestic Laboratories

	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Hypothyroidism	136	0.0	269	0.4
Congenital Adrenal Hyperplasia	185	0.0	515	0.2
Galactosemia	99	0.0	271	0.4
Phenylketonuria	202	0.5	808	0.1
Maple Syrup Urine Disease (Leu)	162	0.0	648	0.8
Maple Syrup Urine Disease (Val)	138	0.0	552	0.4
Homocystinuria (Met)	155	0.0	620	0.0
Tyrosinemia I, II, III (Tyr)	173	1.7	692	0.1
Tyrosinemia I (SUAC)	88	1.1	62	1.6
Citrullinemia	153	0.0	612	0.0
C0(L) Screen	230	0.0	600	0.3
C3 Screen	111	0.0	729	0.4
C3DC Screen	91	0.0	574	0.5
C4 Screen	102	7.8	668	0.3
C5 Screen	113	2.7	742	0.0
C5DC Screen	111	0.0	744	0.3
C5OH Screen	110	0.9	385	0.0
C6 Screen	109	0.0	706	0.4
C8 Screen	114	0.0	751	0.4
C10 Screen	107	0.0	703	0.3
C10:1 Screen	53	0.0	472	0.4
C14 Screen	210	1.0	585	0.2
C14:1 Screen	111	0.0	734	0.0
C16 Screen	170	8.2	670	0.0
C18 Screen	102	5.9	408	0.0
Biotinidase Deficiency	172	0.6	473	0.4
GALT Deficiency	131	0.0	524	0.2
Cystic Fibrosis (IRT)	179	1.1	486	0.0

relative to expected value (EV) by participants is excellent with a small mean bias for all participants for T_4 and TSH. In Figure 11, the bias plot for IRT shows good recovery for the participants' mean relative to the CDC assayed value, although the values among participants show a large scatter and wide confidence interval. A similar situation is seen for the bias and scatter around the assay values with GALT in Figure 12. Four values reported for GALT are far outside the confidence interval. For 17-OHP in Figure 13, note that one method with many users shows values generally higher than the other methods. The participant mean value is in good agreement with the EV and yields a small mean bias value. With Gal in Figure 14, note that the scatter for one method is distinctly higher than that for all other methods and the participants' mean bias is small. The bias plot for Phe in Figure 15 illustrates a tight scatter of values with excellent agreement for the participants' mean bias and the EV. In Figure 16, the Leu values show a tight scatter for all methods with a small negative bias. With Met (Figure 17) all methods show a consistently negative bias with a large bias difference from the EV, except for the derivatized MS/MS kit method. The scatter for the Tyr bias values (Figure 18) is small and consistent within- and among-methods with close agreement between the mean bias and the EV. Figure 19 for Val illustrates good among-method variance and mean bias agreement with the EV. The Cit bias data (Figure 20) show one method with a distinct difference from all other methods, with a tight cluster of values and good agreement with the EV. For SUAC values in Figure 21, a highly clustered set of values with a negative bias is seen for the non-derivatized MS/MS kit method. The bias values for SUAC have a wide scatter and a large difference among methods and users. Only a few SUAC participants show good recoveries relative to the EV. A marked difference was observed for the derivatized non-kit and kit MS/MS methods. The number of SUAC participants is still relatively small.

Bias plots for derivatized and non-dervatized MS/MS methods are shown for all acylcarnitines as selected representative PT challenges in 2009. Enrichments made

TABLE 4. 2009 Summary of Proficiency Testing Errors by Foreign Laboratories

	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Hypothyroidism	155	1.9	310	8.4
Congenital Adrenal Hyperplasia	383	1.0	1062	1.0
Galactosemia	303	0.7	822	0.9
Phenylketonuria	580	0.5	2320	1.8
Maple Syrup Urine Disease (Leu)	352	1.1	1408	0.6
Maple Syrup Urine Disease (Val)	318	0.9	1272	0.7
Homocystinuria (Met)	333	0.6	1332	0.7
Tyrosinemia I, II, III (Tyr)	383	1.0	1532	0.3
Tyrosinemia I (SUAC)	207	4.3	143	5.6
Citrullinemia	298	1.7	1192	0.4
C0(L) Screen	460	0.0	1245	4.9
C3 Screen	237	2.1	1508	0.8
C3DC Screen	176	4.0	1154	1.6
C4 Screen	228	3.1	1452	1.0
C5 Screen	248	4.0	1577	1.0
C5DC Screen	237	1.7	1543	1.0
C5OH Screen	214	3.7	747	3.6
C6 Screen	236	3.4	1499	1.3
C8 Screen	257	1.2	1633	0.9
C10 Screen	240	2.1	1525	0.8
C10:1 Screen	111	5.4	969	1.4
C14 Screen	468	1.9	1252	1.1
C14:1 Screen	243	2.5	1547	0.6
C16 Screen	358	8.9	1402	0.4
C18 Screen	208	8.2	832	0.6
Biotinidase Deficiency	231	0.9	644	1.4
GALT Deficiency	134	0.0	536	0.2
Cystic Fibrosis (IRT)	302	0.0	813	0.2

with purchased or special synthesized acylcarnitines are based on weighed quantities. Slight variances in enrichments and recoveries may be attributed to impurities in the purchased (synthesized) materials and endogenous analyte concentrations. For C0(L) in Figure 22, although the scatter of values is tight for all methods, one method is different with a clustered positive bias for all users. A similar observation is seen for C3DC (Figure 24) and C5DC (Figure 27). For many of the acylcarnitines, the values for the derivatized MS/MS kit method are tightly clustered and different from the other MS/MS methods. NOTE: This same type of difference is observed also with Cit (Figure 20). The users of derivatized non-kit and kit MS/MS methods show a tight scatter within a method group, but different bias values. The bias data for C3 (Figure 23) and C4 (Figure 25) show a consistent scatter across all methods and the mean bias for both is in excellent agreement with the EV. In Figure 26 for C5, the bias values are minimally scattered with a consistently negative bias for all methods and the participant mean bias. The bias plot for C5OH (Figure 28) and C6 (Figure 29) illustrate a negative cluster of values for all methods with the mean bias in close agreement to the EV. For C8 (Figure 30), the values demonstrate a tight scatter around the expected values for all methods, and the participants' mean value is in close agreement with the EV. The derivatized MS/MS kit shows a close agreement among all users and this observation is similar for all acylcarnitines. 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 EV; however, a negative method bias is noted between the derivatized MS/MS kit and the derivatized non-kit methods. These clustered differences are similar to the MS/MS kit method differences observed for C3DC, C5DC, and Cit, but in the opposite (negative) direction. For C14 (Figure 33) and C14:1 (Figure 34), all methods show reasonable scatter, but one C14 method shows a negatively clustered bias. The mean bias for C14 and C14:1 is in excellent agreement with the EV. C16 (Figure 35) data demonstrate a tight cluster of values with most laboratories showing a negative bias. Figure 36 for C18

illustrates excellent agreement with the EV and reasonable scatter of values within- and among-methods. The derivatized MS/MS and non-derivatized kits show the best agreement and least scatter.

TABLE 5. 2009 Summary of Proficiency Testing Errors for Hemoglobinopathies by Domestic and Foreign Laboratories

Hemoglobinopathies	Domestic	Foreign
Specimens assayed	685	330
Phenotype errors	0.7%	1.5%
Clinical assessment errors	1.0%	1.5%

Overall, there were 10 phenotype errors, six FAS, two FA, and two FAC.

Tables 3 and 4 show the proficiency testing errors reported by disorder in 2009 for all qualitative assessments by domestic laboratories and by foreign laboratories. We applied the laboratory-reported specific cutoff values to our grading algorithm for clinical assessments (Figure 8). Presumptive clinical classifications (qualitative assessments) of some specimens may differ by participant because of specific clinical assessment practices. 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 distributed negative specimens and the rates for false-negative misclassifications on the number of positive specimens. False-positive misclassifications, which are a cost-benefit issue and a credibility factor for follow-up programs, 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 8.4%. For domestic laboratories, the rate was 0.4% or lower for 25 of 28 biomarkers or disorders; for foreign laboratories, the rate was 0.9% or lower for 14 of 28 biomarkers or disorders. Screening programs are designed to avoid false-negative reports; this precautionary design, however, contributes to false-positive reports and may cause many of the false-positive misclassifications. The false-negative rate, expected to be zero, ranged from 0% to 8.9%. False-negative classifications were reported for all biomarkers or disorders except GALT deficiency and C0(L) screen. For 16 biomarkers or disorders, no false-negative errors were reported for the domestic laboratories. A few of our PT specimens fell close to the decision level for classifications 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, and they are not included in Tables 3 and 4. Participants' data for these specimens are used to examine the relative analytical performance of the assays.

Table 5 shows the performance errors for hemoglobinopathies. The percentage of errors for qualitative assessments for sickle cell disease and other hemoglobinopathies ranged from 1.0% to 1.5% for the error categories, with 74 participants. Overall, there were ten phenotype errors for reported data for 2009. The classification errors were essentially the same for phenotype and clinical assessments within the domestic and foreign laboratory groups. Table 7 shows the phenotype challenges that were distributed in 2009 for hemoglobinopathies. In Table 6, methods that were used by participants are shown for multi-tier testing schemes to enhance the specificity of the initial screen for hemoglobinopathies. Most screening laboratories use isoelectric focusing and HPLC methods in only a single tier of testing. Many laboratories utilize second-tier testing with these same methods in repetitive or different

TABLE 6. Sickle Cell and Hemoglobinopathies Methods Used in Multi-Tier Testing for Proficiency Testing

Method	Isoelectric Focusing	BioRad HPLC	Extended Gradient HPLC	Chromsystems HPLC Kit	Electrophoresis - Citrate Agar
1st tier testing	33	39	2	1	2
2nd tier testing	15	15	6	0	2
3rd tier testing	1	0	1	0	3

TABLE 7. Hemoglobin Phenotype Challenges Distributed in 2009

Phenotype	N
FA	3
FS	0
FAC	4
FAS	6
FSC	0
FA Bart's	2

combinations, and only a few used a third-tier test. No screening laboratories report the application of DNA testing for their scheme.

Table 8 shows the performance errors for CFDNA mutation detection. The percentage of errors for qualitative assessments for genotype analysis was small, at 1% of the PT challenges. Table 9 shows the CF mutation (CFTR gene) challenges that were distributed in 2009 for CFDNA.

QUALITY CONTROL

For QC shipments of T_4, TSH, 17-OHP, IRT, Gal, amino acids (Phe, Leu, Met, Tyr, Val, Cit), and acylcarnitines (C0, C2, C3, C3DC, C4, C5, C5DC, C5OH, C6, C8, C10, C14, C16, C18), 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 the set of sheets from the production batch for each laboratory. The QC materials were distributed semiannually. They included the DBS sheets, instructions for storage and analysis, and data-report forms. Data from five analytic runs of each lot and shipment were compiled in the midyear and annual summary reports distributed to each participant. Intervals between runs were not the same for all laboratories because each participant's reported data cover a different time span.

The reported QC data are summarized in Tables 10a–10y, which 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. Linear regressions (Y-intercept and slope) were calculated by method for all analytic values within an analyte QC series. Values outside the 99% CI (outliers) were excluded from the calculations.

Tables 10a–10y provide data about method-related differences in analytic recoveries and method bias. 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. We calculated the within-laboratory SD component of the total SD and used the reported QC data from multiple analytic runs for regression analyses. We calculated the Y-intercept and slope in each table, using all analyte concentrations within a lot series (e.g., lots 911, 912, 913). 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

TABLE 8. Genotype Analysis of Cystic Fibrosis Mutation Detection Specimens in 2009

	Specimens Assayed (N)	Correct Results	Incorrect Results	Not Evaluated*	Sample Failure
Q1, 2009	190	99%	1%	10%	1%
Q2, 2009	204	99%	1%	12%	1%
Q3, 2009	200	99%	1%	17%	3%
Q4, 2009	215	99%	1%	5%	0%
Total	809	99%	1%	11%	1%

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

TABLE 9. Cystic Fibrosis Mutation (CFTR gene) Challenges Distributed in 2009

Mutation	N
Wild Type (no mutations)	16
F508del	10
G551D	2
W1282X	1
R560T	1
621+1G→T	1
N1303K	1
2789+5G→A	1
I507del	1
CFTRdelE2,3	1
G542X	1
3120+1G→A	1
L467P	1
621+1G→T	1
R1162X	1

endogenous concentration level for an analyte. For Phe, Leu, Met, Tyr, Val, and Cit, participants also measured the endogenous concentrations by analyzing the nonenriched QC lots; the Y-intercepts and measured endogenous levels for these analytes were similar for most methods. Ideally, the slope should be 1.0, and most slopes were close to this value; however, the range was 0.6 to 4.3 because of a few methods and analytes.

Slope deviations may be related 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.

REFERENCES

1. CLSI. *Blood collection on filter paper for newborn screening programs; Approved standard–Fifth edition*. CLSI document LA4-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.

FIGURE 8. EXPLANATION OF NSQAP GRADING ALGORITHM

Part 1.
The expected clinical assessment (EA) for a proficiency testing (PT) specimen is determined by comparing the expected value (EV), which is the sum of endogenous and enrichment values, with the CDC cutoff. The production of a PT specimen is designed so that the 99% confidence interval (CI) for the expected value (EV) of a positive specimen falls above the CDC cutoff, and the 99% CI for the expected value (EV) of a negative specimen falls below the CDC cutoff. Specimens that do not meet this 99% CI criterion are declared not-gradable/not-evaluated (NE).

Part 2.
When your reported clinical assessment (RA) differs from the expected clinical assessment (EA), the expected value (EV) is compared with the cutoff that you provide. This determines what your laboratory expected clinical assessment (LA) should be. If the expected clinical assessment (EA) and the laboratory expected clinical assessment (LA) are the same, but different from your reported clinical assessment (RA), your grade is either false-negative or false-positive. If the expected clinical assessment (EA) and the laboratory expected clinical assessment (LA) are not the same, your reported clinical assessment (RA) will not be graded as incorrect because of a significant difference between the CDC cutoff and your cutoff (see examples below). If you do not provide a cutoff, your laboratory expected clinical assessment (LA) cannot be determined; and your grade will be based on the CDC cutoff.

Part 3.
NSQAP's determination of a final clinical assessment for a specimen is based on the Clinical Laboratory Improvement Amendments (CLIA) regulations (http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.929), 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." A NSQAP gradable specimen must have 80% or more agreement among domestic laboratories. A specimen with less than 80% agreement is not-gradable/not-evaluated (NE).

Examples of Grading Scenarios

Analyte	CDC Cutoff	Expected Value (EV)	Lab Cutoff	Assessment: (EA) EV/CDC cutoff	Assessment: (LA) EV/Lab cutoff	Assessment: (RA) Lab reported	Lab Grade
TSH	25	13	30	Neg	Neg	Pos	FP
TSH	25	13	10	Neg	Pos	Pos	CD
Leu	4.1	6.7	4.5	Pos	Pos	Neg	FN
Leu	4.1	6.7	8.0	Pos	Neg	Neg	CD

FN = False negative
FP = False positive
CD = Cutoff Difference - clinical assessment is not judged as incorrect

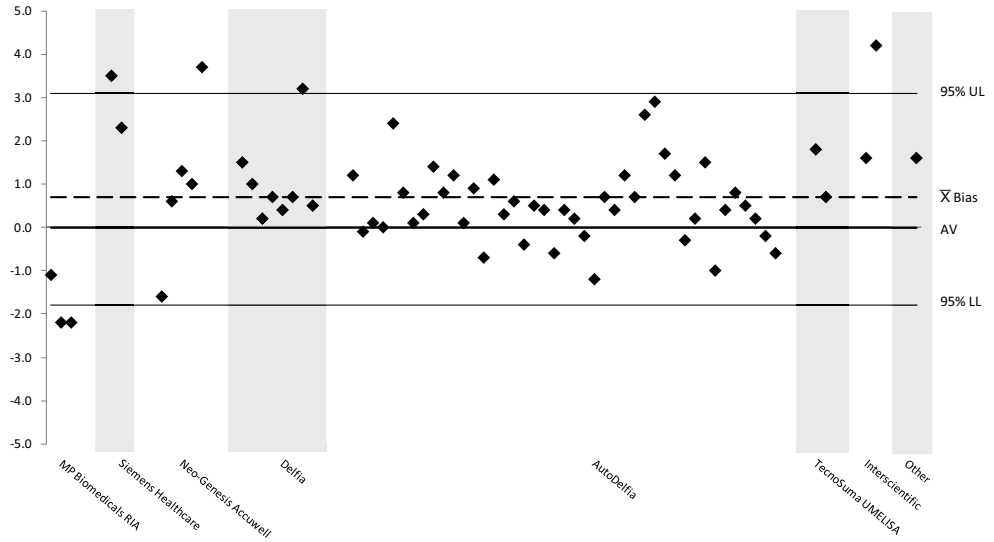
TSH = Thyroid-stimulating Hormone
Leu = Leucine

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

FIGURES 9-10. Reproducibility of Results by Different Methods – Thyroxine and Thyroid-Stimulating Hormone

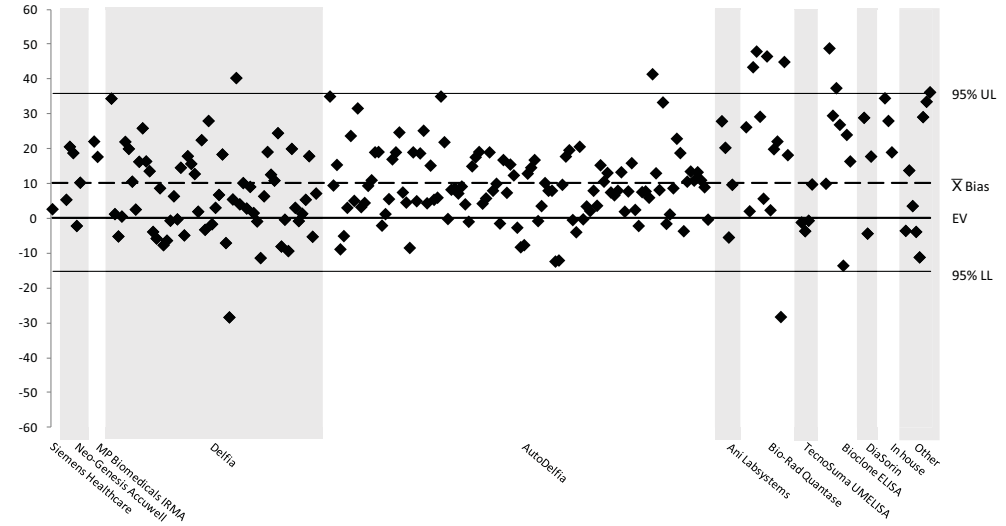
Quarter 1	
Specimen 2	
CDC Assayed	7.0
Participant Mean	7.7
Participant Bias[2]	0.7

Figure 9. Bias Plot of Thyroxine Values by Method
Quarter 1, Specimen 2
Assayed Value (AV)[3] 7.0 µg/dL serum



Quarter 3	
Specimen 4	
Enriched	80.0
CDC Assayed	81.4
Participant Mean	90.3
Participant Bias[2]	10.3

Figure 10. Bias Plot of Thyroid-Stimulating Hormone Values by Method
Quarter 3, Specimen 4
Expected Value (EV)[1] 80.0 µIU/mL serum



[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 Different Methods – Cystic Fibrosis (IRT) and Galactose-1-Phosphate Uridyltransferase (GALT)

Figure 11. Bias Plot of Cystic Fibrosis (IRT) Values by Method
Quarter 3, Specimen 4
Assayed Value (AV)[3] 144.5 ng/mL whole blood

Quarter 3	
Specimen 4	
CDC Assayed	144.5
Participant Mean	153.9
Participant Bias[2]	9.4

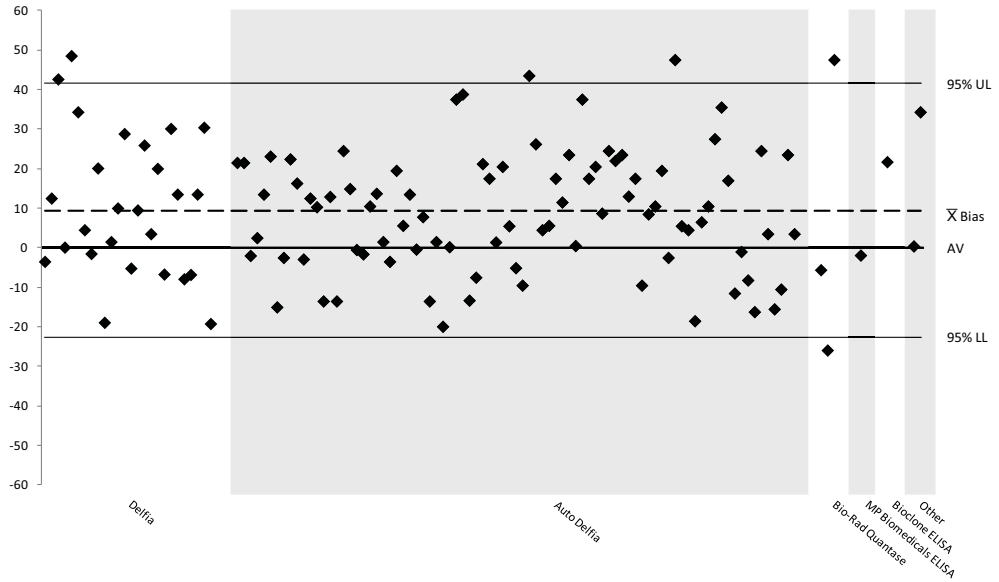
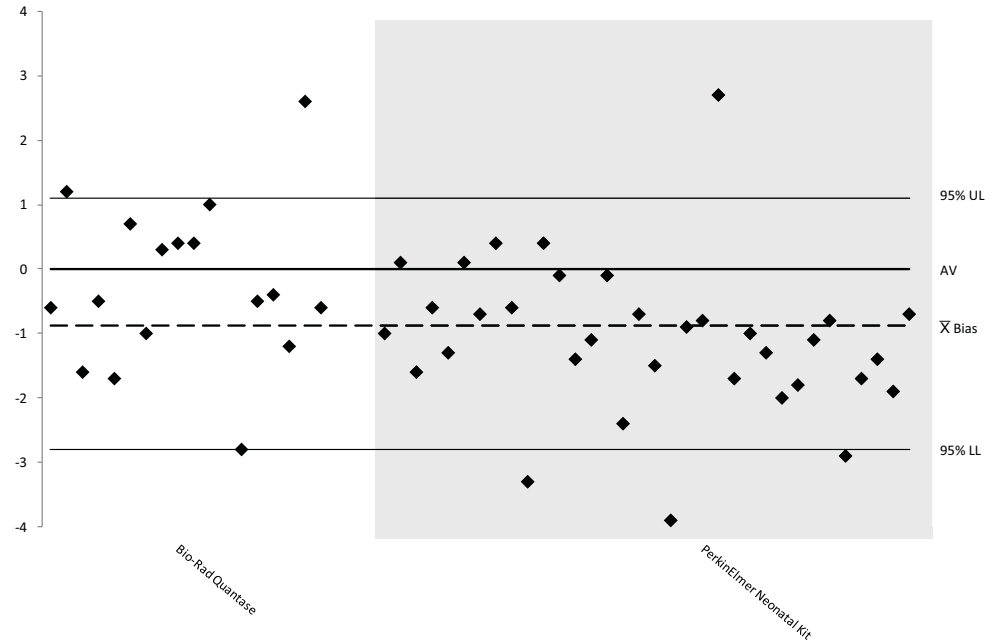


Figure 12. Bias Plot of Galactose-1-Phosphate Uridyltransferase (GALT) Values by Method
Quarter 3, Specimen 3
Assayed Value (AV)[3] 7.5 U/g Hb

Quarter 3	
Specimen 3	
CDC Assayed	7.5
Participant Mean	6.6
Participant Bias[2]	-0.9

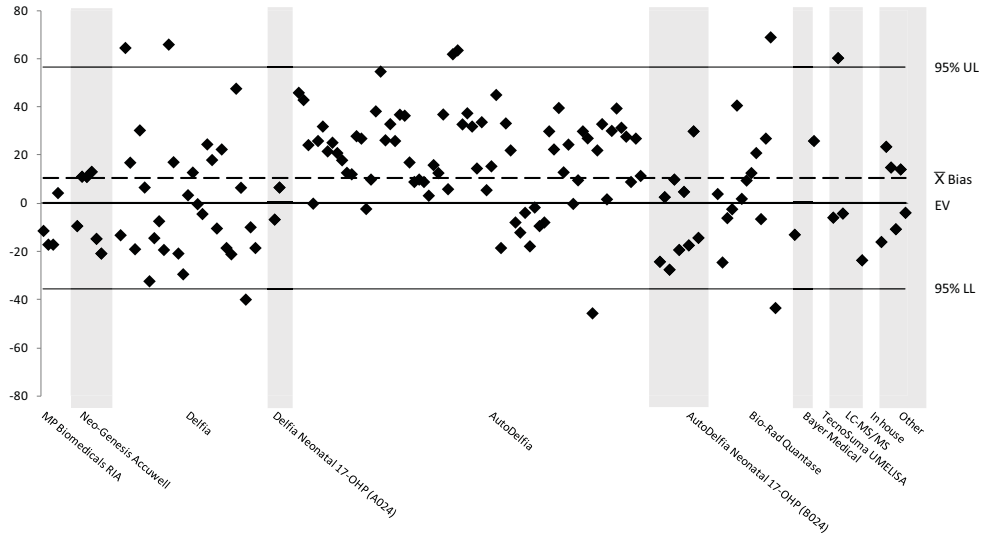


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\bar{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\bar{X}$) excludes outlier 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 Different Methods – 17 α-Hydroxyprogesterone and Total Galactose

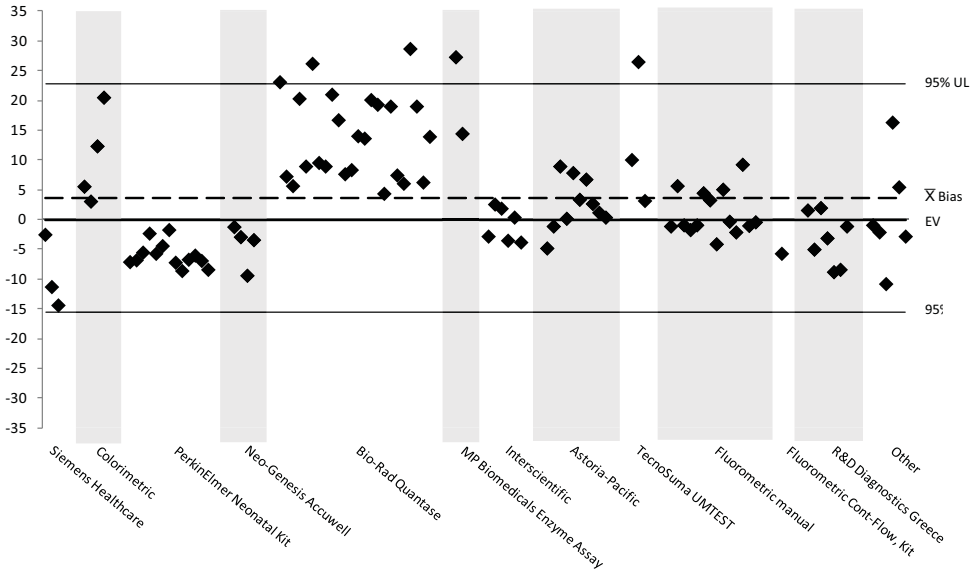
Quarter 1	
Specimen 2	
Enriched	98.0
CDC Assayed	87.6
Participant Mean	108.5
Participant Bias[2]	10.3

Figure 13. Bias Plot of 17 α-Hydroxyprogesterone Values by Method
Quarter 1, Specimen 2
Expected Value (EV)[1] 98.2 ng/mL serum



Quarter 3	
Specimen 1	
Enriched	30.0
CDC Assayed	31.2
Participant Mean	34.5
Participant Bias[2]	3.5

Figure 14. Bias Plot of Total Galactose Values by Method
Quarter 3, Specimen 1
Expected Value (EV)[1] 31.0 mg/dL whole blood

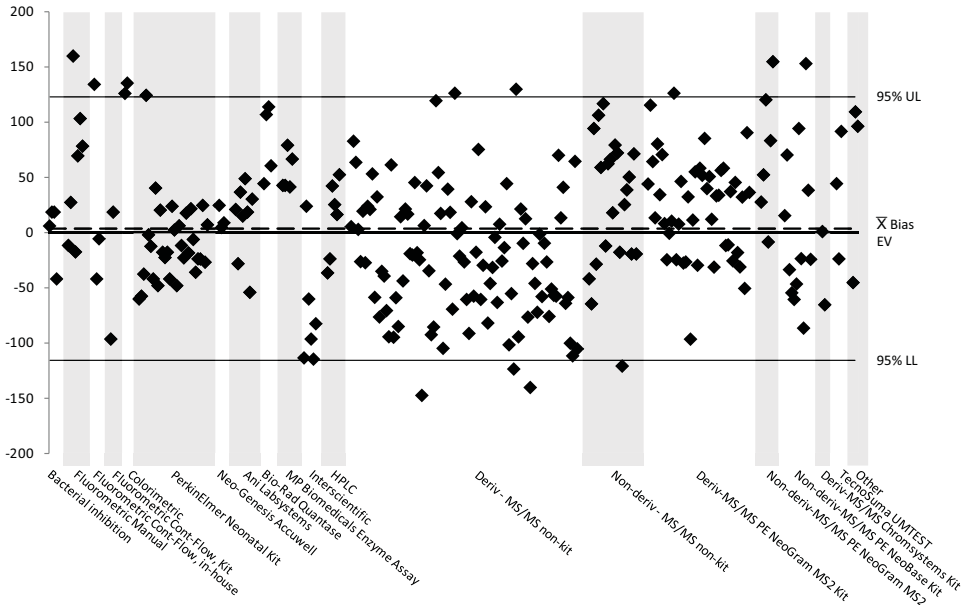


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\overline{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\overline{X}$) excludes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

FIGURES 15-16 Reproducibility of Results by Different Methods – Phenylalanine and Leucine

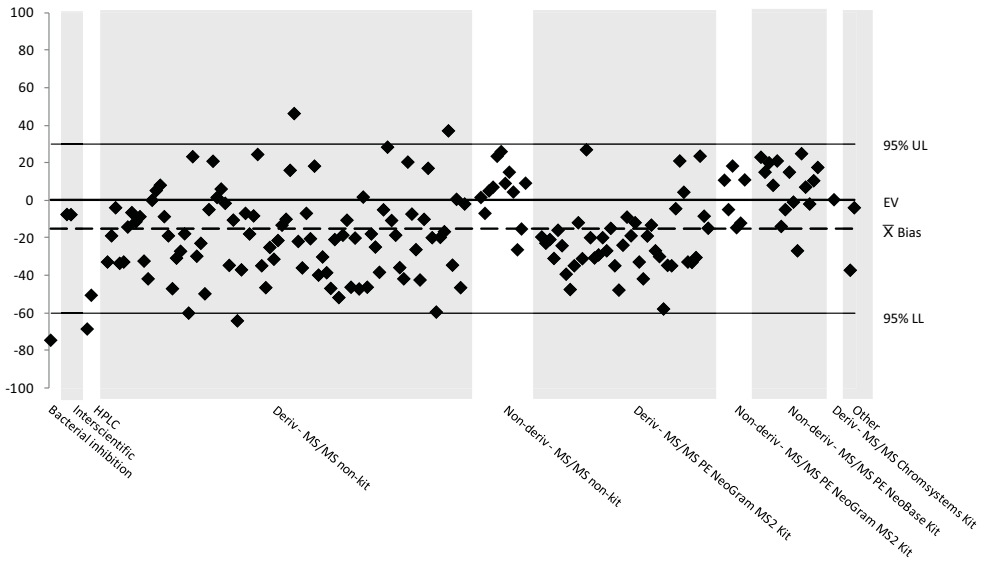
Quarter 1	
Specimen 3	
Enriched	363.60
CDC Assayed	387.84
Participant Mean	408.93
Participant Bias[2]	2.91

Figure 15. Bias Plot of Phenylalanine Values by Method
Quarter 1, Specimen 3
Expected Value (EV)[1] 406.02 µmol/L whole blood



Quarter 3	
Specimen 3	
Enriched	0.00
CDC Assayed	152.60
Participant Mean	129.64
Participant Bias[2]	-15.33

Figure 16. Bias Plot of Leucine Values by Method
Quarter 3, Specimen 3
Expected Value (EV)[1] 144.97 µmol/L whole blood

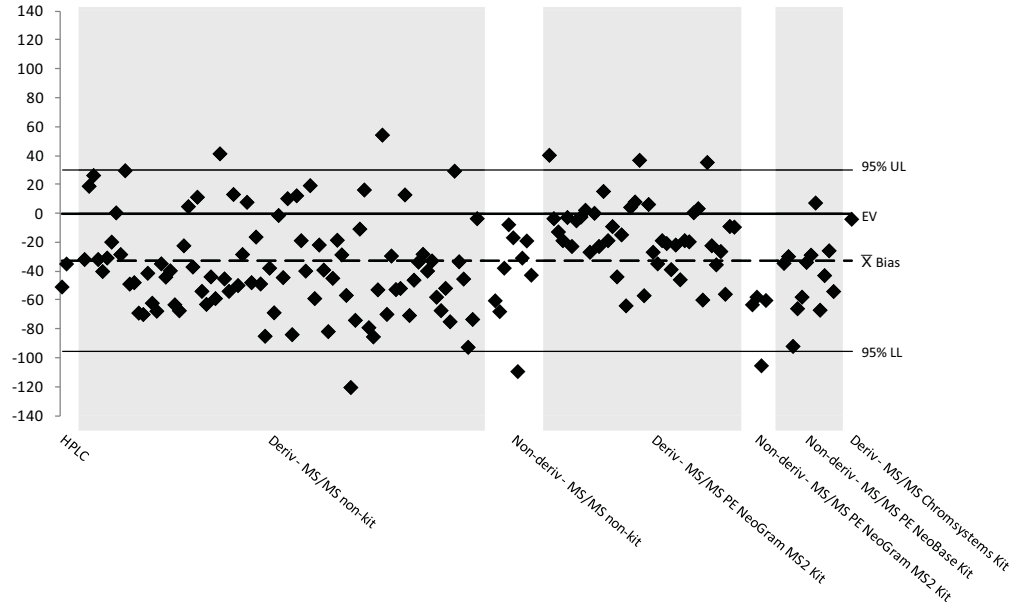


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\overline{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\overline{X}$) excludes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

FIGURES 17-18. Reproducibility of Results by Different Methods – Methionine and Tyrosine

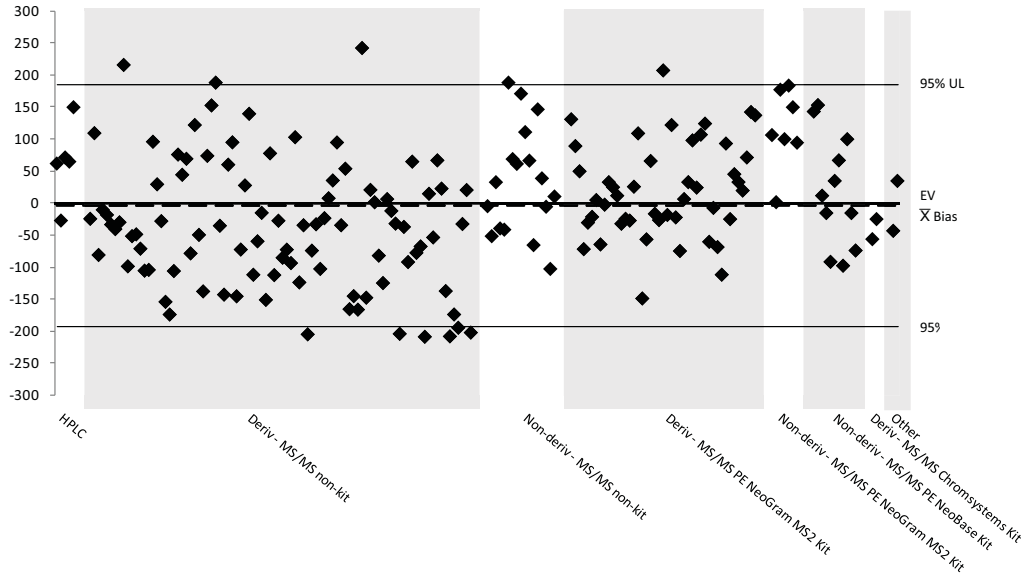
Quarter 1	
Specimen 5	
Enriched	234.85
CDC Assayed	248.27
Participant Mean	215.31
Participant Bias[2]	-32.96

Figure 17. Bias Plot of Methionine Values by Method
Quarter 1, Specimen 5
Expected Value (EV)[1] 248.27 µmol/L whole blood



Quarter 1	
Specimen 1	
Enriched	607.20
CDC Assayed	618.24
Participant Mean	663.55
Participant Bias[2]	-4.37

Figure 18. Bias Plot of Tyrosine Values by Method
Quarter 1, Specimen 1
Expected Value (EV)[1] 667.92 µmol/L whole blood

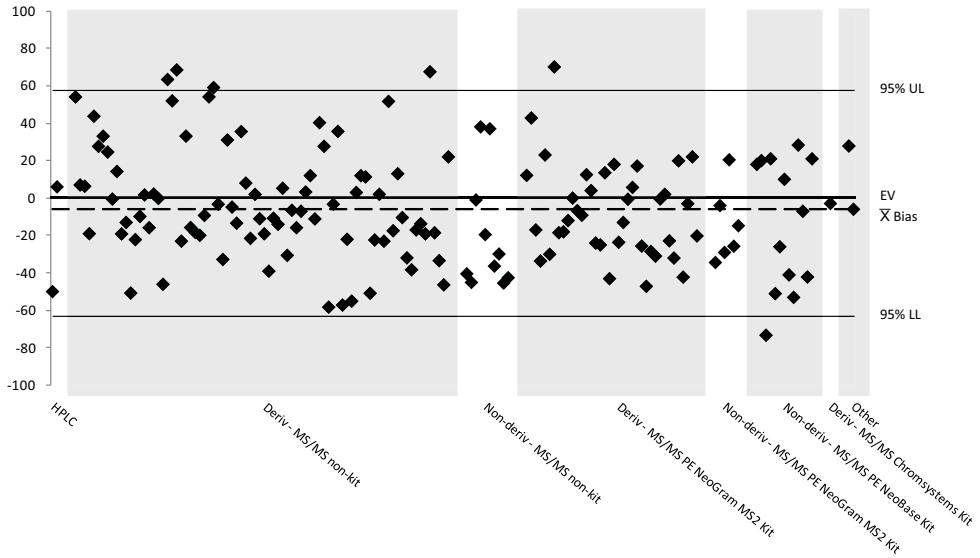


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\overline{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\overline{X}$) excludes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

FIGURES 19-20. Reproducibility of Results by Different Methods – Valine and Citrulline

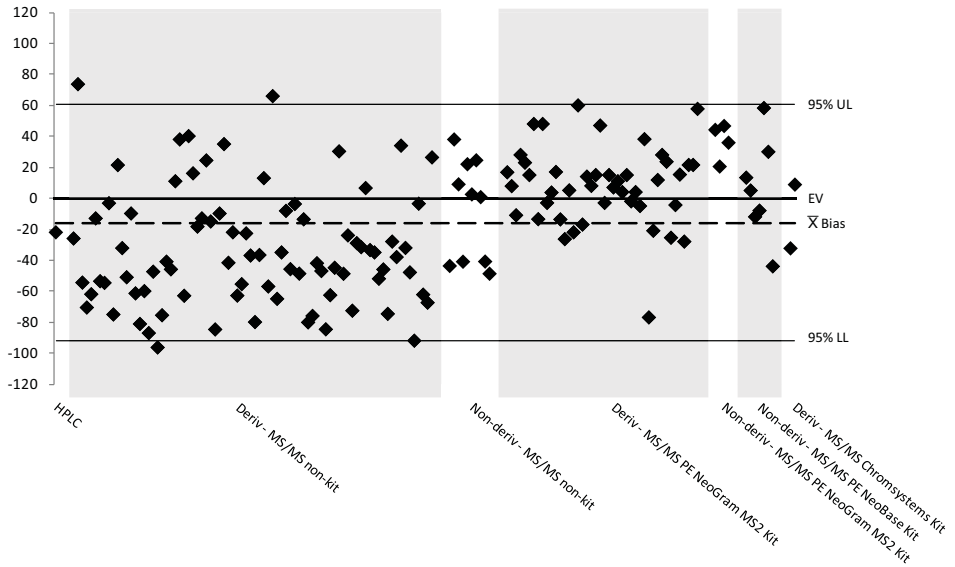
Quarter 3	
Specimen 3	
Enriched	0.00
CDC Assayed	162.45
Participant Mean	165.34
Participant Bias[2]	-5.66

Figure 19. Bias Plot of Valine Values by Method
Quarter 3, Specimen 3
Expected Value (EV)[1] 171.0 µmol/L whole blood



Quarter 1	
Specimen 2	
Enriched	171.30
CDC Assayed	171.30
Participant Mean	178.42
Participant Bias[2]	-15.72

Figure 20. Bias Plot of Citrulline Values by Method
Quarter 1, Specimen 2
Expected Value (EV)[1] 194.14 µmol/L whole blood



[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.

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

Figure 21. Bias Plot of Succinylacetone (SUAC) Values by Method
Quarter 3, Specimen 5
Expected Value (EV)[1] 20.07 µmol/L whole blood

Quarter 3	
Specimen 5	
Enriched	20.00
CDC Assayed	19.81
Participant Mean	15.84
Participant Bias[2]	-4.23

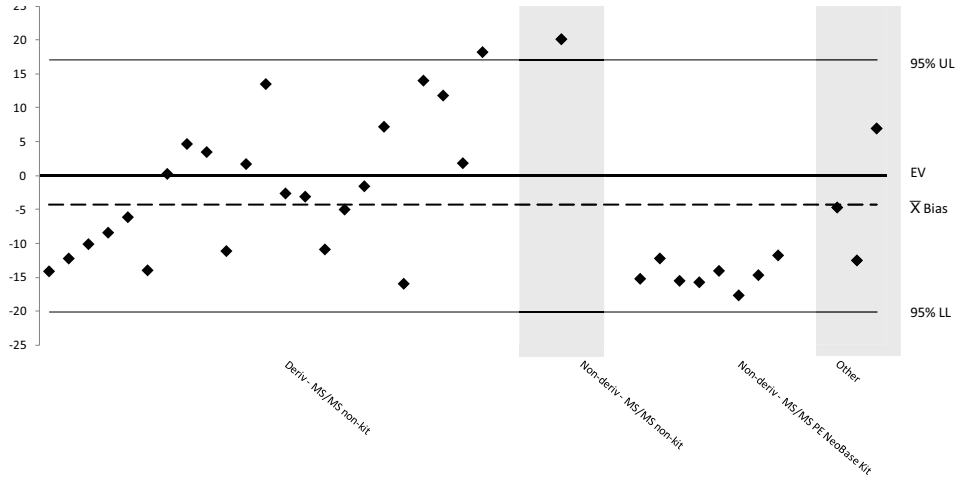
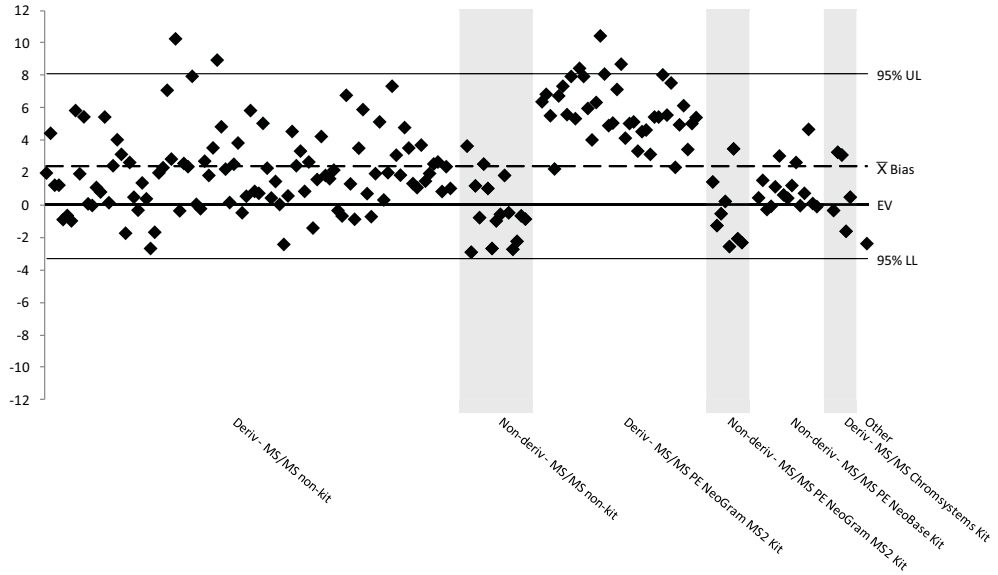


Figure 22. Bias Plot of Free Carnitine (C0(L)) Values by Method
Quarter 4, Specimen 3
Expected Value (EV)[1] 7.69 µmol/L whole blood

Quarter 4	
Specimen 3	
Enriched	0.00
CDC Assayed	7.69
Participant Mean	10.09
Participant Bias[2]	2.40

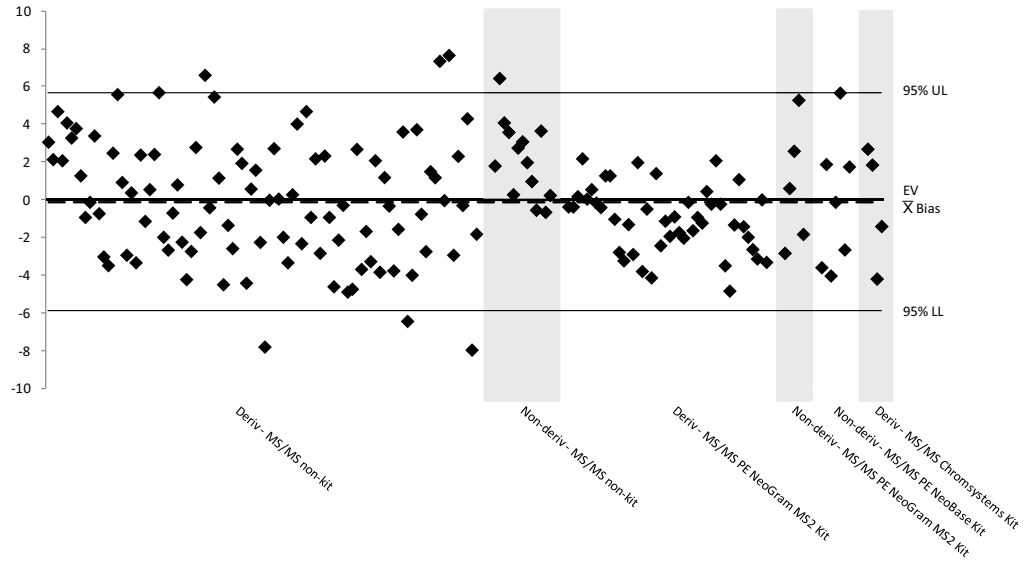


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]Participant bias ($\overline{X}$) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias ($\overline{X}$) excludes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

FIGURES 23-24. Reproducibility of Results by Different Methods – Propionylcarnitine (C3) and Malonylcarnitine (C3DC)

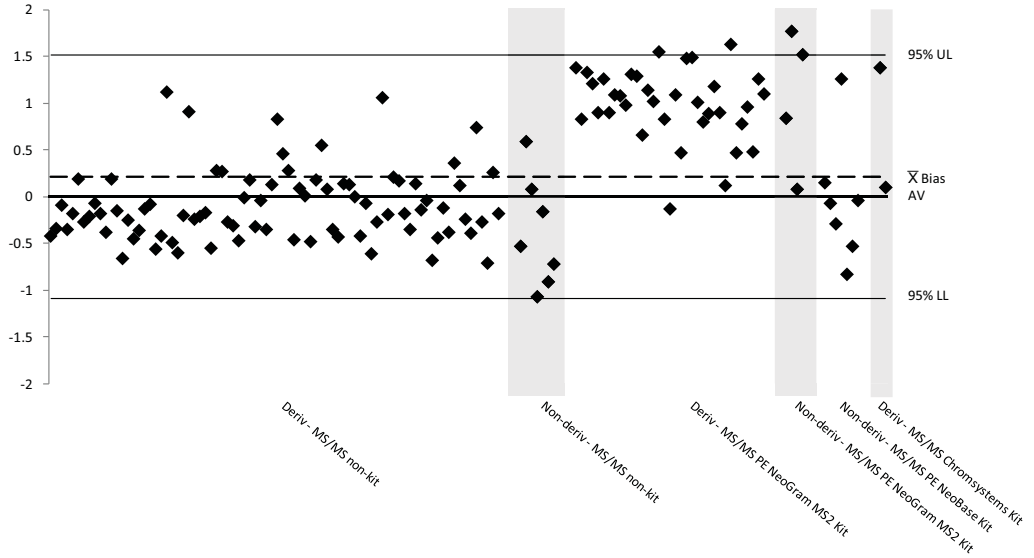
Quarter 1	
Specimen 1	
Enriched	12.50
CDC Assayed	16.84
Participant Mean	16.81
Participant Bias[2]	-0.10

Figure 23. Bias Plot of Propionylcarnitine (C3) Values by Method
Quarter 1, Specimen 1
Expected Value (EV)[1] 16.91 µmol/L whole blood



Quarter 3	
Specimen 3	
CDC Assayed	1.12
Participant Mean	1.33
Participant Bias[2]	0.21

Figure 24. Bias Plot of Malonylcarnitine (C3DC) Values by Method
Quarter 3, Specimen 3
Assayed Value (AV)[3] 1.12 µmol/L whole blood



[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 Different Methods – Butyrylcarnitine (C4) and Isovalerylcarnitine (C5)

Figure 25. Bias Plot of Butyrylcarnitine (C4) Values by Method
Quarter 1, Specimen 1
Expected Value (EV)[1] 0.47 µmol/L whole blood

Quarter 1	
Specimen 1	
Enriched	0.00
CDC Assayed	0.46
Participant Mean	0.48
Participant Bias[2]	0.01

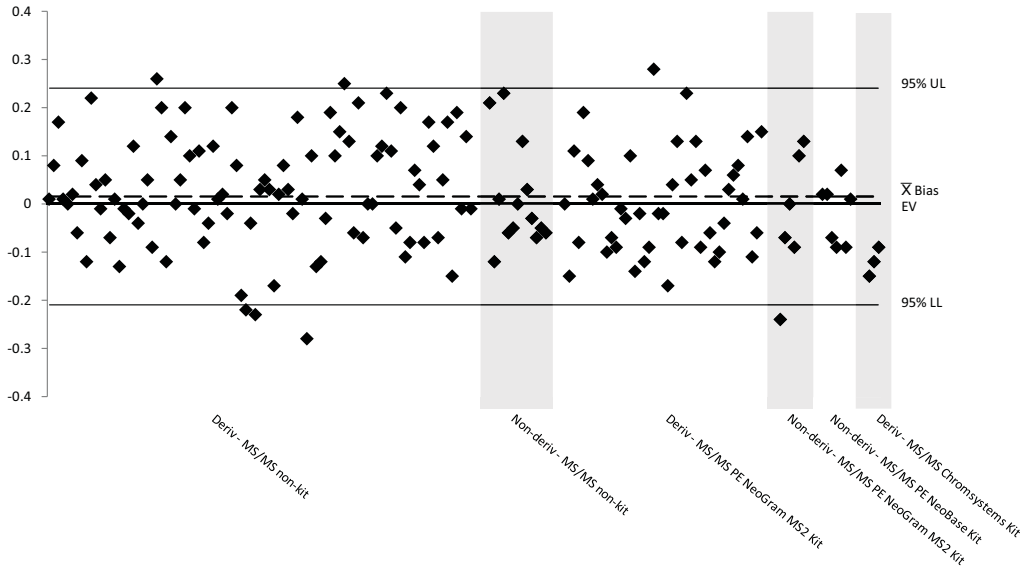
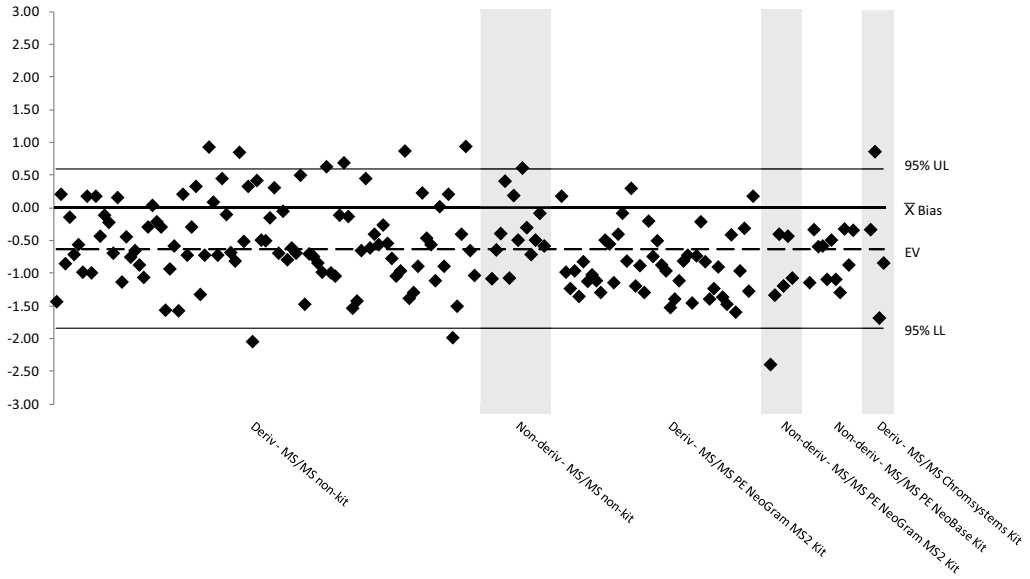


Figure 26. Bias Plot of Isovalerylcarnitine (C5) Values of Method
Quarter 1, Specimen 5
Expected Value (EV)[1] 4.20 µmol/L whole blood

Quarter 1	
Specimen 5	
Enriched	4.00
CDC Assayed	4.65
Participant Mean	3.57
Participant Bias[2]	-0.63



[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.

FIGURES 27-28. Reproducibility of Results by Different Methods – Glutarylcarnitine (C5DC) and 3-Hydroxyisovalerylcarnitine (C5OH)

Figure 27. Bias Plot of Glutarylcarnitine (C5DC) Values by Method
Quarter 3, Specimen 2
Assayed Value (AV)[3] 0.89 µmol/L whole blood

Quarter 3	
Specimen 2	
CDC Assayed	0.89
Participant Mean	2.01
Participant Bias[2]	1.12

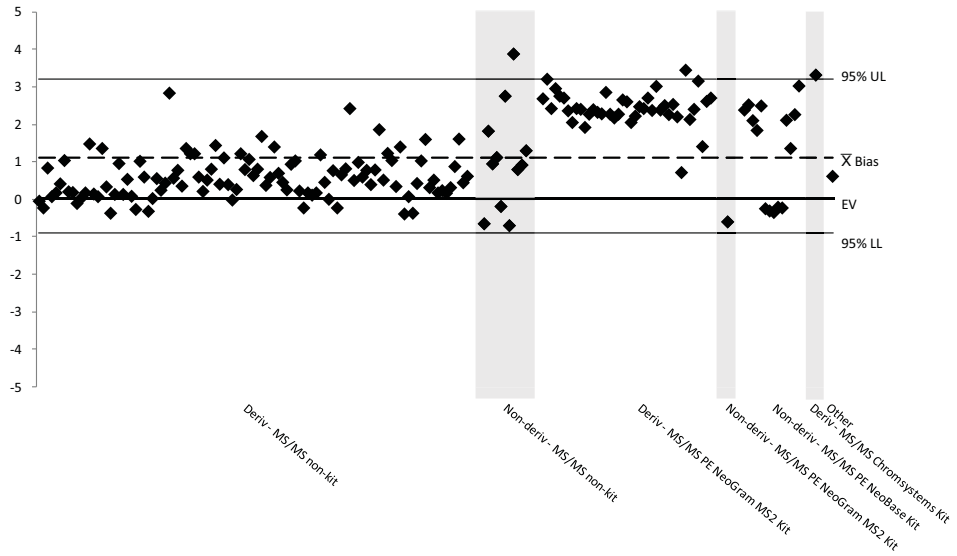
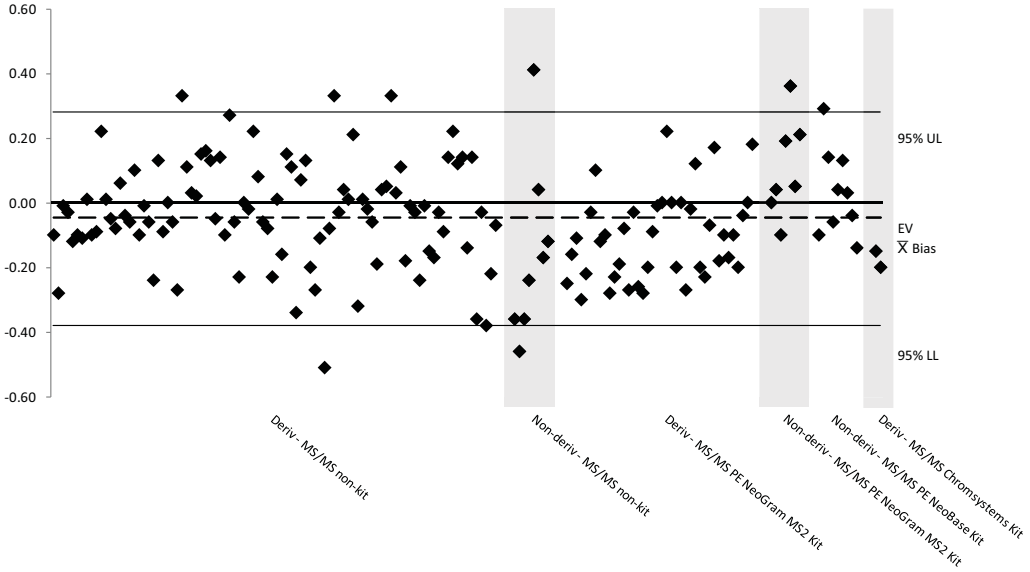


Figure 28. Bias Plot of 3-Hydroxyisovalerylcarnitine (C5OH) Values by Method
Quarter 3, Specimen 3
Expected Value (EV)[1] 0.76 µmol/L whole blood

Quarter 3	
Specimen 3	
Enriched	0.00
CDC Assayed	0.76
Participant Mean	0.71
Participant Bias[2]	-0.05



[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 Different Methods – Hexanoylcarnitine (C6) and Octanoylcarnitine (C8)

Figure 29. Bias Plot of Hexanoylcarnitine (C6) Values by Method
Quarter 1, Specimen 2
Expected Value (EV)[1] 2.15 µmol/L whole blood

Quarter 1	
Specimen 2	
Enriched	2.00
CDC Assayed	2.21
Participant Mean	1.83
Participant Bias[2]	-0.32

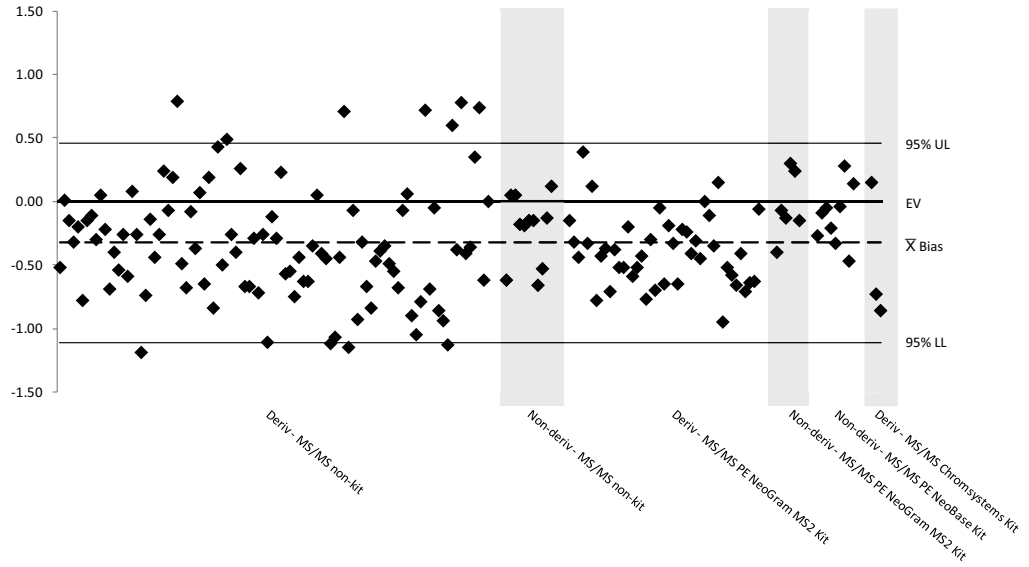
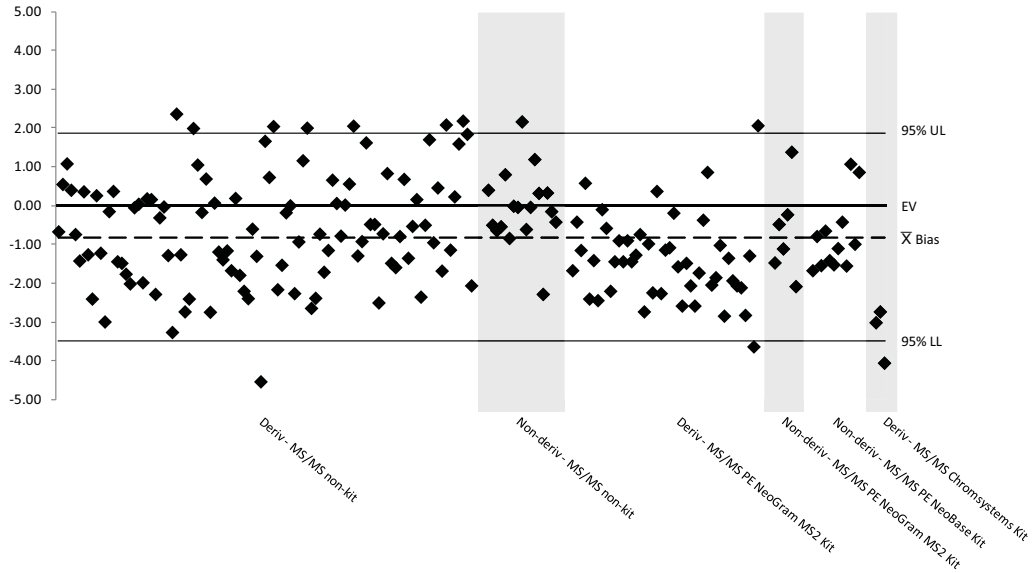


Figure 30. Bias Plot of Octanoylcarnitine (C8) Values by Method
Quarter 1, Specimen 2
Expected Value (EV)[1] 7.86 µmol/L whole blood

Quarter 1	
Specimen 2	
Enriched	7.50
CDC Assayed	8.46
Participant Mean	7.05
Participant Bias[2]	-0.81



[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.

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

Figure 31. Bias Plot of Decanoylcarnitine (C10) Values by Method
Quarter 1, Specimen 2
Expected Value (EV)[1] 1.87 µmol/L whole blood

Quarter 1	
Specimen 2	
Enriched	1.50
CDC Assayed	2.26
Participant Mean	2.05
Participant Bias[2]	0.18

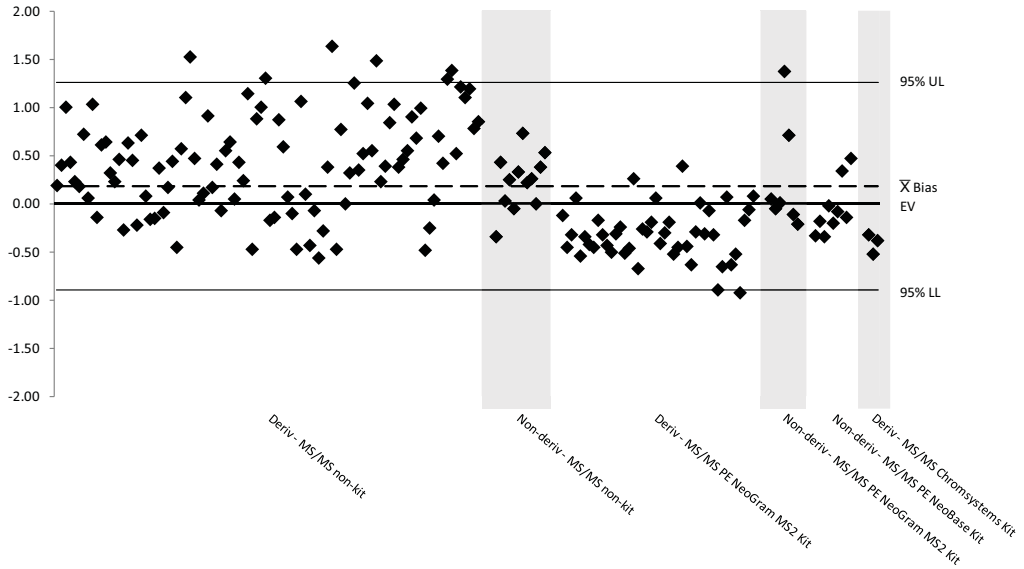
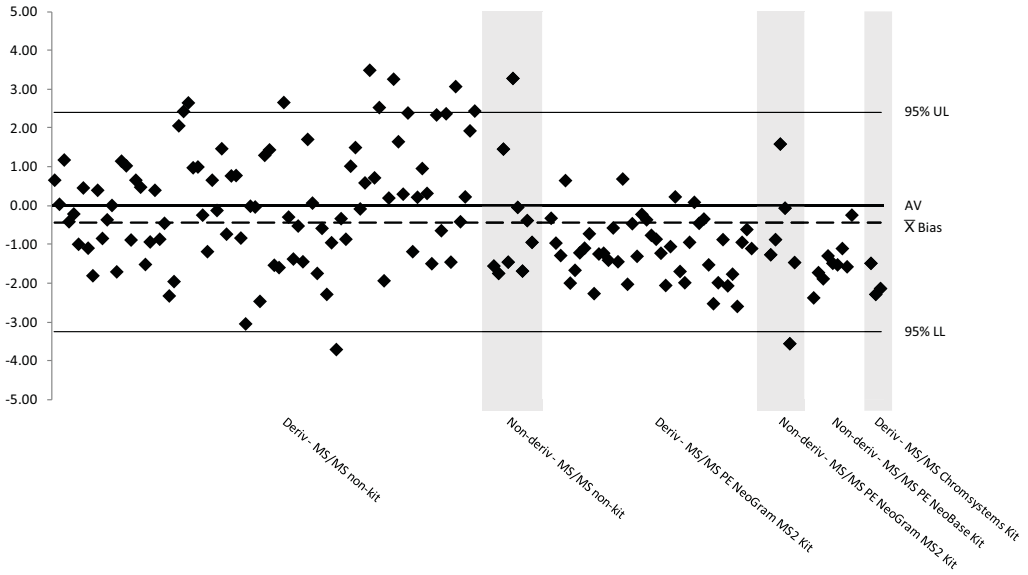


Figure 32. Bias Plot of Decenoylcarnitine (C10:1) Values by Method
Quarter 1, Specimen 2
Assayed Value (AV)[3] 5.36 µmol/L whole blood

Quarter 1	
Specimen 2	
CDC Assayed	5.36
Participant Mean	4.92
Participant Bias[2]	-0.44



[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 Different Methods – Myristoylcarnitine (C14) and Tetradecenoylcarnitine (C14:1)

Figure 33. Bias Plot of Myristoylcarnitine (C14) Values by Method
Quarter 1, Specimen 4
Expected Value (EV)[1] 2.11 µmol/L whole blood

Quarter 1	
Specimen 4	
Enriched	2.00
CDC Assayed	2.07
Participant Mean	1.94
Participant Bias[2]	-0.17

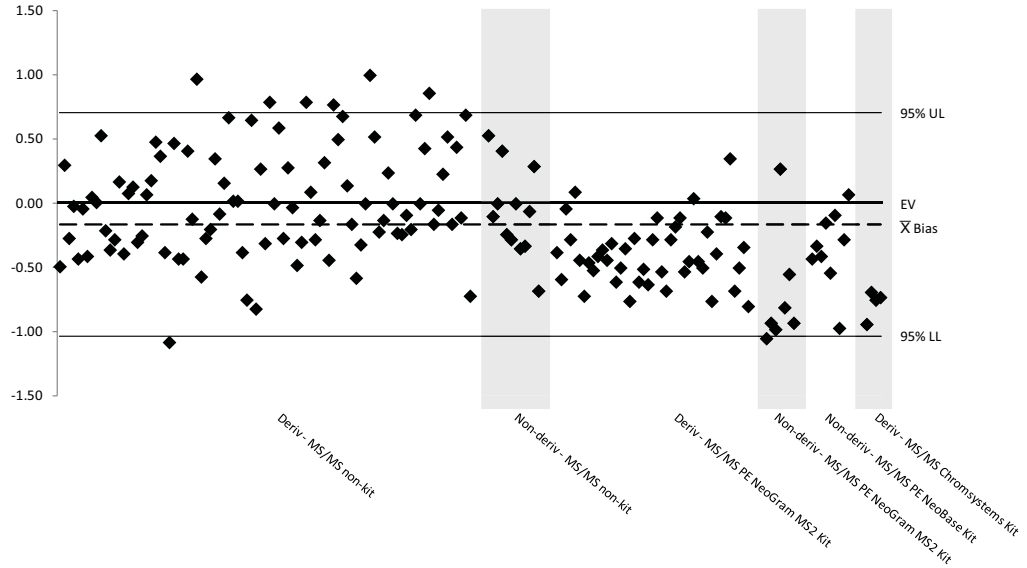
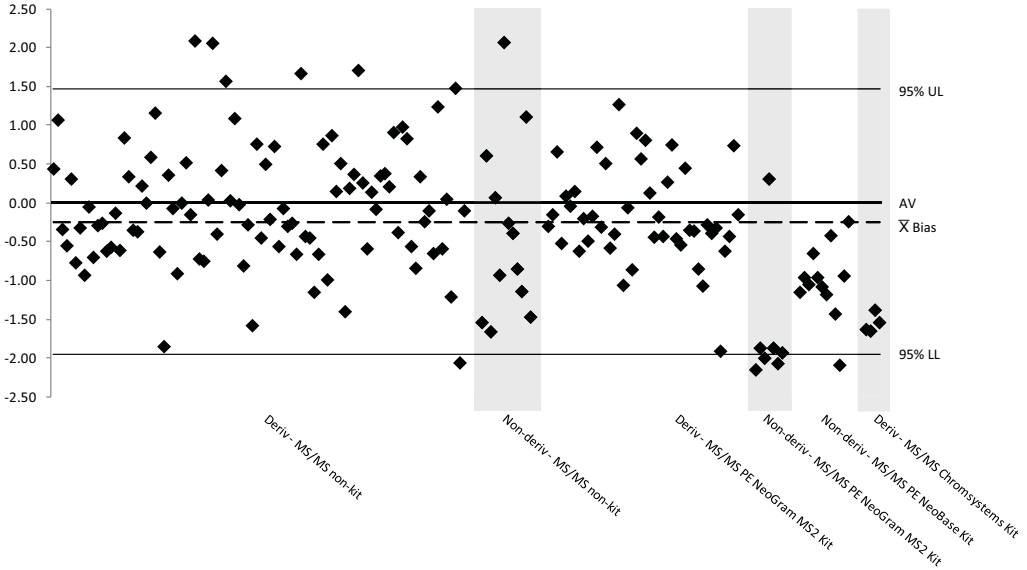


Figure 34. Bias Plot of Tetradecenoylcarnitine (C14:1) Values by Method
Quarter 1, Specimen 4
Assayed Value (AV)[3] 3.86 µmol/L whole blood

Quarter 1	
Specimen 4	
CDC Assayed	3.86
Participant Mean	3.62
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 Different Methods – Palmitoylcarnitine (C16) and Stearoylcarnitine (C18)

Figure 35. Bias Plot of Palmitoylcarnitine (C16) Values by Method
Quarter 4, Specimen 2
Expected Value (EV)[1] 11.07 µmol/L whole blood

Quarter 4	
Specimen 2	
Enriched	10.00
CDC Assayed	10.93
Participant Mean	9.34
Participant Bias[2]	-1.73

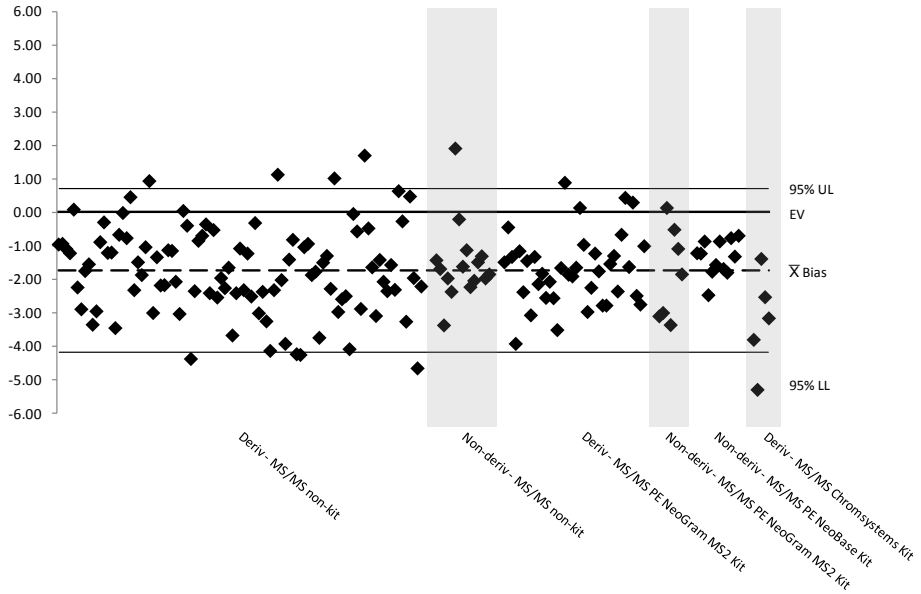
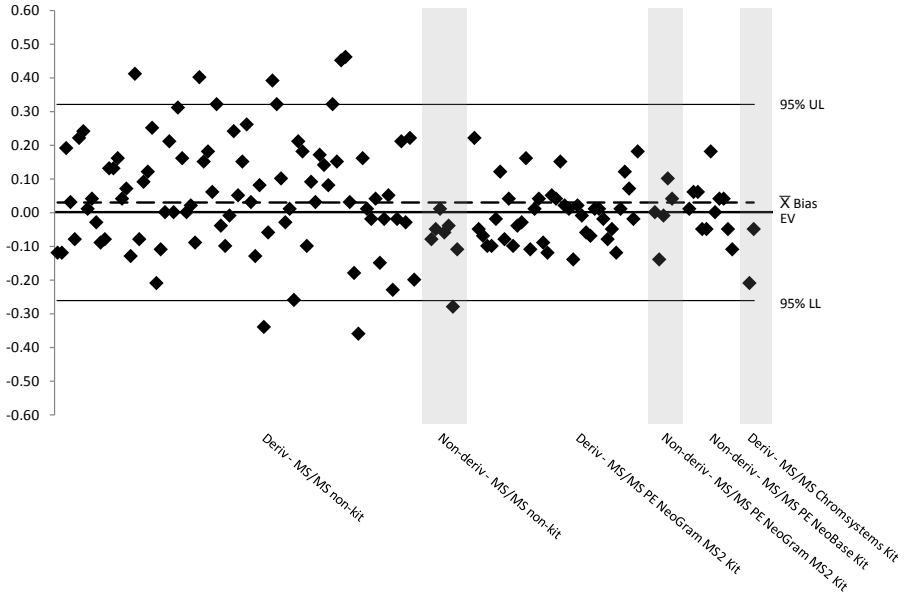


Figure 36. Bias Plot of Stearoylcarnitine (C18) Values by Method
Quarter 3, Specimen 2
Expected Value (EV)[1] 0.60 µmol/L whole blood

Quarter 3	
Specimen 2	
Enriched	0.00
CDC Assayed	0.64
Participant Mean	0.63
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.

Quality Control Index by Analyte

Analyte	Page
Thyroid-Stimulating Hormone (TSH)	35
Thyroxine (T_4)	38
17 α-Hydroxyprogesterone (17-OHP)	39
Total Galactose (Gal)	40
Phenylalanine (Phe)	44
Leucine (Leu)	52
Methionine (Met)	56
Tyrosine (Tyr)	58
Valine (Val)	62
Citrulline (Cit)	64
Free Carnitine (C0)	66
Acetylcarnitine (C2)	68
Propionylcarnitine (C3)	70
Malonylcarnitine (C3DC)	72
Butyrylcarnitine (C4)	74
Isovalerylcarnitine (C5)	76
Glutarylcarnitine (C5DC)	78
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Hexanoylcarnitine (C6)	82
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Myristoylcarnitine (C14)	88
Palmitoylcarnitine (C16)	90
Stearoylcarnitine (C18)	92
Immunoreactive Trypsinogen (IRT)	94

TABLE 10a. 2009 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 811 – Enriched 25 μIU/mL serum						
Siemens Healthcare Diagnostics	40	27.5	3.9	4.6	-2.7	1.2
Neo-Genesis Accuwell	50	26.9	2.8	4.6	-2.6	1.2
MP Biomedicals IRMA	20	30.1	3.5	3.8	4.8	1.0
MP Biomedicals (ICN) ELISA	10	21.4	2.0	2.0	-2.6	0.9
Delfia	466	25.5	2.7	3.6	-1.2	1.0
AutoDelfia	789	24.7	2.3	2.9	-1.8	1.0
Ani Labsystems	69	26.7	3.0	4.2	-1.6	1.1
Bio-Rad Quantase	80	30.8	3.0	5.9	3.8	1.0
TecnoSuma UMELISA	10	22.9	2.1	2.1	-4.8	1.0
Bioclone ELISA	50	26.8	3.9	8.9	-6.2	1.3
DiaSorin	90	25.5	3.4	5.5	1.1	1.0
In House	50	26.5	2.6	5.8	3.2	0.9
Other	40	27.4	2.4	8.5	2.6	1.0
Lot 812 – Enriched 40 μIU/mL serum						
Siemens Healthcare Diagnostics	40	42.4	5.2	7.0	-2.7	1.2
Neo-Genesis Accuwell	50	43.3	5.5	9.9	-2.6	1.2
MP Biomedicals IRMA	20	41.8	4.6	6.4	4.8	1.0
MP Biomedicals (ICN) ELISA	10	28.2	2.8	2.8	-2.6	0.9
Delfia	470	37.2	3.5	4.6	-1.2	1.0
AutoDelfia	786	36.8	3.0	3.8	-1.8	1.0
Ani Labsystems	68	37.6	3.9	5.5	-1.6	1.1
Bio-Rad Quantase	80	43.9	4.1	6.5	3.8	1.0
TecnoSuma UMELISA	10	34.4	5.2	5.2	-4.8	1.0
Bioclone ELISA	50	43.8	4.1	14.3	-6.2	1.3
DiaSorin	89	39.2	4.7	5.7	1.1	1.0
In House	50	39.5	3.0	7.7	3.2	0.9
Other	40	39.8	4.7	11.0	2.6	1.0

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

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 813 – Enriched 80 μIU/mL serum						
Siemens Healthcare Diagnostics	40	91.0	7.6	11.6	-2.7	1.2
Neo-Genesis Accuwell	50	90.5	8.9	16.2	-2.6	1.2
MP Biomedicals IRMA	20	82.3	7.3	7.9	4.8	1.0
MP Biomedicals (ICN) ELISA	10	67.0	5.4	5.4	-2.6	0.9
Delfia	476	80.0	8.0	9.7	-1.2	1.0
AutoDelfia	784	79.5	6.5	8.8	-1.8	1.0
Ani Labsystems	69	83.4	7.6	9.8	-1.6	1.1
Bio-Rad Quantase	77	87.4	10.9	15.2	3.8	1.0
TecnoSuma UMELISA	10	79.0	10.1	10.1	-4.8	1.0
Bioclone ELISA	50	96.7	11.2	32.4	-6.2	1.3
DiaSorin	87	78.3	7.9	9.7	1.1	1.0
In House	47	76.8	7.7	9.6	3.2	0.9
Other	40	79.5	9.0	21.2	2.6	1.0
Lot 911 – Enriched 25 μIU/mL serum						
Siemens Healthcare Diagnostics	29	30.2	2.1	2.5	-3.0	1.3
Neo-Genesis Accuwell	60	27.5	3.6	5.8	-2.6	1.2
MP Biomedicals IRMA	10	39.4	5.5	5.5	6.5	1.2
MP Biomedicals (ICN) ELISA	9	18.5	2.7	2.7	-7.2	1.0
Delfia	493	26.7	2.2	2.9	-1.8	1.2
AutoDelfia	875	28.2	2.0	2.7	-0.9	1.2
Ani Labsystems	50	26.1	2.1	7.3	-1.8	1.1
Bio-Rad Quantase	67	34.2	3.3	8.0	9.2	1.0
TecnoSuma UMELISA	38	25.7	3.2	3.8	-3.7	1.2
Bioclone ELISA	39	36.7	3.7	8.1	-5.0	1.7
DiaSorin	89	27.8	3.0	3.0	0.6	1.1
ECLIA	10	26.7	1.6	1.6	0.6	1.1
In House	59	30.1	2.2	3.9	-0.3	1.2
Other	60	27.8	2.2	4.6	0.6	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 912 – Enriched 40 µIU/mL serum						
Siemens Healthcare Diagnostics	30	47.6	5.1	8.8	-3.0	1.3
Neo-Genesis Accuwell	59	42.6	5.3	7.2	-2.6	1.2
MP Biomedicals IRMA	10	52.8	7.8	7.8	6.5	1.2
MP Biomedicals (ICN) ELISA	10	33.1	3.3	3.3	-7.2	1.0
Delfia	492	44.6	3.6	4.6	-1.8	1.2
AutoDelfia	893	46.1	3.3	4.6	-0.9	1.2
Ani Labsystems	50	43.6	4.1	12.4	-1.8	1.1
Bio-Rad Quantase	67	46.5	4.5	10.5	9.2	1.0
TecnoSuma UMELISA	40	45.7	8.1	8.1	-3.7	1.2
Bioclone ELISA	40	61.5	9.8	14.8	-5.0	1.7
DiaSorin	86	44.4	4.2	4.7	0.6	1.1
ECLIA	10	45.1	2.4	2.4	0.6	1.1
In House	60	47.7	4.4	7.1	-0.3	1.2
Other	60	45.8	3.6	6.3	0.6	1.1
Lot 913 – Enriched 80 µIU/mL serum						
Siemens Healthcare Diagnostics	30	100.8	7.5	15.6	-3.0	1.3
Neo-Genesis Accuwell	58	90.9	8.4	12.5	-2.6	1.2
MP Biomedicals IRMA	10	105.7	4.4	4.4	6.5	1.2
MP Biomedicals (ICN) ELISA	10	74.2	7.4	7.4	-7.2	1.0
Delfia	489	90.2	6.9	9.0	-1.8	1.2
AutoDelfia	891	92.5	6.5	9.2	-0.9	1.2
Ani Labsystems	50	88.3	7.0	22.9	-1.8	1.1
Bio-Rad Quantase	70	86.6	8.5	22.2	9.2	1.0
TecnoSuma UMELISA	40	92.7	10.7	13.2	-3.7	1.2
Bioclone ELISA	40	128.3	17.4	28.1	-5.0	1.7
DiaSorin	86	87.8	6.5	7.2	0.6	1.1
ECLIA	10	86.6	6.3	6.3	0.6	1.1
In House	60	96.4	9.3	17.6	-0.3	1.2
Other	59	89.3	4.8	10.7	0.6	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 10b. 2009 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 801 – Enriched 2 µg/dL serum						
Siemens Healthcare Diagnostics	19	2.5	0.2	0.2	0.0	1.2
MP Biomedicals RIA	30	1.6	0.2	0.5	-0.4	0.9
Neo-Genesis Accuwell	79	1.7	0.6	0.7	-0.6	1.1
Delfia	165	1.8	0.3	0.4	-0.1	1.0
AutoDelfia	573	1.9	0.4	0.5	0.0	0.9
TecnoSuma UMELISA	19	3.4	0.7	0.7	0.1	1.7
Interscientific NeoMAP Multiplex	49	1.6	0.2	0.3	-0.6	1.0
Other	10	2.7	0.4	0.4	0.3	1.1
Lot 802 – Enriched 7 µg/dL serum						
Siemens Healthcare Diagnostics	20	8.6	1.0	1.3	0.0	1.2
MP Biomedicals RIA	30	5.9	1.0	1.1	-0.4	0.9
Neo-Genesis Accuwell	78	7.1	1.0	1.2	-0.6	1.1
Delfia	172	6.7	0.8	1.0	-0.1	1.0
AutoDelfia	584	6.7	0.7	0.8	0.0	0.9
TecnoSuma UMELISA	20	11.7	1.6	1.6	0.1	1.7
Interscientific NeoMAP Multiplex	48	6.4	0.5	0.5	-0.6	1.0
Other	10	8.0	0.8	0.8	0.3	1.1
Lot 803 – Enriched 11 µg/dL serum						
Siemens Healthcare Diagnostics	20	13.6	1.3	1.3	0.0	1.2
MP Biomedicals RIA	30	10.1	1.0	1.9	-0.4	0.9
Neo-Genesis Accuwell	80	12.0	1.8	2.5	-0.6	1.1
Delfia	163	10.4	1.2	1.4	-0.1	1.0
AutoDelfia	577	10.4	1.0	1.2	0.0	0.9
TecnoSuma UMELISA	20	18.5	2.8	2.8	0.1	1.7
Interscientific NeoMAP Multiplex	50	11.0	0.8	1.2	-0.6	1.0
Other	10	12.8	1.1	1.1	0.3	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 10c. 2009 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 751 - Enriched 25 ng/mL serum						
MP Biomedicals RIA	49	28.5	3.0	3.8	6.2	0.9
Neo-Genesis Accuwell	90	31.1	5.7	6.7	5.9	1.0
Delfia	194	25.1	3.5	5.2	-0.4	1.0
Delfia Neonatal 17-OHP (A024)	123	23.7	2.9	4.3	2.0	0.9
AutoDelfia	940	27.1	3.0	3.9	-0.8	1.1
AutoDelfia Neonatal 17-OHP (B024)	310	22.9	2.5	3.9	1.8	0.9
Bio-Rad Quantase	130	27.0	3.5	7.2	7.5	0.8
TecnoSuma UMELISA	29	35.2	6.5	9.2	-3.4	1.5
LC-MS/MS	40	31.7	7.1	8.0	13.1	0.9
In House	38	25.3	2.6	5.4	3.7	0.9
Other	49	28.5	3.5	4.4	6.1	1.0
Lot 752 - Enriched 50 ng/mL serum						
MP Biomedicals RIA	48	49.1	3.1	4.7	6.2	0.9
Neo-Genesis Accuwell	100	54.8	13.9	21.4	5.9	1.0
Delfia	188	48.5	6.2	9.4	-0.4	1.0
Delfia Neonatal 17-OHP (A024)	125	47.1	5.8	9.9	2.0	0.9
AutoDelfia	940	53.8	5.5	8.0	-0.8	1.1
AutoDelfia Neonatal 17-OHP (B024)	302	44.7	4.4	6.3	1.8	0.9
Bio-Rad Quantase	130	46.3	6.9	12.9	7.5	0.8
TecnoSuma UMELISA	30	70.6	16.6	17.7	-3.4	1.5
LC-MS/MS	40	61.5	10.6	11.5	13.1	0.9
In House	40	51.5	5.8	13.6	3.7	0.9
Other	50	57.0	7.5	9.6	6.1	1.0
Lot 753 - Enriched 100 ng/mL serum						
MP Biomedicals RIA	48	93.8	7.9	11.3	6.2	0.9
Neo-Genesis Accuwell	90	105.1	12.6	16.7	5.9	1.0
Delfia	196	99.5	12.2	19.1	-0.4	1.0
Delfia Neonatal 17-OHP (A024)	124	90.4	9.2	18.2	2.0	0.9
AutoDelfia	943	109.7	10.7	16.4	-0.8	1.1
AutoDelfia Neonatal 17-OHP (B024)	314	87.0	10.0	15.4	1.8	0.9
Bio-Rad Quantase	128	85.4	11.9	24.6	7.5	0.8
TecnoSuma UMELISA	30	147.7	31.4	42.0	-3.4	1.5
LC-MS/MS	40	98.6	15.8	32.2	13.1	0.9
In House	37	94.7	12.5	24.9	3.7	0.9
Other	49	102.0	11.2	11.2	6.1	1.0

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

TABLE 10d. 2009 Quality Control Data
Summaries of Statistical Analyses

TOTAL GALACTOSE (mg Gal/dL whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 825 – Enriched 5 mg/dL whole blood						
Fluorometric Manual	123	4.9	0.7	1.5	0.0	1.0
Fluorometric Cont Flow, Kit	10	5.4	0.7	0.7	1.0	0.9
Colorimetric	38	6.6	0.7	1.0	0.4	1.2
PerkinElmer Neonatal Kit	40	5.9	0.6	0.9	1.9	0.9
Neo-Genesis Accuwell	39	5.9	0.4	0.4	0.2	1.0
Bio-Rad Quantase	108	6.3	1.1	1.9	-1.5	1.4
MP Biomedicals Enzyme Assay	30	10.7	1.0	2.7	4.3	1.5
Interscientific Enzyme	48	5.3	0.5	0.5	-0.4	1.0
Astoria-Pacific	126	7.0	0.9	2.3	1.7	1.1
R&D Diagnostics Greece	40	4.2	0.7	0.9	-1.1	1.0
Other	40	4.9	0.5	1.0	0.2	1.1
Lot 826 – Enriched 10 mg/dL whole blood						
Fluorometric Manual	122	10.0	1.0	1.6	0.0	1.0
Fluorometric Cont Flow, Kit	10	10.7	1.2	1.2	1.0	0.9
Colorimetric	39	12.2	2.0	2.8	0.4	1.2
PerkinElmer Neonatal Kit	40	10.9	1.2	1.3	1.9	0.9
Neo-Genesis Accuwell	40	9.6	0.9	1.6	0.2	1.0
Bio-Rad Quantase	107	12.4	2.5	3.5	-1.5	1.4
MP Biomedicals Enzyme Assay	30	18.9	1.9	4.1	4.3	1.5
Interscientific Enzyme	50	8.8	0.8	1.6	-0.4	1.0
Astoria-Pacific	128	12.1	1.6	2.8	1.7	1.1
R&D Diagnostics Greece	40	8.5	0.8	2.0	-1.1	1.0
Other	40	10.1	0.8	2.2	0.2	1.1

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

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 827 – Enriched 15 mg/dL whole blood						
Fluorometric Manual	126	15.4	1.4	2.3	0.0	1.0
Fluorometric Cont Flow, Kit	10	14.7	1.4	1.4	1.0	0.9
Colorimetric	40	18.8	2.5	4.0	0.4	1.2
PerkinElmer Neonatal Kit	39	15.2	1.3	1.6	1.9	0.9
Neo-Genesis Accuwell	40	16.0	1.3	1.6	0.2	1.0
Bio-Rad Quantase	109	19.4	2.9	4.8	-1.5	1.4
MP Biomedicals Enzyme Assay	30	29.9	2.5	4.6	4.3	1.5
Interscientific Enzyme	50	13.8	1.3	2.8	-0.4	1.0
Astoria-Pacific	128	18.0	2.0	3.4	1.7	1.1
R&D Diagnostics Greece	39	13.1	1.2	3.6	-1.1	1.0
Other	40	17.9	1.0	6.2	0.2	1.1
Lot 828 – Enriched 30 mg/dL whole blood						
Fluorometric Manual	123	30.0	2.9	3.8	0.0	1.0
Fluorometric Cont Flow, Kit	10	20.2	0.0	0.0	1.0	0.9
Colorimetric	39	36.7	6.2	9.7	0.4	1.2
PerkinElmer Neonatal Kit	40	27.9	2.6	2.8	1.9	0.9
Neo-Genesis Accuwell	40	31.2	2.4	4.0	0.2	1.0
Bio-Rad Quantase	107	41.9	7.7	11.4	-1.5	1.4
MP Biomedicals Enzyme Assay	29	48.8	2.2	5.2	4.3	1.5
Interscientific Enzyme	49	29.4	2.6	2.6	-0.4	1.0
Astoria-Pacific	128	33.6	3.6	7.0	1.7	1.1
R&D Diagnostics Greece	40	28.3	2.4	5.2	-1.1	1.0
Other	40	31.2	1.5	6.3	0.2	1.1

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

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 921 - Enriched 5 mg/dL whole blood						
Fluorometric Manual	121	5.1	0.8	1.7	-0.3	1.0
Colorimetric	40	5.8	0.8	1.2	-0.8	1.3
PerkinElmer Neonatal Kit	119	4.3	0.6	0.7	0.5	0.8
Neo-Genesis Accuwell	30	5.7	0.3	0.3	0.7	0.9
Bio-Rad Quantase	118	6.9	1.0	1.5	-0.5	1.4
MP Biomedicals Enzyme Assay	40	9.9	1.3	1.3	2.9	1.5
Interscientific Enzyme	30	5.1	0.7	0.7	-0.2	0.9
Astoria-Pacific	120	7.6	0.6	0.7	2.0	1.0
TecnoSuma UMTEST	40	5.4	1.0	1.7	-0.2	1.1
R&D Diagnostics Greece	59	5.5	0.7	1.0	0.3	1.0
Other	58	6.3	1.0	3.3	-0.7	1.3
Lot 922 - Enriched 10 mg/dL whole blood						
Fluorometric Manual	128	10.0	1.1	2.4	-0.3	1.0
Colorimetric	39	11.6	1.2	2.4	-0.8	1.3
PerkinElmer Neonatal Kit	118	8.7	0.7	0.9	0.5	0.8
Neo-Genesis Accuwell	28	10.2	0.5	0.5	0.7	0.9
Bio-Rad Quantase	118	12.8	1.7	2.4	-0.5	1.4
MP Biomedicals Enzyme Assay	39	17.8	1.9	2.1	2.9	1.5
Interscientific Enzyme	29	8.6	0.9	1.2	-0.2	0.9
Astoria-Pacific	117	12.0	0.8	1.0	2.0	1.0
TecnoSuma UMTEST	37	10.9	1.4	1.4	-0.2	1.1
R&D Diagnostics Greece	59	10.1	1.4	1.4	0.3	1.0
Other	60	12.4	1.9	6.5	-0.7	1.3

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

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 923 - Enriched 15 mg/dL whole blood						
Fluorometric Manual	126	15.0	0.9	2.3	-0.3	1.0
Colorimetric	40	17.9	1.5	3.0	-0.8	1.3
PerkinElmer Neonatal Kit	115	12.8	0.9	1.5	0.5	0.8
Neo-Genesis Accuwell	29	14.1	0.7	0.7	0.7	0.9
Bio-Rad Quantase	117	19.3	2.8	3.4	-0.5	1.4
MP Biomedicals Enzyme Assay	39	25.2	1.7	2.1	2.9	1.5
Interscientific Enzyme	30	13.1	1.0	2.0	-0.2	0.9
Astoria-Pacific	119	17.5	1.1	1.4	2.0	1.0
TecnoSuma UMTEST	39	17.1	1.9	2.0	-0.2	1.1
R&D Diagnostics Greece	59	15.1	2.0	2.1	0.3	1.0
Other	58	17.7	2.9	8.2	-0.7	1.3
Lot 924 - Enriched 30 mg/dL whole blood						
Fluorometric Manual	130	31.0	2.0	4.5	-0.3	1.0
Colorimetric	40	37.2	3.4	8.2	-0.8	1.3
PerkinElmer Neonatal Kit	117	24.5	1.9	3.2	0.5	0.8
Neo-Genesis Accuwell	30	29.1	1.9	2.6	0.7	0.9
Bio-Rad Quantase	118	40.6	5.9	7.8	-0.5	1.4
MP Biomedicals Enzyme Assay	38	46.6	2.2	2.4	2.9	1.5
Interscientific Enzyme	30	27.7	1.6	5.5	-0.2	0.9
Astoria-Pacific	117	33.4	1.8	2.2	2.0	1.0
TecnoSuma UMTEST	39	33.7	4.2	5.2	-0.2	1.1
R&D Diagnostics Greece	60	30.4	4.5	4.7	0.3	1.0
Other	60	38.6	5.7	17.4	-0.7	1.3

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

TABLE 10e. 2009 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 825 – Nonenriched 0 μmol/L whole blood						
Bacterial Inhibition Assays	30	71.91	9.72	14.10	65.43	1.24
Fluorometric Manual	60	108.70	14.51	33.48	103.84	0.96
Fluorometric Cont Flow, In house	10	125.00	5.27	5.27	100.87	1.36
Fluorometric Cont Flow, Kit	20	129.24	21.09	74.70	133.73	1.12
Colorimetric	89	111.46	15.10	22.09	101.16	1.19
PerkinElmer Neonatal Kit	216	90.64	9.73	11.73	82.50	0.90
Neo-Genesis Accuwell	10	93.93	13.17	13.17	90.10	1.04
Ani Labsystems	88	104.26	11.64	18.35	99.55	1.06
Bio-Rad Quantase	40	120.47	29.72	30.52	98.75	1.30
MP Biomedicals Enzyme Assay	20	57.12	14.12	25.19	38.95	1.02
Interscientific Enzyme	49	90.48	14.10	15.18	83.39	0.79
HPLC	30	89.03	11.11	15.02	82.80	0.90
Derivatized - MS/MS Non-kit	671	81.24	6.51	12.86	78.02	0.84
Non-derivatized - MS/MS Non-kit	166	97.80	8.73	16.79	95.07	0.99
Derivatized - MS/MS PE NeoGram MS2 Kit	236	89.35	7.23	11.04	87.54	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	92.51	9.72	13.44	91.10	0.94
Non-derivatized - MS/MS PE NeoBase Kit	69	84.22	5.17	8.29	79.81	0.87
Derivatized - MS/MS Chromsystems Kit	48	87.93	5.72	7.07	87.10	0.92
TecnoSuma UMTEST	18	128.44	18.95	27.76	74.17	1.23
Other	10	75.87	9.49	9.49	74.50	0.72

*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 826 – Enriched 182 µmol/L whole blood						
Bacterial Inhibition Assays	28	271.59	40.03	105.88	65.43	1.24
Fluorometric Manual	60	278.54	24.00	44.65	103.84	0.96
Fluorometric Cont Flow, In house	10	309.00	20.25	20.25	100.87	1.36
Fluorometric Cont Flow, Kit	20	334.72	27.41	110.77	133.73	1.12
Colorimetric	89	300.04	21.72	47.50	101.16	1.19
PerkinElmer Neonatal Kit	214	237.92	19.80	28.16	82.50	0.90
Neo-Genesis Accuwell	10	272.70	22.67	22.67	90.10	1.04
Ani Labsystems	88	285.98	21.28	55.44	99.55	1.06
Bio-Rad Quantase	40	297.63	57.77	59.46	98.75	1.30
MP Biomedicals Enzyme Assay	20	197.78	37.90	37.90	38.95	1.02
Interscientific Enzyme	50	217.63	27.02	29.26	83.39	0.79
HPLC	30	241.53	16.79	36.05	82.80	0.90
Derivatized - MS/MS Non-kit	671	225.69	17.25	35.06	78.02	0.84
Non-derivatized - MS/MS Non-kit	167	269.58	19.05	38.41	95.07	0.99
Derivatized - MS/MS PE NeoGram MS2 Kit	236	247.62	18.90	27.87	87.54	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	260.62	25.16	30.03	91.10	0.94
Non-derivatized - MS/MS PE NeoBase Kit	67	232.80	13.60	19.65	79.81	0.87
Derivatized - MS/MS Chromsystems Kit	50	252.83	22.20	29.53	87.10	0.92
TecnoSuma UMTEST	20	286.27	57.66	104.51	74.17	1.23
Other	10	196.40	6.91	6.91	74.50	0.72

*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 827 – Enriched 424 μmol/L whole blood						
Bacterial Inhibition Assays	30	610.98	87.18	327.49	65.43	1.24
Fluorometric Manual	49	497.50	45.64	45.64	103.84	0.96
Fluorometric Cont Flow, In house	10	692.00	49.17	49.17	100.87	1.36
Fluorometric Cont Flow, Kit	20	622.72	68.71	229.78	133.73	1.12
Colorimetric	89	609.39	42.41	85.84	101.16	1.19
PerkinElmer Neonatal Kit	212	455.77	35.37	53.22	82.50	0.90
Neo-Genesis Accuwell	10	530.55	31.31	31.31	90.10	1.04
Ani Labsystems	89	552.45	35.75	97.85	99.55	1.06
Bio-Rad Quantase	38	663.86	50.31	57.35	98.75	1.30
MP Biomedicals Enzyme Assay	20	472.62	64.53	64.53	38.95	1.02
Interscientific Enzyme	50	417.36	49.48	53.34	83.39	0.79
HPLC	30	460.19	24.78	50.52	82.80	0.90
Derivatized - MS/MS Non-kit	666	435.33	32.80	65.19	78.02	0.84
Non-derivatized - MS/MS Non-kit	166	519.40	36.31	70.49	95.07	0.99
Derivatized - MS/MS PE NeoGram MS2 Kit	237	477.52	36.06	52.86	87.54	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	491.85	38.62	66.57	91.10	0.94
Non-derivatized - MS/MS PE NeoBase Kit	67	445.94	27.22	39.75	79.81	0.87
Derivatized - MS/MS Chromsystems Kit	49	481.82	35.44	44.86	87.10	0.92
TecnoSuma UMTEST	19	477.73	42.93	87.52	74.17	1.23
Other	10	391.17	33.78	33.78	74.50	0.72

*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 828 – Enriched 667 μmol/L whole blood						
Bacterial Inhibition Assays	30	886.28	100.24	397.67	65.43	1.24
Fluorometric Manual	60	754.23	64.34	74.63	103.84	0.96
Fluorometric Cont Flow, In house	10	1012.0	53.50	53.50	100.87	1.36
Fluorometric Cont Flow, Kit	20	867.54	87.18	264.12	133.73	1.12
Colorimetric	90	893.04	66.52	142.63	101.16	1.19
PerkinElmer Neonatal Kit	213	687.26	48.39	79.94	82.50	0.90
Neo-Genesis Accuwell	10	781.69	30.61	30.61	90.10	1.04
Ani Labsystems	89	810.33	51.08	149.84	99.55	1.06
Bio-Rad Quantase	39	964.52	87.68	98.61	98.75	1.30
MP Biomedicals Enzyme Assay	20	722.65	82.27	82.31	38.95	1.02
Interscientific Enzyme	49	612.30	58.86	77.75	83.39	0.79
HPLC	29	690.74	37.23	38.08	82.80	0.90
Derivatized - MS/MS Non-kit	666	638.42	46.47	95.98	78.02	0.84
Non-derivatized - MS/MS Non-kit	166	754.80	51.01	108.33	95.07	0.99
Derivatized - MS/MS PE NeoGram MS2 Kit	236	690.90	49.71	75.99	87.54	0.91
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	720.70	62.53	95.87	91.10	0.94
Non-derivatized - MS/MS PE NeoBase Kit	68	662.02	44.36	69.41	79.81	0.87
Derivatized - MS/MS Chromsystems Kit	49	702.42	43.55	61.83	87.10	0.92
TecnoSuma UMTEST	20	967.43	161.22	255.38	74.17	1.23
Other	10	546.02	37.42	37.42	74.50	0.72

*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 921 - Nonenriched 0 µmol/L whole blood						
Bacterial Inhibition Assays	20	65.76	10.86	12.62	64.82	0.86
Fluorometric Manual	70	110.19	14.74	32.82	110.88	1.04
Fluorometric Cont Flow, In house	20	126.91	12.41	12.41	120.57	1.39
Fluorometric Cont Flow, Kit	40	88.69	6.42	17.90	88.94	1.04
Colorimetric	89	97.94	12.53	21.65	94.73	1.32
PerkinElmer Neonatal Kit	271	77.45	9.77	13.94	70.17	0.98
Neo-Genesis Accuwell	20	88.64	17.00	17.00	78.28	1.13
Ani Labsystems	80	61.28	8.11	38.16	68.74	0.82
Bio-Rad Quantase	30	114.42	18.65	26.93	98.27	1.31
MP Biomedicals Enzyme Assay	20	90.77	33.24	71.13	61.96	1.03
Interscientific Enzyme	30	73.48	9.25	9.25	78.25	0.81
HPLC	20	76.90	4.67	7.53	68.08	1.02
Derivatized - MS/MS Non-kit	683	73.87	6.66	10.93	71.26	0.87
Non-derivatized - MS/MS Non-kit	218	88.30	7.08	15.83	82.08	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	243	85.21	7.63	10.09	80.76	1.00
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	86.75	10.29	11.95	78.41	1.06
Non-derivatized - MS/MS PE NeoBase Kit	136	81.05	4.75	8.44	75.54	0.95
Derivatized - MS/MS Chromsystems Kit	50	82.26	7.13	18.71	75.06	0.93
TecnoSuma UMTEST	47	102.77	18.63	30.77	77.64	1.30
Other	64	86.57	10.82	19.63	87.67	0.96

*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 922 - Enriched 182 µmol/L whole blood						
Bacterial Inhibition Assays	20	220.58	23.68	23.68	64.82	0.86
Fluorometric Manual	70	306.21	32.07	55.39	110.88	1.04
Fluorometric Cont Flow, In house	20	367.59	19.15	26.44	120.57	1.39
Fluorometric Cont Flow, Kit	40	281.43	17.20	48.84	88.94	1.04
Colorimetric	90	331.99	22.37	54.84	94.73	1.32
PerkinElmer Neonatal Kit	275	243.99	22.31	32.63	70.17	0.98
Neo-Genesis Accuwell	18	272.25	15.19	18.18	78.28	1.13
Ani Labsystems	80	218.52	18.36	136.05	68.74	0.82
Bio-Rad Quantase	30	313.10	32.14	48.52	98.27	1.31
MP Biomedicals Enzyme Assay	19	214.46	51.91	51.91	61.96	1.03
Interscientific Enzyme	29	228.21	17.77	19.90	78.25	0.81
HPLC	20	245.24	12.18	27.65	68.08	1.02
Derivatized - MS/MS Non-kit	683	228.59	19.71	35.50	71.26	0.87
Non-derivatized - MS/MS Non-kit	219	273.17	21.46	44.28	82.08	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	244	262.01	23.86	31.48	80.76	1.00
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	264.79	19.56	28.79	78.41	1.06
Non-derivatized - MS/MS PE NeoBase Kit	136	243.43	13.62	20.83	75.54	0.95
Derivatized - MS/MS Chromsystems Kit	50	241.84	16.11	39.35	75.06	0.93
TecnoSuma UMTEST	48	296.85	58.62	100.54	77.64	1.30
Other	69	261.28	22.33	47.41	87.67	0.96

*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 923 - Enriched 424 µmol/L whole blood						
Bacterial Inhibition Assays	20	430.02	43.23	46.51	64.82	0.86
Fluorometric Manual	57	539.70	48.78	71.52	110.88	1.04
Fluorometric Cont Flow, In house	20	703.86	43.64	79.69	120.57	1.39
Fluorometric Cont Flow, Kit	40	525.03	33.85	61.36	88.94	1.04
Colorimetric	90	651.88	34.41	111.28	94.73	1.32
PerkinElmer Neonatal Kit	274	472.47	35.46	55.67	70.17	0.98
Neo-Genesis Accuwell	20	551.31	33.92	40.02	78.28	1.13
Ani Labsystems	80	432.36	28.75	266.76	68.74	0.82
Bio-Rad Quantase	30	652.10	58.89	120.40	98.27	1.31
MP Biomedicals Enzyme Assay	20	487.92	103.53	136.70	61.96	1.03
Interscientific Enzyme	28	430.15	33.49	41.70	78.25	0.81
HPLC	20	496.19	29.78	58.82	68.08	1.02
Derivatized - MS/MS Non-kit	694	438.51	38.58	67.32	71.26	0.87
Non-derivatized - MS/MS Non-kit	217	522.02	36.51	82.64	82.08	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	243	492.80	39.10	52.93	80.76	1.00
Non-derivatized - MS/MS PE NeoGram MS2 Kit	28	518.34	31.76	47.81	78.41	1.06
Non-derivatized - MS/MS PE NeoBase Kit	137	470.02	26.42	40.10	75.54	0.95
Derivatized - MS/MS Chromsystems Kit	49	457.31	31.96	61.83	75.06	0.93
TecnoSuma UMTEST	50	600.06	95.40	169.47	77.64	1.30
Other	70	496.89	45.02	114.01	87.67	0.96

*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 924 - Enriched 666 µmol/L whole blood						
Bacterial Inhibition Assays	20	640.23	60.80	91.24	64.82	0.86
Fluorometric Manual	68	809.73	65.17	93.80	110.88	1.04
Fluorometric Cont Flow, In house	20	1052.36	73.59	167.47	120.57	1.39
Fluorometric Cont Flow, Kit	40	785.85	33.85	110.56	88.94	1.04
Colorimetric	90	977.80	52.38	175.83	94.73	1.32
PerkinElmer Neonatal Kit	274	730.24	55.74	87.27	70.17	0.98
Neo-Genesis Accuwell	19	840.78	35.53	35.53	78.28	1.13
Ani Labsystems	70	599.29	52.19	407.78	68.74	0.82
Bio-Rad Quantase	30	973.93	80.29	184.59	98.27	1.31
MP Biomedicals Enzyme Assay	20	767.38	151.97	185.72	61.96	1.03
Interscientific Enzyme	30	612.36	77.21	85.25	78.25	0.81
HPLC	20	757.08	45.96	64.02	68.08	1.02
Derivatized - MS/MS Non-kit	687	657.12	55.23	108.37	71.26	0.87
Non-derivatized - MS/MS Non-kit	219	800.48	58.98	137.32	82.08	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	246	753.86	66.43	102.13	80.76	1.00
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	794.03	79.38	107.08	78.41	1.06
Non-derivatized - MS/MS PE NeoBase Kit	137	711.71	40.84	54.76	75.54	0.95
Derivatized - MS/MS Chromsystems Kit	50	707.31	46.59	97.03	75.06	0.93
TecnoSuma UMTEST	50	971.04	113.01	200.76	77.64	1.30
Other	70	723.31	59.01	156.69	87.67	0.96

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

TABLE 10f. 2009 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 825 – Nonenriched 0 μmol/L whole blood						
Bacterial Inhibition Assays	20	191.51	27.25	49.39	150.81	1.08
Colorimetric	10	330.60	22.05	22.05	342.98	0.68
PerkinElmer Neonatal Kit	30	178.17	14.30	22.77	168.17	0.95
Bio-Rad Quantase	10	212.40	16.23	16.23	193.09	0.87
Interscientific Enzyme	30	184.62	49.77	72.84	181.58	0.93
Derivatized - MS/MS Non-kit	695	176.40	15.07	32.61	174.64	0.83
Non-derivatized - MS/MS Non-kit	84	219.66	16.47	42.93	218.47	0.90
Derivatized - MS/MS PE NeoGram MS2 Kit	238	167.91	15.51	20.26	166.84	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	177.82	17.85	17.85	187.93	0.74
Non-derivatized - MS/MS PE NeoBase Kit	59	209.33	13.04	22.00	204.70	0.85
Derivatized - MS/MS Chromsystems Kit	20	179.85	18.94	27.10	177.70	0.85
Lot 826 – Enriched 229 μmol/L whole blood						
Bacterial Inhibition Assays	20	368.91	46.62	47.68	150.81	1.08
Colorimetric	10	503.10	16.08	16.08	342.98	0.68
PerkinElmer Neonatal Kit	30	378.24	31.63	41.71	168.17	0.95
Bio-Rad Quantase	10	363.09	37.52	37.52	193.09	0.87
Interscientific Enzyme	30	368.48	48.29	48.29	181.58	0.93
Derivatized - MS/MS Non-kit	696	365.81	31.61	62.41	174.64	0.83
Non-derivatized - MS/MS Non-kit	87	423.94	24.25	73.67	218.47	0.90
Derivatized - MS/MS PE NeoGram MS2 Kit	235	358.63	30.59	36.59	166.84	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	369.01	40.47	40.47	187.93	0.74
Non-derivatized - MS/MS PE NeoBase Kit	60	399.13	26.48	36.16	204.70	0.85
Derivatized - MS/MS Chromsystems Kit	20	371.83	49.14	50.94	177.70	0.85

*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 827 – Enriched 534 µmol/L whole blood						
Bacterial Inhibition Assays	20	674.06	56.83	56.83	150.81	1.08
Colorimetric	10	732.60	18.55	18.55	342.98	0.68
PerkinElmer Neonatal Kit	30	662.77	51.88	76.58	168.17	0.95
Bio-Rad Quantase	10	662.43	51.43	51.43	193.09	0.87
Interscientific Enzyme	30	717.09	40.55	56.37	181.58	0.93
Derivatized - MS/MS Non-kit	695	613.43	50.31	100.80	174.64	0.83
Non-derivatized - MS/MS Non-kit	87	695.13	48.49	122.42	218.47	0.90
Derivatized - MS/MS PE NeoGram MS2 Kit	233	614.16	46.13	54.56	166.84	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	591.99	53.22	53.22	187.93	0.74
Non-derivatized - MS/MS PE NeoBase Kit	60	643.47	41.20	51.02	204.70	0.85
Derivatized - MS/MS Chromsystems Kit	20	623.66	88.53	88.84	177.70	0.85
Lot 828 – Enriched 839 µmol/L whole blood						
Bacterial Inhibition Assays	20	1099.5	97.21	125.58	150.81	1.08
Colorimetric	10	897.30	46.28	46.28	342.98	0.68
PerkinElmer Neonatal Kit	30	975.59	61.09	79.92	168.17	0.95
Bio-Rad Quantase	10	927.62	73.17	73.17	193.09	0.87
Interscientific Enzyme	30	938.53	84.45	99.74	181.58	0.93
Derivatized - MS/MS Non-kit	702	877.15	70.10	138.03	174.64	0.83
Non-derivatized - MS/MS Non-kit	87	974.08	66.16	202.63	218.47	0.90
Derivatized - MS/MS PE NeoGram MS2 Kit	235	873.69	68.54	92.08	166.84	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	805.17	80.29	83.89	187.93	0.74
Non-derivatized - MS/MS PE NeoBase Kit	60	924.13	55.77	76.93	204.70	0.85
Derivatized - MS/MS Chromsystems Kit	20	892.59	113.00	114.39	177.70	0.85

*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 921 – Nonenriched 0 μmol/L whole blood						
Bacterial Inhibition Assays	20	136.58	48.64	71.82	69.29	1.22
Colorimetric	10	204.16	6.92	6.92	197.03	0.69
PerkinElmer Neonatal Kit	19	162.50	15.06	16.26	159.16	0.99
Bio-Rad Quantase	10	216.20	16.13	16.13	226.99	0.97
Interscientific Enzyme	20	199.13	17.04	17.04	191.74	0.83
HPLC	10	125.90	8.99	8.99	123.70	1.05
Derivatized - MS/MS Non-kit	659	166.12	15.42	28.58	162.27	0.88
Non-derivatized - MS/MS Non-kit	116	197.31	14.67	21.64	193.86	0.91
Derivatized - MS/MS PE NeoGram MS2 Kit	244	163.65	15.28	19.53	159.94	0.94
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	165.87	17.55	22.94	159.30	0.86
Non-derivatized - MS/MS PE NeoBase Kit	100	201.58	14.02	18.92	190.79	0.96
Derivatized - MS/MS Chromsystems Kit	50	165.58	13.94	19.31	155.93	0.86
Lot 922 – Enriched 229 μmol/L whole blood						
Bacterial Inhibition Assays	20	317.41	55.30	58.51	69.29	1.22
Colorimetric	10	333.07	23.87	23.87	197.03	0.69
PerkinElmer Neonatal Kit	20	383.34	38.41	41.72	159.16	0.99
Bio-Rad Quantase	10	445.74	52.25	52.25	226.99	0.97
Interscientific Enzyme	20	373.10	14.13	14.13	191.74	0.83
HPLC	10	358.61	18.69	18.69	123.70	1.05
Derivatized - MS/MS Non-kit	661	361.10	31.89	66.38	162.27	0.88
Non-derivatized - MS/MS Non-kit	116	398.64	28.29	42.34	193.86	0.91
Derivatized - MS/MS PE NeoGram MS2 Kit	246	375.57	34.21	38.10	159.94	0.94
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	351.69	26.35	58.32	159.30	0.86
Non-derivatized - MS/MS PE NeoBase Kit	100	398.83	21.63	33.19	190.79	0.96
Derivatized - MS/MS Chromsystems Kit	50	350.23	23.30	46.07	155.93	0.86

*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 923 – Enriched 534 µmol/L whole blood						
Bacterial Inhibition Assays	20	599.34	41.52	129.68	69.29	1.22
Colorimetric	10	591.78	37.62	37.62	197.03	0.69
PerkinElmer Neonatal Kit	20	683.07	61.99	76.53	159.16	0.99
Bio-Rad Quantase	10	786.04	90.49	90.49	226.99	0.97
Interscientific Enzyme	18	630.77	6.58	6.58	191.74	0.83
HPLC	10	685.94	44.26	44.26	123.70	1.05
Derivatized - MS/MS Non-kit	655	626.26	54.55	97.86	162.27	0.88
Non-derivatized - MS/MS Non-kit	120	678.91	48.50	86.14	193.86	0.91
Derivatized - MS/MS PE NeoGram MS2 Kit	244	652.77	55.15	64.02	159.94	0.94
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	605.55	53.07	81.28	159.30	0.86
Non-derivatized - MS/MS PE NeoBase Kit	100	695.26	41.54	76.90	190.79	0.96
Derivatized - MS/MS Chromsystems Kit	48	590.60	45.89	80.17	155.93	0.86
Lot 924 – Enriched 839 µmol/L whole blood						
Bacterial Inhibition Assays	20	1180.36	103.69	290.18	69.29	1.22
Colorimetric	10	767.80	33.27	33.27	197.03	0.69
PerkinElmer Neonatal Kit	19	992.53	78.82	78.82	159.16	0.99
Bio-Rad Quantase	10	1021.66	104.71	104.71	226.99	0.97
Interscientific Enzyme	20	891.95	56.68	56.68	191.74	0.83
HPLC	10	1001.06	69.45	69.45	123.70	1.05
Derivatized - MS/MS Non-kit	652	904.47	73.11	133.24	162.27	0.88
Non-derivatized - MS/MS Non-kit	118	960.81	59.39	121.15	193.86	0.91
Derivatized - MS/MS PE NeoGram MS2 Kit	246	956.75	85.19	113.27	159.94	0.94
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	885.88	66.53	137.62	159.30	0.86
Non-derivatized - MS/MS PE NeoBase Kit	100	1002.26	52.78	103.10	190.79	0.96
Derivatized - MS/MS Chromsystems Kit	48	891.07	50.28	98.60	155.93	0.86

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

TABLE 10g. 2009 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 825 – Nonenriched 0 μmol/L whole blood						
PerkinElmer Neonatal Kit	30	27.18	3.88	3.88	20.21	0.96
Derivatized - MS/MS Non-kit	665	25.50	4.02	5.92	21.32	0.81
Non-derivatized - MS/MS Non-kit	86	23.67	4.12	8.86	14.35	0.91
Derivatized - MS/MS PE NeoGram MS2 Kit	220	26.87	3.50	5.94	24.86	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	18.49	5.05	5.09	15.71	0.68
Non-derivatized - MS/MS PE NeoBase Kit	50	22.05	2.30	5.67	13.99	0.79
Derivatized - MS/MS Chromsystems Kit	39	23.89	2.35	2.95	19.79	0.83
Lot 826 – Enriched 67 μmol/L whole blood						
PerkinElmer Neonatal Kit	29	80.14	10.87	10.87	20.21	0.96
Derivatized - MS/MS Non-kit	679	72.93	8.54	13.85	21.32	0.81
Non-derivatized - MS/MS Non-kit	87	66.20	7.30	19.58	14.35	0.91
Derivatized - MS/MS PE NeoGram MS2 Kit	221	80.22	6.81	9.23	24.86	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	51.96	9.49	10.89	15.71	0.68
Non-derivatized - MS/MS PE NeoBase Kit	50	59.91	4.10	10.16	13.99	0.79
Derivatized - MS/MS Chromsystems Kit	39	72.00	8.62	8.87	19.79	0.83
Lot 827 – Enriched 201 μmol/L whole blood						
PerkinElmer Neonatal Kit	30	206.15	26.42	31.54	20.21	0.96
Derivatized - MS/MS Non-kit	665	182.18	17.19	29.37	21.32	0.81
Non-derivatized - MS/MS Non-kit	89	193.75	20.44	52.82	14.35	0.91
Derivatized - MS/MS PE NeoGram MS2 Kit	225	201.23	16.39	20.09	24.86	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	162.16	27.22	30.76	15.71	0.68
Non-derivatized - MS/MS PE NeoBase Kit	49	169.95	14.70	26.20	13.99	0.79
Derivatized - MS/MS Chromsystems Kit	39	183.75	15.92	17.43	19.79	0.83
Lot 828 – Enriched 403 μmol/L whole blood						
PerkinElmer Neonatal Kit	29	410.22	38.15	39.48	20.21	0.96
Derivatized - MS/MS Non-kit	664	351.46	31.37	56.58	21.32	0.81
Non-derivatized - MS/MS Non-kit	89	382.80	36.81	104.10	14.35	0.91
Derivatized - MS/MS PE NeoGram MS2 Kit	223	375.38	29.56	37.72	24.86	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	285.56	39.83	62.72	15.71	0.68
Non-derivatized - MS/MS PE NeoBase Kit	50	336.85	19.61	39.53	13.99	0.79
Derivatized - MS/MS Chromsystems Kit	40	354.86	30.42	41.46	19.79	0.83

*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 921 – Nonenriched 0 μmol/L whole blood						
PerkinElmer Neonatal Kit	20	27.30	2.83	3.04	25.19	0.97
Derivatized - MS/MS Non-kit	664	24.41	4.14	6.59	21.45	0.82
Non-derivatized - MS/MS Non-kit	123	19.29	2.82	4.48	13.16	0.84
Derivatized - MS/MS PE NeoGram MS2 Kit	226	27.75	3.68	4.67	25.67	0.97
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	21.73	3.79	6.26	8.95	0.80
Non-derivatized - MS/MS PE NeoBase Kit	100	23.10	1.82	3.21	13.30	0.90
Derivatized - MS/MS Chromsystems Kit	30	16.81	1.82	6.60	11.79	0.65
Lot 922 – Enriched 67 μmol/L whole blood						
PerkinElmer Neonatal Kit	20	89.10	8.43	9.19	25.19	0.97
Derivatized - MS/MS Non-kit	662	73.99	7.76	12.58	21.45	0.82
Non-derivatized - MS/MS Non-kit	124	61.99	5.76	12.48	13.16	0.84
Derivatized - MS/MS PE NeoGram MS2 Kit	224	89.47	8.86	10.99	25.67	0.97
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	56.66	11.40	13.46	8.95	0.80
Non-derivatized - MS/MS PE NeoBase Kit	96	65.71	3.56	6.63	13.30	0.90
Derivatized - MS/MS Chromsystems Kit	30	51.83	6.32	21.99	11.79	0.65
Lot 923 – Enriched 201 μmol/L whole blood						
PerkinElmer Neonatal Kit	20	216.70	21.31	25.34	25.19	0.97
Derivatized - MS/MS Non-kit	656	184.50	18.58	29.38	21.45	0.82
Non-derivatized - MS/MS Non-kit	128	183.44	14.25	39.28	13.16	0.84
Derivatized - MS/MS PE NeoGram MS2 Kit	225	217.44	19.71	23.51	25.67	0.97
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	153.96	27.57	36.02	8.95	0.80
Non-derivatized - MS/MS PE NeoBase Kit	94	187.32	12.52	21.17	13.30	0.90
Derivatized - MS/MS Chromsystems Kit	30	138.26	15.34	53.15	11.79	0.65
Lot 924 – Enriched 403 μmol/L whole blood						
PerkinElmer Neonatal Kit	20	415.31	40.71	43.58	25.19	0.97
Derivatized - MS/MS Non-kit	656	352.70	31.77	48.55	21.45	0.82
Non-derivatized - MS/MS Non-kit	122	353.35	29.40	70.01	13.16	0.84
Derivatized - MS/MS PE NeoGram MS2 Kit	224	415.78	35.89	45.58	25.67	0.97
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	339.83	37.01	49.37	8.95	0.80
Non-derivatized - MS/MS PE NeoBase Kit	96	380.66	21.23	38.89	13.30	0.90
Derivatized - MS/MS Chromsystems Kit	30	275.78	27.49	94.78	11.79	0.65

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

TABLE 10h. 2009 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 825 – Nonenriched 0 μmol/L whole blood						
Fluorometric Manual	10	126.60	13.24	13.24	98.55	1.31
PerkinElmer Neonatal Kit	29	62.02	5.34	5.72	57.29	1.05
HPLC	20	70.77	10.46	16.42	65.63	1.08
Derivatized - MS/MS Non-kit	698	60.13	6.03	10.87	56.39	1.04
Non-derivatized - MS/MS Non-kit	138	71.92	8.68	16.31	68.01	1.18
Derivatized - MS/MS PE NeoGram MS2 Kit	236	61.32	5.26	8.38	54.68	1.06
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	63.86	11.69	14.84	61.72	1.08
Non-derivatized - MS/MS PE NeoBase Kit	66	63.76	7.42	9.28	58.51	1.06
Derivatized - MS/MS Chromsystems Kit	19	62.63	4.01	4.01	55.93	1.01
Lot 826 – Enriched 276 μmol/L whole blood						
Fluorometric Manual	10	433.50	40.41	40.41	98.55	1.31
PerkinElmer Neonatal Kit	30	341.19	34.87	40.06	57.29	1.05
HPLC	20	352.97	18.21	45.21	65.63	1.08
Derivatized - MS/MS Non-kit	704	339.01	28.90	59.65	56.39	1.04
Non-derivatized - MS/MS Non-kit	139	385.27	32.76	77.55	68.01	1.18
Derivatized - MS/MS PE NeoGram MS2 Kit	235	339.05	29.12	40.14	54.68	1.06
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	354.27	39.66	64.65	61.72	1.08
Non-derivatized - MS/MS PE NeoBase Kit	68	346.25	22.25	29.76	58.51	1.06
Derivatized - MS/MS Chromsystems Kit	20	327.44	29.59	32.55	55.93	1.01

*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 827 – Enriched 497 µmol/L whole blood						
Fluorometric Manual	10	720.70	76.30	76.30	98.55	1.31
PerkinElmer Neonatal Kit	28	575.77	51.19	55.50	57.29	1.05
HPLC	20	607.46	41.67	69.02	65.63	1.08
Derivatized - MS/MS Non-kit	702	567.45	47.66	93.65	56.39	1.04
Non-derivatized - MS/MS Non-kit	139	657.17	68.06	130.08	68.01	1.18
Derivatized - MS/MS PE NeoGram MS2 Kit	236	577.24	45.97	63.23	54.68	1.06
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	601.02	76.28	119.44	61.72	1.08
Non-derivatized - MS/MS PE NeoBase Kit	70	581.04	36.99	61.46	58.51	1.06
Derivatized - MS/MS Chromsystems Kit	20	552.14	57.86	57.86	55.93	1.01
Lot 828 – Enriched 773 µmol/L whole blood						
Fluorometric Manual	10	1141.2	108.41	108.41	98.55	1.31
PerkinElmer Neonatal Kit	29	871.93	73.03	73.03	57.29	1.05
HPLC	20	901.11	51.50	74.04	65.63	1.08
Derivatized - MS/MS Non-kit	706	861.44	69.14	139.40	56.39	1.04
Non-derivatized - MS/MS Non-kit	140	979.42	88.64	203.84	68.01	1.18
Derivatized - MS/MS PE NeoGram MS2 Kit	236	879.23	78.18	105.61	54.68	1.06
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	895.13	101.53	153.01	61.72	1.08
Non-derivatized - MS/MS PE NeoBase Kit	68	883.75	64.40	81.36	58.51	1.06
Derivatized - MS/MS Chromsystems Kit	20	841.65	66.60	70.65	55.93	1.01

*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 921 – Nonenriched 0 μmol/L whole blood						
Fluorometric Manual	10	116.50	10.90	10.90	93.51	1.01
PerkinElmer Neonatal Kit	20	64.81	7.12	10.61	60.31	0.90
HPLC	20	61.77	2.81	4.79	53.48	0.95
Derivatized - MS/MS Non-kit	641	59.07	5.68	10.53	52.09	0.87
Non-derivatized - MS/MS Non-kit	195	64.70	7.30	15.38	54.79	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	233	65.98	6.44	9.30	60.40	0.93
Non-derivatized - MS/MS PE NeoGram MS2 Kit	27	60.91	7.76	7.76	60.25	0.89
Non-derivatized - MS/MS PE NeoBase Kit	134	61.84	4.40	8.85	55.11	0.86
Derivatized - MS/MS Chromsystems Kit	40	61.20	6.58	9.93	53.13	0.89
Lot 922 – Enriched 276 μmol/L whole blood						
Fluorometric Manual	10	360.30	18.82	18.82	93.51	1.01
PerkinElmer Neonatal Kit	20	304.45	32.85	40.83	60.31	0.90
HPLC	20	307.44	13.28	49.29	53.48	0.95
Derivatized - MS/MS Non-kit	656	284.82	26.47	47.48	52.09	0.87
Non-derivatized - MS/MS Non-kit	190	311.83	22.69	52.68	54.79	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	236	315.24	28.51	38.18	60.40	0.93
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	310.16	44.58	46.63	60.25	0.89
Non-derivatized - MS/MS PE NeoBase Kit	135	287.87	18.90	39.30	55.11	0.86
Derivatized - MS/MS Chromsystems Kit	40	295.35	21.38	32.55	53.13	0.89

*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 923 – Enriched 497 µmol/L whole blood						
Fluorometric Manual	10	555.10	58.11	58.11	93.51	1.01
PerkinElmer Neonatal Kit	20	503.05	40.61	66.42	60.31	0.90
HPLC	20	521.62	37.87	85.96	53.48	0.95
Derivatized - MS/MS Non-kit	646	474.49	41.48	78.06	52.09	0.87
Non-derivatized - MS/MS Non-kit	191	527.64	40.39	103.30	54.79	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	236	512.80	41.99	59.61	60.40	0.93
Non-derivatized - MS/MS PE NeoGram MS2 Kit	26	492.56	27.52	32.11	60.25	0.89
Non-derivatized - MS/MS PE NeoBase Kit	136	475.24	30.77	64.97	55.11	0.86
Derivatized - MS/MS Chromsystems Kit	28	471.97	42.86	45.33	53.13	0.89
Lot 924 – Enriched 773 µmol/L whole blood						
Fluorometric Manual	10	907.30	88.45	88.45	93.51	1.01
PerkinElmer Neonatal Kit	20	760.81	87.46	100.90	60.31	0.90
HPLC	20	798.48	50.65	114.74	53.48	0.95
Derivatized - MS/MS Non-kit	636	728.84	62.85	114.66	52.09	0.87
Non-derivatized - MS/MS Non-kit	197	813.90	58.50	167.89	54.79	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	236	788.93	73.52	92.58	60.40	0.93
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	753.02	99.66	103.40	60.25	0.89
Non-derivatized - MS/MS PE NeoBase Kit	126	730.45	45.43	94.17	55.11	0.86
Derivatized - MS/MS Chromsystems Kit	30	756.68	86.29	95.72	53.13	0.89

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

TABLE 10i. 2009 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 825 – Nonenriched 0 μmol/L whole blood						
PerkinElmer Neonatal Kit	29	180.51	13.05	21.18	175.81	0.79
Derivatized - MS/MS Non-kit	612	173.82	18.50	34.78	167.04	0.73
Non-derivatized - MS/MS Non-kit	90	154.21	14.74	33.08	148.43	0.72
Derivatized - MS/MS PE NeoGram MS2 Kit	207	161.61	20.15	29.09	157.67	0.70
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	156.08	13.27	20.54	153.95	0.69
Non-derivatized - MS/MS PE NeoBase Kit	60	166.97	11.96	32.88	160.19	0.74
Derivatized - MS/MS Chromsystems Kit	20	136.05	8.60	17.81	129.91	0.58
Lot 826 – Enriched 257 μmol/L whole blood						
PerkinElmer Neonatal Kit	30	375.60	34.80	54.33	175.81	0.79
Derivatized - MS/MS Non-kit	622	346.93	35.40	59.19	167.04	0.73
Non-derivatized - MS/MS Non-kit	90	324.03	24.34	66.82	148.43	0.72
Derivatized - MS/MS PE NeoGram MS2 Kit	210	328.70	37.67	56.24	157.67	0.70
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	328.17	38.58	55.99	153.95	0.69
Non-derivatized - MS/MS PE NeoBase Kit	60	342.96	30.12	66.06	160.19	0.74
Derivatized - MS/MS Chromsystems Kit	20	271.15	18.93	43.97	129.91	0.58
Lot 827 – Enriched 599 μmol/L whole blood						
PerkinElmer Neonatal Kit	30	646.81	55.29	80.12	175.81	0.79
Derivatized - MS/MS Non-kit	621	596.02	56.70	91.33	167.04	0.73
Non-derivatized - MS/MS Non-kit	89	580.23	48.22	119.81	148.43	0.72
Derivatized - MS/MS PE NeoGram MS2 Kit	210	580.79	61.90	100.89	157.67	0.70
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	571.93	57.01	82.31	153.95	0.69
Non-derivatized - MS/MS PE NeoBase Kit	60	596.52	42.13	110.85	160.19	0.74
Derivatized - MS/MS Chromsystems Kit	20	470.31	34.11	67.56	129.91	0.58
Lot 828 – Enriched 941 μmol/L whole blood						
PerkinElmer Neonatal Kit	29	927.13	97.13	107.34	175.81	0.79
Derivatized - MS/MS Non-kit	624	855.28	78.58	138.08	167.04	0.73
Non-derivatized - MS/MS Non-kit	90	825.77	66.21	188.63	148.43	0.72
Derivatized - MS/MS PE NeoGram MS2 Kit	206	812.92	101.93	140.51	157.67	0.70
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	807.16	54.17	125.22	153.95	0.69
Non-derivatized - MS/MS PE NeoBase Kit	60	859.78	61.09	168.52	160.19	0.74
Derivatized - MS/MS Chromsystems Kit	20	675.60	34.58	92.19	129.91	0.58

*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 921 – Nonenriched 0 μmol/L whole blood						
PerkinElmer Neonatal Kit	19	210.35	27.08	27.33	200.36	0.90
Derivatized - MS/MS Non-kit	621	179.25	20.08	40.85	172.63	0.74
Non-derivatized - MS/MS Non-kit	107	170.88	15.53	34.39	159.53	0.84
Derivatized - MS/MS PE NeoGram MS2 Kit	234	184.98	22.87	30.91	175.29	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	166.34	23.47	25.51	155.98	0.70
Non-derivatized - MS/MS PE NeoBase Kit	109	178.72	12.52	20.58	168.26	0.82
Derivatized - MS/MS Chromsystems Kit	29	171.47	18.95	42.74	156.08	0.69
Lot 922 – Enriched 256 μmol/L whole blood						
PerkinElmer Neonatal Kit	19	428.04	56.93	56.93	200.36	0.90
Derivatized - MS/MS Non-kit	628	358.43	39.98	64.87	172.63	0.74
Non-derivatized - MS/MS Non-kit	109	361.56	28.18	56.57	159.53	0.84
Derivatized - MS/MS PE NeoGram MS2 Kit	236	376.78	39.35	55.72	175.29	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	326.59	36.95	36.95	155.98	0.70
Non-derivatized - MS/MS PE NeoBase Kit	108	368.20	25.72	40.34	168.26	0.82
Derivatized - MS/MS Chromsystems Kit	30	327.51	26.64	53.94	156.08	0.69
Lot 923 – Enriched 598 μmol/L whole blood						
PerkinElmer Neonatal Kit	19	716.69	86.30	86.60	200.36	0.90
Derivatized - MS/MS Non-kit	613	606.33	59.29	102.72	172.63	0.74
Non-derivatized - MS/MS Non-kit	110	659.11	62.55	111.01	159.53	0.84
Derivatized - MS/MS PE NeoGram MS2 Kit	235	641.59	64.78	87.30	175.29	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	558.36	61.57	61.57	155.98	0.70
Non-derivatized - MS/MS PE NeoBase Kit	107	649.50	41.63	69.42	168.26	0.82
Derivatized - MS/MS Chromsystems Kit	28	539.40	43.64	51.56	156.08	0.69
Lot 924 – Enriched 940 μmol/L whole blood						
PerkinElmer Neonatal Kit	20	1059.67	150.36	150.36	200.36	0.90
Derivatized - MS/MS Non-kit	628	876.68	85.92	145.00	172.63	0.74
Non-derivatized - MS/MS Non-kit	110	955.91	77.55	159.84	159.53	0.84
Derivatized - MS/MS PE NeoGram MS2 Kit	237	944.82	111.64	157.97	175.29	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	821.92	57.28	58.13	155.98	0.70
Non-derivatized - MS/MS PE NeoBase Kit	107	946.90	59.45	105.23	168.26	0.82
Derivatized - MS/MS Chromsystems Kit	28	828.28	75.54	78.28	156.08	0.69

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

TABLE 10j. 2009 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 825 – Nonenriched 0 μmol/L whole blood						
PerkinElmer Neonatal Kit	28	31.78	2.82	3.11	31.89	0.93
Derivatized - MS/MS Non-kit	658	23.54	3.14	5.85	21.34	0.70
Non-derivatized - MS/MS Non-kit	87	31.31	5.44	7.11	29.88	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	235	29.10	1.99	3.15	28.96	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	28.58	4.61	5.69	30.67	0.88
Non-derivatized - MS/MS PE NeoBase Kit	60	27.60	2.34	3.67	27.71	0.81
Derivatized - MS/MS Chromsystems Kit	30	26.76	2.29	7.12	26.23	0.75
Lot 826 – Enriched 57 μmol/L whole blood						
PerkinElmer Neonatal Kit	30	81.69	4.22	11.13	31.89	0.93
Derivatized - MS/MS Non-kit	651	59.47	6.99	14.12	21.34	0.70
Non-derivatized - MS/MS Non-kit	89	81.21	11.92	21.15	29.88	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	237	77.92	5.10	7.48	28.96	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	80.24	14.90	16.82	30.67	0.88
Non-derivatized - MS/MS PE NeoBase Kit	60	73.45	5.54	8.53	27.71	0.81
Derivatized - MS/MS Chromsystems Kit	30	69.09	7.78	20.25	26.23	0.75
Lot 827 – Enriched 171 μmol/L whole blood						
PerkinElmer Neonatal Kit	30	196.43	11.18	20.54	31.89	0.93
Derivatized - MS/MS Non-kit	655	140.83	14.96	33.85	21.34	0.70
Non-derivatized - MS/MS Non-kit	88	179.86	22.78	35.87	29.88	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	235	179.60	10.79	17.58	28.96	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	185.84	25.95	25.95	30.67	0.88
Non-derivatized - MS/MS PE NeoBase Kit	60	166.24	10.81	19.22	27.71	0.81
Derivatized - MS/MS Chromsystems Kit	30	154.70	17.70	38.80	26.23	0.75
Lot 828 – Enriched 343 μmol/L whole blood						
PerkinElmer Neonatal Kit	30	347.69	26.37	32.02	31.89	0.93
Derivatized - MS/MS Non-kit	653	263.24	27.54	58.96	21.34	0.70
Non-derivatized - MS/MS Non-kit	88	337.95	49.35	70.06	29.88	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	235	327.46	19.43	30.52	28.96	0.87
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	328.63	41.33	50.72	30.67	0.88
Non-derivatized - MS/MS PE NeoBase Kit	59	303.25	15.84	29.23	27.71	0.81
Derivatized - MS/MS Chromsystems Kit	30	285.03	25.91	68.02	26.23	0.75

*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 921 - Nonenriched 0 μmol/L whole blood						
PerkinElmer Neonatal Kit	20	34.45	3.57	3.60	35.02	0.98
Derivatized - MS/MS Non-kit	655	25.09	2.81	5.96	24.42	0.74
Non-derivatized - MS/MS Non-kit	111	27.60	6.53	9.34	24.38	0.90
Derivatized - MS/MS PE NeoGram MS2 Kit	236	31.25	2.51	3.57	30.58	0.92
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	29.19	2.98	6.36	27.91	0.88
Non-derivatized - MS/MS PE NeoBase Kit	98	30.14	2.70	4.36	28.86	0.85
Derivatized - MS/MS Chromsystems Kit	40	28.03	2.73	4.74	27.49	0.81
Lot 922 - Enriched 57 μmol/L whole blood						
PerkinElmer Neonatal Kit	20	91.43	8.68	9.31	35.02	0.98
Derivatized - MS/MS Non-kit	649	66.41	6.62	14.57	24.42	0.74
Non-derivatized - MS/MS Non-kit	111	74.74	10.47	13.65	24.38	0.90
Derivatized - MS/MS PE NeoGram MS2 Kit	236	84.29	6.30	9.87	30.58	0.92
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	79.84	6.36	15.71	27.91	0.88
Non-derivatized - MS/MS PE NeoBase Kit	100	76.80	5.63	8.63	28.86	0.85
Derivatized - MS/MS Chromsystems Kit	40	74.92	4.52	9.67	27.49	0.81
Lot 923 - Enriched 171 μmol/L whole blood						
PerkinElmer Neonatal Kit	20	202.18	19.51	21.49	35.02	0.98
Derivatized - MS/MS Non-kit	645	149.79	14.01	30.48	24.42	0.74
Non-derivatized - MS/MS Non-kit	116	173.39	20.31	28.21	24.38	0.90
Derivatized - MS/MS PE NeoGram MS2 Kit	235	184.65	12.56	20.31	30.58	0.92
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	172.69	13.96	34.55	27.91	0.88
Non-derivatized - MS/MS PE NeoBase Kit	100	173.84	13.96	17.04	28.86	0.85
Derivatized - MS/MS Chromsystems Kit	40	163.43	12.00	25.17	27.49	0.81
Lot 924 - Enriched 343 μmol/L whole blood						
PerkinElmer Neonatal Kit	20	369.24	33.71	33.71	35.02	0.98
Derivatized - MS/MS Non-kit	648	277.91	26.46	61.85	24.42	0.74
Non-derivatized - MS/MS Non-kit	116	334.37	39.27	56.06	24.38	0.90
Derivatized - MS/MS PE NeoGram MS2 Kit	236	347.00	24.07	41.91	30.58	0.92
Non-derivatized - MS/MS PE NeoGram MS2 Kit	30	331.14	19.90	65.70	27.91	0.88
Non-derivatized - MS/MS PE NeoBase Kit	99	321.95	21.26	33.30	28.86	0.85
Derivatized - MS/MS Chromsystems Kit	40	306.56	26.00	41.17	27.49	0.81

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

TABLE 10k. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	771	38.22	3.85	7.89	38.43	1.04
Non-derivatized MS/MS Non-kit	118	39.41	4.56	8.71	38.96	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	265	47.61	4.16	6.99	47.68	1.39
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	35.97	3.08	10.31	36.57	0.96
Non-derivatized-MS/MS PE NeoBase Kit	60	39.05	3.62	5.61	39.22	0.99
Derivatized-MS/MS Chromsystems Kit	30	43.71	3.64	4.40	44.04	1.05
Lot 866 – Enriched 25 μmol/L whole blood						
Derivatized - MS/MS Non-kit	768	65.39	5.96	12.97	38.43	1.04
Non-derivatized MS/MS Non-kit	120	66.51	7.44	14.23	38.96	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	266	82.85	7.34	12.61	47.68	1.39
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	61.34	6.06	17.00	36.57	0.96
Non-derivatized-MS/MS PE NeoBase Kit	60	64.28	6.07	8.11	39.22	0.99
Derivatized-MS/MS Chromsystems Kit	29	71.14	5.65	5.89	44.04	1.05
Lot 867 – Enriched 50 μmol/L whole blood						
Derivatized - MS/MS Non-kit	766	89.41	8.94	17.48	38.43	1.04
Non-derivatized MS/MS Non-kit	119	89.97	10.34	18.88	38.96	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	267	116.09	10.49	18.12	47.68	1.39
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	84.37	6.10	24.49	36.57	0.96
Non-derivatized-MS/MS PE NeoBase Kit	60	88.47	7.19	11.92	39.22	0.99
Derivatized-MS/MS Chromsystems Kit	30	96.33	7.07	8.95	44.04	1.05
Lot 868 – Enriched 75 μmol/L whole blood						
Derivatized - MS/MS Non-kit	768	117.08	11.23	23.37	38.43	1.04
Non-derivatized MS/MS Non-kit	120	121.12	14.22	27.94	38.96	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	264	151.99	13.73	24.36	47.68	1.39
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	107.93	9.97	31.88	36.57	0.96
Non-derivatized-MS/MS PE NeoBase Kit	50	113.40	9.87	14.90	39.22	0.99
Derivatized-MS/MS Chromsystems Kit	29	123.17	7.76	14.14	44.04	1.05

*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 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	732	14.56	1.64	2.77	13.61	1.35
Non-derivatized - MS/MS Non-kit	133	14.14	1.80	4.16	13.07	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	260	19.62	1.78	2.63	18.39	1.97
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	11.70	3.30	5.09	9.97	1.01
Non-derivatized - MS/MS PE NeoBase Kit	128	15.01	1.13	2.35	14.32	1.14
Derivatized - MS/MS Chromsystems Kit	30	14.27	1.29	2.50	13.05	1.27
Lot 962 – Enriched 10 μmol/L whole blood						
Derivatized - MS/MS Non-kit	741	26.11	2.52	4.85	13.61	1.35
Non-derivatized - MS/MS Non-kit	130	23.02	2.41	4.99	13.07	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	261	36.68	3.24	4.95	18.39	1.97
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	18.39	2.63	4.03	9.97	1.01
Non-derivatized - MS/MS PE NeoBase Kit	127	25.04	1.90	3.44	14.32	1.14
Derivatized - MS/MS Chromsystems Kit	29	23.92	1.75	4.23	13.05	1.27
Lot 963 – Enriched 20 μmol/L whole blood						
Derivatized - MS/MS Non-kit	756	39.77	3.91	7.11	13.61	1.35
Non-derivatized - MS/MS Non-kit	130	34.85	3.06	6.70	13.07	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	264	56.99	5.64	8.02	18.39	1.97
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	27.93	5.11	6.10	9.97	1.01
Non-derivatized - MS/MS PE NeoBase Kit	124	36.37	2.25	4.83	14.32	1.14
Derivatized - MS/MS Chromsystems Kit	30	38.17	3.82	7.26	13.05	1.27
Lot 964 – Enriched 30 μmol/L whole blood						
Derivatized - MS/MS Non-kit	746	54.96	4.86	9.05	13.61	1.35
Non-derivatized - MS/MS Non-kit	132	47.67	4.45	13.06	13.07	1.12
Derivatized - MS/MS PE NeoGram MS2 Kit	256	78.59	6.29	10.59	18.39	1.97
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	42.27	13.59	18.63	9.97	1.01
Non-derivatized - MS/MS PE NeoBase Kit	126	49.26	3.66	6.29	14.32	1.14
Derivatized - MS/MS Chromsystems Kit	30	51.74	5.55	10.24	13.05	1.27

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

TABLE 10l. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	811	16.71	2.17	5.56	16.97	0.99
Non-derivatized MS/MS Non-kit	106	14.22	1.31	1.89	14.65	1.13
Derivatized - MS/MS PE NeoGram MS2 Kit	271	16.98	1.67	3.31	17.19	0.62
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	14.60	1.08	2.15	15.00	1.21
Non-derivatized-MS/MS PE NeoBase Kit	48	11.17	0.91	1.66	11.68	0.86
Derivatized-MS/MS Chromsystems Kit	20	16.00	1.19	1.59	15.67	0.99
Lot 866 – Enriched 10 μmol/L whole blood						
Derivatized - MS/MS Non-kit	811	27.47	3.48	7.32	16.97	0.99
Non-derivatized MS/MS Non-kit	108	26.52	2.28	3.08	14.65	1.13
Derivatized - MS/MS PE NeoGram MS2 Kit	270	23.89	1.81	3.49	17.19	0.62
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	27.92	2.36	4.36	15.00	1.21
Non-derivatized-MS/MS PE NeoBase Kit	49	20.91	1.46	2.97	11.68	0.86
Derivatized-MS/MS Chromsystems Kit	19	25.37	2.00	2.14	15.67	0.99
Lot 867 – Enriched 20 μmol/L whole blood						
Derivatized - MS/MS Non-kit	811	36.38	4.33	9.02	16.97	0.99
Non-derivatized MS/MS Non-kit	107	37.36	3.09	4.67	14.65	1.13
Derivatized - MS/MS PE NeoGram MS2 Kit	269	29.34	1.95	3.46	17.19	0.62
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	38.92	3.75	5.68	15.00	1.21
Non-derivatized-MS/MS PE NeoBase Kit	48	29.00	1.89	4.29	11.68	0.86
Derivatized-MS/MS Chromsystems Kit	20	34.72	3.24	3.24	15.67	0.99
Lot 868 – Enriched 30 μmol/L whole blood						
Derivatized - MS/MS Non-kit	809	46.77	5.15	11.57	16.97	0.99
Non-derivatized MS/MS Non-kit	106	48.26	4.19	5.37	14.65	1.13
Derivatized - MS/MS PE NeoGram MS2 Kit	271	35.92	2.53	3.96	17.19	0.62
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	51.43	3.44	6.60	15.00	1.21
Non-derivatized-MS/MS PE NeoBase Kit	39	36.94	2.83	3.94	11.68	0.86
Derivatized-MS/MS Chromsystems Kit	19	45.76	3.05	3.61	15.67	0.99

*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 961 – Nonenriched 0 µmol/L whole blood						
Derivatized - MS/MS Non-kit	729	10.79	1.18	2.22	10.58	1.01
Non-derivatized - MS/MS Non-kit	127	10.53	1.11	1.62	10.24	1.19
Derivatized - MS/MS PE NeoGram MS2 Kit	269	9.55	0.90	1.83	9.43	0.64
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	11.03	1.37	2.33	10.72	1.30
Non-derivatized - MS/MS PE NeoBase Kit	120	7.48	0.49	0.97	7.15	0.83
Derivatized - MS/MS Chromsystems Kit	30	10.06	0.87	1.25	9.73	1.06
Lot 962 – Enriched 10 µmol/L whole blood						
Derivatized - MS/MS Non-kit	728	20.47	2.00	4.03	10.58	1.01
Non-derivatized - MS/MS Non-kit	128	21.69	1.84	2.74	10.24	1.19
Derivatized - MS/MS PE NeoGram MS2 Kit	265	15.81	1.14	2.43	9.43	0.64
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	23.40	1.17	1.97	10.72	1.30
Non-derivatized - MS/MS PE NeoBase Kit	114	15.19	0.90	1.61	7.15	0.83
Derivatized - MS/MS Chromsystems Kit	30	19.57	1.23	2.05	9.73	1.06
Lot 963 – Enriched 20 µmol/L whole blood						
Derivatized - MS/MS Non-kit	740	30.74	3.22	6.47	10.58	1.01
Non-derivatized - MS/MS Non-kit	131	34.27	2.89	5.69	10.24	1.19
Derivatized - MS/MS PE NeoGram MS2 Kit	262	21.82	1.62	2.92	9.43	0.64
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	36.56	3.17	3.95	10.72	1.30
Non-derivatized - MS/MS PE NeoBase Kit	117	23.28	1.51	2.90	7.15	0.83
Derivatized - MS/MS Chromsystems Kit	30	31.51	1.78	1.94	9.73	1.06
Lot 964 – Enriched 30 µmol/L whole blood						
Derivatized - MS/MS Non-kit	739	41.16	4.02	8.24	10.58	1.01
Non-derivatized - MS/MS Non-kit	126	46.16	3.63	6.31	10.24	1.19
Derivatized - MS/MS PE NeoGram MS2 Kit	264	28.80	2.23	3.76	9.43	0.64
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	50.06	5.10	6.79	10.72	1.30
Non-derivatized - MS/MS PE NeoBase Kit	120	32.50	2.30	4.40	7.15	0.83
Derivatized - MS/MS Chromsystems Kit	29	41.46	2.20	2.20	9.73	1.06

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

TABLE 10m. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	796	1.67	0.24	0.43	1.75	1.02
Non-derivatized MS/MS Non-kit	113	1.74	0.22	0.54	1.74	1.15
Derivatized - MS/MS PE NeoGram MS2 Kit	274	1.33	0.10	0.15	1.38	0.88
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	1.55	0.33	0.45	1.74	1.12
Non-derivatized-MS/MS PE NeoBase Kit	58	1.33	0.10	0.23	1.43	0.86
Derivatized-MS/MS Chromsystems Kit	20	1.68	0.29	0.38	1.91	0.95
Lot 866 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	789	4.93	0.58	1.10	1.75	1.02
Non-derivatized MS/MS Non-kit	110	5.26	0.53	0.75	1.74	1.15
Derivatized - MS/MS PE NeoGram MS2 Kit	276	4.10	0.29	0.38	1.38	0.88
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	5.39	0.60	1.10	1.74	1.12
Non-derivatized-MS/MS PE NeoBase Kit	60	4.07	0.28	0.63	1.43	0.86
Derivatized-MS/MS Chromsystems Kit	20	5.00	0.90	1.17	1.91	0.95
Lot 867 – Enriched 7.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	790	9.36	1.08	1.92	1.75	1.02
Non-derivatized MS/MS Non-kit	110	10.25	1.01	1.32	1.74	1.15
Derivatized - MS/MS PE NeoGram MS2 Kit	274	7.99	0.48	0.72	1.38	0.88
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	10.10	1.01	2.01	1.74	1.12
Non-derivatized-MS/MS PE NeoBase Kit	60	7.99	0.45	1.24	1.43	0.86
Derivatized-MS/MS Chromsystems Kit	20	9.17	1.19	1.64	1.91	0.95
Lot 868 – Enriched 12 μmol/L whole blood						
Derivatized - MS/MS Non-kit	785	14.02	1.58	3.18	1.75	1.02
Non-derivatized MS/MS Non-kit	110	15.63	1.69	2.26	1.74	1.15
Derivatized - MS/MS PE NeoGram MS2 Kit	275	11.96	0.79	1.16	1.38	0.88
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	15.20	1.77	3.89	1.74	1.12
Non-derivatized-MS/MS PE NeoBase Kit	49	11.59	0.90	1.45	1.43	0.86
Derivatized-MS/MS Chromsystems Kit	20	13.17	1.58	1.72	1.91	0.95

*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)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	725	0.95	0.14	0.20	0.88	1.06
Non-derivatized - MS/MS Non-kit	145	0.95	0.14	0.17	0.87	1.10
Derivatized - MS/MS PE NeoGram MS2 Kit	259	0.74	0.06	0.08	0.67	0.88
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	0.97	0.12	0.26	0.68	1.20
Non-derivatized - MS/MS PE NeoBase Kit	127	0.77	0.06	0.10	0.68	0.86
Derivatized - MS/MS Chromsystems Kit	29	0.87	0.12	0.14	0.82	1.06
Lot 962 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	738	4.02	0.45	0.74	0.88	1.06
Non-derivatized - MS/MS Non-kit	145	4.08	0.39	0.54	0.87	1.10
Derivatized - MS/MS PE NeoGram MS2 Kit	261	3.26	0.23	0.30	0.67	0.88
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	4.11	0.40	0.86	0.68	1.20
Non-derivatized - MS/MS PE NeoBase Kit	127	3.19	0.25	0.36	0.68	0.86
Derivatized - MS/MS Chromsystems Kit	30	3.86	0.28	0.59	0.82	1.06
Lot 963 – Enriched 7.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	729	8.69	0.92	1.46	0.88	1.06
Non-derivatized - MS/MS Non-kit	147	9.00	0.90	1.34	0.87	1.10
Derivatized - MS/MS PE NeoGram MS2 Kit	258	7.17	0.44	0.60	0.67	0.88
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	9.22	1.23	2.13	0.68	1.20
Non-derivatized - MS/MS PE NeoBase Kit	126	7.05	0.45	0.76	0.68	0.86
Derivatized - MS/MS Chromsystems Kit	30	8.90	0.76	1.15	0.82	1.06
Lot 964 – Enriched 12 μmol/L whole blood						
Derivatized - MS/MS Non-kit	743	13.63	1.52	2.60	0.88	1.06
Non-derivatized - MS/MS Non-kit	146	14.08	1.25	1.97	0.87	1.10
Derivatized - MS/MS PE NeoGram MS2 Kit	263	11.29	0.84	1.10	0.67	0.88
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	15.35	3.27	4.98	0.68	1.20
Non-derivatized - MS/MS PE NeoBase Kit	128	11.09	0.72	1.23	0.68	0.86
Derivatized - MS/MS Chromsystems Kit	29	13.44	1.17	1.45	0.82	1.06

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

TABLE 10n. 2009 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 865 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	560	0.1	0.02	0.03	0.08	0.47
Non-derivatized - MS/MS Non-kit	40	0.2	0.03	0.17	0.24	0.26
Derivatized - MS/MS PE NeoGram MS2 Kit	229	0.1	0.02	0.03	0.12	1.23
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	0.5	0.10	0.18	0.52	1.06
Non-derivatized - MS/MS PE NeoBase Kit	40	0.3	0.04	0.21	0.28	0.42
Derivatized - MS/MS Chromsystems Kit	20	0.1	0.01	0.03	0.08	0.96
Lot 866 - Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	574	0.3	0.07	0.12	0.08	0.47
Non-derivatized - MS/MS Non-kit	40	0.4	0.07	0.26	0.24	0.26
Derivatized - MS/MS PE NeoGram MS2 Kit	239	0.8	0.08	0.18	0.12	1.23
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	1.1	0.13	0.44	0.52	1.06
Non-derivatized - MS/MS PE NeoBase Kit	40	0.5	0.07	0.33	0.28	0.42
Derivatized - MS/MS Chromsystems Kit	20	0.6	0.06	0.17	0.08	0.96
Lot 867 - Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	574	0.8	0.13	0.28	0.08	0.47
Non-derivatized - MS/MS Non-kit	40	0.6	0.08	0.39	0.24	0.26
Derivatized - MS/MS PE NeoGram MS2 Kit	240	2.0	0.19	0.49	0.12	1.23
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	2.2	0.28	0.85	0.52	1.06
Non-derivatized - MS/MS PE NeoBase Kit	40	0.9	0.15	0.59	0.28	0.42
Derivatized - MS/MS Chromsystems Kit	20	1.5	0.16	0.48	0.08	0.96
Lot 868 - Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	574	1.5	0.23	0.53	0.08	0.47
Non-derivatized - MS/MS Non-kit	40	1.0	0.10	0.61	0.24	0.26
Derivatized - MS/MS PE NeoGram MS2 Kit	240	3.8	0.40	0.88	0.12	1.23
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	3.7	0.39	1.50	0.52	1.06
Non-derivatized - MS/MS PE NeoBase Kit	40	1.5	0.14	0.90	0.28	0.42
Derivatized - MS/MS Chromsystems Kit	20	3.0	0.32	0.97	0.08	0.96

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d6-C5DC, d3-C8, d3-C3, or d3-C16.

*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 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	568	0.03	0.02	0.03	0.05	0.52
Non-derivatized - MS/MS Non-kit	56	0.11	0.05	0.09	0.11	0.26
Derivatized - MS/MS PE NeoGram MS2 Kit	202	0.03	0.01	0.01	0.06	1.32
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.32	0.10	0.20	0.32	1.48
Non-derivatized - MS/MS PE NeoBase Kit	58	0.17	0.03	0.16	0.18	0.38
Derivatized - MS/MS Chromsystems Kit	20	0.03	0.01	0.02	0.05	0.93
Lot 962 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	565	0.31	0.07	0.13	0.05	0.52
Non-derivatized - MS/MS Non-kit	60	0.25	0.07	0.18	0.11	0.26
Derivatized - MS/MS PE NeoGram MS2 Kit	199	0.72	0.07	0.13	0.06	1.32
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	1.04	0.17	0.48	0.32	1.48
Non-derivatized - MS/MS PE NeoBase Kit	59	0.37	0.05	0.23	0.18	0.38
Derivatized - MS/MS Chromsystems Kit	20	0.52	0.05	0.28	0.05	0.93
Lot 963 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	567	0.84	0.16	0.28	0.05	0.52
Non-derivatized - MS/MS Non-kit	60	0.51	0.12	0.33	0.11	0.26
Derivatized - MS/MS PE NeoGram MS2 Kit	192	2.11	0.19	0.28	0.06	1.32
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	2.59	0.72	1.22	0.32	1.48
Non-derivatized - MS/MS PE NeoBase Kit	60	0.78	0.06	0.46	0.18	0.38
Derivatized - MS/MS Chromsystems Kit	20	1.50	0.11	0.69	0.05	0.93
Lot 964 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	568	1.60	0.26	0.57	0.05	0.52
Non-derivatized - MS/MS Non-kit	60	0.89	0.15	0.60	0.11	0.26
Derivatized - MS/MS PE NeoGram MS2 Kit	198	3.99	0.39	0.50	0.06	1.32
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	4.75	1.07	2.11	0.32	1.48
Non-derivatized - MS/MS PE NeoBase Kit	60	1.32	0.14	0.74	0.18	0.38
Derivatized - MS/MS Chromsystems Kit	20	2.83	0.25	1.17	0.05	0.93

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d6-C5DC, d3-C8, d3-C3, or d3-C16.

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

TABLE 10o. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	785	0.28	0.07	0.10	0.27	0.90
Non-derivatized MS/MS Non-kit	114	0.28	0.08	0.16	0.26	0.85
Derivatized - MS/MS PE NeoGram MS2 Kit	264	0.25	0.06	0.07	0.23	0.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	0.37	0.16	0.21	0.41	0.80
Non-derivatized-MS/MS PE NeoBase Kit	59	0.24	0.03	0.05	0.24	0.82
Derivatized-MS/MS Chromsystems Kit	20	0.20	0.01	0.05	0.14	0.73
Lot 866 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	786	1.23	0.17	0.23	0.27	0.90
Non-derivatized MS/MS Non-kit	118	1.13	0.12	0.30	0.26	0.85
Derivatized - MS/MS PE NeoGram MS2 Kit	265	1.02	0.18	0.19	0.23	0.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	1.23	0.29	0.32	0.41	0.80
Non-derivatized-MS/MS PE NeoBase Kit	60	1.11	0.09	0.17	0.24	0.82
Derivatized-MS/MS Chromsystems Kit	19	0.91	0.05	0.13	0.14	0.73
Lot 867 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	789	2.43	0.30	0.44	0.27	0.90
Non-derivatized MS/MS Non-kit	117	2.29	0.22	0.67	0.26	0.85
Derivatized - MS/MS PE NeoGram MS2 Kit	264	1.97	0.26	0.32	0.23	0.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	2.44	0.45	0.50	0.41	0.80
Non-derivatized-MS/MS PE NeoBase Kit	60	2.22	0.14	0.41	0.24	0.82
Derivatized-MS/MS Chromsystems Kit	20	1.82	0.16	0.29	0.14	0.73
Lot 868 – Enriched 5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	787	4.84	0.54	0.84	0.27	0.90
Non-derivatized MS/MS Non-kit	115	4.56	0.41	1.38	0.26	0.85
Derivatized - MS/MS PE NeoGram MS2 Kit	265	3.98	0.59	0.64	0.23	0.74
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	4.38	0.87	0.93	0.41	0.80
Non-derivatized-MS/MS PE NeoBase Kit	49	4.40	0.30	0.54	0.24	0.82
Derivatized-MS/MS Chromsystems Kit	19	3.89	0.29	0.57	0.14	0.73

*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 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	712	0.15	0.05	0.06	0.12	0.97
Non-derivatized - MS/MS Non-kit	134	0.15	0.04	0.10	0.12	0.93
Derivatized - MS/MS PE NeoGram MS2 Kit	239	0.13	0.04	0.05	0.10	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.31	0.14	0.16	0.28	0.82
Non-derivatized - MS/MS PE NeoBase Kit	120	0.13	0.02	0.04	0.07	0.85
Derivatized - MS/MS Chromsystems Kit	30	0.09	0.01	0.02	0.05	0.82
Lot 962 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	712	1.05	0.13	0.18	0.12	0.97
Non-derivatized - MS/MS Non-kit	135	1.01	0.13	0.19	0.12	0.93
Derivatized - MS/MS PE NeoGram MS2 Kit	241	0.88	0.15	0.16	0.10	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	1.02	0.34	0.34	0.28	0.82
Non-derivatized - MS/MS PE NeoBase Kit	129	0.88	0.07	0.12	0.07	0.85
Derivatized - MS/MS Chromsystems Kit	28	0.82	0.07	0.07	0.05	0.82
Lot 963 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	714	2.53	0.31	0.42	0.12	0.97
Non-derivatized - MS/MS Non-kit	135	2.47	0.27	0.42	0.12	0.93
Derivatized - MS/MS PE NeoGram MS2 Kit	247	2.13	0.30	0.33	0.10	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	2.38	0.58	0.66	0.28	0.82
Non-derivatized - MS/MS PE NeoBase Kit	127	2.14	0.18	0.30	0.07	0.85
Derivatized - MS/MS Chromsystems Kit	30	2.12	0.14	0.27	0.05	0.82
Lot 964 – Enriched 5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	719	4.98	0.59	0.81	0.12	0.97
Non-derivatized - MS/MS Non-kit	136	4.79	0.55	0.77	0.12	0.93
Derivatized - MS/MS PE NeoGram MS2 Kit	245	4.20	0.56	0.63	0.10	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	4.36	0.82	0.82	0.28	0.82
Non-derivatized - MS/MS PE NeoBase Kit	126	4.34	0.31	0.49	0.07	0.85
Derivatized - MS/MS Chromsystems Kit	30	4.18	0.31	0.74	0.05	0.82

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

TABLE 10p. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	802	0.16	0.04	0.07	0.17	0.96
Non-derivatized MS/MS Non-kit	118	0.15	0.03	0.06	0.14	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	272	0.14	0.04	0.05	0.15	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	0.20	0.08	0.11	0.21	0.80
Non-derivatized-MS/MS PE NeoBase Kit	59	0.13	0.02	0.02	0.14	0.83
Derivatized-MS/MS Chromsystems Kit	20	0.15	0.01	0.01	0.15	0.97
Lot 866 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	803	0.67	0.10	0.16	0.17	0.96
Non-derivatized MS/MS Non-kit	118	0.63	0.07	0.21	0.14	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	275	0.58	0.09	0.11	0.15	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	0.63	0.18	0.23	0.21	0.80
Non-derivatized-MS/MS PE NeoBase Kit	60	0.57	0.06	0.09	0.14	0.83
Derivatized-MS/MS Chromsystems Kit	19	0.64	0.05	0.05	0.15	0.97
Lot 867 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	804	1.60	0.20	0.30	0.17	0.96
Non-derivatized MS/MS Non-kit	114	1.58	0.15	0.48	0.14	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	274	1.37	0.18	0.21	0.15	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	1.40	0.32	0.39	0.21	0.80
Non-derivatized-MS/MS PE NeoBase Kit	59	1.40	0.10	0.22	0.14	0.83
Derivatized-MS/MS Chromsystems Kit	19	1.57	0.12	0.12	0.15	0.97
Lot 868 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	813	3.05	0.35	0.56	0.17	0.96
Non-derivatized MS/MS Non-kit	117	3.05	0.36	1.03	0.14	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	275	2.66	0.37	0.41	0.15	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	2.60	0.52	0.73	0.21	0.80
Non-derivatized-MS/MS PE NeoBase Kit	50	2.63	0.26	0.40	0.14	0.83
Derivatized-MS/MS Chromsystems Kit	19	3.06	0.23	0.24	0.15	0.97

*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 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	758	0.09	0.03	0.04	0.07	0.96
Non-derivatized - MS/MS Non-kit	144	0.07	0.02	0.03	0.06	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	257	0.08	0.02	0.03	0.06	0.89
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.16	0.05	0.05	0.21	0.83
Non-derivatized - MS/MS PE NeoBase Kit	118	0.07	0.01	0.01	0.05	0.86
Derivatized - MS/MS Chromsystems Kit	37	0.08	0.01	0.03	0.03	0.98
Lot 962 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	756	0.55	0.08	0.11	0.07	0.96
Non-derivatized - MS/MS Non-kit	145	0.53	0.06	0.08	0.06	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	261	0.50	0.08	0.09	0.06	0.89
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.61	0.15	0.15	0.21	0.83
Non-derivatized - MS/MS PE NeoBase Kit	130	0.48	0.05	0.07	0.05	0.86
Derivatized - MS/MS Chromsystems Kit	37	0.52	0.09	0.11	0.03	0.98
Lot 963 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	747	1.49	0.18	0.25	0.07	0.96
Non-derivatized - MS/MS Non-kit	146	1.52	0.15	0.22	0.06	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	265	1.37	0.18	0.20	0.06	0.89
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	1.56	0.35	0.38	0.21	0.83
Non-derivatized - MS/MS PE NeoBase Kit	126	1.32	0.10	0.19	0.05	0.86
Derivatized - MS/MS Chromsystems Kit	39	1.43	0.17	0.28	0.03	0.98
Lot 964 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	758	2.96	0.34	0.47	0.07	0.96
Non-derivatized - MS/MS Non-kit	142	2.97	0.22	0.36	0.06	0.97
Derivatized - MS/MS PE NeoGram MS2 Kit	267	2.74	0.33	0.43	0.06	0.89
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	2.63	0.46	0.46	0.21	0.83
Non-derivatized - MS/MS PE NeoBase Kit	129	2.65	0.19	0.37	0.05	0.86
Derivatized - MS/MS Chromsystems Kit	38	3.02	0.48	0.48	0.03	0.98

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

TABLE 10q. 2009 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 865 - Assayed 0.06 μmol/L whole blood						
Derivatized - MS/MS Non-kit	787	0.04	0.02	0.02	-0.03	1.32
Non-derivatized - MS/MS Non-kit	87	0.07	0.03	0.06	-0.06	2.18
Derivatized - MS/MS PE NeoGram MS2 Kit	261	0.07	0.01	0.02	-0.12	3.17
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	0.15	0.04	0.11	-0.12	5.19
Non-derivatized - MS/MS PE NeoBase Kit	50	0.12	0.03	0.05	-0.01	2.69
Derivatized - MS/MS Chromsystems Kit	20	0.08	0.01	0.03	-0.17	4.11
Lot 866 - Assayed 0.23 μmol/L whole blood						
Derivatized - MS/MS Non-kit	801	0.29	0.06	0.10	-0.03	1.32
Non-derivatized - MS/MS Non-kit	90	0.44	0.07	0.29	-0.06	2.18
Derivatized - MS/MS PE NeoGram MS2 Kit	267	0.61	0.05	0.07	-0.12	3.17
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	1.12	0.18	0.59	-0.12	5.19
Non-derivatized - MS/MS PE NeoBase Kit	50	0.63	0.07	0.13	-0.01	2.69
Derivatized - MS/MS Chromsystems Kit	20	0.77	0.09	0.29	-0.17	4.11
Lot 867 - Assayed 0.39 μmol/L whole blood						
Derivatized - MS/MS Non-kit	784	0.49	0.08	0.16	-0.03	1.32
Non-derivatized - MS/MS Non-kit	90	0.80	0.09	0.49	-0.06	2.18
Derivatized - MS/MS PE NeoGram MS2 Kit	270	1.13	0.07	0.13	-0.12	3.17
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	1.90	0.34	1.12	-0.12	5.19
Non-derivatized - MS/MS PE NeoBase Kit	50	1.10	0.09	0.19	-0.01	2.69
Derivatized - MS/MS Chromsystems Kit	20	1.43	0.16	0.48	-0.17	4.11
Lot 868 - Assayed 0.72 μmol/L whole blood						
Derivatized - MS/MS Non-kit	789	0.92	0.15	0.32	-0.03	1.32
Non-derivatized - MS/MS Non-kit	90	1.51	0.18	0.91	-0.06	2.18
Derivatized - MS/MS PE NeoGram MS2 Kit	269	2.16	0.16	0.25	-0.12	3.17
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	3.60	0.50	2.29	-0.12	5.19
Non-derivatized - MS/MS PE NeoBase Kit	39	1.90	0.14	0.21	-0.01	2.69
Derivatized - MS/MS Chromsystems Kit	20	2.79	0.37	0.91	-0.17	4.11

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d3-C5, d9-C5, d3-C8, or d6-C5DC as an internal standard for C5DC.

*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 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	723	0.03	0.01	0.02	0.03	0.51
Non-derivatized - MS/MS Non-kit	137	0.04	0.02	0.04	0.03	0.76
Derivatized - MS/MS PE NeoGram MS2 Kit	252	0.02	0.01	0.01	0.01	1.06
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.10	0.05	0.06	0.09	2.51
Non-derivatized - MS/MS PE NeoBase Kit	110	0.07	0.02	0.03	0.07	0.92
Derivatized - MS/MS Chromsystems Kit	37	0.02	0.02	0.02	0.02	1.35
Lot 962 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	731	0.28	0.05	0.10	0.03	0.51
Non-derivatized - MS/MS Non-kit	140	0.39	0.06	0.25	0.03	0.76
Derivatized - MS/MS PE NeoGram MS2 Kit	254	0.53	0.04	0.05	0.01	1.06
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	1.31	0.23	0.44	0.09	2.51
Non-derivatized - MS/MS PE NeoBase Kit	114	0.54	0.06	0.15	0.07	0.92
Derivatized - MS/MS Chromsystems Kit	37	0.71	0.14	0.17	0.02	1.35
Lot 963 – Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	731	0.54	0.09	0.18	0.03	0.51
Non-derivatized - MS/MS Non-kit	140	0.79	0.10	0.49	0.03	0.76
Derivatized - MS/MS PE NeoGram MS2 Kit	256	1.07	0.08	0.11	0.01	1.06
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	2.62	0.32	0.83	0.09	2.51
Non-derivatized - MS/MS PE NeoBase Kit	112	1.00	0.10	0.21	0.07	0.92
Derivatized - MS/MS Chromsystems Kit	40	1.34	0.13	0.25	0.02	1.35
Lot 964 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	733	1.30	0.20	0.41	0.03	0.51
Non-derivatized - MS/MS Non-kit	140	1.94	0.25	1.23	0.03	0.76
Derivatized - MS/MS PE NeoGram MS2 Kit	250	2.66	0.21	0.25	0.01	1.06
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	6.37	0.88	2.11	0.09	2.51
Non-derivatized - MS/MS PE NeoBase Kit	113	2.37	0.27	0.46	0.07	0.92
Derivatized - MS/MS Chromsystems Kit	39	3.41	0.34	0.57	0.02	1.35

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d3-C5, d9-C5, d3-C8, or d6-C5DC as an internal standard for C5DC.

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

TABLE 10r. 2009 Quality Control Data
Summaries of Statistical Analyses

3-HYDROXYISOVALERYLCARNITINE (μmol C5OH/L whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	730	0.47	0.08	0.14	0.48	0.76
Non-derivatized MS/MS Non-kit	86	0.73	0.07	0.55	0.69	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	276	0.44	0.08	0.13	0.44	0.67
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	0.58	0.18	0.27	0.57	0.56
Non-derivatized-MS/MS PE NeoBase Kit	20	0.43	0.03	0.04	0.43	0.41
Derivatized-MS/MS Chromsystems Kit	18	0.36	0.02	0.05	0.35	0.56
Lot 866 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	732	1.25	0.18	0.32	0.48	0.76
Non-derivatized MS/MS Non-kit	84	1.51	0.16	1.09	0.69	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	276	1.12	0.16	0.30	0.44	0.67
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	1.12	0.26	0.27	0.57	0.56
Non-derivatized-MS/MS PE NeoBase Kit	20	0.85	0.08	0.11	0.43	0.41
Derivatized-MS/MS Chromsystems Kit	17	0.91	0.06	0.10	0.35	0.56
Lot 867 – Enriched 2 μmol/L whole blood						
Derivatized - MS/MS Non-kit	731	1.98	0.28	0.52	0.48	0.76
Non-derivatized MS/MS Non-kit	88	2.48	0.22	1.71	0.69	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	274	1.77	0.24	0.46	0.44	0.67
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	1.69	0.31	0.36	0.57	0.56
Non-derivatized-MS/MS PE NeoBase Kit	20	1.24	0.10	0.10	0.43	0.41
Derivatized-MS/MS Chromsystems Kit	18	1.47	0.13	0.19	0.35	0.56
Lot 868 – Enriched 3 μmol/L whole blood						
Derivatized - MS/MS Non-kit	726	2.77	0.37	0.67	0.48	0.76
Non-derivatized MS/MS Non-kit	88	3.37	0.25	2.12	0.69	0.89
Derivatized - MS/MS PE NeoGram MS2 Kit	277	2.47	0.37	0.66	0.44	0.67
Non-derivatized - MS/MS PE NeoGram MS2 Kit	40	2.26	0.51	0.56	0.57	0.56
Non-derivatized-MS/MS PE NeoBase Kit	20	1.68	0.13	0.20	0.43	0.41
Derivatized-MS/MS Chromsystems Kit	17	2.05	0.18	0.20	0.35	0.56

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

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

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 961 - Nonenriched 0 µmol/L whole blood						
Derivatized - MS/MS Non-kit	687	0.47	0.08	0.12	0.45	0.85
Non-derivatized - MS/MS Non-kit	120	0.56	0.07	0.24	0.55	0.77
Derivatized - MS/MS PE NeoGram MS2 Kit	269	0.42	0.07	0.09	0.40	0.73
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.74	0.22	0.23	0.73	0.58
Non-derivatized - MS/MS PE NeoBase Kit	49	0.67	0.07	0.50	0.66	0.77
Derivatized - MS/MS Chromsystems Kit	20	0.35	0.05	0.05	0.34	0.62
Lot 962 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS Non-kit	699	0.87	0.12	0.19	0.45	0.85
Non-derivatized - MS/MS Non-kit	120	0.92	0.11	0.35	0.55	0.77
Derivatized - MS/MS PE NeoGram MS2 Kit	272	0.76	0.13	0.15	0.40	0.73
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	1.04	0.26	0.26	0.73	0.58
Non-derivatized - MS/MS PE NeoBase Kit	50	1.05	0.10	0.77	0.66	0.77
Derivatized - MS/MS Chromsystems Kit	19	0.65	0.07	0.11	0.34	0.62
Lot 963 - Enriched 1.5 µmol/L whole blood						
Derivatized - MS/MS Non-kit	702	1.69	0.22	0.37	0.45	0.85
Non-derivatized - MS/MS Non-kit	120	1.70	0.23	0.65	0.55	0.77
Derivatized - MS/MS PE NeoGram MS2 Kit	275	1.47	0.22	0.27	0.40	0.73
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	1.57	0.35	0.35	0.73	0.58
Non-derivatized - MS/MS PE NeoBase Kit	50	1.79	0.16	1.43	0.66	0.77
Derivatized - MS/MS Chromsystems Kit	20	1.26	0.15	0.17	0.34	0.62
Lot 964 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS Non-kit	708	2.61	0.30	0.55	0.45	0.85
Non-derivatized - MS/MS Non-kit	120	2.49	0.26	0.93	0.55	0.77
Derivatized - MS/MS PE NeoGram MS2 Kit	273	2.25	0.32	0.45	0.40	0.73
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	2.21	0.43	0.43	0.73	0.58
Non-derivatized - MS/MS PE NeoBase Kit	50	2.61	0.20	2.11	0.66	0.77
Derivatized - MS/MS Chromsystems Kit	20	1.89	0.18	0.18	0.34	0.62

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

TABLE 10s. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	804	0.07	0.03	0.04	0.07	0.84
Non-derivatized MS/MS Non-kit	114	0.06	0.02	0.06	0.05	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	271	0.05	0.02	0.03	0.08	0.57
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	0.05	0.03	0.07	0.09	0.88
Non-derivatized-MS/MS PE NeoBase Kit	57	0.04	0.01	0.01	0.06	0.69
Derivatized-MS/MS Chromsystems Kit	18	0.05	0.01	0.01	0.06	0.74
Lot 866 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	816	0.50	0.08	0.12	0.07	0.84
Non-derivatized MS/MS Non-kit	113	0.54	0.06	0.30	0.05	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	274	0.40	0.07	0.08	0.08	0.57
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	0.54	0.08	0.11	0.09	0.88
Non-derivatized-MS/MS PE NeoBase Kit	60	0.43	0.04	0.10	0.06	0.69
Derivatized-MS/MS Chromsystems Kit	17	0.45	0.02	0.04	0.06	0.74
Lot 867 – Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	808	0.89	0.12	0.19	0.07	0.84
Non-derivatized MS/MS Non-kit	109	0.96	0.10	0.56	0.05	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	275	0.67	0.10	0.11	0.08	0.57
Non-derivatized - MS/MS PE NeoGram MS2 Kit	47	1.00	0.18	0.21	0.09	0.88
Non-derivatized-MS/MS PE NeoBase Kit	60	0.76	0.05	0.19	0.06	0.69
Derivatized-MS/MS Chromsystems Kit	18	0.79	0.06	0.07	0.06	0.74
Lot 868 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	816	2.18	0.28	0.45	0.07	0.84
Non-derivatized MS/MS Non-kit	111	2.45	0.22	1.51	0.05	0.95
Derivatized - MS/MS PE NeoGram MS2 Kit	279	1.50	0.25	0.29	0.08	0.57
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	2.26	0.41	0.52	0.09	0.88
Non-derivatized-MS/MS PE NeoBase Kit	50	1.78	0.16	0.46	0.06	0.69
Derivatized-MS/MS Chromsystems Kit	18	1.92	0.18	0.20	0.06	0.74

*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 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	729	0.05	0.02	0.04	0.04	0.88
Non-derivatized - MS/MS Non-kit	121	0.02	0.01	0.01	0.00	0.99
Derivatized - MS/MS PE NeoGram MS2 Kit	275	0.04	0.02	0.02	0.07	0.65
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.02	0.01	0.02	0.02	0.94
Non-derivatized - MS/MS PE NeoBase Kit	119	0.03	0.01	0.02	0.02	0.78
Derivatized - MS/MS Chromsystems Kit	38	0.04	0.02	0.02	0.04	0.73
Lot 962 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	724	0.46	0.07	0.10	0.04	0.88
Non-derivatized - MS/MS Non-kit	133	0.47	0.05	0.10	0.00	0.99
Derivatized - MS/MS PE NeoGram MS2 Kit	270	0.40	0.07	0.09	0.07	0.65
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.50	0.08	0.13	0.02	0.94
Non-derivatized - MS/MS PE NeoBase Kit	129	0.40	0.04	0.07	0.02	0.78
Derivatized - MS/MS Chromsystems Kit	40	0.40	0.04	0.10	0.04	0.73
Lot 963 – Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	732	0.92	0.12	0.18	0.04	0.88
Non-derivatized - MS/MS Non-kit	139	0.98	0.10	0.23	0.00	0.99
Derivatized - MS/MS PE NeoGram MS2 Kit	273	0.74	0.10	0.14	0.07	0.65
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	0.95	0.10	0.17	0.02	0.94
Non-derivatized - MS/MS PE NeoBase Kit	126	0.79	0.06	0.11	0.02	0.78
Derivatized - MS/MS Chromsystems Kit	40	0.80	0.09	0.15	0.04	0.73
Lot 964 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	726	2.25	0.26	0.39	0.04	0.88
Non-derivatized - MS/MS Non-kit	137	2.47	0.19	0.48	0.00	0.99
Derivatized - MS/MS PE NeoGram MS2 Kit	271	1.67	0.21	0.29	0.07	0.65
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	2.36	0.22	0.38	0.02	0.94
Non-derivatized - MS/MS PE NeoBase Kit	129	1.97	0.15	0.28	0.02	0.78
Derivatized - MS/MS Chromsystems Kit	40	1.87	0.17	0.22	0.04	0.73

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

TABLE 10t. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	834	0.11	0.03	0.04	0.11	1.02
Non-derivatized MS/MS Non-kit	136	0.11	0.02	0.06	0.10	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	272	0.09	0.03	0.04	0.08	0.86
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	0.14	0.05	0.07	0.12	0.96
Non-derivatized-MS/MS PE NeoBase Kit	59	0.08	0.02	0.02	0.08	0.93
Derivatized-MS/MS Chromsystems Kit	18	0.07	0.01	0.01	0.05	0.79
Lot 866 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	848	0.65	0.18	0.22	0.11	1.02
Non-derivatized MS/MS Non-kit	134	0.65	0.07	0.16	0.10	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	275	0.53	0.09	0.09	0.08	0.86
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	0.60	0.13	0.14	0.12	0.96
Non-derivatized-MS/MS PE NeoBase Kit	60	0.57	0.05	0.08	0.08	0.93
Derivatized-MS/MS Chromsystems Kit	17	0.46	0.04	0.09	0.05	0.79
Lot 867 – Enriched 1.0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	849	1.08	0.16	0.24	0.11	1.02
Non-derivatized MS/MS Non-kit	132	1.09	0.12	0.27	0.10	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	277	0.90	0.14	0.15	0.08	0.86
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	1.05	0.18	0.21	0.12	0.96
Non-derivatized-MS/MS PE NeoBase Kit	59	0.97	0.07	0.13	0.08	0.93
Derivatized-MS/MS Chromsystems Kit	18	0.79	0.08	0.18	0.05	0.79
Lot 868 – Enriched 2.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	831	2.68	0.30	0.50	0.11	1.02
Non-derivatized MS/MS Non-kit	131	2.73	0.29	0.72	0.10	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	276	2.23	0.33	0.36	0.08	0.86
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	2.54	0.46	0.59	0.12	0.96
Non-derivatized-MS/MS PE NeoBase Kit	49	2.41	0.23	0.30	0.08	0.93
Derivatized-MS/MS Chromsystems Kit	17	2.03	0.16	0.35	0.05	0.79

*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 961 - Nonenriched 0 µmol/L whole blood						
Derivatized - MS/MS Non-kit	749	0.05	0.02	0.03	0.04	1.02
Non-derivatized - MS/MS Non-kit	175	0.05	0.01	0.04	0.03	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	261	0.03	0.02	0.02	0.02	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	0.09	0.03	0.03	0.09	0.89
Non-derivatized - MS/MS PE NeoBase Kit	126	0.03	0.01	0.01	0.02	0.86
Derivatized - MS/MS Chromsystems Kit	39	0.03	0.01	0.02	-0.02	0.90
Lot 962 - Enriched 0.5 µmol/L whole blood						
Derivatized - MS/MS Non-kit	765	0.54	0.08	0.12	0.04	1.02
Non-derivatized - MS/MS Non-kit	177	0.54	0.06	0.09	0.03	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	256	0.43	0.07	0.08	0.02	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	0.53	0.10	0.13	0.09	0.89
Non-derivatized - MS/MS PE NeoBase Kit	138	0.45	0.04	0.06	0.02	0.86
Derivatized - MS/MS Chromsystems Kit	37	0.40	0.05	0.06	-0.02	0.90
Lot 963 - Enriched 1.0 µmol/L whole blood						
Derivatized - MS/MS Non-kit	754	1.06	0.14	0.20	0.04	1.02
Non-derivatized - MS/MS Non-kit	176	1.07	0.09	0.15	0.03	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	265	0.86	0.14	0.16	0.02	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	1.00	0.27	0.27	0.09	0.89
Non-derivatized - MS/MS PE NeoBase Kit	126	0.88	0.07	0.11	0.02	0.86
Derivatized - MS/MS Chromsystems Kit	38	0.84	0.08	0.13	-0.02	0.90
Lot 964 - Enriched 2.5 µmol/L whole blood						
Derivatized - MS/MS Non-kit	749	2.60	0.29	0.48	0.04	1.02
Non-derivatized - MS/MS Non-kit	181	2.66	0.22	0.35	0.03	1.05
Derivatized - MS/MS PE NeoGram MS2 Kit	259	2.13	0.25	0.29	0.02	0.84
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	2.32	0.45	0.49	0.09	0.89
Non-derivatized - MS/MS PE NeoBase Kit	128	2.18	0.16	0.26	0.02	0.86
Derivatized - MS/MS Chromsystems Kit	40	2.26	0.20	0.53	-0.02	0.90

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

TABLE 10u. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	801	0.14	0.03	0.05	0.15	1.19
Non-derivatized MS/MS Non-kit	124	0.14	0.03	0.11	0.15	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	273	0.09	0.02	0.03	0.09	0.77
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	0.16	0.05	0.07	0.15	1.01
Non-derivatized-MS/MS PE NeoBase Kit	58	0.11	0.01	0.05	0.12	0.91
Derivatized-MS/MS Chromsystems Kit	20	0.09	0.01	0.01	0.08	0.82
Lot 866 – Enriched 0.25 μmol/L whole blood						
Derivatized - MS/MS Non-kit	819	0.45	0.09	0.13	0.15	1.19
Non-derivatized MS/MS Non-kit	126	0.43	0.07	0.18	0.15	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	273	0.29	0.05	0.06	0.09	0.77
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	0.39	0.08	0.10	0.15	1.01
Non-derivatized-MS/MS PE NeoBase Kit	58	0.34	0.03	0.05	0.12	0.91
Derivatized-MS/MS Chromsystems Kit	19	0.29	0.03	0.04	0.08	0.82
Lot 867 – Enriched 0.75 μmol/L whole blood						
Derivatized - MS/MS Non-kit	809	1.03	0.15	0.23	0.15	1.19
Non-derivatized MS/MS Non-kit	126	0.94	0.14	0.35	0.15	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	274	0.68	0.10	0.12	0.09	0.77
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	0.92	0.15	0.16	0.15	1.01
Non-derivatized-MS/MS PE NeoBase Kit	58	0.81	0.05	0.11	0.12	0.91
Derivatized-MS/MS Chromsystems Kit	19	0.69	0.06	0.11	0.08	0.82
Lot 868 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	804	1.93	0.24	0.43	0.15	1.19
Non-derivatized MS/MS Non-kit	125	1.75	0.23	0.65	0.15	1.07
Derivatized - MS/MS PE NeoGram MS2 Kit	276	1.25	0.18	0.21	0.09	0.77
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	1.65	0.26	0.29	0.15	1.01
Non-derivatized-MS/MS PE NeoBase Kit	47	1.48	0.13	0.19	0.12	0.91
Derivatized-MS/MS Chromsystems Kit	19	1.31	0.11	0.13	0.08	0.82

*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 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	713	0.04	0.02	0.02	0.00	1.19
Non-derivatized - MS/MS Non-kit	137	0.04	0.02	0.04	0.01	1.23
Derivatized - MS/MS PE NeoGram MS2 Kit	259	0.02	0.01	0.02	0.00	0.79
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.09	0.03	0.04	0.07	0.90
Non-derivatized - MS/MS PE NeoBase Kit	129	0.03	0.01	0.01	0.01	0.85
Derivatized - MS/MS Chromsystems Kit	40	0.02	0.01	0.01	-0.02	0.94
Lot 962 – Enriched 0.25 μmol/L whole blood						
Derivatized - MS/MS Non-kit	733	0.29	0.05	0.08	0.00	1.19
Non-derivatized - MS/MS Non-kit	143	0.31	0.04	0.08	0.01	1.23
Derivatized - MS/MS PE NeoGram MS2 Kit	259	0.20	0.04	0.05	0.00	0.79
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.28	0.07	0.08	0.07	0.90
Non-derivatized - MS/MS PE NeoBase Kit	139	0.21	0.02	0.04	0.01	0.85
Derivatized - MS/MS Chromsystems Kit	40	0.21	0.03	0.04	-0.02	0.94
Lot 963 – Enriched 0.75 μmol/L whole blood						
Derivatized - MS/MS Non-kit	722	0.84	0.12	0.19	0.00	1.19
Non-derivatized - MS/MS Non-kit	148	0.87	0.11	0.18	0.01	1.23
Derivatized - MS/MS PE NeoGram MS2 Kit	263	0.57	0.10	0.11	0.00	0.79
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.73	0.20	0.20	0.07	0.90
Non-derivatized - MS/MS PE NeoBase Kit	128	0.61	0.05	0.09	0.01	0.85
Derivatized - MS/MS Chromsystems Kit	40	0.64	0.09	0.09	-0.02	0.94
Lot 964 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	735	1.82	0.22	0.41	0.00	1.19
Non-derivatized - MS/MS Non-kit	149	1.88	0.19	0.38	0.01	1.23
Derivatized - MS/MS PE NeoGram MS2 Kit	258	1.21	0.18	0.21	0.00	0.79
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	1.43	0.31	0.31	0.07	0.90
Non-derivatized - MS/MS PE NeoBase Kit	123	1.30	0.09	0.16	0.01	0.85
Derivatized - MS/MS Chromsystems Kit	40	1.42	0.15	0.16	-0.02	0.94

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

TABLE 10v. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	777	0.12	0.03	0.05	0.13	0.97
Non-derivatized MS/MS Non-kit	118	0.10	0.03	0.05	0.09	0.98
Derivatized - MS/MS PE NeoGram MS2 Kit	271	0.09	0.03	0.03	0.09	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	0.10	0.03	0.08	0.11	0.67
Non-derivatized-MS/MS PE NeoBase Kit	58	0.07	0.01	0.02	0.08	0.86
Derivatized-MS/MS Chromsystems Kit	30	0.10	0.02	0.04	0.12	0.91
Lot 866 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	790	0.62	0.10	0.16	0.13	0.97
Non-derivatized MS/MS Non-kit	116	0.58	0.07	0.19	0.09	0.98
Derivatized - MS/MS PE NeoGram MS2 Kit	271	0.50	0.07	0.08	0.09	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	0.44	0.11	0.14	0.11	0.67
Non-derivatized-MS/MS PE NeoBase Kit	59	0.50	0.04	0.07	0.08	0.86
Derivatized-MS/MS Chromsystems Kit	30	0.60	0.11	0.29	0.12	0.91
Lot 867 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	786	1.59	0.23	0.36	0.13	0.97
Non-derivatized MS/MS Non-kit	118	1.53	0.16	0.49	0.09	0.98
Derivatized - MS/MS PE NeoGram MS2 Kit	274	1.29	0.16	0.17	0.09	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	1.14	0.16	0.26	0.11	0.67
Non-derivatized-MS/MS PE NeoBase Kit	58	1.38	0.10	0.20	0.08	0.86
Derivatized-MS/MS Chromsystems Kit	30	1.50	0.21	0.64	0.12	0.91
Lot 868 – Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	781	3.02	0.38	0.62	0.13	0.97
Non-derivatized MS/MS Non-kit	117	3.03	0.37	0.99	0.09	0.98
Derivatized - MS/MS PE NeoGram MS2 Kit	277	2.51	0.30	0.35	0.09	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	2.12	0.26	0.50	0.11	0.67
Non-derivatized-MS/MS PE NeoBase Kit	50	2.64	0.22	0.41	0.08	0.86
Derivatized-MS/MS Chromsystems Kit	30	2.85	0.50	1.21	0.12	0.91

*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 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	737	0.08	0.02	0.03	0.04	1.00
Non-derivatized - MS/MS Non-kit	142	0.07	0.02	0.04	0.04	1.00
Derivatized - MS/MS PE NeoGram MS2 Kit	261	0.06	0.02	0.02	0.03	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	0.06	0.02	0.02	0.04	0.70
Non-derivatized - MS/MS PE NeoBase Kit	127	0.05	0.01	0.02	0.02	0.87
Derivatized - MS/MS Chromsystems Kit	38	0.06	0.01	0.02	0.02	0.79
Lot 962 – Enriched 0.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	741	0.53	0.08	0.11	0.04	1.00
Non-derivatized - MS/MS Non-kit	149	0.53	0.06	0.10	0.04	1.00
Derivatized - MS/MS PE NeoGram MS2 Kit	259	0.45	0.07	0.08	0.03	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.38	0.12	0.12	0.04	0.70
Non-derivatized - MS/MS PE NeoBase Kit	127	0.44	0.03	0.07	0.02	0.87
Derivatized - MS/MS Chromsystems Kit	37	0.41	0.06	0.08	0.02	0.79
Lot 963 – Enriched 1.5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	740	1.48	0.20	0.27	0.04	1.00
Non-derivatized - MS/MS Non-kit	145	1.49	0.15	0.26	0.04	1.00
Derivatized - MS/MS PE NeoGram MS2 Kit	260	1.25	0.16	0.18	0.03	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	1.04	0.26	0.26	0.04	0.70
Non-derivatized - MS/MS PE NeoBase Kit	126	1.27	0.10	0.18	0.02	0.87
Derivatized - MS/MS Chromsystems Kit	40	1.14	0.13	0.18	0.02	0.79
Lot 964 – Enriched 3.0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	745	3.08	0.34	0.50	0.04	1.00
Non-derivatized - MS/MS Non-kit	149	3.07	0.30	0.50	0.04	1.00
Derivatized - MS/MS PE NeoGram MS2 Kit	263	2.61	0.31	0.35	0.03	0.85
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	2.16	0.74	0.74	0.04	0.70
Non-derivatized - MS/MS PE NeoBase Kit	127	2.65	0.24	0.40	0.02	0.87
Derivatized - MS/MS Chromsystems Kit	39	2.43	0.21	0.43	0.02	0.79

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

TABLE 10w. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	793	1.14	0.16	0.25	1.12	0.84
Non-derivatized MS/MS Non-kit	115	1.16	0.17	0.33	1.10	0.86
Derivatized - MS/MS PE NeoGram MS2 Kit	275	1.12	0.17	0.19	1.09	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	1.12	0.21	0.22	1.07	0.84
Non-derivatized-MS/MS PE NeoBase Kit	58	1.11	0.10	0.17	1.09	0.86
Derivatized-MS/MS Chromsystems Kit	29	1.09	0.18	0.33	1.15	0.79
Lot 866 – Enriched 4 μmol/L whole blood						
Derivatized - MS/MS Non-kit	797	4.44	0.49	0.78	1.12	0.84
Non-derivatized MS/MS Non-kit	112	4.48	0.51	1.10	1.10	0.86
Derivatized - MS/MS PE NeoGram MS2 Kit	274	4.28	0.52	0.54	1.09	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	49	4.49	0.44	0.63	1.07	0.84
Non-derivatized-MS/MS PE NeoBase Kit	59	4.43	0.36	0.45	1.09	0.86
Derivatized-MS/MS Chromsystems Kit	30	4.38	1.00	1.60	1.15	0.79
Lot 867 – Enriched 8 μmol/L whole blood						
Derivatized - MS/MS Non-kit	799	7.87	0.82	1.40	1.12	0.84
Non-derivatized MS/MS Non-kit	113	7.95	0.87	2.05	1.10	0.86
Derivatized - MS/MS PE NeoGram MS2 Kit	274	7.57	0.80	0.89	1.09	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	50	7.52	0.87	1.35	1.07	0.84
Non-derivatized-MS/MS PE NeoBase Kit	59	8.06	0.61	0.87	1.09	0.86
Derivatized-MS/MS Chromsystems Kit	30	7.45	1.21	2.26	1.15	0.79
Lot 868 – Enriched 12 μmol/L whole blood						
Derivatized - MS/MS Non-kit	798	11.21	1.17	1.94	1.12	0.84
Non-derivatized MS/MS Non-kit	111	11.50	1.22	2.88	1.10	0.86
Derivatized - MS/MS PE NeoGram MS2 Kit	275	10.78	1.22	1.33	1.09	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	48	11.30	1.11	1.19	1.07	0.84
Non-derivatized-MS/MS PE NeoBase Kit	49	11.28	0.89	1.16	1.09	0.86
Derivatized-MS/MS Chromsystems Kit	30	10.59	1.77	3.11	1.15	0.79

*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 961 - Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	735	0.74	0.10	0.15	0.60	0.85
Non-derivatized - MS/MS Non-kit	139	0.72	0.09	0.12	0.61	0.86
Derivatized - MS/MS PE NeoGram MS2 Kit	263	0.70	0.10	0.11	0.58	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.76	0.13	0.19	0.69	0.83
Non-derivatized - MS/MS PE NeoBase Kit	126	0.70	0.07	0.11	0.57	0.85
Derivatized - MS/MS Chromsystems Kit	40	0.66	0.09	0.15	0.54	0.75
Lot 962 - Enriched 4 μmol/L whole blood						
Derivatized - MS/MS Non-kit	743	3.86	0.42	0.56	0.60	0.85
Non-derivatized - MS/MS Non-kit	146	3.94	0.37	0.49	0.61	0.86
Derivatized - MS/MS PE NeoGram MS2 Kit	266	3.77	0.40	0.43	0.58	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	4.00	0.75	0.75	0.69	0.83
Non-derivatized - MS/MS PE NeoBase Kit	128	3.81	0.34	0.52	0.57	0.85
Derivatized - MS/MS Chromsystems Kit	40	3.27	0.29	0.43	0.54	0.75
Lot 963 - Enriched 8 μmol/L whole blood						
Derivatized - MS/MS Non-kit	733	7.36	0.76	1.02	0.60	0.85
Non-derivatized - MS/MS Non-kit	144	7.46	0.62	0.78	0.61	0.86
Derivatized - MS/MS PE NeoGram MS2 Kit	269	7.01	0.68	0.77	0.58	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	7.21	0.72	0.87	0.69	0.83
Non-derivatized - MS/MS PE NeoBase Kit	125	7.28	0.64	0.90	0.57	0.85
Derivatized - MS/MS Chromsystems Kit	40	6.76	0.57	1.19	0.54	0.75
Lot 964 - Enriched 12 μmol/L whole blood						
Derivatized - MS/MS Non-kit	739	10.96	1.07	1.50	0.60	0.85
Non-derivatized - MS/MS Non-kit	145	11.05	0.86	1.20	0.61	0.86
Derivatized - MS/MS PE NeoGram MS2 Kit	263	10.58	1.09	1.18	0.58	0.82
Non-derivatized - MS/MS PE NeoGram MS2 Kit	18	10.82	0.79	0.81	0.69	0.83
Non-derivatized - MS/MS PE NeoBase Kit	124	10.85	0.96	1.27	0.57	0.85
Derivatized - MS/MS Chromsystems Kit	40	9.56	0.90	1.41	0.54	0.75

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

TABLE 10x. 2009 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 865 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	752	0.92	0.14	0.26	0.92	0.81
Non-derivatized MS/MS Non-kit	97	0.78	0.11	0.24	0.76	0.72
Derivatized - MS/MS PE NeoGram MS2 Kit	268	0.88	0.12	0.12	0.86	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	0.97	0.15	0.25	0.93	0.85
Non-derivatized-MS/MS PE NeoBase Kit	50	0.90	0.07	0.10	0.91	0.83
Derivatized-MS/MS Chromsystems Kit	20	0.67	0.04	0.21	0.67	0.58
Lot 866 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	753	1.71	0.23	0.44	0.92	0.81
Non-derivatized MS/MS Non-kit	98	1.47	0.19	0.48	0.76	0.72
Derivatized - MS/MS PE NeoGram MS2 Kit	265	1.67	0.18	0.20	0.86	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	1.78	0.20	0.30	0.93	0.85
Non-derivatized-MS/MS PE NeoBase Kit	48	1.74	0.12	0.14	0.91	0.83
Derivatized-MS/MS Chromsystems Kit	20	1.26	0.16	0.44	0.67	0.58
Lot 867 – Enriched 2 μmol/L whole blood						
Derivatized - MS/MS Non-kit	767	2.55	0.35	0.72	0.92	0.81
Non-derivatized MS/MS Non-kit	97	2.17	0.25	0.65	0.76	0.72
Derivatized - MS/MS PE NeoGram MS2 Kit	263	2.46	0.25	0.28	0.86	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	38	2.56	0.40	0.60	0.93	0.85
Non-derivatized-MS/MS PE NeoBase Kit	50	2.59	0.19	0.23	0.91	0.83
Derivatized-MS/MS Chromsystems Kit	20	1.84	0.15	0.55	0.67	0.58
Lot 868 – Enriched 5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	751	4.96	0.63	1.31	0.92	0.81
Non-derivatized MS/MS Non-kit	97	4.37	0.51	1.38	0.76	0.72
Derivatized - MS/MS PE NeoGram MS2 Kit	263	4.90	0.52	0.56	0.86	0.81
Non-derivatized - MS/MS PE NeoGram MS2 Kit	39	5.19	0.82	1.37	0.93	0.85
Non-derivatized-MS/MS PE NeoBase Kit	39	5.07	0.38	0.42	0.91	0.83
Derivatized-MS/MS Chromsystems Kit	19	3.60	0.23	0.93	0.67	0.58

*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 961 – Nonenriched 0 μmol/L whole blood						
Derivatized - MS/MS Non-kit	671	0.65	0.10	0.14	0.59	0.86
Non-derivatized - MS/MS Non-kit	118	0.59	0.08	0.12	0.54	0.85
Derivatized - MS/MS PE NeoGram MS2 Kit	244	0.59	0.09	0.09	0.55	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	0.73	0.12	0.12	0.69	0.89
Non-derivatized - MS/MS PE NeoBase Kit	116	0.58	0.04	0.06	0.52	0.87
Derivatized - MS/MS Chromsystems Kit	40	0.54	0.05	0.14	0.45	0.68
Lot 962 – Enriched 1 μmol/L whole blood						
Derivatized - MS/MS Non-kit	676	1.38	0.20	0.30	0.59	0.86
Non-derivatized - MS/MS Non-kit	115	1.35	0.10	0.22	0.54	0.85
Derivatized - MS/MS PE NeoGram MS2 Kit	243	1.34	0.16	0.17	0.55	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	1.53	0.20	0.26	0.69	0.89
Non-derivatized - MS/MS PE NeoBase Kit	117	1.35	0.11	0.15	0.52	0.87
Derivatized - MS/MS Chromsystems Kit	38	1.06	0.13	0.16	0.45	0.68
Lot 963 – Enriched 2 μmol/L whole blood						
Derivatized - MS/MS Non-kit	679	2.29	0.30	0.51	0.59	0.86
Non-derivatized - MS/MS Non-kit	115	2.19	0.17	0.33	0.54	0.85
Derivatized - MS/MS PE NeoGram MS2 Kit	242	2.20	0.26	0.29	0.55	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	20	2.48	0.46	0.54	0.69	0.89
Non-derivatized - MS/MS PE NeoBase Kit	118	2.21	0.16	0.21	0.52	0.87
Derivatized - MS/MS Chromsystems Kit	40	1.76	0.18	0.28	0.45	0.68
Lot 964 – Enriched 5 μmol/L whole blood						
Derivatized - MS/MS Non-kit	675	4.90	0.58	1.05	0.59	0.86
Non-derivatized - MS/MS Non-kit	117	4.81	0.35	0.86	0.54	0.85
Derivatized - MS/MS PE NeoGram MS2 Kit	247	4.72	0.51	0.52	0.55	0.83
Non-derivatized - MS/MS PE NeoGram MS2 Kit	19	5.16	0.53	0.56	0.69	0.89
Non-derivatized - MS/MS PE NeoBase Kit	114	4.88	0.33	0.45	0.52	0.87
Derivatized - MS/MS Chromsystems Kit	40	3.87	0.33	0.56	0.45	0.68

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

TABLE10y. 2009 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 791 – Assayed 16.1 ng/mL whole blood						
MP Biomedicals ELISA	30	26.9	4.3	13.4	18.2	0.6
Delfia	386	16.5	2.4	2.9	-0.9	1.1
AutoDelfia	1051	16.2	1.6	1.9	-0.7	1.1
Bio-Rad Quantase	70	12.6	1.6	2.0	-0.8	0.7
Bioclone ELISA	40	13.1	2.3	2.4	-4.2	0.8
Other	39	25.4	3.5	8.8	8.7	0.9
Lot 792 – Assayed 38.8 ng/mL whole blood						
MP Biomedicals ELISA	30	39.5	6.6	21.8	18.2	0.6
Delfia	391	41.3	4.8	5.9	-0.9	1.1
AutoDelfia	1047	42.2	3.7	4.5	-0.7	1.1
Bio-Rad Quantase	68	25.5	3.1	4.0	-0.8	0.7
Bioclone ELISA	38	25.9	3.0	4.5	-4.2	0.8
Other	39	42.2	3.5	6.7	8.7	0.9
Lot 793 – Assayed 69.2 ng/mL whole blood						
MP Biomedicals ELISA	30	58.7	8.0	26.9	18.2	0.6
Delfia	386	76.1	7.6	9.6	-0.9	1.1
AutoDelfia	1052	78.5	6.5	8.1	-0.7	1.1
Bio-Rad Quantase	65	44.9	6.0	7.1	-0.8	0.7
Bioclone ELISA	39	48.3	5.6	5.7	-4.2	0.8
Other	38	68.7	6.9	18.5	8.7	0.9
Lot 794 – Assayed 133.7 ng/mL whole blood						
MP Biomedicals ELISA	30	92.9	11.4	40.7	18.2	0.6
Delfia	392	145.4	16.5	19.7	-0.9	1.1
AutoDelfia	1061	147.2	11.5	14.1	-0.7	1.1
Bio-Rad Quantase	70	94.2	17.1	20.0	-0.8	0.7
Bioclone ELISA	39	108.6	12.7	21.3	-4.2	0.8
Other	38	130.0	15.5	24.7	8.7	0.9

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

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

Director
Thomas R. Frieden, M.D., M.P.H.
Acting Director
National Center for Environmental Health
Henry Falk, M.D., M.P.H.
Director
Division of Laboratory Sciences
Eric J. Sampson, Ph.D.
Chief
Newborn Screening and Molecular Biology Branch
Carla Cuthbert, Ph.D.
Chief Emeritus
Newborn Screening and Molecular Biology Branch
W. Harry Hannon, Ph.D.

Contributors: Barbara W. Adam
Carol Bell
Dana Chafin
Paul Dantonio
Victor R. De Jesus, Ph.D.
Marie C. Earley, Ph.D.
Elizabeth M. Hall
L. Omar Henderson, Ph.D.
Sharon Kerr
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Zuzheng (Roy) Luo
Joanne Mei, Ph.D.
Nancy Meredith
Hien Nguyen
Shannon O'Brien
David Simms
Sherri Stevens
Robert Vogt, Ph.D.
Golriz Yazdanpanah
Hui Zhou, Ph.D.

Production: Sarah Brown
Felicia Manning
Teresa Moore
Connie Singleton

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
SILVER SPRING, MD 20910

President
Susan U. Neill, Ph.D., M.B.A.
Chairman, Newborn Screening and Genetics in Public Health Committee
Cheryl Hermerath, M.B.A., DLM(ASCP), RM(NRCM)
Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee
Gary Hoffman, B.S.

INQUIRIES TO:

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