# Newborn Screening Quality Assurance Program

## 2003 ANNUAL SUMMARY REPORT

Volume 21 January 2004

***Celebrating 25 Years of Service to Newborn Screening Laboratories Worldwide***

## The Dried-Blood Spot Program

Most people would agree the work of the Newborn Screening Quality Assurance Program (NSQAP) is important to the health of babies around the world. But what is not widely known is how much is done by a small group of people. For example, did you know...

- **NSQAP employs 22 in the Division of Laboratory Sciences, NCEH, CDC.**
- **NSQAP produces 500,000 dried-blood spots (DBS) each year.**
- **NSQAP provides services for 35 disorders.**
- **387 laboratories in 54 countries are enrolled in NSQAP quality control and proficiency testing programs.**
- **19 DBS quality control materials are produced for T4, TSH, 17-OHP, total galactose, amino acids, acylcarnitines, and anti-HIV-1 and are shipped twice each year.**
- **6 DBS proficiency testing programs are offered for metabolic disorders, tandem mass spectrometry (MS/MS)-measured analytes, sickle cell disease and other hemoglobinopathies, cystic fibrosis, Type 1 diabetes, and anti-HIV-1 and are shipped four times each year.**
- **27 reports (annual and quarterly) are produced each year.**

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

FROM THE

# EDITOR

## *A Look Back ... On the 25th Anniversary of Our QA Program*

In 1963, Dr. Robert Guthrie introduced a simple blood-spot test for detecting phenylketonuria (PKU). This event marked the beginning of screening for inborn errors of metabolism. Between 1965 and 1972, CDC operated a PKU method development and standardization program, which was discontinued because of resource commitment to other priorities. In 1978, after consultation visits with Dr. Guthrie, CDC revitalized its laboratory improvement efforts and concentrated on the support of neonatal hypothyroid screening programs. The Endocrinology Laboratory initiated a pilot study of dried-blood spot (DBS) quality control (QC) materials for thyroxine ($T_4$) and thyroid-stimulating hormone (TSH). Distribution of these first DBS QC materials began in July 1978.

CDC soon organized and hosted the *Conference on a National Model for Standardization of Hypothyroid Screening Programs*, which developed, by broad consensus, guidelines for use in directing the establishment and administration of neonatal hypothyroid testing. In November 1979, we mailed the first DBS proficiency testing (PT) specimens for $T_4$ and TSH to participants.

During the years between 1983 and 2003, we added routine monitoring of the quality of the filter paper matrix and quality assurance services for the DBS testing of many more analytes. The number of disorders covered by our proficiency testing and quality control services grew from 1 to 35, and the number of laboratories participating in the program grew from 31 in the United States to 387 in 54 countries. The Association of Public Health Laboratories (APHL) became our cosponsor in 1992. Harry Hannon, Ph.D., the only Director of the program, had a vision, created the program, and continues to dedicate his public health career to improving the quality of newborn screening laboratories around the world.

In July, we marked a major milestone in our history by celebrating the 25th anniversary of service to newborn screening laboratories worldwide. Thank you for being our partners in the global newborn screening community.

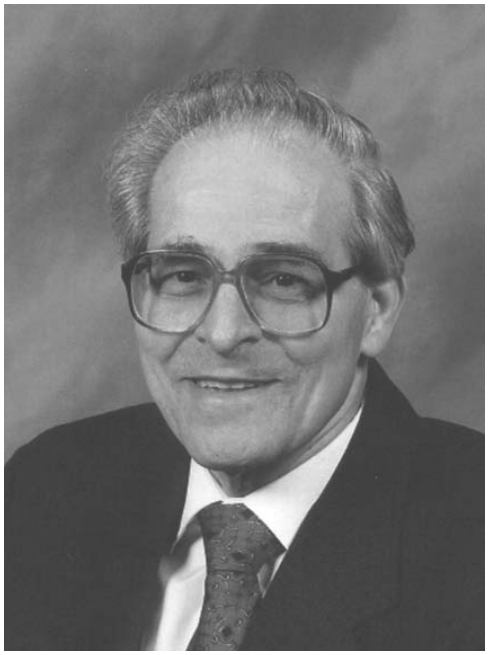


Editor and Program Administrator

# *Annual Report Dedicated to Dussault and Joseph*

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.

Jean H. Dussault, M.D.
1941-2003



J. Mehsen Joseph, Ph.D.
1928-2003

Jean H. Dussault died March 23, 2003. He had reduced his research activities but remained as a Senior Scientist in the Unit of Molecular Medicine Genetics at the CHUL Research Centre, Sainte-Foy, Quebec, Canada. He was an international expert in the field of thyroid hormones; and with his colleagues, had over 200 publications. In 1972, his efforts led to the development of a dried-blood spot neonatal diagnostic test for congenital hypothyroidism (CH). About 150 million newborns have been tested for CH using this test. He declined to apply for a patent for this test because he considered his discovery to be a part of public domain. Dr. Dussault received much recognition and many awards for his outstanding accomplishments. He was the 1998 recipient of the Robert Guthrie Award given by the International Society for Neonatal Screening. He will be remembered as a highly productive and compassionate physician-scientist.

J. Mehsen Joseph, "Dr. Joe," died June 11, 2003. He was the Director of Maryland's State Public Health Laboratory for the last 27 years. His accomplishments are exceptional and only a few can be mentioned. He was an ardent proponent of newborn screening and instrumental in establishing Maryland's Newborn Screening Laboratory in 1963. This was the beginning of today's national newborn screening program in which state public health laboratories provide most newborn screening services. His last project was obtaining two tandem mass spectrometers for expansion of Maryland's screening profile. Dr. Joseph was the author of over 80 publications and a member of over a dozen professional organizations where he held many positions of leadership. His legacies are the many improvements in the Nation's ability to conduct laboratory practice and the many laboratorians for whom he served as teacher, mentor, and model in their professional careers.

## NSQAP
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**Program Information Web site:**
http://www.cdc.gov/nceh/dls/newborn_screening.htm

**Data-reporting Web site:**
http://www2.cdc.gov/nceh/NewbornScreening

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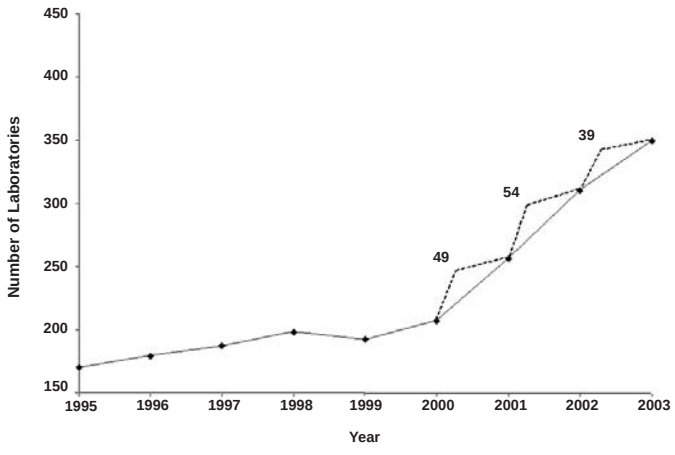
## INTRODUCTION

The 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. We continually strive to produce certified dried-blood spot (DBS) materials for reference and quality control (QC) analysis, to improve the quality and scope of our services, and to provide immediate consultative assistance. Through our interactive efforts with the program's participants, we aspire to meet their growing and changing needs. We always welcome comments and suggestions on 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 using dried-blood spot (DBS) specimens collected at birth, combined with follow-up diagnostic studies and treatment, helps prevent mental retardation and premature death. These blood specimens are routinely collected from more than 95% 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 25 years, the Centers for Disease Control and Prevention (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, we also

FIGURE 1. Laboratory Participation in the Newborn Screening Quality Assurance Program, 1995-2003



accept other laboratories and international participants into the QA program. All laboratories in the United States that test DBS specimens participate voluntarily in NSQAP. Currently, the program provides QA services for congenital hypothyroidism, phenylketonuria, galactosemia, congenital adrenal hyperplasia, maple syrup urine disease, homocystinuria, biotinidase deficiency, galactose-1-phosphate uridyltransferase (GALT) deficiency, cystic fibrosis (CF), and hemoglobinopathies. QA services are also provided for fatty acid oxidation and organic acid disorders. Information about tandem mass spectrometry (MS/MS) services is reported separately in the MS/MS annual report.

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 high-volume specimen throughput that is required. The QC materials, which are intended to 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 gives each laboratory an independent external assessment of its 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 eight years, NSQAP has grown substantially, both in the number of participants and in the scope of global participation (Figure 1). In 2003, 349 newborn screening laboratories in 50 countries (at least one laboratory per country) were active program participants; of these, 282 participated in the PT component and 255 in the QC part (Figure 2). DBS materials for 24 analytes, including analytes measured for the separate MS/MS program, were distributed to participating laboratories (Figures 3-5). This report contains summaries of all QC data reported in 2003, including the MS/MS QC data for amino acids and the first MS/MS QC data for eight acylcarnitine analytes: C2, C3, C4, C5, C6, C8, C14, and C16. For biotinidase, GALT, and hemoglobins, QC materials were not distributed because of the limited availability of appropriate blood sources.

**FIGURE 2. Fifty Countries Participated in the Newborn Screening Quality Assurance Program in 2003**


**FIGURE 3. Number of Participants in Proficiency Testing Programs, 2003**

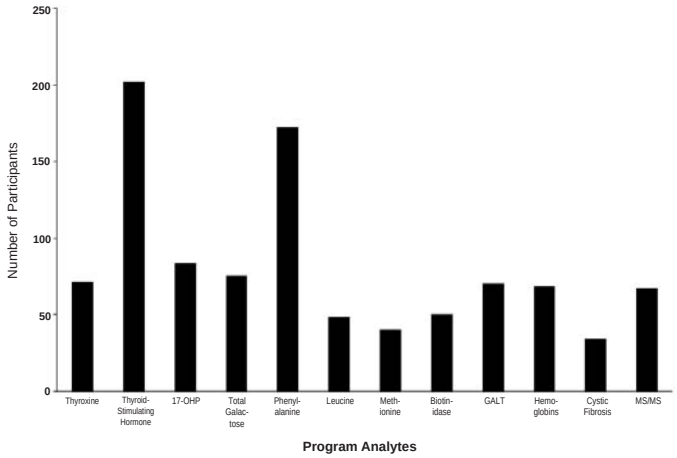



**FIGURE 4. Number of Participants in Quality Control Programs, 2003**

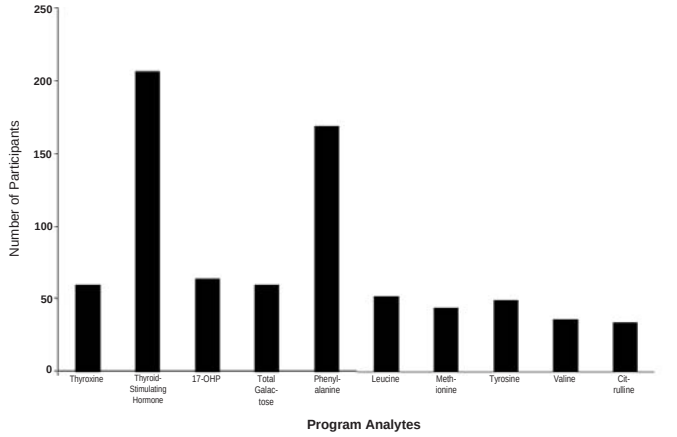
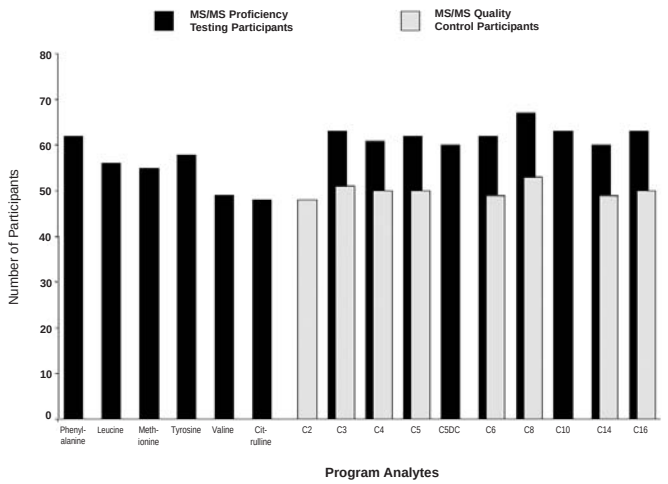


**FIGURE 5. Number of Participants in MS/MS-Specific Programs, 2003**




*Amino acids quality control materials are analyzed by many methods. MS/MS participants are included in Figure 4. Quality control materials are not available for C5DC and C10.*

## NEW ACTIVITIES

In 2003, NSQAP had 88 participants from Spanish-speaking countries. We completed the translation of the data-entry instructions for the NSQAP data-reporting Web site into Spanish. Two NCEH scientists, a Castilian Spanish-speaker and a Latin American Spanish-speaker, collaborated with the CDC en Español translator to validate the translation. The new data-reporting Web site instructions document was sent to our Spanish clients in January 2003.

NSQAP cosponsored and helped organize the 3rd Annual MS/MS Program Implementation Meeting, "Improving the Efficacy and Effectiveness of Tandem Mass Spectrometry Screening for Newborns," on January 12-14, 2003, in Berkeley, California. The conference provided a forum for State program representatives to discuss logistical issues faced when planning, implementing, and evaluating newborn screening programs using MS/MS technology. Over 160 scientists and physicians attended this meeting.

In January 2003, we began distributing five-specimen panels for Type 1 Diabetes composed of spots from the validated-specimen library described in *Genetic Risk for Type 1 Diabetes Using Dried-Blood Spots*. Four research laboratories that do population-based testing participate in the pilot PT.

In March 2003, the United States Government Accounting Office released its report, *Newborn Screening: Characteristics of State Programs*, to Congressional Requesters. The report presents a thorough summary of state newborn screening programs' current practices. NSQAP contributed to the investigation. To view the full report, visit www.gao.gov/cgi-bin/getrpt?GAO-03-449.

A few years ago APHL organized a subcommittee of the Newborn Screening and Genetics in Public Health Committee for 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 May 2003, this subcommittee held a meeting 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 June 2003, the United States Postal Service (USPS) adopted revisions to the mailing standards related to the requirements and packaging standards for mailable types of Division 6.2 infectious materials. The changes will provide a greater level of safety for handling and transporting infectious substances. Note that (1) the inner envelope or foldover flap for the collection card should be labeled with a small international biohazard label, and (2) the DBS can be shipped by mail with no reasonable expectation of occupational exposure to blood or other potentially infectious material.

In July 2003, NSQAP celebrated its 25th anniversary of service to newborn screening laboratories around the world. We continually strive to improve the scope of our services and to meet the growing and changing needs of our participants. We have grown from eight domestic participants testing for one disorder in 1978 to over 350 worldwide participants testing for more than 30 disorders today.

NSQAP operated a pilot PT program for laboratories testing DBS by MS/MS for detection of amino acid metabolic disorders, urea cycle disorders, fatty acid oxidation disorders, and organic acid metabolic disorders. We added a presumptive-classification grading component to the MS/MS PT program for amino acids last year and brought the acylcarnitines to evaluation status in July 2003. The first set of acylcarnitine quality control materials was shipped in July 2003, and those data are presented for the first time in this annual report.

A pilot PT program is underway to serve those laboratories screening newborns for biomarkers of CF. In July 2002, we began distributing panels of DBS for immunoreactive trypsinogen (IRT) measurements in a pilot PT program format; and in October 2003, we added

a DNA confirmatory testing component. Twenty-one laboratories participate in IRT only and fourteen participate in IRT/DNA.

In July 2003, NCCLS document LA4-A4—*Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fourth Edition* was published. This document addresses issues associated with specimen collection, the filter paper collection device, and the transfer of blood onto filter paper. For more information, visit www.nccls.org.

NSQAP is investigating the development of specimens for toxoplasmosis antibody detection in DBS using serum from infected individuals. Toxoplasmosis anti-IgG and anti-IgM testing of DBS detected the appropriate antibody titers and showed the feasibility of establishing a pilot PT program.

NSQAP will cosponsor the 2004 Newborn Screening and Genetic Testing Symposium, May 3-6, 2004. The conference will be held at the Crowne Plaza Ravinia Hotel, Atlanta, Georgia, and will be preceded by half-day workshops on QA/QC and Follow-up. For more information, visit www.aphl.org.

**FILTER PAPER**

The paper disk punched to aliquot DBS specimens is a volumetric measurement and 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 isotopic-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 and serum absorption of the disks. To avoid the variability contributed by uncontrolled red blood cell (RBC) lysis, we initially used lysed-cell whole blood for variance studies with filter paper. The results of later studies have indicated that RBC lysis during the process is not sufficient to contribute substantially to the variance; however, the mean serum volume per disk is different with intact-cell blood. For historical reference and for maintaining uniformity of testing on all the paper production lots, we have continued using the lysed-cell procedure. We also measure performance with intact-cell preparations. The published and standardized acceptable volumes per 1/8-inch disk are 1.30 ± 0.19 µL (mean value and 95% confidence interval) for lysed-cell blood and 1.54 ± 0.17 µL for intact-cell blood.[1] As shown in Figures 6-9, the mean values and confidence intervals (CI) are the filter-paper evaluation parameters published in the NCCLS approved standard.[1] As shown in Figures 7 and 9, the second mean value (solid line) is the mean value produced from the NSQAP database, which was added for reference. The mean values for all lots are within the 95% CI defined by NCCLS but are below the mean values indicated by the NCCLS standard.[1]

In 2002, the mean value and CI for the intact cell measurements were examined and discussed during a routinely scheduled review period for revision of the NCCLS standard. The NCCLS committee decided to retain the original values, which were not produced at CDC, in the revised standard. Soon NSQAP will have accumulated sufficient data for intact cell measurements among lots to calculate a mean value and CI for intact cell assessments of different lots. In future summary reports, our mean value and CI will be included in the figures.

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2003 were W981, W001, and W011 of Grade 903. All filter paper lots were analyzed for agreement with the evaluation parameters according to the NCCLS approved standard.[1]

Each year, with the extensive cooperation of manufacturers (Schleicher & Schuell and Whatman) of filter papers approved by the Food and Drug Administration (FDA) for blood collection, we have conducted routine evalua-

*Filter paper lots used in the CDC production of QC and PT specimens distributed in 2003 were W981 and W001, W011 of Grade 903.*

tions of new lots and compared new lots with previous lots. The criteria for acceptable performance are the approved limits established in the NCCLS standard.[1] Each manufacturer is also expected to establish its own testing program using the NCCLS standard and make

**FIGURE 6. Schleicher and Schuell Grade 903 Filter Paper Serum Volume by Lot Number - Lysed Red Blood Cells**

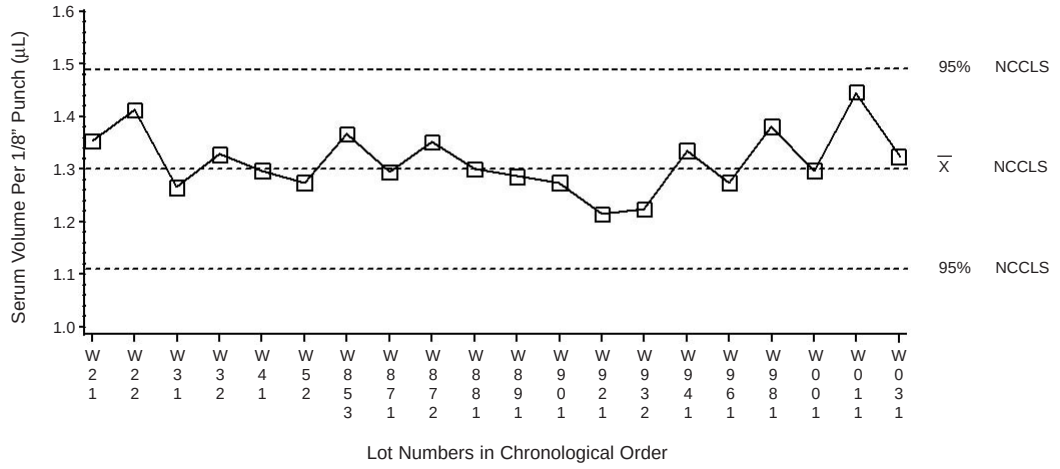
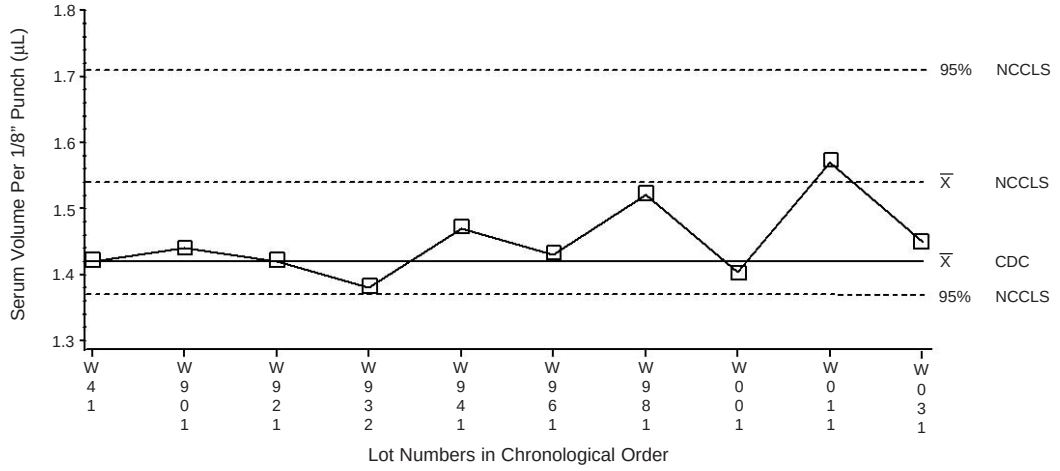



**FIGURE 7. Schleicher and Schuell Grade 903 Filter Paper Serum Volume by Lot Number - Intact Red Blood Cells**




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 quality assurance program and do not constitute preferential endorsement of any product over other specimen collection papers approved by the FDA.

The serum-absorbance volumes of 20 lots of Grade 903 filter paper (Schleicher & Schuell, Keene, NH) determined from lysed-RBC blood and for 10 lots determined from intact-RBC blood, are shown in chronological order. For W031, the most recent production lot of Grade 903 filter paper, we found the mean serum-absorbance volume to be 1.40 µL for a 1/8-inch disk for lysed-cell blood and 1.51 µL per 1/8-inch disk for intact-cell blood. Each mean value is within the acceptable range for the matrix used. Lot W031 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within the acceptable limits).

In 1996, the FDA approved the filter paper, BFC180, produced by Whatman Inc. (Fairfield, NJ) as a blood collection device. The BFC180 was evaluated by CDC according to the criteria previously described.[1] The serum-

**FIGURE 8. Whatman BFC180 Filter Paper**
**Serum Volume by Lot Number - Lysed Red Blood Cells**

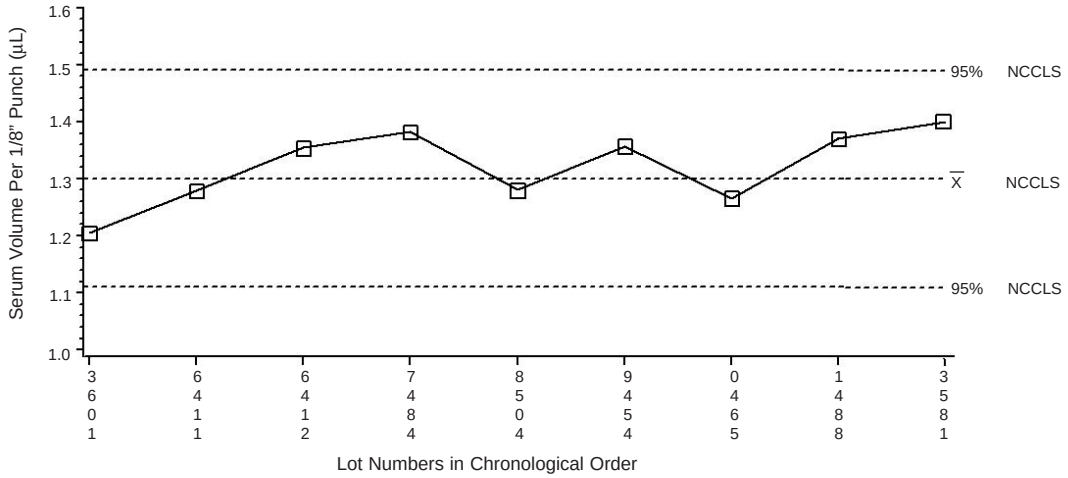
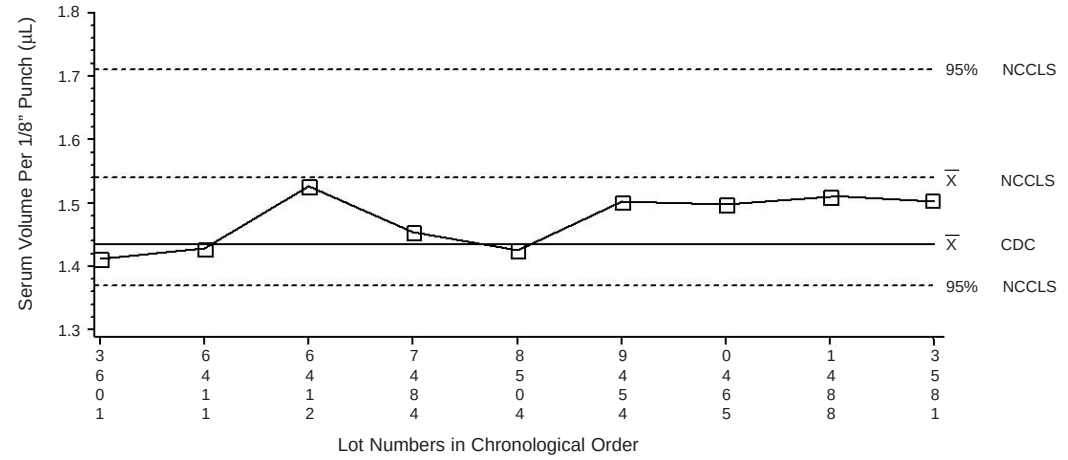



**FIGURE 9. Whatman BFC180 Filter Paper**
**Serum Volume by Lot Number - Intact Red Blood Cells**




absorbance volumes for nine lots of BFC180 filter paper determined from lysed-RBC blood and determined from intact-RBC blood, are shown in chronological order. For 3581, the most recent production lot of BFC180 filter paper, we found the mean serum-absorbance volume to be 1.42 µL for a 1/8-inch disk for lysed-cell blood and 1.45 µL per 1/8-inch disk for intact-cell blood. Each mean value is within the acceptable range for the matrix used. Lot 3581 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within the acceptable limits).

## SPECIMEN PREPARATION AND DATA HANDLING

Tables and figures show the enriched concentrations of all PT specimens and QC lots as well as the summarized quantitative data. The total concentration of each specimen or lot was equal to 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. Except for biotinidase and GALT, all DBS specimens in the PT surveys and QC production lots were prepared from whole blood of 55% hematocrit. Purified analytes or natural donor blood, except for thyroid-stimulating hormone (TSH), which used the Second International Reference Preparation (80/558), were used for all enrichments. For galactosemia, enrichments were made with galactose, galactose-1-phosphate, or both so that both free galactose (galactose alone) and total galactose (free galactose plus galactose present as galactose-1-phosphate) could be measured. For biotinidase and GALT, individual donor blood was used. All reported analytic values outside the 99% confidence limits were excluded from the summaries of quantitative results.

*When reporting cutoff values, we requested the decision level for sorting test results that are reported as presumptive positive (outside limits) from results reported as negative (within limits).*

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 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 2003, we applied the laboratory-reported specific cutoff values, when available, to our judgment algorithm for clinical assessments; otherwise, we used the NSQAP-assigned working cutoff values that are based on the national mean value for this assessment.

## CUTOFFS

When reporting cutoff values, we requested the decision level for sorting test results that are reported as presumptive positive (outside limits) from results reported as negative (within limits). The reported cutoff values are summarized in Table 1 for domestic and foreign laboratories. The values for the mean (arithmetic average) and the mode (most frequent value) are shown for each analyte. The mean cutoff values for domestic and foreign laboratories were similar except those for 17 α-hydroxyprogesterone (17-OHP), which were twice as high for domestic laboratories. The cutoff values for IRT are 30% higher for domestic laboratories than for foreign laboratories. The range (Min/Max) of cutoff values is large for TSH, 17-OHP, total galactose (Gal), and IRT for both domestic and foreign laboratories. The mean and mode of cutoff values for phenylalanine (Phe) are the same for domestic and foreign laboratories; however, the range is much larger for foreign laboratories. Cutoff values for leucine

**TABLE 1. 2003 Summary of Cutoff Values of Domestic and Foreign Laboratories**

| Domestic Analyte | N | Mean | Mode | Min/Max |
|---|---|---|---|---|
| $T_4$ | 28 | 6.3 | 6 | 3.5-10 |
| TSH | 48 | 31.5 | 25 | 19.4-61 |
| 17-OHP | 28 | 48.6 | 50 | 25-65 |
| Galactose | 26 | 10.8 | 10 | 5-20 |
| Phenylalanine | 53 | 3 | 4 | 2-4 |
| Leucine | 17 | 4.1 | 4 | 2-7 |
| Methionine | 18 | 1.5 | 2 | 0.9-3 |
| IRT | 7 | 93.6 | 90 | 66-114 |

| Foreign Analyte | N | Mean | Mode | Min/Max |
|---|---|---|---|---|
| $T_4$ | 23 | 6.4 | 6 | 1.5-14.3 |
| TSH | 132 | 24.5 | 20 | 10-50 |
| 17-OHP | 41 | 28 | 22 | 15-65 |
| Galactose | 39 | 12.1 | 10 | 4.8-27.3 |
| Phenylalanine | 98 | 3.3 | 4 | 1.5-20 |
| Leucine | 22 | 4.7 | 4 | 2-7 |
| Methionine | 18 | 1.3 | 1.2 | 0.7-3 |
| IRT | 22 | 68.9 | 70 | 55-86 |

(Leu) and methionine (Met) are almost identical for domestic and foreign laboratories.

**TABLE 2. 2003 Summary of Performance Evaluation Errors by Domestic and Foreign Laboratories**

| **Domestic** | Positive Specimens Assayed (N) | False-Negative Errors (%) | Negative Specimens Assayed (N) | False-Positive Errors (%) |
|---|---|---|---|---|
| Hypothyroidism | 248 | 0 | 737 | 0.5 |
| Phenylketonuria | 280 | 0 | 720 | 0.4 |
| Galactosemia | 133 | 0 | 371 | 0 |
| Congential Adrenal Hyperplasia | 142 | 0.7 | 399 | 0.5 |
| Maple Syrup Urine Disease | 77 | 0 | 290 | 2.1 |
| Homocystinuria | 74 | 0 | 277 | 0.7 |
| Biotinidase Deficiency | 84 | 0 | 336 | 0 |
| GALT Deficiency | 225 | 0 | 630 | 0.2 |
| Cystic Fibrosis (IRT) - Pilot Phase | 67 | 1.5 | 83 | 0 |
| **Foreign** | Positive Specimens Assayed (N) | False-Negative Errors (%) | Negative Specimens Assayed (N) | False-Positive Errors (%) |
| Hypothyroidism | 598 | 0.2 | 1782 | 1.7 |
| Phenylketonuria | 469 | 1.1 | 1256 | 2.0 |
| Galactosemia | 189 | 0.5 | 524 | 0.2 |
| Congential Adrenal Hyperplasia | 200 | 0.5 | 572 | 1.6 |
| Maple Syrup Urine Disease | 89 | 1.1 | 332 | 2.4 |
| Homocystinuria | 77 | 1.3 | 288 | 4.2 |
| Biotinidase Deficiency | 91 | 0 | 364 | 0.5 |
| GALT Deficiency | 83 | 2.4 | 212 | 1.9 |
| Cystic Fibrosis (IRT) - Pilot Phase | 163 | 6.7 | 192 | 3.1 |

## PROFICIENCY TESTING

All PT panels contained five blind-coded 75-µL or 100-µL DBS specimens. Specimens in the PT panels contained either endogenous levels or were enriched with predetermined levels of $T_4$, TSH, Phe, Gal, 17-OHP, Leu, and Met. Specimens for the CF panel were prepared with IRT enriched blood. Special separate panels for biotinidase deficiency and for GALT deficiency were prepared with purchased blood from donors with enzyme deficiencies. Specimens for the hemoglobinopathies panel were prepared from umbilical cord blood.

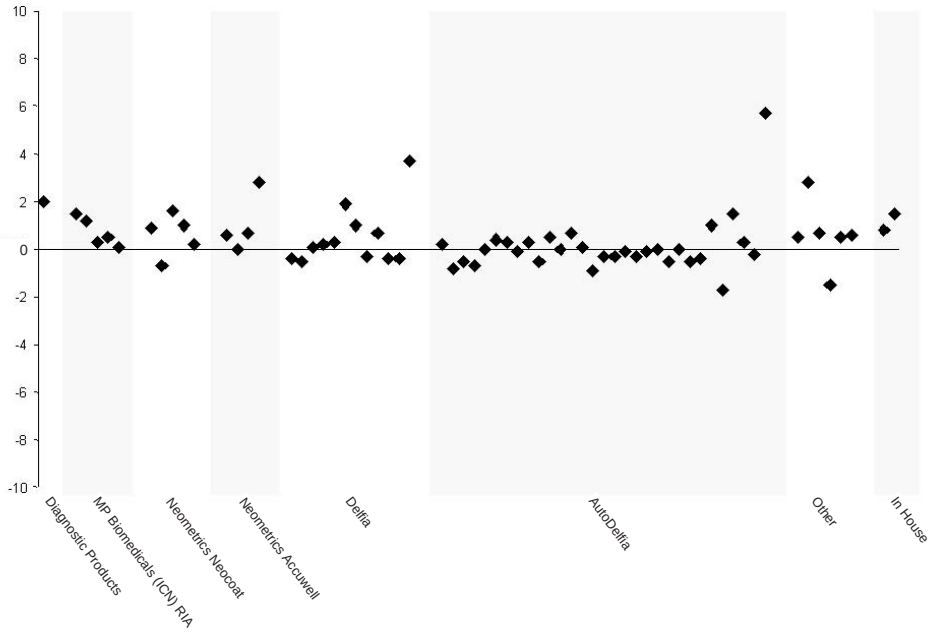
Specimen sets were packaged in a zip-close metallized plastic bag with desiccant, instructions for analysis, and data-report forms for those laboratories that did not report data by Internet. We prepared and distributed quarterly reports of all results that had been received by the cutoff dates. In this annual report, the comparisons of results by different methods (Figures 10-25) are illustrated with the reported PT data. These comparisons are achieved by the use of bias plots of reported results relative to either the CDC expected value (endogenous plus enrichment level) or for IRT, the CDC assayed value. The expected value is subtracted from the reported value, and the result is plotted. Time intervals are within quarter or among quarters. Also, a summary of the specimen data for all PT challenges in 2003 is tabulated in the left margin for each analyte. Note in the margin of Figures 10 and 11 that all $T_4$ specimens are enriched with 4.0 µg/dL of $T_4$ but have different CDC assayed values. This is because some specimens were prepared from $T_4$ depleted base pools and others from normal base pools. The selected normal base pools had different endogenous $T_4$ levels. This process yields specimens with different values from a common enrichment.

The representative specimens selected for the bias plots (Figure 10-25) were either above or below the cutoff values for the analyte or were replicate specimens among quarters. In general, the quantitative comparisons (Figures 10-25) for PT challenges are reasonable within a method but vary among methods. The PT quantitative results are grouped by kit or method to illustrate any method-related differences in analyte recoveries. Because some of the pools in a routine PT survey represent a unique donor specimen, differences in endogenous materials in the donor specimens may influence method-related differences. The $T_4$ and TSH results (Figures 10-13) show a reasonably consistent performance among the different methods, with four methods showing some higher values for $T_4$ and three methods showing higher for TSH. The "Other" method group shows the greatest scatter of values among users. Comparisons of values for most methods for 17-OHP and Gal (Figures 14-17) show higher values than the expected value except for one Gal method that gave values close to the expected value for the higher value specimen (Figure 17). For Phe (Figures 18-19), the reported results show high variability within- and among-methods. One Phe method shows low variability among users and close agreement to the expected value. The values reported for Leu (Figures 20-21) show variability but good reproducibility on the same specimen among quarters. One Leu method shows close agreement

# FIGURES 10-11. Reproducibility of Results by Different Methods - Thyroxine

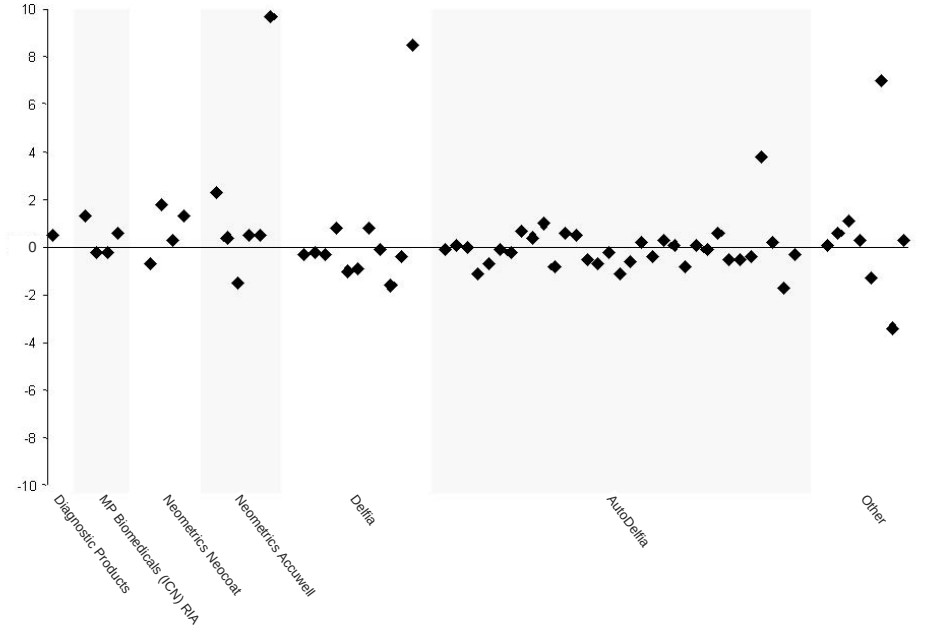
| | Quarter 1 | Quarter 2 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 3.1 | 10 |
| Reported Mean | 2.9 | 9.2 |
| *Specimen 2* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 7 | 10.3 |
| Reported Mean | 6.7 | 8.5 |
| *Specimen 3* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 8.6 | 4.7 |
| Reported Mean | 8.1 | 4.8 |
| *Specimen 4* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 10.3 | 4.8 |
| Reported Mean | 8.5 | 5.1 |
| *Specimen 5* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 14.5 | 14.5 |
| Reported Mean | 15.6 | 16.2 |

**Figure 10. Bias Plot of Thyroxine Values by Method**
**Quarter 2, Specimen 3**
**Expected Value (EV)[1] 4.5 µg/dL serum**




| | Quarter 3 | Quarter 4 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 8.6 | 8.8 |
| Reported Mean | 8.0 | 8.0 |
| *Specimen 2* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 4.7 | 3.9 |
| Reported Mean | 4.5 | 4.4 |
| *Specimen 3* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 11.4 | 12.8 |
| Reported Mean | 10.2 | 11.4 |
| *Specimen 4* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 11.6 | 9.2 |
| Reported Mean | 11.5 | 6.4 |
| *Specimen 5* | | |
| Enriched | 4 | 4 |
| CDC Assayed | 13.4 | 14.5 |
| Reported Mean | 10.9 | 16.4 |

**Figure 11. Bias Plot of Thyroxine Values by Method**
**Quarter 3, Specimen 2**
**Expected Value (EV)[1] 4.5 µg/dL serum**

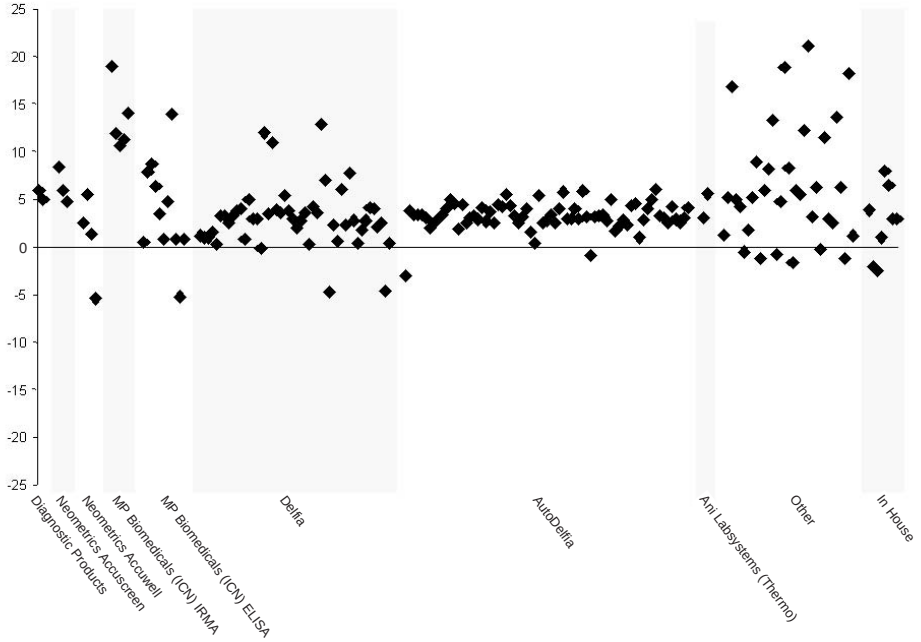



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

# FIGURES 12-13. Reproducibility of Results by Different Methods - Thyroid-Stimulating Hormone

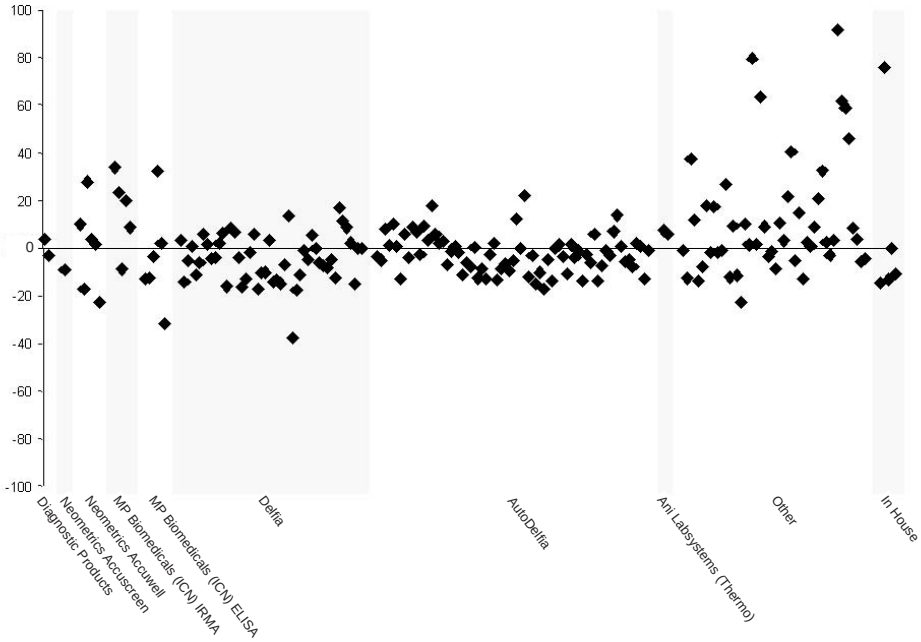
| | Quarter 1 | Quarter 2 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 75 | 10 |
| CDC Assayed | 65 | 10 |
| Reported Mean | 81.3 | 13.5 |
| *Specimen 2* | | |
| Enriched | 9 | 9 |
| CDC Assayed | 9 | 9 |
| Reported Mean | 9.9 | 10 |
| *Specimen 3* | | |
| Enriched | 9 | 65 |
| CDC Assayed | 11 | 65 |
| Reported Mean | 11.5 | 70.8 |
| *Specimen 4* | | |
| Enriched | 9 | 70 |
| CDC Assayed | 9 | 78 |
| Reported Mean | 9.9 | 79.5 |
| *Specimen 5* | | |
| Enriched | 9 | 9 |
| CDC Assayed | 9 | 9 |
| Reported Mean | 9.8 | 10.5 |

**Figure 12. Bias Plot of Thyroid-Stimulating Hormone Values by Method**
**Quarter 2, Specimen 1**
**Expected Value (EV)[1] 10.0 µIU/mL serum**




| | Quarter 3 | Quarter 4 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 9 | 10 |
| CDC Assayed | 11 | 6 |
| Reported Mean | 11.6 | 10.1 |
| *Specimen 2* | | |
| Enriched | 65 | 60 |
| CDC Assayed | 65 | 62 |
| Reported Mean | 71.8 | 66.7 |
| *Specimen 3* | | |
| Enriched | 9 | 9 |
| CDC Assayed | 13 | 15 |
| Reported Mean | 10.9 | 10.6 |
| *Specimen 4* | | |
| Enriched | 9 | 18 |
| CDC Assayed | 13 | 22 |
| Reported Mean | 13.9 | 15.2 |
| *Specimen 5* | | |
| Enriched | 9 | 9 |
| CDC Assayed | 11 | 9 |
| Reported Mean | 11 | 10.0 |

**Figure 13. Bias Plot of Thyroid-Stimulating Hormone Values by Method**
**Quarter 3, Specimen 2**
**Expected Value (EV)[1] 73.0 µIU/mL serum**

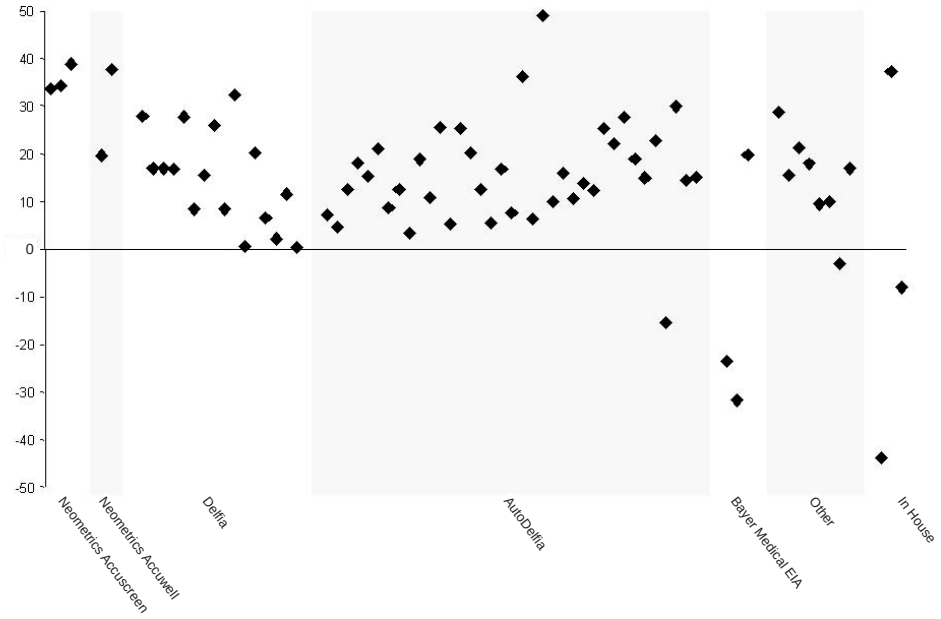



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

# FIGURES 14-15. Reproducibility of Results by Different Methods - 17 α-Hydroxyprogesterone

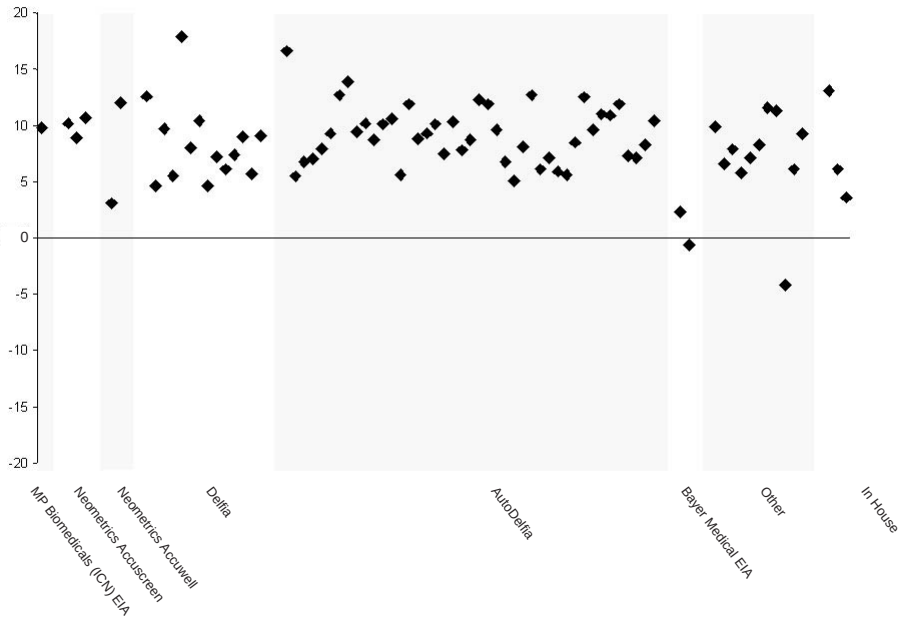
| | Quarter 1 | Quarter 2 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 65 | 5 |
| CDC Assayed | 61.2 | 16.4 |
| Reported Mean | 81.7 | 19 |
| *Specimen 2* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0 | 2 |
| Reported Mean | 3.2 | 3 |
| *Specimen 3* | | |
| Enriched | 0 | 5 |
| CDC Assayed | 1 | 7 |
| Reported Mean | 3.1 | 10 |
| *Specimen 4* | | |
| Enriched | 0 | 5 |
| CDC Assayed | 2 | 5 |
| Reported Mean | 3.3 | 7.7 |
| *Specimen 5* | | |
| Enriched | 70 | 70 |
| CDC Assayed | 81 | 81 |
| Reported Mean | 96.2 | 98.6 |

**Figure 14. Bias Plot of 17 α-Hydroxyprogresterone Values by Method**
**Quarter 1, Specimen 1**
**Expected Value (EV)[1] 65.0 ng/mL serum**




| | Quarter 3 | Quarter 4 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 0 | 30 |
| CDC Assayed | 1 | 30.5 |
| Reported Mean | 2.8 | 36.8 |
| *Specimen 2* | | |
| Enriched | 5 | 0 |
| CDC Assayed | 7 | 0.2 |
| Reported Mean | 10.1 | 0.9 |
| *Specimen 3* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.8 | 0.8 |
| Reported Mean | 2.1 | 2.3 |
| *Specimen 4* | | |
| Enriched | 85 | 0 |
| CDC Assayed | 86 | 0.8 |
| Reported Mean | 107.3 | 3.0 |
| *Specimen 5* | | |
| Enriched | 0 | 70 |
| CDC Assayed | 0.8 | 81 |
| Reported Mean | 1.8 | 99.1 |

**Figure 15. Bias Plot of 17 α-Hydroxyprogesterone Values by Method**
**Quarter 2, Specimen 1**
**Expected Value (EV)[1] 10.4 ng/mL serum**

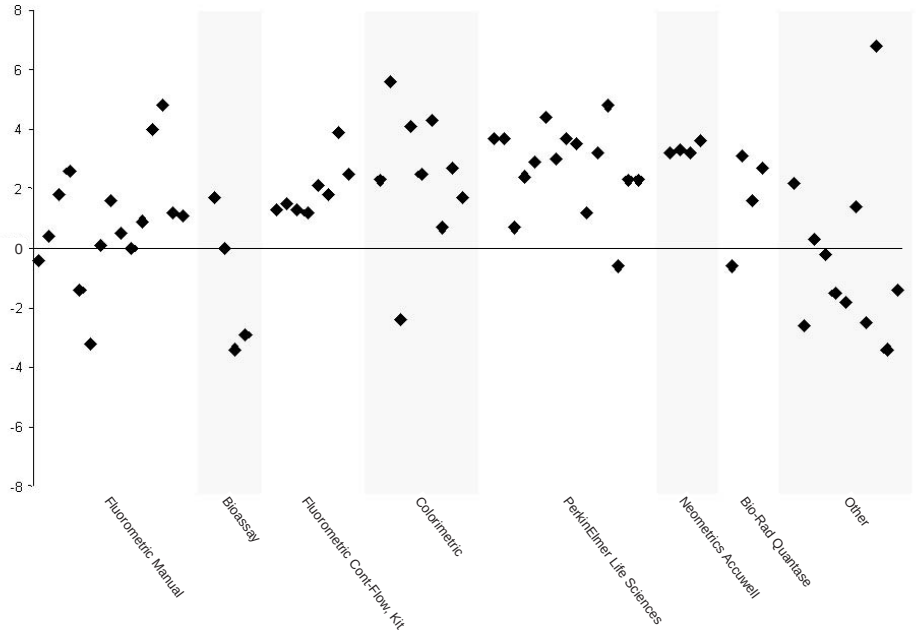



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

# FIGURES 16-17. Reproducibility of Results by Different Methods - Total Galactose

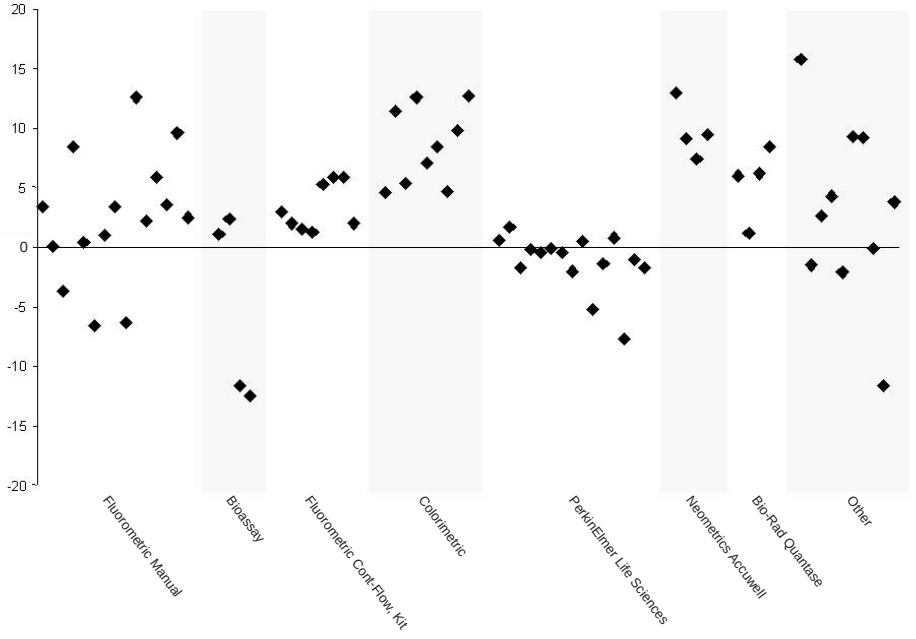
| | Quarter 1 | Quarter 2 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 0 | 5 |
| CDC Assayed | 0.3 | 6.2 |
| Reported Mean | 2.5 | 6.9 |
| *Specimen 2* | | |
| Enriched | 0 | 21 |
| CDC Assayed | 0.7 | 21.2 |
| Reported Mean | 2 | 24.6 |
| *Specimen 3* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.6 | 0.3 |
| Reported Mean | 2.5 | 2.7 |
| *Specimen 4* | | |
| Enriched | 21 | 0 |
| CDC Assayed | 21.2 | 0.3 |
| Reported Mean | 24.7 | 2.6 |
| *Specimen 5* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.2 | 0.2 |
| Reported Mean | 2.3 | 2.6 |

**Figure 16. Bias Plot of Total Galactose Values by Method**
**Quarter 2, Specimen 1**
**Expected Value (EV)[1] 5.4 mg/dL whole blood**




| | Quarter 3 | Quarter 4 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 0 | 21 |
| CDC Assayed | 0.6 | 22.1 |
| Reported Mean | 2.4 | 25.3 |
| *Specimen 2* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.3 | 0 |
| Reported Mean | 2.4 | 2.6 |
| *Specimen 3* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.1 | 0 |
| Reported Mean | 2.1 | 2.1 |
| *Specimen 4* | | |
| Enriched | 0 | 15 |
| CDC Assayed | 0 | 15.8 |
| Reported Mean | 2.4 | 17.7 |
| *Specimen 5* | | |
| Enriched | 24 | 0 |
| CDC Assayed | 25.6 | 0.2 |
| Reported Mean | 29.1 | 2.5 |

**Figure 17. Bias Plot of Total Galactose Values by Method**
**Quarter 2, Specimen 2**
**Expected Value (EV)[1] 21.6 mg/dL whole blood**

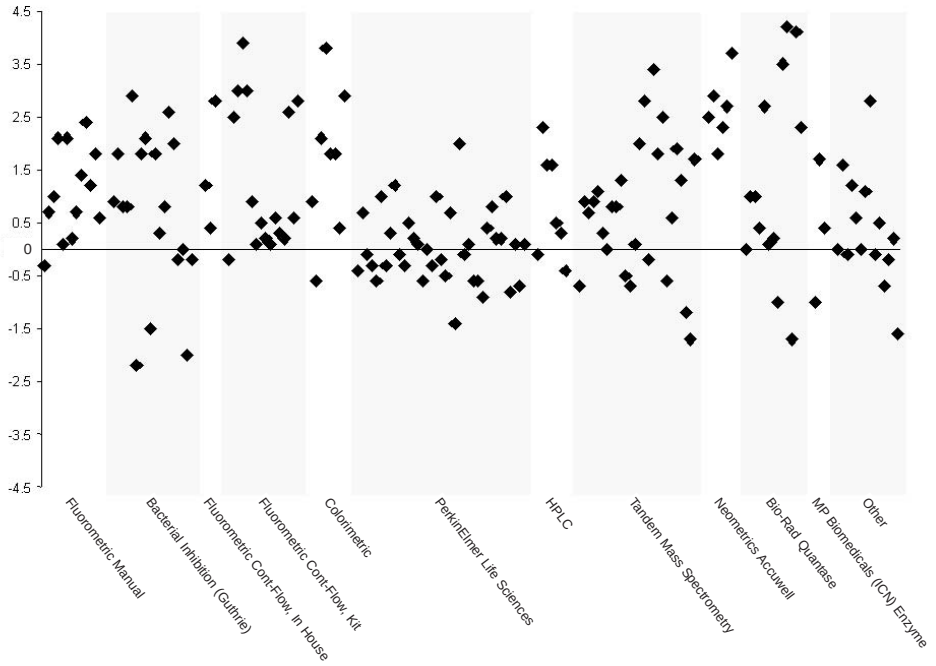



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

# FIGURES 18-19. Reproducibility of Results by Different Methods - Phenylalanine

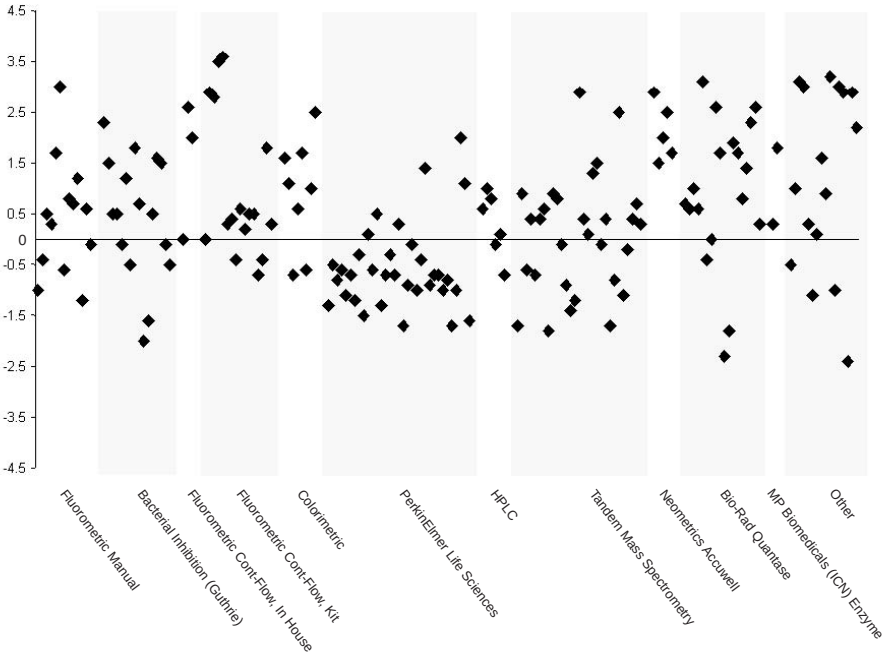
| | Quarter 1 | Quarter 2 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 5.5 | 2.5 |
| CDC Assayed | 5.2 | 3.3 |
| Reported Mean | 6.2 | 4.2 |
| *Specimen 2* | | |
| Enriched | 6 | 0 |
| CDC Assayed | 5.7 | 1 |
| Reported Mean | 7.4 | 1.4 |
| *Specimen 3* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 1 | 4 |
| Reported Mean | 1.6 | 0.7 |
| *Specimen 4* | | |
| Enriched | 0 | 6 |
| CDC Assayed | 1 | 7.6 |
| Reported Mean | 1.5 | 7 |
| *Specimen 5* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.3 | 0.3 |
| Reported Mean | 0.6 | 0.6 |

**Figure 18. Bias Plot of Phenylalanine Values by Method**
**Quarter 2, Specimen 4**
**Expected Value (EV)[1] 6.2 mg/dL whole blood**




| | Quarter 3 | Quarter 4 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 0 | 5.5 |
| CDC Assayed | 1 | 5.9 |
| Reported Mean | 1.5 | 6.9 |
| *Specimen 2* | | |
| Enriched | 0 | 2 |
| CDC Assayed | 0.4 | 3.1 |
| Reported Mean | 0.6 | 2.7 |
| *Specimen 3* | | |
| Enriched | 5 | 0 |
| CDC Assayed | 7.2 | 1.6 |
| Reported Mean | 7.0 | 1.5 |
| *Specimen 4* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 1.1 | 1.4 |
| Reported Mean | 1.2 | 1.3 |
| *Specimen 5* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 1.6 | 0.3 |
| Reported Mean | 1.6 | 0.5 |

**Figure 19. Bias Plot of Phenylalanine Values by Method**
**Quarter 3, Specimen 3**
**Expected Value (EV)[1] 6.5 mg/dL whole blood**

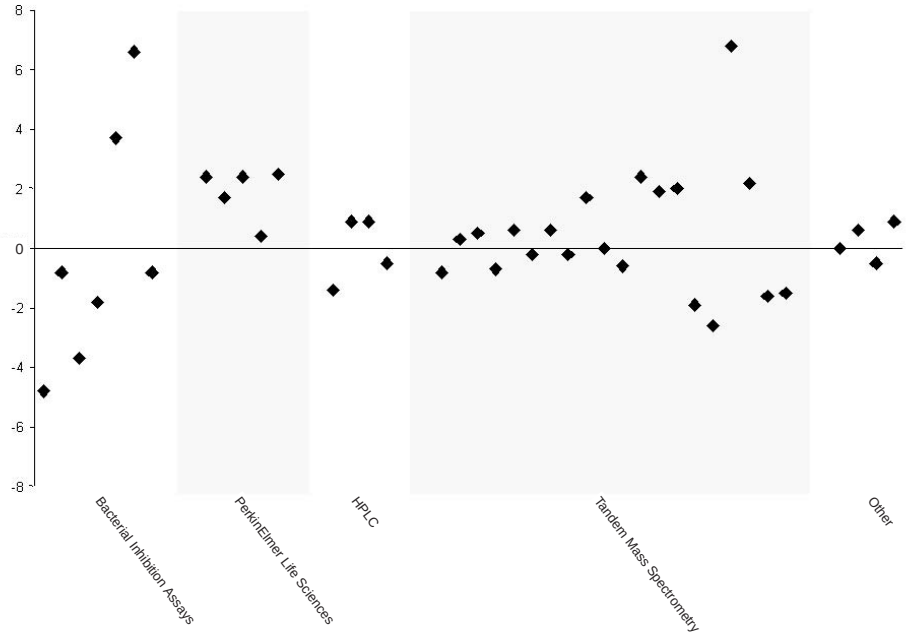



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

# FIGURES 20-21. Reproducibility of Results by Different Methods - Leucine

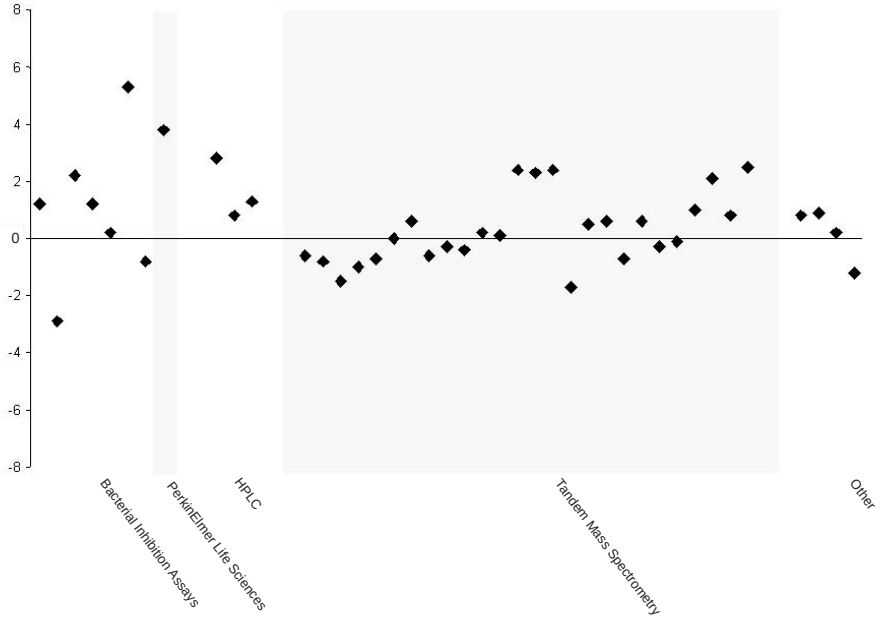
| | Quarter 1 | Quarter 2 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 0 | 5 |
| CDC Assayed | 1.2 | 6.7 |
| Reported Mean | 1.2 | 7.7 |
| *Specimen 2* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 2.9 | 2.6 |
| Reported Mean | 2.6 | 2.5 |
| *Specimen 3* | | |
| Enriched | 6 | 0 |
| CDC Assayed | 7.2 | 1.7 |
| Reported Mean | 8 | 1.4 |
| *Specimen 4* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 2.6 | 1.8 |
| Reported Mean | 2.6 | 1.3 |
| *Specimen 5* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 1.4 | 1.4 |
| Reported Mean | 1.3 | 1.3 |

**Figure 20. Bias Plot of Leucine Values by Method**
**Quarter 1, Specimen 3**
**Expected Value (EV)[1] 7.8 mg/dL whole blood**




| | Quarter 3 | Quarter 4 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 6 | 5.5 |
| CDC Assayed | 7.2 | 5.7 |
| Reported Mean | 8.2 | 6.9 |
| *Specimen 2* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 1.7 | 1.4 |
| Reported Mean | 1.6 | 1.6 |
| *Specimen 3* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 3.3 | 2.4 |
| Reported Mean | 3.5 | 2.7 |
| *Specimen 4* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 1.9 | 2.2 |
| Reported Mean | 2.0 | 2.1 |
| *Specimen 5* | | |
| Enriched | 3 | 0 |
| CDC Assayed | 6.7 | 1.4 |
| Reported Mean | 5.7 | 1.4 |

**Figure 21. Bias Plot of Leucine Values by Method**
**Quarter 3, Specimen 1**
**Expected Value (EV)[1] 7.8 mg/dL whole blood**

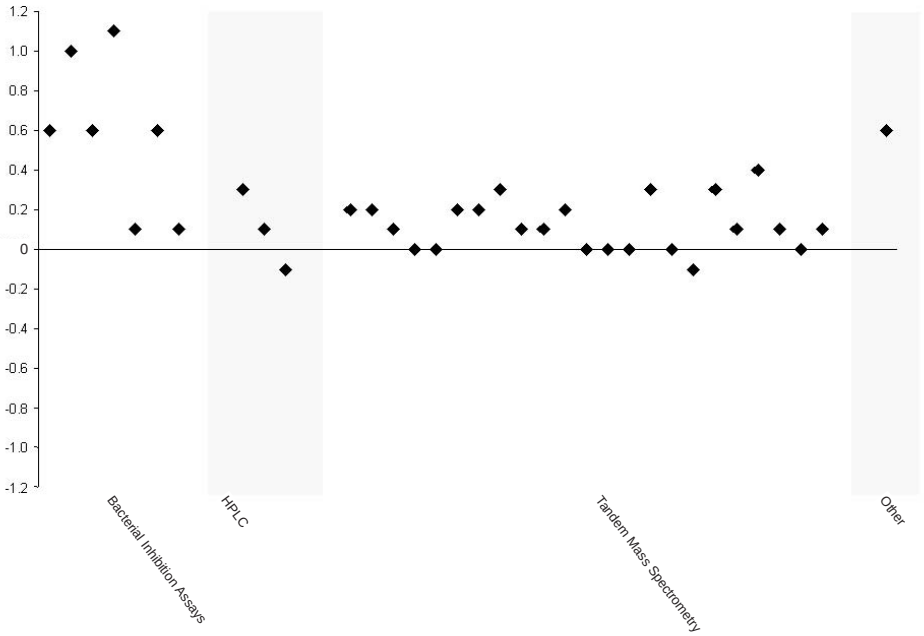



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

# FIGURES 22-23. Reproducibility of Results by Different Methods - Methionine

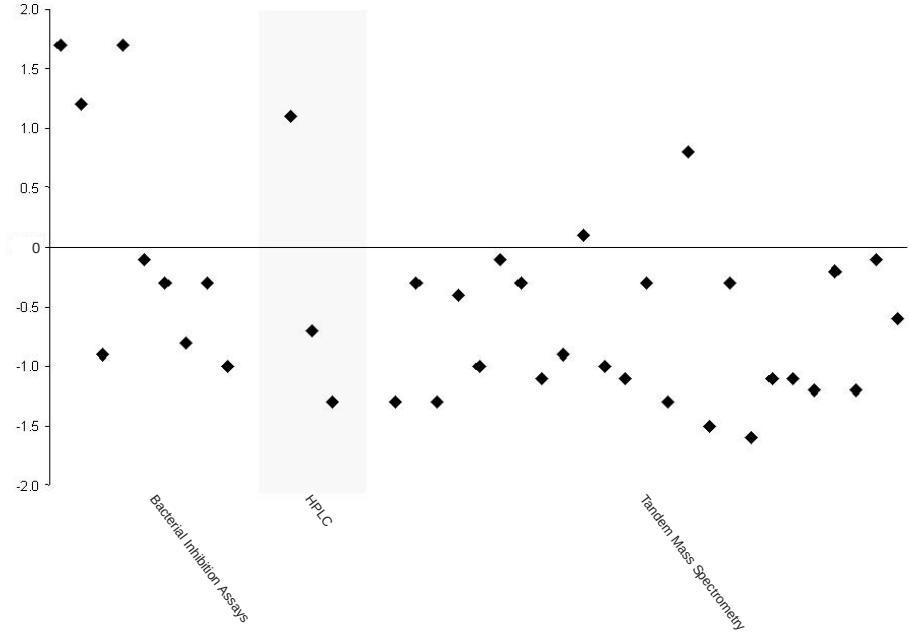
| | Quarter 1 | Quarter 2 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 3 | 3 |
| CDC Assayed | 2.7 | 3 |
| Reported Mean | 2.9 | 3.5 |
| *Specimen 2* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.4 | 0.5 |
| Reported Mean | 0.5 | 0.6 |
| *Specimen 3* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.4 | 0.2 |
| Reported Mean | 0.4 | 0.2 |
| *Specimen 4* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.5 | 0.1 |
| Reported Mean | 0.6 | 0.2 |
| *Specimen 5* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.1 | 0.1 |
| Reported Mean | 0.3 | 0.1 |

**Figure 22. Bias Plot of Methionine Values by Method**
**Quarter 2, Specimen 2**
**Expected Value (EV)[1] 0.4 mg/dL whole blood**




| | Quarter 3 | Quarter 4 |
|---|---|---|
| *Specimen 1* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.4 | 0.3 |
| Reported Mean | 0.3 | 0.4 |
| *Specimen 2* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.2 | 0.1 |
| Reported Mean | 0.2 | 0.3 |
| *Specimen 3* | | |
| Enriched | 0 | 2.5 |
| CDC Assayed | 0.3 | 2.7 |
| Reported Mean | 0.5 | 2.8 |
| *Specimen 4* | | |
| Enriched | 3.5 | 1 |
| CDC Assayed | 3.9 | 1.4 |
| Reported Mean | 3.8 | 1.3 |
| *Specimen 5* | | |
| Enriched | 0 | 0 |
| CDC Assayed | 0.3 | 0.1 |
| Reported Mean | 0.4 | 0.2 |

**Figure 23. Bias Plot of Methionine Values by Method**
**Quarter 3, Specimen 4**
**Expected Value (EV)[1] 4.3 mg/dL whole blood**

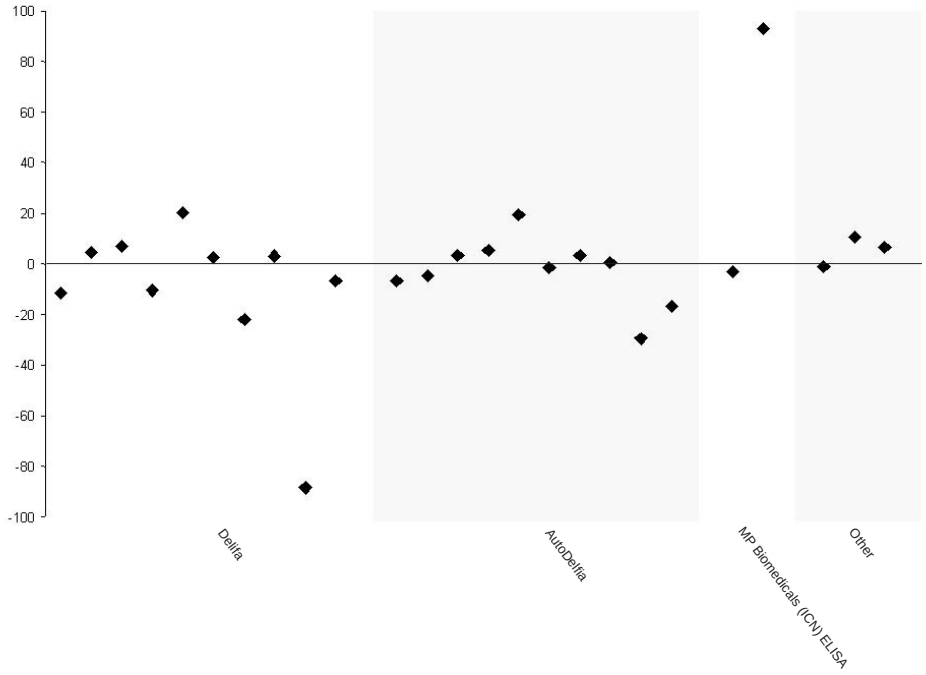



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

# FIGURES 24-25. Reproducibility of Results by Different Methods - Immunoreactive Trypsinogen (IRT)

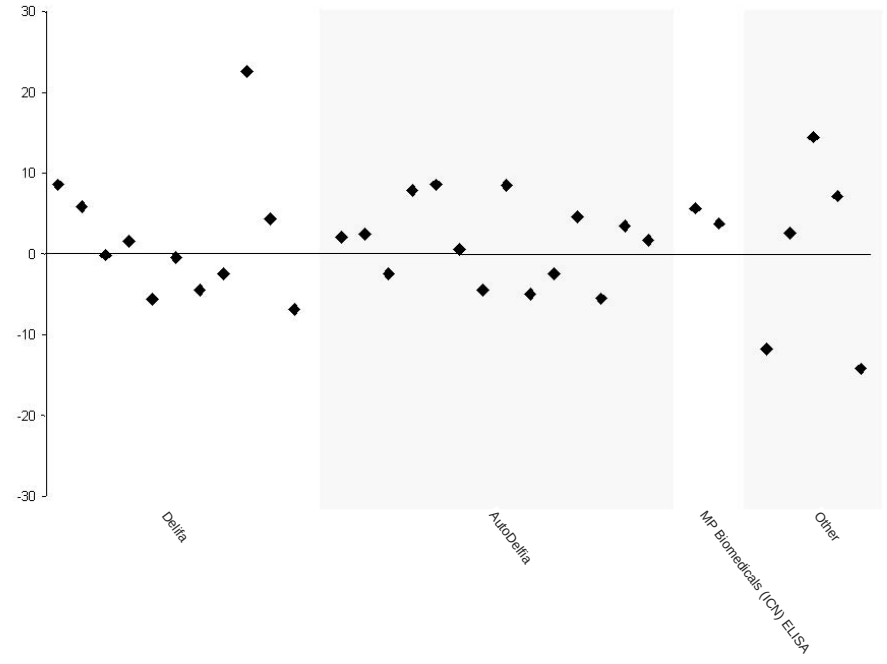
| | Quarter 1 | Quarter 2 |
|---|---|---|
| *Specimen 1* | | |
| CDC Assayed | 12.8 | 144.9 |
| Reported Mean | 11.7 | 128.2 |
| *Specimen 2* | | |
| CDC Assayed | 119.5 | 35.4 |
| Reported Mean | 118.4 | 31.8 |
| *Specimen 3* | | |
| CDC Assayed | 35.4 | 44.6 |
| Reported Mean | 37.2 | 41.3 |
| *Specimen 4* | | |
| CDC Assayed | 173.4 | 119.5 |
| Reported Mean | 182.6 | 117.9 |
| *Specimen 5* | | |
| CDC Assayed | 44.6 | 12.8 |
| Reported Mean | 46.8 | 12.1 |

**Figure 24. Bias Plot of Cystic Fibrosis (IRT) Values by Method**
**Quarter 1, Specimen 2**
**Assayed Value (AV)[1] 119.5 ng/mL whole blood**




| | Quarter 3 | Quarter 4 |
|---|---|---|
| *Specimen 1* | | |
| CDC Assayed | 12.8 | 36.2 |
| Reported Mean | 12.8 | 36.9 |
| *Specimen 2* | | |
| CDC Assayed | 144.9 | 314.3 |
| Reported Mean | 139.4 | 315.7 |
| *Specimen 3* | | |
| CDC Assayed | 35.4 | 12.6 |
| Reported Mean | 36.3 | 10.9 |
| *Specimen 4* | | |
| CDC Assayed | 173.4 | 23.5 |
| Reported Mean | 180.1 | 22.8 |
| *Specimen 5* | | |
| CDC Assayed | 119.5 | 177.3 |
| Reported Mean | 121.5 | 186.7 |

**Figure 25. Bias Plot of Cystic Fibrosis (IRT) Values by Method**
**Quarter 3, Specimen 3**
**Assayed Value (AV)[1] 35.4 ng/mL whole blood**




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

to the expected value and low variability among users. One method for Met (Figures 22-23) produced higher values than the others, and another method shows close agreement to the expected value for the lower value specimen (Figure 22). All methods for the higher value Met specimen (Figure 23) show values below the expected value. For IRT (Figures 24-25), the reported results show close agreement with the CDC assayed value for all methods for both levels of challenge.

Table 2 shows the performance evaluation errors reported by disorder in 2003 for all qualitative assessments by domestic laboratories and by foreign laboratories. We applied the laboratory-reported specific cutoff values to our judgment algorithm for clinical assessments (see "Cutoffs" section). 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. The rates for false-positive misclassifications were based on the number of distributed negative specimens, and the rates for false-negative misclassifications were based 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 4.2%. For domestic laboratories, the rate was 0.7% or lower for eight of nine disorders; and for foreign laboratories, the rate was 1.6% or greater for seven of nine disorders. Screening programs are designed to avoid false-negative reports; this precautionary design, however, contributes to false-positive reports and may be the cause of many of the false-positive misclassifications. The false-negative rate, expected to be zero, ranged from 0% to 2.4%, not including 6.7% for the pilot cystic fibrosis (IRT) program. False-negative classifications were reported for the eight disorders, with the highest rate reported for GALT deficiency. For seven 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 are not included in Table 2. Participants' data for these specimens are used to examine the relative analytical performance of the assays. Table 3 shows the performance errors for hemoglobinopathies. The percentage of errors for qualitative assessments for sickle cell disease and other hemoglobinopathies ranged from 0.3% to 1.1% for the error categories, with 60 of 68 laboratories correctly classifying all specimens. The classification errors are essentially the same for phenotype and clinical assessments within the domestic and foreign laboratory groups. Table 4 shows the most common reasons for false-negative errors reported by domestic participants upon follow-up by NSQAP. Low quantitative values are the most frequent explanation.

**TABLE 3. Summary of Performance Evaluation Errors for Hemoglobinopathies by Domestic and Foreign Laboratories**

| Hemoglobinopathies | Domestic | Foreign |
|---|---|---|
| Specimens assayed | 985 | 285 |
| Phenotype errors | 0.3% | 0.8% |
| Clinical assessment errors | 0.6% | 1.1% |

*Overall, there were six phenotype errors in 2003, one FA, three FS, and two FAD.*

**TABLE 4. Most Common Reasons for False-Negative Errors Reported by Laboratories**

Low quantitative value
Transcription error
Analytic testing error

## QUALITY CONTROL

For QC shipments of $T_4$, TSH, 17-OHP, Gal, amino acids (Phe, Leu, Met, Tyr, Val, Cit), and acylcarnitines (C2, C3, C4, C5, C6, C8, C14, C16), each lot contained a different analyte concentration. To ensure that a laboratory received representative sheets of the production batch, we used a randomizing system to select the set of sheets from the production batch for each laboratory. The QC materials were distributed semiannually and included the blood-spot 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 that were 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.

Figure 26 shows a performance comparison of different methods for measuring 17-OHP from one set of QC materials distributed in 2003. The Y-intercept, which was not measured by participants, is the CDC assayed endogenous 17-OHP level. Slope and Y-intercept data presented in this figure are shown in Table 5c (Lots 151-153). For method comparison, one method has a slope of 1.0 with a Y-intercept of 1.8 ng/mL and falls near the top of the cluster of lines. The reported QC data are summarized in Tables 5a-5r, which show the analyte by series of QC lots, the number of measurements (N), the mean values, and the 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% confidence limits (outliers) were excluded from the calculations.

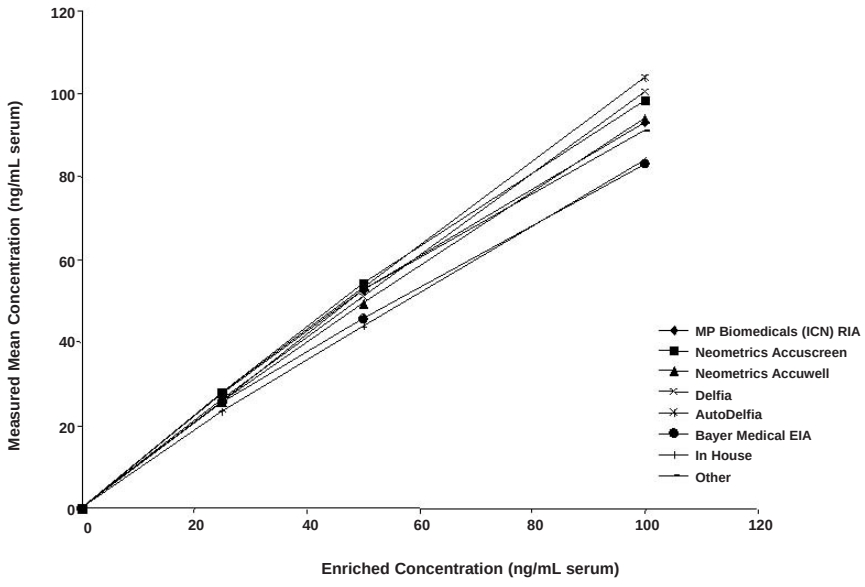
*Generally, slope values substantially different from 1.0 indicate that a method has an analytic bias.*

Tables 5a-5r, which summarize reported QC results, provide data about method-related differences in analytic recoveries and method bias. Because we prepared each QC lot series from a single 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 311, 312, and 313). Because only three or four concentrations of QC materials are available for each analyte, a bias error in any one pool can markedly influence the slope and intercept. The Y-intercept provides one measure of the endogenous concentration level for an analyte. For 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, ranging from 0.8 to 1.2. One 17-OHP method and one Gal method show a lower-than-expected slope of 0.7 (Lots 351-353) and 0.6 (Lots 245-248), respectively. Two other Gal methods yield slopes of 1.4 (Lots 245-248 and 321-324) and for one Gal method a slope of 1.5 (Lots 321-324). The slope for one method for Cit was 0.7 (Lot 245-248). The Gal methods show the greatest variation in slopes among all analytes. These slope deviations may be related to analytic ranges for calibration curves or to low recoveries for one specimen 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. Hannon WH, Baily CM, Bartoshesky LE, Davin B, Hoffman GL, King PP, et al. Blood collection on filter paper for newborn screening programs. Fourth edition, approved standard. Wayne (PA): NCCLS; 2003 NCCLS Document LA4-A4.

**FIGURE 26. Comparison of Different Methods for Detecting 17 α-Hydroxyprogesterone in Dried-Blood Spots (QC Lots 151-153)**




*NOTE: Y-intercept = CDC measured endogenous level*

TABLE 5a. 2003 Quality Control Data
Summaries of Statistical Analyses

**THYROXINE** (µg $T_4$/dL serum)

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 101 - Enriched 2 µg/dL serum | | | | | | |
| Diagnostic Products | 30 | 2.5 | 0.4 | 0.4 | 0.6 | 0.9 |
| MP Biomedicals (ICN) RIA | 136 | 2.4 | 0.4 | 0.6 | 0.7 | 0.9 |
| Neometrics Accuscreen | 20 | 3.2 | 0.2 | 0.2 | 0.8 | 1.1 |
| Neometrics Neocoat | 109 | 2.4 | 0.4 | 0.5 | 0.5 | 1.0 |
| Neometrics Accuwell | 158 | 2.5 | 0.5 | 0.8 | 0.5 | 1.0 |
| Delfia | 250 | 2.0 | 0.6 | 0.8 | 0.4 | 0.8 |
| AutoDelfia | 686 | 2.1 | 0.7 | 0.8 | 0.3 | 0.9 |
| Other | 70 | 2.2 | 0.4 | 0.5 | 0.3 | 1.0 |
| Lot 102 - Enriched 5.5 µg/dL serum | | | | | | |
| Diagnostic Products | 30 | 5.4 | 1.0 | 1.0 | 0.6 | 0.9 |
| MP Biomedicals (ICN) RIA | 138 | 5.6 | 0.7 | 0.8 | 0.7 | 0.9 |
| Neometrics Accuscreen | 20 | 6.4 | 0.9 | 0.9 | 0.8 | 1.1 |
| Neometrics Neocoat | 107 | 5.7 | 0.7 | 0.7 | 0.5 | 1.0 |
| Neometrics Accuwell | 156 | 5.9 | 0.8 | 1.4 | 0.5 | 1.0 |
| Delfia | 236 | 5.1 | 0.7 | 0.9 | 0.4 | 0.8 |
| AutoDelfia | 669 | 5.2 | 0.9 | 1.5 | 0.3 | 0.9 |
| Other | 70 | 5.7 | 0.6 | 0.8 | 0.3 | 1.0 |
| Lot 103 - Enriched 8 µg/dL serum | | | | | | |
| Diagnostic Products | 30 | 8.0 | 1.3 | 1.3 | 0.6 | 0.9 |
| MP Biomedicals (ICN) RIA | 140 | 7.7 | 0.9 | 1.0 | 0.7 | 0.9 |
| Neometrics Accuscreen | 20 | 10.0 | 0.9 | 0.9 | 0.8 | 1.1 |
| Neometrics Neocoat | 110 | 8.1 | 0.9 | 1.0 | 0.5 | 1.0 |
| Neometrics Accuwell | 156 | 8.5 | 0.9 | 1.3 | 0.5 | 1.0 |
| Delfia | 256 | 6.9 | 1.0 | 1.1 | 0.4 | 0.8 |
| AutoDelfia | 669 | 7.4 | 1.2 | 2.0 | 0.3 | 0.9 |
| Other | 68 | 8.0 | 0.9 | 1.1 | 0.3 | 1.0 |

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

## THYROXINE (µg $T_4$/dL serum)

- Continued -

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| **Lot 201 - Enriched 2 µg/dL serum** | | | | | | |
| Diagnostic Products | 10 | 2.8 | 0.4 | 0.4 | 0.5 | 1.0 |
| MP Biomedicals (ICN) RIA | 50 | 2.2 | 0.3 | 0.6 | 0.1 | 1.0 |
| Neometrics Neocoat | 30 | 1.6 | 0.3 | 0.4 | -0.6 | 1.1 |
| Neometrics Accuwell | 59 | 1.9 | 0.4 | 0.4 | -0.3 | 1.1 |
| Delfia | 107 | 1.9 | 0.6 | 0.7 | -0.1 | 1.0 |
| AutoDelfia | 261 | 2.0 | 0.4 | 0.6 | 0.2 | 0.9 |
| Other | 30 | 1.7 | 0.3 | 0.3 | -0.5 | 1.1 |
| **Lot 202 - Enriched 5.5 µg/dL serum** | | | | | | |
| Diagnostic Products | 10 | 5.9 | 1.0 | 1.0 | 0.5 | 1.0 |
| MP Biomedicals (ICN) RIA | 60 | 5.6 | 0.7 | 0.8 | 0.1 | 1.0 |
| Neometrics Neocoat | 30 | 5.2 | 0.9 | 1.0 | -0.6 | 1.1 |
| Neometrics Accuwell | 60 | 5.9 | 0.7 | 1.0 | -0.3 | 1.1 |
| Delfia | 107 | 5.4 | 0.7 | 1.8 | -0.1 | 1.0 |
| AutoDelfia | 254 | 5.2 | 0.6 | 1.6 | 0.2 | 0.9 |
| Other | 30 | 5.4 | 0.5 | 0.8 | -0.5 | 1.1 |
| **Lot 203 - Enriched 8 µg/dL serum** | | | | | | |
| Diagnostic Products | 10 | 9.2 | 1.0 | 1.0 | 0.5 | 1.0 |
| MP Biomedicals (ICN) RIA | 60 | 8.4 | 0.9 | 1.0 | 0.1 | 1.0 |
| Neometrics Neocoat | 30 | 8.1 | 1.0 | 1.5 | -0.6 | 1.1 |
| Neometrics Accuwell | 59 | 8.6 | 1.2 | 1.3 | -0.3 | 1.1 |
| Delfia | 97 | 8.0 | 1.1 | 3.0 | -0.1 | 1.0 |
| AutoDelfia | 253 | 7.4 | 0.7 | 2.4 | 0.2 | 0.9 |
| Other | 29 | 8.2 | 0.9 | 1.1 | -0.5 | 1.1 |

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

TABLE 5b. 2003 Quality Control Data
Summaries of Statistical Analyses

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

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 211 - Enriched 25 µIU/mL serum | | | | | | |
| Diagnostic Products | 80 | 28.2 | 2.4 | 4.3 | 2.2 | 1.0 |
| Neometrics Accuscreen | 50 | 23.7 | 5.9 | 6.2 | -1.5 | 1.0 |
| Neometrics Accuwell | 160 | 23.6 | 3.4 | 5.6 | 1.1 | 0.9 |
| MP Biomedicals (ICN) IRMA | 187 | 31.6 | 19.1 | 19.2 | 4.9 | 1.1 |
| MP Biomedicals (ICN) ELISA | 188 | 25.9 | 3.7 | 5.1 | 3.5 | 0.9 |
| Delfia | 1213 | 24.6 | 4.5 | 5.7 | 0.5 | 1.0 |
| AutoDelfia | 1373 | 25.1 | 5.7 | 6.4 | 0.3 | 1.0 |
| Ani Labsystems (Thermo) | 80 | 27.6 | 4.4 | 5.9 | 2.3 | 1.1 |
| In House | 244 | 25.7 | 4.5 | 8.5 | 0.8 | 1.0 |
| Other | 1187 | 28.3 | 3.9 | 8.7 | 1.6 | 1.1 |
| Lot 212 - Enriched 40 µIU/mL serum | | | | | | |
| Diagnostic Products | 80 | 44.0 | 3.6 | 6.8 | 2.2 | 1.0 |
| Neometrics Accuscreen | 50 | 39.5 | 5.0 | 6.6 | -1.5 | 1.0 |
| Neometrics Accuwell | 158 | 35.7 | 5.5 | 7.4 | 1.1 | 0.9 |
| MP Biomedicals (ICN) IRMA | 187 | 46.8 | 4.2 | 6.9 | 4.9 | 1.1 |
| MP Biomedicals (ICN) ELISA | 190 | 39.3 | 5.1 | 6.1 | 3.5 | 0.9 |
| Delfia | 1146 | 40.5 | 5.4 | 7.8 | 0.5 | 1.0 |
| AutoDelfia | 1335 | 40.4 | 4.9 | 6.1 | 0.3 | 1.0 |
| Ani Labsystems (Thermo) | 80 | 46.5 | 6.2 | 10.5 | 2.3 | 1.1 |
| In House | 245 | 42.1 | 5.1 | 12.5 | 0.8 | 1.0 |
| Other | 1194 | 45.0 | 5.9 | 13.2 | 1.6 | 1.1 |
| Lot 213 - Enriched 80 µIU/mL serum | | | | | | |
| Diagnostic Products | 76 | 85.6 | 6.5 | 8.9 | 2.2 | 1.0 |
| Neometrics Accuscreen | 50 | 79.9 | 9.8 | 10.2 | -1.5 | 1.0 |
| Neometrics Accuwell | 159 | 71.8 | 13.1 | 18.4 | 1.1 | 0.9 |
| MP Biomedicals (ICN) IRMA | 184 | 89.6 | 8.0 | 11.0 | 4.9 | 1.1 |
| MP Biomedicals (ICN) ELISA | 190 | 75.1 | 11.8 | 15.0 | 3.5 | 0.9 |
| Delfia | 1155 | 78.9 | 9.4 | 14.5 | 0.5 | 1.0 |
| AutoDelfia | 1340 | 80.1 | 8.5 | 11.6 | 0.3 | 1.0 |
| Ani Labsystems (Thermo) | 80 | 86.7 | 6.5 | 15.5 | 2.3 | 1.1 |
| In House | 241 | 81.9 | 11.4 | 30.7 | 0.8 | 1.0 |
| Other | 1202 | 87.6 | 11.1 | 22.9 | 1.6 | 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/mL serum)

- Continued -

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| **Lot 311 - Enriched 25 µIU/mL serum** | | | | | | |
| Diagnostic Products | 29 | 29.7 | 2.2 | 2.8 | -2.3 | 1.2 |
| Neometrics Accuscreen | 10 | 28.2 | 3.8 | 3.8 | -0.2 | 1.1 |
| Neometrics Accuwell | 58 | 26.2 | 4.3 | 4.3 | -1.7 | 1.1 |
| MP Biomedicals (ICN) IRMA | 60 | 34.0 | 2.8 | 5.9 | 7.8 | 1.0 |
| MP Biomedicals (ICN) ELISA | 70 | 27.2 | 9.3 | 10.9 | 2.0 | 1.0 |
| Delfia | 511 | 25.3 | 3.2 | 5.0 | 0.2 | 1.0 |
| AutoDelfia | 513 | 25.5 | 2.3 | 3.4 | -1.1 | 1.0 |
| Ani Labsystems (Thermo) | 20 | 25.6 | 2.4 | 9.0 | -5.1 | 1.2 |
| In House | 79 | 26.9 | 3.1 | 5.0 | 3.1 | 1.0 |
| Other | 443 | 27.6 | 4.0 | 9.5 | -0.2 | 1.1 |
| **Lot 312 - Enriched 40 µIU/mL serum** | | | | | | |
| Diagnostic Products | 30 | 46.3 | 5.6 | 8.0 | -2.3 | 1.2 |
| Neometrics Accuscreen | 10 | 43.5 | 4.2 | 4.2 | -0.2 | 1.1 |
| Neometrics Accuwell | 58 | 40.4 | 6.1 | 7.3 | -1.7 | 1.1 |
| MP Biomedicals (ICN) IRMA | 59 | 49.3 | 6.4 | 8.5 | 7.8 | 1.0 |
| MP Biomedicals (ICN) ELISA | 68 | 42.8 | 3.2 | 6.5 | 2.0 | 1.0 |
| Delfia | 455 | 40.7 | 5.0 | 8.4 | 0.2 | 1.0 |
| AutoDelfia | 493 | 39.6 | 3.6 | 4.4 | -1.1 | 1.0 |
| Ani Labsystems (Thermo) | 20 | 38.4 | 3.4 | 10.6 | -5.1 | 1.2 |
| In House | 79 | 41.9 | 5.9 | 10.4 | 3.1 | 1.0 |
| Other | 434 | 44.4 | 5.5 | 13.9 | -0.2 | 1.1 |
| **Lot 313 - Enriched 80 µIU/mL serum** | | | | | | |
| Diagnostic Products | 30 | 97.6 | 7.1 | 25.2 | -2.3 | 1.2 |
| Neometrics Accuscreen | 10 | 89.0 | 11.4 | 11.4 | -0.2 | 1.1 |
| Neometrics Accuwell | 58 | 85.1 | 12.7 | 16.4 | -1.7 | 1.1 |
| MP Biomedicals (ICN) IRMA | 59 | 91.4 | 8.8 | 10.2 | 7.8 | 1.0 |
| MP Biomedicals (ICN) ELISA | 68 | 83.2 | 8.1 | 12.4 | 2.0 | 1.0 |
| Delfia | 519 | 80.9 | 9.9 | 16.1 | 0.2 | 1.0 |
| AutoDelfia | 514 | 82.2 | 6.9 | 10.7 | -1.1 | 1.0 |
| Ani Labsystems (Thermo) | 20 | 87.9 | 7.4 | 7.4 | -5.1 | 1.2 |
| In House | 77 | 79.9 | 15.0 | 25.5 | 3.1 | 1.0 |
| Other | 440 | 88.9 | 8.8 | 23.5 | -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.

TABLE 5c. 2003 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 151 - Enriched 25 ng/mL serum | | | | | | |
| MP Biomedicals (ICN) RIA | 58 | 25.9 | 2.6 | 3.0 | 5.8 | 0.9 |
| Neometrics Accuscreen | 40 | 27.9 | 3.5 | 3.5 | 5.9 | 0.9 |
| Neometrics Accuwell | 88 | 25.7 | 3.3 | 3.5 | 3.4 | 0.9 |
| Delfia | 349 | 26.4 | 3.9 | 6.2 | 1.8 | 1.0 |
| AutoDelfia | 747 | 28.1 | 3.2 | 4.2 | 2.7 | 1.0 |
| Bayer Medical EIA | 40 | 25.6 | 2.7 | 11.5 | 6.9 | 0.8 |
| In House | 30 | 23.3 | 2.4 | 4.2 | 3.3 | 0.8 |
| Other | 129 | 27.8 | 2.6 | 4.6 | 8.6 | 0.8 |
| Lot 152 - Enriched 50 ng/mL serum | | | | | | |
| MP Biomedicals (ICN) RIA | 60 | 52.6 | 3.8 | 6.3 | 5.8 | 0.9 |
| Neometrics Accuscreen | 40 | 54.2 | 3.8 | 8.5 | 5.9 | 0.9 |
| Neometrics Accuwell | 88 | 49.4 | 6.6 | 7.9 | 3.4 | 0.9 |
| Delfia | 349 | 50.9 | 8.2 | 12.2 | 1.8 | 1.0 |
| AutoDelfia | 743 | 53.1 | 5.4 | 7.2 | 2.7 | 1.0 |
| Bayer Medical EIA | 38 | 45.6 | 5.2 | 21.0 | 6.9 | 0.8 |
| In House | 29 | 43.9 | 6.4 | 10.7 | 3.3 | 0.8 |
| Other | 124 | 52.6 | 5.3 | 7.1 | 8.6 | 0.8 |
| Lot 153 - Enriched 100 ng/mL serum | | | | | | |
| MP Biomedicals (ICN) RIA | 60 | 93.0 | 7.6 | 8.0 | 5.8 | 0.9 |
| Neometrics Accuscreen | 40 | 98.3 | 6.1 | 6.9 | 5.9 | 0.9 |
| Neometrics Accuwell | 87 | 93.9 | 15.1 | 16.7 | 3.4 | 0.9 |
| Delfia | 355 | 100.2 | 15.1 | 24.9 | 1.8 | 1.0 |
| AutoDelfia | 744 | 103.7 | 12.1 | 16.1 | 2.7 | 1.0 |
| Bayer Medical EIA | 40 | 82.9 | 16.9 | 42.1 | 6.9 | 0.8 |
| In House | 29 | 83.8 | 11.6 | 25.1 | 3.3 | 0.8 |
| Other | 131 | 91.1 | 9.7 | 18.2 | 8.6 | 0.8 |

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

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

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 351 - Enriched 25 ng/mL serum | | | | | | |
| MP Biomedicals (ICN) RIA | 20 | 26.0 | 2.2 | 2.4 | 5.0 | 0.9 |
| Neometrics Accuwell | 29 | 29.4 | 5.2 | 5.4 | 3.7 | 1.0 |
| Delfia | 134 | 28.1 | 3.2 | 6.2 | -2.0 | 1.2 |
| AutoDelfia | 283 | 28.5 | 3.0 | 3.6 | 1.4 | 1.1 |
| Bayer Medical EIA | 20 | 22.9 | 2.8 | 11.6 | 3.2 | 0.7 |
| In House | 20 | 21.3 | 4.6 | 4.6 | -0.6 | 0.8 |
| Other | 59 | 30.8 | 4.7 | 6.2 | 6.1 | 1.0 |
| Lot 352 - Enriched 50 ng/mL serum | | | | | | |
| MP Biomedicals (ICN) RIA | 20 | 50.0 | 2.5 | 4.7 | 5.0 | 0.9 |
| Neometrics Accuwell | 29 | 53.6 | 7.3 | 8.9 | 3.7 | 1.0 |
| Delfia | 134 | 55.0 | 6.3 | 13.2 | -2.0 | 1.2 |
| AutoDelfia | 285 | 53.1 | 4.9 | 6.7 | 1.4 | 1.1 |
| Bayer Medical EIA | 20 | 39.2 | 6.2 | 19.4 | 3.2 | 0.7 |
| In House | 19 | 35.7 | 7.4 | 7.4 | -0.6 | 0.8 |
| Other | 59 | 58.5 | 5.3 | 6.9 | 6.1 | 1.0 |
| Lot 353 - Enriched 100 ng/mL serum | | | | | | |
| MP Biomedicals (ICN) RIA | 20 | 91.9 | 4.2 | 6.2 | 5.0 | 0.9 |
| Neometrics Accuwell | 30 | 105.0 | 14.4 | 16.4 | 3.7 | 1.0 |
| Delfia | 138 | 115.2 | 14.0 | 30.9 | -2.0 | 1.2 |
| AutoDelfia | 286 | 107.4 | 10.7 | 14.7 | 1.4 | 1.1 |
| Bayer Medical EIA | 20 | 78.6 | 8.2 | 35.7 | 3.2 | 0.7 |
| In House | 20 | 79.5 | 13.4 | 13.4 | -0.6 | 0.8 |
| Other | 60 | 108.0 | 12.2 | 16.4 | 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 5d. 2003 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 245 - Enriched 5 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 360 | 5.0 | 1.1 | 1.6 | -0.2 | 1.0 |
| Bioassay | 50 | 3.7 | 0.5 | 0.6 | 0.5 | 0.6 |
| Fluor Cont Flo, Kit | 197 | 7.1 | 0.7 | 1.1 | 1.4 | 1.1 |
| Colorimetric | 179 | 6.1 | 1.0 | 1.8 | 0.6 | 1.1 |
| PerkinElmer Life Sciences | 312 | 7.8 | 1.1 | 1.1 | 3.8 | 0.8 |
| Neometrics Accuwell | 86 | 6.5 | 0.9 | 1.4 | -1.9 | 1.4 |
| Bio-Rad Quantase | 138 | 4.7 | 0.9 | 1.3 | -3.0 | 1.1 |
| Other | 236 | 5.3 | 1.2 | 1.7 | -1.2 | 1.2 |
| Lot 246 - Enriched 10 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 346 | 9.8 | 1.3 | 1.9 | -0.2 | 1.0 |
| Bioassay | 50 | 6.7 | 0.3 | 0.9 | 0.5 | 0.6 |
| Fluor Cont Flo, Kit | 198 | 12.0 | 1.0 | 1.6 | 1.4 | 1.1 |
| Colorimetric | 178 | 11.4 | 1.5 | 2.6 | 0.6 | 1.1 |
| PerkinElmer Life Sciences | 312 | 11.6 | 1.4 | 1.6 | 3.8 | 0.8 |
| Neometrics Accuwell | 90 | 12.0 | 1.5 | 2.0 | -1.9 | 1.4 |
| Bio-Rad Quantase | 140 | 7.7 | 2.1 | 2.5 | -3.0 | 1.1 |
| Other | 231 | 9.8 | 1.6 | 2.4 | -1.2 | 1.2 |
| Lot 247 - Enriched 15 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 352 | 15.4 | 1.6 | 2.0 | -0.2 | 1.0 |
| Bioassay | 50 | 9.4 | 0.7 | 1.8 | 0.5 | 0.6 |
| Fluor Cont Flo, Kit | 197 | 17.7 | 1.5 | 2.4 | 1.4 | 1.1 |
| Colorimetric | 180 | 17.6 | 2.6 | 4.1 | 0.6 | 1.1 |
| PerkinElmer Life Sciences | 315 | 15.3 | 1.6 | 1.8 | 3.8 | 0.8 |
| Neometrics Accuwell | 90 | 16.5 | 1.7 | 1.9 | -1.9 | 1.4 |
| Bio-Rad Quantase | 138 | 11.0 | 1.6 | 2.9 | -3.0 | 1.1 |
| Other | 228 | 16.2 | 2.6 | 5.1 | -1.2 | 1.2 |

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

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

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 248 - Enriched 30 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 347 | 30.5 | 3.2 | 4.1 | -0.2 | 1.0 |
| Bioassay | 40 | 18.9 | 0.6 | 1.6 | 0.5 | 0.6 |
| Fluor Cont Flo, Kit | 198 | 34.2 | 2.3 | 4.2 | 1.4 | 1.1 |
| Colorimetric | 178 | 33.6 | 6.7 | 7.3 | 0.6 | 1.1 |
| PerkinElmer Life Sciences | 308 | 27.4 | 3.0 | 3.4 | 3.8 | 0.8 |
| Neometrics Accuwell | 90 | 40.8 | 5.7 | 8.8 | -1.9 | 1.4 |
| Bio-Rad Quantase | 140 | 31.9 | 7.9 | 12.2 | -3.0 | 1.1 |
| Other | 235 | 34.1 | 5.4 | 11.3 | -1.2 | 1.2 |
| Lot 321 - Enriched 5 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 129 | 5.5 | 0.9 | 1.6 | 0.4 | 1.1 |
| Bioassay | 10 | 2.9 | 0.2 | 0.2 | -1.0 | 0.8 |
| Fluor Cont Flo, Kit | 60 | 7.1 | 0.5 | 1.0 | 1.8 | 1.1 |
| Colorimetric | 80 | 8.1 | 0.8 | 1.8 | 1.3 | 1.4 |
| PerkinElmer Life Sciences | 127 | 7.9 | 1.1 | 1.4 | 3.9 | 0.8 |
| Neometrics Accuwell | 29 | 8.8 | 0.8 | 1.0 | 1.8 | 1.5 |
| Bio-Rad Quantase | 59 | 6.6 | 0.8 | 1.8 | 0.5 | 1.4 |
| Other | 49 | 5.6 | 10.5 | 10.8 | -0.5 | 1.2 |
| Lot 322 - Enriched 10 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 125 | 11.0 | 1.3 | 2.2 | 0.4 | 1.1 |
| Bioassay | 10 | 7.6 | 0.5 | 0.5 | -1.0 | 0.8 |
| Fluor Cont Flo, Kit | 60 | 13.0 | 0.9 | 1.3 | 1.8 | 1.1 |
| Colorimetric | 78 | 14.9 | 1.8 | 3.0 | 1.3 | 1.4 |
| PerkinElmer Life Sciences | 128 | 11.7 | 1.2 | 1.8 | 3.9 | 0.8 |
| Neometrics Accuwell | 30 | 16.3 | 1.0 | 1.2 | 1.8 | 1.5 |
| Bio-Rad Quantase | 56 | 14.9 | 1.5 | 4.1 | 0.5 | 1.4 |
| Other | 50 | 12.0 | 2.5 | 3.4 | -0.5 | 1.2 |

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

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

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 323 - Enriched 15 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 126 | 17.1 | 1.4 | 3.0 | 0.4 | 1.1 |
| Bioassay | 10 | 11.2 | 2.1 | 2.1 | -1.0 | 0.8 |
| Fluor Cont Flo, Kit | 60 | 18.4 | 1.0 | 1.5 | 1.8 | 1.1 |
| Colorimetric | 79 | 22.7 | 2.8 | 5.5 | 1.3 | 1.4 |
| PerkinElmer Life Sciences | 129 | 15.4 | 1.4 | 2.3 | 3.9 | 0.8 |
| Neometrics Accuwell | 29 | 24.5 | 1.9 | 2.2 | 1.8 | 1.5 |
| Bio-Rad Quantase | 60 | 23.1 | 2.0 | 4.8 | 0.5 | 1.4 |
| Other | 47 | 18.6 | 3.4 | 5.3 | -0.5 | 1.2 |
| Lot 324 - Enriched 30 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 128 | 32.4 | 3.2 | 5.0 | 0.4 | 1.1 |
| Fluor Cont Flo, Kit | 58 | 34.7 | 2.2 | 3.0 | 1.8 | 1.1 |
| Colorimetric | 78 | 42.8 | 4.2 | 6.2 | 1.3 | 1.4 |
| PerkinElmer Life Sciences | 129 | 27.3 | 2.3 | 3.8 | 3.9 | 0.8 |
| Neometrics Accuwell | 30 | 45.3 | 3.2 | 3.9 | 1.8 | 1.5 |
| Bio-Rad Quantase | 50 | 42.3 | 4.3 | 14.7 | 0.5 | 1.4 |
| Other | 52 | 36.9 | 5.3 | 8.1 | -0.5 | 1.2 |

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

TABLE 5e. 2003 Quality Control Data
Summaries of Statistical Analyses

**PHENYLALANINE** (mg Phe/dL whole blood)

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 245 - Nonenriched 0 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 209 | 1.6 | 0.3 | 0.4 | 1.6 | 1.0 |
| Bacterial Inhibition | 368 | 1.6 | 0.2 | 0.7 | 1.6 | 0.9 |
| Fluor Cont Flo, In-house | 127 | 1.9 | 0.2 | 0.3 | 1.8 | 1.1 |
| Fluor Cont Flo, Kit | 360 | 1.9 | 0.3 | 0.5 | 1.9 | 1.1 |
| Colorimetric | 335 | 1.4 | 0.3 | 0.5 | 1.0 | 1.1 |
| PerkinElmer Life Sciences | 824 | 1.3 | 0.2 | 0.3 | 1.2 | 0.9 |
| HPLC | 217 | 1.4 | 0.2 | 0.2 | 1.3 | 1.0 |
| Tandem Mass Spec | 904 | 1.5 | 0.2 | 0.4 | 1.4 | 1.0 |
| Neometrics Accuwell | 199 | 1.4 | 0.3 | 0.4 | 1.0 | 1.1 |
| Bio-Rad Quantase | 286 | 1.4 | 0.5 | 0.7 | 0.8 | 1.0 |
| MP Biomedicals (ICN) Enzyme | 30 | 1.4 | 0.3 | 0.3 | 1.4 | 0.9 |
| Other | 239 | 1.8 | 0.3 | 0.6 | 1.5 | 1.0 |
| Lot 246 - Enriched 3 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 207 | 4.8 | 0.7 | 0.9 | 1.6 | 1.0 |
| Bacterial Inhibition | 430 | 4.3 | 0.7 | 0.8 | 1.6 | 0.9 |
| Fluor Cont Flo, In-house | 130 | 5.1 | 0.4 | 0.9 | 1.8 | 1.1 |
| Fluor Cont Flo, Kit | 360 | 5.0 | 0.4 | 0.9 | 1.9 | 1.1 |
| Colorimetric | 340 | 4.3 | 0.6 | 0.9 | 1.0 | 1.1 |
| PerkinElmer Life Sciences | 815 | 3.8 | 0.5 | 0.6 | 1.2 | 0.9 |
| HPLC | 245 | 4.3 | 04 | 0.6 | 1.3 | 1.0 |
| Tandem Mass Spec | 876 | 4.3 | 04 | 0.8 | 1.4 | 1.0 |
| Neometrics Accuwell | 194 | 4.2 | 0.5 | 0.8 | 1.0 | 1.1 |
| Bio-Rad Quantase | 320 | 3.7 | 0.7 | 1.0 | 0.8 | 1.0 |
| MP Biomedicals (ICN) Enzyme | 30 | 4.0 | 0.5 | 0.5 | 1.4 | 0.9 |
| Other | 260 | 4.2 | 0.5 | 0.8 | 1.5 | 1.0 |
| Lot 247 - Enriched 7 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 208 | 8.9 | 1.0 | 1.4 | 1.6 | 1.0 |
| Bacterial Inhibition | 436 | 7.9 | 1.1 | 1.5 | 1.6 | 0.9 |
| Fluor Cont Flo, In-house | 130 | 9.5 | 0.8 | 2.0 | 1.8 | 1.1 |
| Fluor Cont Flo, Kit | 345 | 9.4 | 0.9 | 1.7 | 1.9 | 1.1 |
| Colorimetric | 340 | 8.2 | 1.0 | 1.9 | 1.0 | 1.1 |
| PerkinElmer Life Sciences | 814 | 7.3 | 0.9 | 1.0 | 1.2 | 0.9 |
| HPLC | 218 | 8.6 | 0.7 | 1.1 | 1.3 | 1.0 |
| Tandem Mass Spec | 878 | 8.2 | 0.8 | 1.5 | 1.4 | 1.0 |
| Neometrics Accuwell | 199 | 7.9 | 1.1 | 1.4 | 1.0 | 1.1 |
| Bio-Rad Quantase | 320 | 6.9 | 1.1 | 2.0 | 0.8 | 1.0 |
| MP Biomedicals (ICN) Enzyme | 30 | 7.7 | 0.4 | 0.4 | 1.4 | 0.9 |
| Other | 263 | 7.9 | 0.6 | 1.3 | 1.5 | 1.0 |

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

**PHENYLALANINE** (mg Phe/dL whole blood)
- Continued -

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 248 - Enriched 11 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 207 | 13.1 | 1.6 | 2.0 | 1.6 | 1.0 |
| Bacterial Inhibition | 432 | 11.2 | 1.5 | 2.3 | 1.6 | 0.9 |
| Fluor Cont Flo, In-house | 130 | 14.5 | 1.0 | 3.0 | 1.8 | 1.1 |
| Fluor Cont Flo, Kit | 340 | 13.7 | 1.1 | 2.6 | 1.9 | 1.1 |
| Colorimetric | 340 | 13.9 | 1.6 | 2.5 | 1.0 | 1.1 |
| PerkinElmer Life Sciences | 792 | 11.0 | 1.1 | 1.2 | 1.2 | 0.9 |
| HPLC | 248 | 12.5 | 1.1 | 2.2 | 1.3 | 1.0 |
| Tandem Mass Spec | 880 | 12.2 | 1.2 | 2.3 | 1.4 | 1.0 |
| Neometrics Accuwell | 198 | 13.9 | 1.4 | 2.4 | 1.0 | 1.1 |
| Bio-Rad Quantase | 320 | 12.5 | 1.8 | 2.9 | 0.8 | 1.0 |
| MP Biomedicals (ICN) Enzyme | 30 | 11.1 | 1.2 | 1.2 | 1.4 | 0.9 |
| Other | 261 | 12.3 | 1.0 | 1.9 | 1.5 | 1.0 |
| Lot 321 - Nonenriched 0 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 79 | 1.8 | 0.3 | 0.4 | 1.7 | 1.0 |
| Bacterial Inhibition | 107 | 1.5 | 0.2 | 0.5 | 1.5 | 0.9 |
| Fluor Cont Flo, In-house | 39 | 2.1 | 0.3 | 0.5 | 2.1 | 1.2 |
| Fluor Cont Flo, Kit | 118 | 2.2 | 0.2 | 0.5 | 2.1 | 1.1 |
| Colorimetric | 105 | 1.9 | 0.3 | 0.6 | 1.9 | 1.3 |
| PerkinElmer Life Sciences | 287 | 1.5 | 0.3 | 0.3 | 1.6 | 0.9 |
| HPLC | 66 | 1.5 | 0.3 | 0.3 | 1.5 | 1.0 |
| Tandem Mass Spec | 413 | 1.6 | 0.2 | 0.3 | 1.6 | 1.0 |
| Neometrics Accuwell | 40 | 1.9 | 0.3 | 0.4 | 2.0 | 1.3 |
| Bio-Rad Quantase | 108 | 1.5 | 0.3 | 0.4 | 1.6 | 1.1 |
| MP Biomedicals (ICN) Enzyme | 10 | 1.4 | 0.4 | 0.4 | 1.4 | 0.9 |
| Other | 89 | 1.9 | 0.4 | 0.7 | 2.0 | 1.2 |
| Lot 322 - Enriched 3 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 79 | 4.8 | 0.7 | 0.7 | 1.7 | 1.0 |
| Bacterial Inhibition | 140 | 4.2 | 0.7 | 1.2 | 1.5 | 0.9 |
| Fluor Cont Flo, In-house | 40 | 5.7 | 0.4 | 0.7 | 2.1 | 1.2 |
| Fluor Cont Flo, Kit | 120 | 5.4 | 0.5 | 1.1 | 2.1 | 1.1 |
| Colorimetric | 109 | 5.6 | 0.5 | 1.5 | 1.9 | 1.3 |
| PerkinElmer Life Sciences | 298 | 4.4 | 0.6 | 0.7 | 1.6 | 0.9 |
| HPLC | 80 | 4.5 | 0.5 | 0.6 | 1.5 | 1.0 |
| Tandem Mass Spec | 403 | 4.5 | 0.4 | 0.8 | 1.6 | 1.0 |
| Neometrics Accuwell | 40 | 5.9 | 0.4 | 0.8 | 2.0 | 1.3 |
| Bio-Rad Quantase | 108 | 4.8 | 0.5 | 0.8 | 1.6 | 1.1 |
| MP Biomedicals (ICN) Enzyme | 10 | 4.1 | 0.4 | 0.4 | 1.4 | 0.9 |
| Other | 89 | 5.5 | 0.9 | 1.1 | 2.0 | 1.2 |

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

**PHENYLALANINE** (mg Phe/dL whole blood)
- Continued -

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 323 - Enriched 7 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 76 | 9.0 | 1.3 | 1.3 | 1.7 | 1.0 |
| Bacterial Inhibition | 139 | 8.1 | 1.0 | 1.9 | 1.5 | 0.9 |
| Fluor Cont Flo, In-house | 40 | 10.7 | 0.6 | 1.4 | 2.1 | 1.2 |
| Fluor Cont Flo, Kit | 120 | 9.9 | 0.7 | 1.5 | 2.1 | 1.1 |
| Colorimetric | 109 | 11.2 | 0.7 | 2.6 | 1.9 | 1.3 |
| PerkinElmer Life Sciences | 291 | 8.3 | 0.9 | 1.0 | 1.6 | 0.9 |
| HPLC | 67 | 9.2 | 1.0 | 1.5 | 1.5 | 1.0 |
| Tandem Mass Spec | 406 | 8.7 | 0.8 | 1.5 | 1.6 | 1.0 |
| Neometrics Accuwell | 39 | 11.2 | 0.8 | 1.6 | 2.0 | 1.3 |
| Bio-Rad Quantase | 108 | 9.8 | 1.3 | 1.8 | 1.6 | 1.1 |
| MP Biomedicals (ICN) Enzyme | 10 | 8.1 | 0.7 | 0.7 | 1.4 | 0.9 |
| Other | 89 | 10.5 | 1.3 | 2.3 | 2.0 | 1.2 |
| Lot 324 - Enriched 11 mg/dL whole blood | | | | | | |
| Fluorometric Manual | 76 | 13.3 | 2.1 | 2.2 | 1.7 | 1.0 |
| Bacterial Inhibition | 133 | 11.3 | 1.4 | 2.8 | 1.5 | 0.9 |
| Fluor Cont Flo, In-house | 40 | 15.4 | 0.9 | 2.3 | 2.1 | 1.2 |
| Fluor Cont Flo, Kit | 119 | 14.5 | 1.0 | 2.2 | 2.1 | 1.1 |
| Colorimetric | 110 | 15.7 | 1.0 | 3.6 | 1.9 | 1.3 |
| PerkinElmer Life Sciences | 295 | 11.9 | 1.2 | 1.5 | 1.6 | 0.9 |
| HPLC | 79 | 12.9 | 1.2 | 1.9 | 1.5 | 1.0 |
| Tandem Mass Spec | 410 | 12.6 | 1.3 | 2.2 | 1.6 | 1.0 |
| Neometrics Accuwell | 40 | 15.9 | 1.0 | 1.8 | 2.0 | 1.3 |
| Bio-Rad Quantase | 108 | 13.7 | 1.4 | 2.1 | 1.6 | 1.1 |
| MP Biomedicals (ICN) Enzyme | 10 | 11.7 | 1.1 | 1.1 | 1.4 | 0.9 |
| Other | 88 | 15.0 | 2.8 | 3.8 | 2.0 | 1.2 |

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

TABLE 5f. 2003 Quality Control Data
Summaries of Statistical Analyses

**LEUCINE** (mg Leu/dL whole blood)

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 245 - Nonenriched 0 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 160 | 1.7 | 0.5 | 1.0 | 1.8 | 0.8 |
| PerkinElmer Life Sciences | 80 | 2.3 | 0.5 | 0.7 | 1.9 | 1.0 |
| HPLC | 158 | 2.0 | 0.7 | 0.7 | 2.0 | 1.0 |
| Tandem Mass Spec | 766 | 2.2 | 0.3 | 0.6 | 2.1 | 0.9 |
| Thin-Layer Chromatography | 30 | 1.5 | 0.5 | 0.5 | 1.7 | 0.8 |
| Other | 48 | 1.5 | 0.3 | 1.8 | 0.6 | 0.9 |
| Lot 246 - Enriched 3 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 170 | 4.3 | 1.1 | 1.4 | 1.8 | 0.8 |
| PerkinElmer Life Sciences | 79 | 4.7 | 0.8 | 1.2 | 1.9 | 1.0 |
| HPLC | 157 | 5.0 | 0.5 | 0.6 | 2.0 | 1.0 |
| Tandem Mass Spec | 759 | 4.5 | 0.5 | 1.1 | 2.1 | 0.9 |
| Thin-Layer Chromatography | 30 | 4.2 | 0.7 | 0.7 | 1.7 | 0.8 |
| Other | 49 | 2.9 | 1.0 | 2.1 | 0.6 | 0.9 |
| Lot 247 - Enriched 7 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 166 | 7.9 | 1.2 | 2.1 | 1.8 | 0.8 |
| PerkinElmer Life Sciences | 79 | 8.8 | 1.0 | 1.9 | 1.9 | 1.0 |
| HPLC | 158 | 9.1 | 0.9 | 1.3 | 2.0 | 1.0 |
| Tandem Mass Spec | 761 | 8.2 | 1.0 | 1.9 | 2.1 | 0.9 |
| Thin-Layer Chromatography | 30 | 7.4 | 0.8 | 0.8 | 1.7 | 0.8 |
| Other | 49 | 5.9 | 1.1 | 1.4 | 0.6 | 0.9 |
| Lot 248 - Enriched 11 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 142 | 10.6 | 2.5 | 4.2 | 1.8 | 0.8 |
| PerkinElmer Life Sciences | 70 | 13.7 | 1.8 | 2.0 | 1.9 | 1.0 |
| HPLC | 158 | 13.3 | 1.6 | 1.9 | 2.0 | 1.0 |
| Tandem Mass Spec | 757 | 11.6 | 1.3 | 2.8 | 2.1 | 0.9 |
| Thin-Layer Chromatography | 30 | 10.3 | 1.0 | 1.0 | 1.7 | 0.8 |
| Other | 49 | 11.8 | 1.6 | 2.8 | 0.6 | 0.9 |

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

**LEUCINE** (mg Leu/dL whole blood)
- Continued -

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 321 Nonenriched 0 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 60 | 1.6 | 0.5 | 1.0 | 1.7 | 1.0 |
| PerkinElmer Life Sciences | 20 | 3.6 | 0.5 | 0.5 | 3.6 | 1.1 |
| HPLC | 50 | 2.7 | 0.4 | 0.8 | 2.6 | 1.0 |
| Tandem Mass Spec | 341 | 2.6 | 0.3 | 0.7 | 2.6 | 0.9 |
| Thin-Layer Chromatography | 10 | 2.0 | 0.7 | 0.7 | 2.2 | 1.0 |
| Other | 9 | 3.9 | 0.3 | 0.3 | 3.8 | 0.9 |
| Lot 322 - Enriched 3 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 70 | 4.6 | 0.8 | 1.5 | 1.7 | 1.0 |
| PerkinElmer Life Sciences | 19 | 6.9 | 1.2 | 1.3 | 3.6 | 1.1 |
| HPLC | 50 | 5.5 | 0.5 | 0.8 | 2.6 | 1.0 |
| Tandem Mass Spec | 339 | 5.1 | 0.6 | 1.3 | 2.6 | 0.9 |
| Thin-Layer Chromatography | 10 | 5.0 | 0.7 | 0.7 | 2.2 | 1.0 |
| Other | 9 | 6.3 | 0.3 | 0.3 | 3.8 | 0.9 |
| Lot 323 - Enriched 7 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 69 | 8.7 | 1.1 | 2.4 | 1.7 | 1.0 |
| PerkinElmer Life Sciences | 20 | 11.6 | 1.2 | 1.2 | 3.6 | 1.1 |
| HPLC | 50 | 9.9 | 0.7 | 1.1 | 2.6 | 1.0 |
| Tandem Mass Spec | 339 | 8.9 | 1.0 | 2.3 | 2.6 | 0.9 |
| Thin-Layer Chromatography | 10 | 9.4 | 0.5 | 0.5 | 2.2 | 1.0 |
| Other | 10 | 10.4 | 0.8 | 0.8 | 3.8 | 0.9 |
| Lot 324 - Enriched 11 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 60 | 12.4 | 1.7 | 4.3 | 1.7 | 1.0 |
| PerkinElmer Life Sciences | 20 | 16.0 | 1.5 | 1.5 | 3.6 | 1.1 |
| HPLC | 48 | 14.1 | 1.1 | 1.4 | 2.6 | 1.0 |
| Tandem Mass Spec | 340 | 12.4 | 2.1 | 3.4 | 2.6 | 0.9 |
| Thin-Layer Chromatography | 10 | 12.4 | 1.1 | 1.1 | 2.2 | 1.0 |
| Other | 10 | 13.7 | 1.1 | 1.1 | 3.8 | 0.9 |

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

TABLE 5g. 2003 Quality Control Data
Summaries of Statistical Analyses

**METHIONINE** (mg Met/dL whole blood)

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 245 Nonenriched 0 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 160 | 0.5 | 0.2 | 0.4 | 0.6 | 1.2 |
| HPLC | 128 | 0.3 | 0.1 | 0.2 | 0.2 | 0.8 |
| Tandem Mass Spec | 740 | 0.4 | 0.1 | 0.1 | 0.3 | 0.8 |
| Thin-Layer Chromatography | 30 | 0.7 | 0.4 | 0.4 | 0.6 | 0.9 |
| Lot 246 - Enriched 1 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 160 | 1.7 | 0.4 | 0.6 | 0.6 | 1.2 |
| HPLC | 122 | 1.0 | 0.2 | 0.3 | 0.2 | 0.8 |
| Tandem Mass Spec | 722 | 1.1 | 0.2 | 0.3 | 0.3 | 0.8 |
| Thin-Layer Chromatography | 30 | 1.5 | 0.5 | 0.5 | 0.6 | 0.9 |
| Lot 247 - Enriched 3 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 168 | 4.3 | 1.3 | 1.9 | 0.6 | 1.2 |
| HPLC | 126 | 2.5 | 0.3 | 0.5 | 0.2 | 0.8 |
| Tandem Mass Spec | 737 | 2.9 | 0.5 | 0.8 | 0.3 | 0.8 |
| Thin-Layer Chromatography | 30 | 2.8 | 0.7 | 0.7 | 0.6 | 0.9 |
| Lot 248 - Enriched 6 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 150 | 7.4 | 1.4 | 2.2 | 0.6 | 1.2 |
| HPLC | 126 | 5.1 | 0.6 | 0.7 | 0.2 | 0.8 |
| Tandem Mass Spec | 740 | 5.4 | 1.0 | 1.7 | 0.3 | 0.8 |
| Thin-Layer Chromatography | 30 | 6.0 | 1.5 | 1.5 | 0.6 | 0.9 |

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

**METHIONINE** (mg Met/dL whole blood)
- Continued -

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 321 - Nonenriched 0 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 39 | 0.3 | 0.1 | 0.4 | 0.6 | 1.1 |
| HPLC | 39 | 0.3 | 0.1 | 0.2 | 0.3 | 0.9 |
| Tandem Mass Spec | 322 | 0.4 | 0.1 | 0.2 | 0.4 | 0.9 |
| Thin-Layer Chromatography | 10 | 0.0 | 0.0 | 0.0 | 0.1 | 0.9 |
| Lot 322 - Enriched 1 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 38 | 1.6 | 0.3 | 1.0 | 0.6 | 1.1 |
| HPLC | 39 | 1.1 | 0.2 | 0.3 | 0.3 | 0.9 |
| Tandem Mass Spec | 322 | 1.3 | 0.3 | 0.4 | 0.4 | 0.9 |
| Thin-Layer Chromatography | 10 | 1.0 | 0.0 | 0.0 | 0.1 | 0.9 |
| Lot 323 - Enriched 3 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 49 | 4.4 | 7.9 | 8.2 | 0.6 | 1.1 |
| HPLC | 40 | 3.0 | 0.5 | 0.6 | 0.3 | 0.9 |
| Tandem Mass Spec | 318 | 3.2 | 0.4 | 0.7 | 0.4 | 0.9 |
| Thin-Layer Chromatography | 10 | 2.6 | 0.5 | 0.5 | 0.1 | 0.9 |
| Lot 324 - Enriched 6 mg/dL whole blood | | | | | | |
| Bacterial Inhibition Assays | 40 | 7.1 | 0.8 | 2.3 | 0.6 | 1.1 |
| HPLC | 39 | 5.5 | 1.0 | 1.1 | 0.3 | 0.9 |
| Tandem Mass Spec | 319 | 5.8 | 0.7 | 1.3 | 0.4 | 0.9 |
| Thin-Layer Chromatography | 10 | 5.2 | 0.4 | 0.4 | 0.1 | 0.9 |

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

TABLE 5h. 2003 Quality Control Data
Summaries of Statistical Analyses

**TYROSINE** (mg Tyr/dL whole blood)

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 245 - Nonenriched 0 mg/dL whole blood | | | | | | |
| PerkinElmer Life Sciences | 10 | 1.7 | 0.2 | 0.2 | 1.6 | 1.2 |
| HPLC | 166 | 1.3 | 0.2 | 0.2 | 1.4 | 0.9 |
| Tandem Mass Spec | 795 | 1.2 | 0.2 | 0.3 | 1.2 | 0.9 |
| Thin-Layer Chromatography | 28 | 0.7 | 0.5 | 0.5 | 0.6 | 0.9 |
| Other | 98 | 1.5 | 0.2 | 0.5 | 1.6 | 1.0 |
| Lot 246 - Enriched 2 mg/dL whole blood | | | | | | |
| PerkinElmer Life Sciences | 10 | 4.0 | 0.2 | 0.2 | 1.6 | 1.2 |
| HPLC | 196 | 3.3 | 0.3 | 0.4 | 1.4 | 0.9 |
| Tandem Mass Spec | 797 | 3.1 | 1.2 | 1.4 | 1.2 | 0.9 |
| Thin-Layer Chromatography | 28 | 2.6 | 0.5 | 0.5 | 0.6 | 0.9 |
| Other | 106 | 3.7 | 0.6 | 1.1 | 1.6 | 1.0 |
| Lot 247 - Enriched 4 mg/dL whole blood | | | | | | |
| PerkinElmer Life Sciences | 10 | 6.2 | 0.5 | 0.5 | 1.6 | 1.2 |
| HPLC | 168 | 5.1 | 0.5 | 0.5 | 1.4 | 0.9 |
| Tandem Mass Spec | 779 | 4.7 | 0.7 | 1.2 | 1.2 | 0.9 |
| Thin-Layer Chromatography | 28 | 3.5 | 0.5 | 0.5 | 0.6 | 0.9 |
| Other | 108 | 5.4 | 0.6 | 1.1 | 1.6 | 1.0 |
| Lot 248 - Enriched 8 mg/dL whole blood | | | | | | |
| PerkinElmer Life Sciences | 10 | 11.0 | 0.5 | 0.5 | 1.6 | 1.2 |
| HPLC | 196 | 8.6 | 0.8 | 1.1 | 1.4 | 0.9 |
| Tandem Mass Spec | 793 | 8.3 | 1.1 | 1.6 | 1.2 | 0.9 |
| Thin-Layer Chromatography | 28 | 7.6 | 0.8 | 0.8 | 0.6 | 0.9 |
| Other | 108 | 9.5 | 1.0 | 2.0 | 1.6 | 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.

**TYROSINE** (mg Tyr/dL whole blood)
- Continued -

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 321 Nonenriched 0 mg/dL whole blood | | | | | | |
| PerkinElmer Life Sciences | 10 | 2.2 | 0.2 | 0.2 | 1.4 | 1.2 |
| HPLC | 60 | 1.3 | 0.2 | 0.3 | 0.6 | 1.0 |
| Tandem Mass Spec | 364 | 1.3 | 0.2 | 0.3 | 0.7 | 1.0 |
| Thin-Layer Chromatography | 12 | 1.0 | 0.0 | 0.0 | 0.7 | 0.8 |
| Other | 10 | 2.2 | 0.2 | 0.2 | 1.6 | 1.0 |
| Lot 322 - Enriched 2 mg/dL whole blood | | | | | | |
| PerkinElmer Life Sciences | 10 | 3.2 | 0.2 | 0.2 | 1.4 | 1.2 |
| HPLC | 69 | 2.2 | 0.3 | 0.4 | 0.6 | 1.0 |
| Tandem Mass Spec | 344 | 2.1 | 0.3 | 0.5 | 0.7 | 1.0 |
| Thin-Layer Chromatography | 12 | 2.0 | 0.0 | 0.0 | 0.7 | 0.8 |
| Other | 10 | 3.1 | 0.3 | 0.3 | 1.6 | 1.0 |
| Lot 323 - Enriched 4 mg/dL whole blood | | | | | | |
| PerkinElmer Life Sciences | 10 | 5.7 | 0.3 | 0.3 | 1.4 | 1.2 |
| HPLC | 60 | 4.3 | 0.5 | 0.9 | 0.6 | 1.0 |
| Tandem Mass Spec | 354 | 4.1 | 0.5 | 0.9 | 0.7 | 1.0 |
| Thin-Layer Chromatography | 12 | 3.3 | 0.5 | 0.5 | 0.7 | 0.8 |
| Other | 10 | 5.2 | 0.6 | 0.6 | 1.6 | 1.0 |
| Lot 324 - Enriched 8 mg/dL whole blood | | | | | | |
| PerkinElmer Life Sciences | 10 | 11.3 | 0.5 | 0.5 | 1.4 | 1.2 |
| HPLC | 66 | 9.1 | 1.0 | 1.5 | 0.6 | 1.0 |
| Tandem Mass Spec | 360 | 8.7 | 1.0 | 1.7 | 0.7 | 1.0 |
| Thin-Layer Chromatography | 12 | 7.0 | 0.6 | 0.6 | 0.7 | 0.8 |
| Other | 10 | 9.9 | 0.9 | 0.9 | 1.6 | 1.0 |

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

TABLE 5i. 2003 Quality Control Data
Summaries of Statistical Analyses

**VALINE** (mg Val/dL whole blood)

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 245 - Nonenriched 0 mg/dL whole blood | | | | | | |
| HPLC | 109 | 2.1 | 0.3 | 0.4 | 2.2 | 0.9 |
| Tandem Mass Spec | 623 | 1.8 | 0.3 | 0.6 | 1.8 | 0.8 |
| Thin-Layer Chromatography | 30 | 0.9 | 0.3 | 0.3 | 1.3 | 0.8 |
| Lot 246 - Enriched 1 mg/dL whole blood | | | | | | |
| HPLC | 109 | 3.1 | 0.4 | 0.5 | 2.2 | 0.9 |
| Tandem Mass Spec | 650 | 2.5 | 0.6 | 0.9 | 1.8 | 0.8 |
| Thin-Layer Chromatography | 30 | 2.3 | 0.5 | 0.5 | 1.3 | 0.8 |
| Lot 247 - Enriched 3 mg/dL whole blood | | | | | | |
| HPLC | 109 | 4.9 | 0.7 | 0.9 | 2.2 | 0.9 |
| Tandem Mass Spec | 650 | 4.1 | 0.6 | 1.2 | 1.8 | 0.8 |
| Thin-Layer Chromatography | 30 | 4.1 | 0.6 | 0.6 | 1.3 | 0.8 |
| Lot 248 - Enriched 6 mg/dL whole blood | | | | | | |
| HPLC | 110 | 7.4 | 0.8 | 1.2 | 2.2 | 0.9 |
| Tandem Mass Spec | 642 | 6.4 | 1.0 | 1.9 | 1.8 | 0.8 |
| Thin-Layer Chromatography | 30 | 5.9 | 0.7 | 0.7 | 1.3 | 0.8 |

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

**VALINE** (mg Val/dL whole blood)
- Continued -

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 321 Nonenriched 0 mg/dL whole blood | | | | | | |
| HPLC | 39 | 2.1 | 0.4 | 0.6 | 2.1 | 0.9 |
| Tandem Mass Spec | 299 | 2.0 | 0.4 | 0.8 | 1.9 | 0.8 |
| Thin-Layer Chromatography | 10 | 1.0 | 0.0 | 0.0 | 1.4 | 0.8 |
| Lot 322 - Enriched 1 mg/dL whole blood | | | | | | |
| HPLC | 40 | 2.9 | 0.3 | 0.6 | 2.1 | 0.9 |
| Tandem Mass Spec | 297 | 2.6 | 0.4 | 0.8 | 1.9 | 0.8 |
| Thin-Layer Chromatography | 10 | 2.6 | 0.5 | 0.5 | 1.4 | 0.8 |
| Lot 323 - Enriched 3 mg/dL whole blood | | | | | | |
| HPLC | 40 | 4.6 | 0.3 | 0.7 | 2.1 | 0.9 |
| Tandem Mass Spec | 295 | 4.2 | 0.6 | 1.3 | 1.9 | 0.8 |
| Thin-Layer Chromatography | 10 | 4.0 | 0.0 | 0.0 | 1.4 | 0.8 |
| Lot 324 - Enriched 6 mg/dL whole blood | | | | | | |
| HPLC | 39 | 7.3 | 0.7 | 1.2 | 2.1 | 0.9 |
| Tandem Mass Spec | 294 | 6.5 | 0.9 | 2.0 | 1.9 | 0.8 |
| Thin-Layer Chromatography | 10 | 6.0 | 0.7 | 0.7 | 1.4 | 0.8 |

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

TABLE 5j. 2003 Quality Control Data
Summaries of Statistical Analyses

**CITRULLINE** (mg Cit/dL whole blood)

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 245 Nonenriched 0 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 645 | 0.5 | 0.1 | 0.2 | 0.5 | 0.8 |
| Thin-Layer Chromatography | 30 | 0.0 | 0.0 | 0.0 | 0.0 | 0.7 |
| Lot 246 - Enriched 0.5 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 651 | 0.9 | 0.2 | 0.4 | 0.5 | 0.8 |
| Thin-Layer Chromatography | 30 | 0.4 | 0.5 | 0.5 | 0.0 | 0.7 |
| Lot 247 - Enriched 1 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 652 | 1.3 | 0.3 | 0.6 | 0.5 | 0.8 |
| Thin-Layer Chromatography | 30 | 0.9 | 0.3 | 0.3 | 0.0 | 0.7 |
| Lot 248 - Enriched 2.5 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 652 | 2.5 | 0.5 | 1.1 | 0.5 | 0.8 |
| Thin-Layer Chromatography | 30 | 1.9 | 0.3 | 0.3 | 0.0 | 0.7 |

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

**CITRULLINE** (mg Cit/dL whole blood)
- Continued -

| Method | N | Mean | Average Within Lab SD | Total SD | Y-Intercept* | Slope |
|---|---|---|---|---|---|---|
| Lot 321 Nonenriched 0 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 318 | 0.5 | 0.1 | 0.3 | 0.5 | 0.9 |
| Thin-Layer Chromatography | 10 | 0.0 | 0.0 | 0.0 | 0.1 | 0.9 |
| Lot 322 - Enriched 0.5 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 317 | 0.9 | 0.2 | 0.5 | 0.5 | 0.9 |
| Thin-Layer Chromatography | 10 | 0.8 | 0.4 | 0.4 | 0.1 | 0.9 |
| Lot 323 - Enriched 1 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 318 | 1.4 | 0.3 | 0.7 | 0.5 | 0.9 |
| Thin-Layer Chromatography | 10 | 1.0 | 0.0 | 0.0 | 0.1 | 0.9 |
| Lot 324 - Enriched 2.5 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 313 | 2.6 | 0.5 | 1.5 | 0.5 | 0.9 |
| Thin-Layer Chromatography | 10 | 2.4 | 0.5 | 0.5 | 0.1 | 0.9 |

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

TABLE 5k. 2003 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 361 Nonenriched 0 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 443 | 13.1 | 2.4 | 6.5 | 13.2 | 1.1 |
| Lot 362 - Enriched 5 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 459 | 18.7 | 85.6 | 85.9 | 13.2 | 1.1 |
| Lot 363 - Enriched 10 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 435 | 23.8 | 4.5 | 9.5 | 13.2 | 1.1 |
| Lot 364 - Enriched 20 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 451 | 34.4 | 6.3 | 13.0 | 13.2 | 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.

TABLE 5l. 2003 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 361 Nonenriched 0 µmol/L whole blood | | | | | | |
| Tandem Mass Spec | 476 | 0.8 | 0.2 | 0.3 | 0.6 | 1.1 |
| Lot 362 - Enriched 3 µmol/L whole blood | | | | | | |
| Tandem Mass Spec | 473 | 3.9 | 0.6 | 1.3 | 0.6 | 1.1 |
| Lot 363 - Enriched 7.5 µmol/L whole blood | | | | | | |
| Tandem Mass Spec | 471 | 9.0 | 1.3 | 2.8 | 0.6 | 1.1 |
| Lot 364 - Enriched 12 µmol/L whole blood | | | | | | |
| Tandem Mass Spec | 474 | 14.5 | 2.4 | 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.

TABLE 5m. 2003 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 361 Nonenriched 0 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 474 | 0.2 | 0.1 | 0.2 | 0.1 | 1.1 |
| Lot 362 - Enriched 1 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 476 | 1.1 | 0.3 | 0.5 | 0.1 | 1.1 |
| Lot 363 - Enriched 2.5 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 479 | 2.7 | 0.5 | 1.2 | 0.1 | 1.1 |
| Lot 364 - Enriched 5 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 479 | 5.4 | 1.1 | 2.5 | 0.1 | 1.1 |

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

TABLE 5n. 2003 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 361 Nonenriched 0 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 477 | 0.1 | 0.1 | 0.1 | 0.1 | 1.0 |
| Lot 362 - Enriched 0.5 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 482 | 0.6 | 0.3 | 0.4 | 0.1 | 1.0 |
| Lot 363 - Enriched 1.5 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 477 | 1.6 | 0.3 | 0.6 | 0.1 | 1.0 |
| Lot 364 - Enriched 3 mg/dL whole blood | | | | | | |
| Tandem Mass Spec | 475 | 3.2 | 0.5 | 1.0 | 0.1 | 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 5o. 2003 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 361 Nonenriched 0 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 466 | 0.0 | 0.1 | 0.1 | 0.0 | 0.9 |
| Lot 362 - Enriched 0.5 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 467 | 0.5 | 0.1 | 0.1 | 0.0 | 0.9 |
| Lot 363 - Enriched 1 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 464 | 0.9 | 0.2 | 0.3 | 0.0 | 0.9 |
| Lot 364 - Enriched 2.5 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 470 | 2.4 | 0.4 | 0.7 | 0.0 | 0.9 |

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

TABLE 5p. 2003 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 361 Nonenriched 0 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 504 | 0.1 | 0.1 | 0.1 | 0.0 | 1.0 |
| Lot 362 - Enriched 0.5 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 505 | 0.5 | 0.2 | 0.3 | 0.0 | 1.0 |
| Lot 363 - Enriched 1 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 493 | 1.0 | 0.2 | 0.3 | 0.0 | 1.0 |
| Lot 364 - Enriched 2.5 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 490 | 2.6 | 0.5 | 0.8 | 0.0 | 1.0 |

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

TABLE 5q. 2003 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 361 Nonenriched 0 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 457 | 0.1 | 0.1 | 0.1 | 0.1 | 0.9 |
| Lot 362 - Enriched 0.5 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 458 | 0.5 | 0.2 | 0.4 | 0.1 | 0.9 |
| Lot 363 - Enriched 1.5 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 460 | 1.4 | 0.5 | 1.2 | 0.1 | 0.9 |
| Lot 364 - Enriched 3 μmol/L whole blood | | | | | | |
| Tandem Mass Spec | 460 | 2.9 | 1.0 | 2.6 | 0.1 | 0.9 |

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

TABLE 5r. 2003 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 361 Nonenriched 0 µmol/L whole blood | | | | | | |
| Tandem Mass Spec | 469 | 0.7 | 0.4 | 0.5 | 0.5 | 0.9 |
| Lot 362 - Enriched 4 µmol/L whole blood | | | | | | |
| Tandem Mass Spec | 462 | 4.0 | 0.6 | 1.5 | 0.5 | 0.9 |
| Lot 363 - Enriched 8 µmol/L whole blood | | | | | | |
| Tandem Mass Spec | 462 | 7.8 | 1.1 | 2.9 | 0.5 | 0.9 |
| Lot 364 - Enriched 12 µmol/L whole blood | | | | | | |
| Tandem Mass Spec | 479 | 11.9 | 1.7 | 4.4 | 0.5 | 0.9 |

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

## NOTES

This ***NEWBORN SCREENING QUALITY ASSURANCE PROGRAM*** report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the **Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories.**

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