

### **QUALITY CONTROL**

**MIDYEAR REPORT** 

Volume 15, No. 1 July 2004

#### INTRODUCTION

The Newborn Screening Quality Program Assurance (NSOAP), Centers for Disease Control and Prevention (CDC), distributed driedblood-spot (DBS) quality control (QC) materials for thyroxine  $(T_A)$ , thyroid-stimulating hormone (TSH), α-hydroxyprogesterone (17-OHP), total galactose (Gal), phenylalanine (Phe), leucine (Leu), methionine (Met), tyrosine (Tyr), valine (Val), citrulline (Cit), and ten acylcarnitines (C2, C3, C4, C5, C5DC, C6, C8, C10, C14, C16) to laboratories operating newborn screening programs and to manufacturers of screening test products. Included with each semiannual shipment of OC specimens were datareport forms to be completed and returned to CDC.

This midyear report contains a summary of the QC data submitted during the first half of 2004 by state, contract, and private laboratories in the United States; international participants; and manufacturers of screening test products.

---- QC DATA ---see pages 3-39

#### QUALITY CONTROL MATERIALS

The QC specimen lots were provided as 6-month supplies of DBSs on filter paper. All DBS QC lots were prepared from whole blood of 55% hematocrit with lysed red blood cells. The QC materials were enriched with predetermined quantities of the selected analytes and dispensed in  $100~\mu L$  aliquots on Schleicher & Schuell (Keene, NH) grade 903 filter paper.

A QC shipment for T<sub>4</sub>, TSH, or 17-OHP consisted of blood-spot materials from three lots per analyte, with each lot containing a different concentration of analyte. A QC shipment for Gal, Phe, Leu, Met, Tyr, Val, Cit, and the acylcarnitines consisted of blood-spot cards from four different lots.

The QC materials were supplied for use as external controls in quantities sufficient to maintain continuity and transcend changes in production lots of routinely used method- or kit-control materials. The external QC materials were intended to supplement the participants' method- or kit-control materials at periodic intervals and to allow participants to monitor the long-term stability of their assays. The QC materials *should not* be used as routine daily QCs.

#### PARTICIPANTS' RESULTS

For this midyear report, we compiled the data that each participant reported from five analytic runs of specimens from each QC lot and calculated mean values and standard deviations from these data. Data values outside the 99% confidence interval for each OC lot were not included in the computations. We could not include qualitative data, data submitted as inequalities or ranges, data submitted in unidentified units, or data from more than five analytic runs per specimen lot per participant. Some participants submitted results in units other than those requested on the data-report forms. To ensure that all results are appropriately entered in the CDC database, participants should convert their results to the requested units before entering them on the data-report forms.

The reported QC data are summarized in tables on pages 3–39, 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. Results of the linear regression analyses are summarized in the tables on pages 3–39.

CDC/APHL

This program is cosponsored by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL).

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#### DISCUSSION

The enriched values of the QC specimen lots, shown in the tables for each lot, do not take into account the endogenous levels of the analytes; however, analytic results indicate that endogenous concentrations are negligible for all analytes except Phe, Leu, Met, Tyr, Val, Cit, and the acylcarnitines. For Phe, Leu, Met, Tyr, Val, Cit, and the acylcarnitines, the nonenriched base pools were distributed as the first QC specimen lot in each series so that participants could measure the endogenous Phe, Leu, Met, Tyr, Val, Cit, or acylcarnitine concentration of the series. OC lots 321-324 and 325-328 were enriched with Gal, Phe, Leu, Met, Tyr, Val, and Cit. QC lots 361-364 and 365-368 were enriched with acylcarnitines. All other QC lots were enriched with one analyte per lot. Gal lots 321-324 and 325-328 were enriched with equimolar quantities of simple galactose and galactose-1phosphate.

The tables, which summarize reported QC results (pages 3-39), provide data for 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 withinlaboratory 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 listed in each table using all analyte concentrations within a lot series (e.g., lots 201, 202, and 203). Because only three or four concentrations of OC 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, Cit, and the acylcarnitines, participants measured the endogenous concentration levels by analyzing the nonenriched QC lots. When endogenous levels were compared for these amino acids, we found them to be similar for all Phe methods; but the range of values for the other amino acids was greater among methods than expected for the nonenriched QC lots. Ideally, the slope should be 1.0, and most slopes were close to this value, ranging from 0.8 to 1.2 but some were a bit farther away. For example, for one Phe method, the slope was 1.4; for one Gal method, the slope was 1.7; for one Val method, the slope was 0.7; and for one 17-OHP method, the slope was 1.3. The Gal methods show the greatest variation in slopes among all analytes. For glutarylcarnitine (C5DC) measured by a kit method, the slope was 1.34 using data from three laboratories. C5DC data from two laboratories were excluded from the calculations because of high values, which would skew the results. For C5DC, numerous different internal standards were used for calculations of values by both non-kit and kit methods. For the non-kit method, laboratories used internal standards as follows: 24 laboratories used D3/C8, 9 used D9/C5, one used D3/C10, one used D3/C12, and one used D3/C14. For the kit method, two laboratories used D3/C12, one used D3/C10, one used D9/C5, and one used D6/C5DC. These differences in internal standards contributed to differences in calculated values. Also, data were not sorted for derivatized and nonderivatized methods, and only one laboratory in each group indicated using a non-derivatized method. These slope deviations may be related to analytic ranges for calibration curves. 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.

Each year, with the extensive cooperation of Schleicher & Schuell, Incorporated, and Whatman Incorporated, we routinely monitor the absorption characteristics of approved filter papers. (Participants may refer to page 8 of the 2004 Screening Newborn **Ouality** Assurance Program summary report\* for charts of the serum absorbancies of 20 grade 903 filter paper lots and to page 9 for charts of the serum absorbancies of 9 BFC 180 filter paper lots that CDC monitored.) The following Schleicher & Schuell filter paper lots were used in the production of QC specimen lots distributed during the first 6 months of 2004: W001 (Lots 201-203, 311-313, 321-324, 351-353) and W011 (Lots 325-328, 361-364, 365-368).

\* Bell CJ, editor. Newborn Screening Quality Assurance Program: 2003 Annual Summary Report. Atlanta: Centers for Disease Control and Prevention, 2004;21:1-53.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S.

Department of Health and Human Services or the Association of Public Health Laboratories.

#### 2004 Quality Control Data Summaries of Statistical Analyses

#### **THYROXINE** (μg T<sub>4</sub>/dL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 201 - Enriched 2 μg/dL serui	m					
Diagnostic Products	10	2.0	0.2	0.2	0.2	0.9
MP Biomedicals (ICN) RIA	49	2.0	0.2	0.4	-0.1	1.0
Neometrics Accuwell	49	2.2	0.4	0.5	-0.3	1.2
Delfia	97	1.8	0.4	0.6	-0.2	0.9
AutoDelfia	243	1.7	0.4	0.7	-0.2	1.0
Other	20	1.7	0.4	0.4	-0.8	1.3

#### Lot 202 - Enriched 5.5 $\mu$ g/dL serum

Diagnostic Products	10	4.8	0.5	0.5	0.2	0.9
MP Biomedicals (ICN) RIA	59	5.4	0.6	0.7	-0.1	1.0
Neometrics Accuwell	49	6.0	8.0	1.0	-0.3	1.2
Delfia	99	4.8	0.8	0.8	-0.2	0.9
AutoDelfia	233	5.3	0.7	1.7	-0.2	1.0
Other	20	6.0	0.7	1.0	-0.8	1.3

Lot 203 - Enriched 8 µg/dL serum

Diagnostic Products	10	7.1	1.0	1.0	0.2	0.9
MP Biomedicals (ICN) RIA	58	8.2	0.9	1.0	-0.1	1.0
Neometrics Accuwell	50	9.4	1.0	1.9	-0.3	1.2
Delfia	96	7.4	1.2	1.6	-0.2	0.9
AutoDelfia	234	7.7	8.0	2.5	-0.2	1.0
Other	20	9.3	1.1	1.1	-0.8	1.3

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

#### 2004 Quality Control Data Summaries of Statistical Analyses

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

			Average Within	_	Υ-	
Method	N	Mean	Lab SD	Total SD	Intercept*	Slope
.ot 311 - Enriched 25 μIU/mL se	rum					
Diagnostic Products	40	30.5	3.7	4.0	1.6	1.1
Neometrics Accuwell	50	22.8	2.7	3.4	-2.6	1.0
MP Biomedicals (ICN) IRMA	70	34.3	3.4	11.2	5.8	1.1
MP Biomedicals (ICN) ELISA	29	26.2	6.1	8.1	-3.6	1.1
Delfia	466	27.0	3.2	4.1	0.7	1.1
AutoDelfia	563	25.7	2.3	3.3	0.1	1.0
Ani Labsystems (Thermo)	20	25.5	1.5	5.8	6.8	0.8
Bio-Rad Quantase	138	26.0	4.4	5.1	-4.5	1.2
TecnoSuma UMELISA	20	26.4	5.1	5.1	-5.3	1.2
Bioclone ELISA	10	29.0	4.9	4.9	2.5	0.9
In house	90	27.2	3.6	4.6	3.0	1.0
Other	310	30.0	3.1	9.0	2.4	1.1
.ot 312 - Enriched 40 μIU/mL se	erum					
Diagnostic Products	39	46.9	4.2	4.5	1.6	1.1
Neometrics Accuwell	59 50	37.5	4.2	6.0	-2.6	1.1
	70	50.0	4.3	15.7	-2.6 5.8	1.0
MP Biomedicals (ICN) IRMA MP Biomedicals (ICN) ELISA	30	39.4	3.1	8.1	-3.6	1.1
Delfia	467	42.9	5.3	7.0	0.7	1.1
AutoDelfia	564	40.3	3.7	5.4	0.7	1.0
Ani Labsystems (Thermo)	20	39.2	3.2	5.4	6.8	0.8
Bio-Rad Quantase	136	42.6	7.1	8.3	-4.5	1.2
TecnoSuma UMELISA	20	38.7	9.7	10.8	-4.5 -5.3	1.2
Bioclone ELISA	10	32.7	8.9	8.9	2.5	0.9
In house	88	43.2	6.2	9.5	3.0	1.0
Other	307	45.2 45.2	4.7	13.1	2.4	1.1
Other	307	45.2	4.7	13.1	2.4	1.1
.ot 313 - Enriched 80 μIU/mL se	rum					
•		02.4	0.0	10.0	1.0	4 4
Diagnostic Products	39	93.1	9.8	10.0	1.6	1.1
Neometrics Accuwell	50	78.2	8.9	18.4	-2.6	1.0
MP Biomedicals (ICN) IRMA	70	95.7	9.9	28.5	5.8	1.1
MP Biomedicals (ICN) ELISA	30	87.3	10.4	30.4	-3.6	1.1
Delfia	467	85.0	8.9	11.5	0.7	1.1
AutoDelfia	565	81.2	6.5	9.9	0.1	1.0
Ani Labsystems (Thermo)	20	69.0	4.9	7.5	6.8	0.8
Bio-Rad Quantase	137	91.6	15.0	18.2	-4.5	1.2
TecnoSuma UMELISA	20	89.7	14.6	14.6	-5.3	1.2
Bioclone ELISA	9	75.9	18.2	18.2	2.5	0.9
In house	87	81.7	13.6	20.2	3.0	1.0
Other	306	89.5	9.2	21.9	2.4	1.1

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

#### 2004 Quality Control Data Summaries of Statistical Analyses

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

			Average		V	
Method	N	Mean	Within Lab SD	Total SD	Y- Intercept*	Slope
ot 351 - Enriched 25 ng/mL se	rum					
MP Biomedicals (ICN) RIA	20	27.0	3.2	7.1	5.3	0.9
Neometrics Accuwell	30	31.0	3.1	3.1	1.4	1.2
Delfia	89	26.8	2.6	3.5	-3.5	1.2
AutoDelfia	321	27.9	2.7	3.9	-2.1	1.1
Bayer Medical EIA	10	26.0	3.9	3.9	-9.6	1.3
In house	20	22.4	4.3	5.6	1.9	0.8
Other	58	29.7	4.3	7.4	2.4	1.0
ot 352 - Enriched 50 ng/mL se	rum					
MP Biomedicals (ICN) RIA	20	48.3	3.3	7.3	5.3	
` ,			5.5	1.5	5.5	0.9
Neometrics Accuwell	29	59.5	8.0	8.0	1.4	1.2
Neometrics Accuwell Delfia	29 98	59.5 52.1	8.0 5.1	8.0 7.4	1.4 -3.5	1.2 1.2
Neometrics Accuwell Delfia AutoDelfia	29 98 323	59.5 52.1 53.4	8.0 5.1 4.8	8.0 7.4 7.7	1.4 -3.5 -2.1	1.2 1.2 1.1
Neometrics Accuwell Delfia AutoDelfia Bayer Medical EIA	29 98 323 10	59.5 52.1 53.4 54.8	8.0 5.1 4.8 5.8	8.0 7.4 7.7 5.8	1.4 -3.5 -2.1 -9.6	1.2 1.2 1.1 1.3
Neometrics Accuwell Delfia AutoDelfia Bayer Medical EIA In house	29 98 323 10 20	59.5 52.1 53.4 54.8 40.9	8.0 5.1 4.8 5.8 5.9	8.0 7.4 7.7 5.8 7.9	1.4 -3.5 -2.1 -9.6 1.9	1.2 1.2 1.1 1.3 0.8
Neometrics Accuwell Delfia AutoDelfia Bayer Medical EIA	29 98 323 10	59.5 52.1 53.4 54.8	8.0 5.1 4.8 5.8	8.0 7.4 7.7 5.8	1.4 -3.5 -2.1 -9.6	1.2 1.2 1.1 1.3
Neometrics Accuwell  Delfia AutoDelfia Bayer Medical EIA In house Other  Lot 353 - Enriched 100 ng/mL s	29 98 323 10 20 59	59.5 52.1 53.4 54.8 40.9 53.2	8.0 5.1 4.8 5.8 5.9 8.5	8.0 7.4 7.7 5.8 7.9 10.8	1.4 -3.5 -2.1 -9.6 1.9 2.4	1.2 1.2 1.1 1.3 0.8 1.0
Neometrics Accuwell  Delfia AutoDelfia Bayer Medical EIA In house Other  Lot 353 - Enriched 100 ng/mL s  MP Biomedicals (ICN) RIA	29 98 323 10 20 59	59.5 52.1 53.4 54.8 40.9 53.2	8.0 5.1 4.8 5.8 5.9 8.5	8.0 7.4 7.7 5.8 7.9 10.8	1.4 -3.5 -2.1 -9.6 1.9 2.4	1.2 1.2 1.1 1.3 0.8 1.0
Neometrics Accuwell  Delfia AutoDelfia Bayer Medical EIA In house Other  Lot 353 - Enriched 100 ng/mL s  MP Biomedicals (ICN) RIA Neometrics Accuwell	29 98 323 10 20 59 erum 20 29	59.5 52.1 53.4 54.8 40.9 53.2	8.0 5.1 4.8 5.8 5.9 8.5	8.0 7.4 7.7 5.8 7.9 10.8	1.4 -3.5 -2.1 -9.6 1.9 2.4	1.2 1.2 1.1 1.3 0.8 1.0
Neometrics Accuwell  Delfia AutoDelfia Bayer Medical EIA In house Other  Lot 353 - Enriched 100 ng/mL s  MP Biomedicals (ICN) RIA Neometrics Accuwell Delfia	29 98 323 10 20 59 erum 20 29 97	59.5 52.1 53.4 54.8 40.9 53.2 91.8 118.8 112.5	8.0 5.1 4.8 5.8 5.9 8.5	8.0 7.4 7.7 5.8 7.9 10.8	1.4 -3.5 -2.1 -9.6 1.9 2.4 5.3 1.4 -3.5	1.2 1.2 1.1 1.3 0.8 1.0
Neometrics Accuwell  Delfia AutoDelfia Bayer Medical EIA In house Other  Other  MP Biomedicals (ICN) RIA Neometrics Accuwell Delfia AutoDelfia	29 98 323 10 20 59 erum 20 29 97 322	91.8 118.8 112.5 113.3	8.0 5.1 4.8 5.8 5.9 8.5 10.6 18.6 11.7 10.9	8.0 7.4 7.7 5.8 7.9 10.8	1.4 -3.5 -2.1 -9.6 1.9 2.4 5.3 1.4 -3.5 -2.1	1.2 1.2 1.1 1.3 0.8 1.0
Neometrics Accuwell Delfia AutoDelfia Bayer Medical EIA In house Other  Lot 353 - Enriched 100 ng/mL s MP Biomedicals (ICN) RIA Neometrics Accuwell Delfia AutoDelfia Bayer Medical EIA	29 98 323 10 20 59 erum 20 29 97 322 10	91.8 118.8 112.5 113.3 125.9	8.0 5.1 4.8 5.8 5.9 8.5 10.6 11.7 10.9 11.1	8.0 7.4 7.7 5.8 7.9 10.8	1.4 -3.5 -2.1 -9.6 1.9 2.4 5.3 1.4 -3.5 -2.1 -9.6	1.2 1.2 1.1 1.3 0.8 1.0 0.9 1.2 1.2 1.1
Neometrics Accuwell  Delfia AutoDelfia Bayer Medical EIA In house Other  Other  MP Biomedicals (ICN) RIA Neometrics Accuwell Delfia AutoDelfia	29 98 323 10 20 59 erum 20 29 97 322	91.8 118.8 112.5 113.3	8.0 5.1 4.8 5.8 5.9 8.5 10.6 18.6 11.7 10.9	8.0 7.4 7.7 5.8 7.9 10.8	1.4 -3.5 -2.1 -9.6 1.9 2.4 5.3 1.4 -3.5 -2.1	1.2 1.2 1.1 1.3 0.8 1.0

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

#### 2004 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
						<u> </u>
Lot 321 - Enriched 5 mg/dL who	le blood					
Fluorometric Manual	120	5.9	0.8	1.9	0.8	1.1
Fluor Cont Flow, Kit	80	7.5	0.6	1.1	2.1	1.1
Colorimetric	52	7.2	1.3	1.5	1.2	1.3
PerkinElmer Neonatal Fluor	128	8.4	1.0	1.5	4.0	0.8
Neometrics Accuwell	30	7.8	8.0	1.9	0.6	1.5
Bio-Rad Quantase	70	7.3	1.1	1.8	-1.2	1.8
Interscientific Enzyme	30	6.0	0.7	1.5	-1.0	1.4
Other	50	6.9	1.5	2.5	0.5	1.2
Lot 322 - Enriched 10 mg/dL wh	ole blood					
Fluorometric Manual	117	11.2	1.1	2.4	0.8	1.1
Fluor Cont Flow, Kit	78	13.3	1.3	1.7	2.1	1.1
Colorimetric	50	14.1	1.6	2.3	1.2	1.3
PerkinElmer Neonatal Fluor	128	11.6	1.1	1.4	4.0	0.8
Neometrics Accuwell	30	15.4	1.3	4.0	0.6	1.5
Bio-Rad Quantase	70	16.9	1.8	2.8	-1.2	1.8
Interscientific Enzyme	30	12.7	1.8	2.8	-1.0	1.4
Other	50	12.6	1.5	2.4	0.5	1.2
Lot 323 - Enriched 15 mg/dL wh		47.4	2.0	2.5	0.9	1 1
Fluorometric Manual	118	17.4	2.0	3.5	0.8	1.1
Fluor Cont Flow, Kit	79 50	19.8	1.3	1.9	2.1	1.1
Colorimetric	50	20.7	2.2	3.9	1.2	1.3
PerkinElmer Neonatal Fluor	128	15.9	1.4	1.7	4.0	0.8
Neometrics Accuwell	30	22.3	2.3	5.6	0.6	1.5
Bio-Rad Quantase	69	26.0	2.8	4.3	-1.2	1.8
Interscientific Enzyme	29	19.3	3.5	4.5	-1.0	1.4
Other	50	19.5	1.6	2.2	0.5	1.2
Lot 324 - Enriched 30 mg/dL wh	ole blood					
Fluorometric Manual	117	32.6	3.4	5.7	0.8	1.1
Fluor Cont Flow, Kit	79	35.9	2.6	3.9	2.1	1.1
Colorimetric	50	39.2	3.8	6.5	1.2	1.3
PerkinElmer Neonatal Fluor	128	28.2	2.3	3.1	4.0	0.8
Neometrics Accuwell	30	44.3	6.0	11.1	0.6	1.5
Bio-Rad Quantase	72	52.3	6.4	8.5	-1.2	1.8
Interscientific Enzyme	30	40.2	5.4	10.5	-1.0	1.4
Other	48	37.9	4.6	6.2	0.5	1.2

<sup>\*</sup>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
at 225 Fariahad Fara/dl who	ام ماط ماد					
Lot 325 - Enriched 5 mg/dL who						
Fluorometric Manual	120	5.9	0.7	2.0	0.3	1.1
Fluor Cont Flow, Kit	80	8.0	0.8	1.4	2.1	1.1
Colorimetric	48	7.9	1.2	1.7	1.4	1.3
PerkinElmer Neonatal Fluor	134	8.1	0.9	1.7	4.1	0.8
Neometrics Accuwell	30	8.2 7.2	1.1	2.1 1.6	1.0	1.4 1.7
Bio-Rad Quantase	70	7.2 5.8	1.0	1.6	-1.3 -1.6	1.7
Interscientific Enzyme Other	29 49	6.8	0.8 1.6	1.4	0.3	1.4
		0.0	1.0	1.7	0.5	1.0
Lot 326 - Enriched 10 mg/dL wh						
Fluorometric Manual	116	10.7	1.2	2.5	0.3	1.1
Fluor Cont Flow, Kit	79	13.2	0.9	1.8	2.1	1.1
Colorimetric	50	14.4	1.5	2.6	1.4	1.3
PerkinElmer Neonatal Fluor	136	12.6	1.1	2.0	4.1	8.0
Neometrics Accuwell	30	15.5	1.7	3.7	1.0	1.4
Bio-Rad Quantase	67	15.8	1.4	2.8	-1.3	1.7
Interscientific Enzyme	30	12.0	1.9	3.7	-1.6	1.4
Other	50	13.4	1.8	2.6	0.3	1.3
ot 327 - Enriched 15 mg/dL wh	ole blood					
Fluorometric Manual	116	16.5	1.6	3.2	0.3	1.1
Fluor Cont Flow, Kit	79	19.2	1.6	2.6	2.1	1.1
Colorimetric	50	20.9	2.5	4.3	1.4	1.3
PerkinElmer Neonatal Fluor	140	17.1	1.5	1.8	4.1	0.8
Neometrics Accuwell	30	22.5	1.7	5.5	1.0	1.4
Bio-Rad Quantase	69	23.7	3.6	5.3	-1.3	1.7
Interscientific Enzyme	30	18.8	2.8	4.1	-1.6	1.4
Other	49	19.4	2.2	2.9	0.3	1.3
ot 328 - Enriched 30 mg/dL wh	nole blood					
Fluorometric Manual	116	32.7	3.5	6.0	0.3	1.1
Fluor Cont Flow, Kit	78	36.1	2.9	4.5	2.1	1.1
Colorimetric	49	40.2	3.8	6.4	1.4	1.3
PerkinElmer Neonatal Fluor	137	29.2	2.7	3.6	4.1	0.8
Neometrics Accuwell	30	44.3	3.7	10.2	1.0	1.4
Bio-Rad Quantase	56	49.7	5.2	5.4	-1.3	1.7
Interscientific Enzyme	30	40.1	5.6	11.7	-1.6	1.4
Other	48	39.3	4.5	5.2	0.3	1.3

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

#### 2004 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
_ot 321 - Nonenriched 0 mg/dL v	vhole bloo	od				
Fluorometric Manual	78	1.8	0.3	0.5	1.9	1.0
Bacterial Inhibition (Guthrie)	80	1.6	0.3	0.6	1.4	1.0
Fluor Cont Flo, In house	19	2.2	0.3	0.3	2.0	1.3
Fluor Cont Flo, Kit	128	2.1	0.2	0.6	2.1	1.1
Colorimetric	70	1.8	0.3	0.5	1.8	1.4
PerkinElmer Neonatal Fluor	263	1.5	0.2	0.3	1.5	1.0
HPLC	70	1.4	0.1	0.2	1.5	1.0
MS/MS Non-Kit	355	1.6	0.2	0.3	1.5	1.0
MS/MS PE Neogram MS2 Kit	50	1.5	0.2	0.2	1.4	0.9
Neometrics Accuwell	30	2.0	0.3	0.4	2.0	1.3
Bio-Rad Quantase	90	1.5	0.3	0.3	1.5	1.1
MP Biomed (ICN) Enzyme	12	1.2	0.3	0.3	1.5	1.3
Interscientific Enzyme	40	1.7	0.5	0.7	1.5	1.1
Other	49	2.4	0.5	8.0	2.3	1.1
<u>_</u>	e blood 80	5.1	0.5	0.7	1.9	1.0
Fluorometric Manual		5.1 4.0	0.5 0.6	0.7 1.1	1.9 1.4	1.0 1.0
Lot 322 - Enriched 3 mg/dL whol Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house	80	_				_
Fluorometric Manual Bacterial Inhibition (Guthrie)	80 100	4.0	0.6	1.1	1.4	1.0
Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house	80 100 19	4.0 5.7	0.6 0.4	1.1 0.5	1.4 2.0	1.0 1.3
Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house Fluor Cont Flo, Kit Colorimetric	80 100 19 128	4.0 5.7 5.5	0.6 0.4 0.4	1.1 0.5 1.0	1.4 2.0 2.1	1.0 1.3 1.1
Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house Fluor Cont Flo, Kit Colorimetric PerkinElmer Neonatal Fluor	80 100 19 128 69	4.0 5.7 5.5 5.9	0.6 0.4 0.4 0.9	1.1 0.5 1.0 1.4	1.4 2.0 2.1 1.8	1.0 1.3 1.1 1.4
Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house Fluor Cont Flo, Kit Colorimetric PerkinElmer Neonatal Fluor HPLC	80 100 19 128 69 265	4.0 5.7 5.5 5.9 4.3	0.6 0.4 0.4 0.9 0.4	1.1 0.5 1.0 1.4 0.5	1.4 2.0 2.1 1.8 1.5	1.0 1.3 1.1 1.4 1.0
Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house Fluor Cont Flo, Kit Colorimetric PerkinElmer Neonatal Fluor HPLC MS/MS Non-Kit	80 100 19 128 69 265 79	4.0 5.7 5.5 5.9 4.3 4.4	0.6 0.4 0.4 0.9 0.4 0.3	1.1 0.5 1.0 1.4 0.5 0.4	1.4 2.0 2.1 1.8 1.5	1.0 1.3 1.1 1.4 1.0 1.0
Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house Fluor Cont Flo, Kit Colorimetric PerkinElmer Neonatal Fluor HPLC MS/MS Non-Kit	80 100 19 128 69 265 79 356	4.0 5.7 5.5 5.9 4.3 4.4 4.5	0.6 0.4 0.4 0.9 0.4 0.3 0.4	1.1 0.5 1.0 1.4 0.5 0.4 0.7	1.4 2.0 2.1 1.8 1.5 1.5	1.0 1.3 1.1 1.4 1.0 1.0
Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house Fluor Cont Flo, Kit Colorimetric PerkinElmer Neonatal Fluor HPLC MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	80 100 19 128 69 265 79 356 47	4.0 5.7 5.5 5.9 4.3 4.4 4.5 4.1	0.6 0.4 0.4 0.9 0.4 0.3 0.4 0.5	1.1 0.5 1.0 1.4 0.5 0.4 0.7	1.4 2.0 2.1 1.8 1.5 1.5 1.5	1.0 1.3 1.1 1.4 1.0 1.0 0.9
Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house Fluor Cont Flo, Kit Colorimetric PerkinElmer Neonatal Fluor HPLC MS/MS Non-Kit MS/MS PE Neogram MS2 Kit Neometrics Accuwell	80 100 19 128 69 265 79 356 47 29	4.0 5.7 5.5 5.9 4.3 4.4 4.5 4.1 5.8 4.7	0.6 0.4 0.4 0.9 0.4 0.3 0.4 0.5 0.5 0.5	1.1 0.5 1.0 1.4 0.5 0.4 0.7 0.5 1.0	1.4 2.0 2.1 1.8 1.5 1.5 1.5 1.4 2.0	1.0 1.3 1.1 1.4 1.0 1.0 0.9 1.3 1.1
Fluorometric Manual Bacterial Inhibition (Guthrie) Fluor Cont Flo, In house Fluor Cont Flo, Kit Colorimetric PerkinElmer Neonatal Fluor HPLC MS/MS Non-Kit MS/MS PE Neogram MS2 Kit Neometrics Accuwell Bio-Rad Quantase	80 100 19 128 69 265 79 356 47 29 85	4.0 5.7 5.5 5.9 4.3 4.4 4.5 4.1 5.8 4.7	0.6 0.4 0.4 0.9 0.4 0.3 0.4 0.5 0.5	1.1 0.5 1.0 1.4 0.5 0.4 0.7 0.5 1.0	1.4 2.0 2.1 1.8 1.5 1.5 1.5 1.4 2.0	1.0 1.3 1.1 1.4 1.0 1.0 0.9 1.3

<sup>\*</sup>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
_ot 323 - Enriched 7 mg/dL who	le blood					
Fluorometric Manual	78	9.2	0.7	0.9	1.9	1.0
Bacterial Inhibition (Guthrie)	99	8.2	1.1	1.5	1.4	1.0
Fluor Cont Flo, In house	20	11.1	0.8	0.8	2.0	1.3
Fluor Cont Flo, Kit	125	10.0	1.3	2.2	2.1	1.1
Colorimetric	69	11.5	0.9	2.6	1.8	1.4
PerkinElmer Neonatal Fluor	266	8.4	0.8	0.9	1.5	1.0
HPLC	69	9.0	1.3	1.4	1.5	1.0
MS/MS Non-Kit	353	8.7	0.8	1.4	1.5	1.0
MS/MS PE Neogram MS2 Kit	49	8.3	1.0	1.0	1.4	0.9
Neometrics Accuwell	30	11.2	0.6	2.0	2.0	1.3
Bio-Rad Quantase	90	9.5	1.0	1.3	1.5	1.1
MP Biomed (ICN) Enzyme	20	10.9	0.9	1.1	1.5	1.3
Interscientific Enzyme	49	9.2	0.9	2.0	1.5	1.1
Other	48	10.3	1.2	2.5	2.3	1.1
Lot 324 - Nonenriched 11 mg/dL Fluorometric Manual	78	13.1	1.1	1.3	1.9	1.0
Bacterial Inhibition (Guthrie)	97	12.1	2.1	2.6	1.4	1.0
Fluor Cont Flo, In house	20	16.4	0.9	0.9	2.0	1.3
Fluor Cont Flo, Kit	128	14.8	1.0	2.6	2.1	1.1
Colorimetric	72	17.1	0.9	3.5	1.8	1.4
PerkinElmer Neonatal Fluor	257	12.5	1.1	1.2	1.5	1.0
HPLC	80	12.5	0.7	1.2	1.5	1.0
MS/MS Non-Kit	354	12.7	1.4	2.2	1.5	1.0
MS/MS PE Neogram MS2 Kit	50	11.8	1.2	1.3	1.4	0.9
Neometrics Accuwell	30	16.2	1.1	2.9	2.0	1.3
Die Ded Overtees	88	13.6	1.1	1.7	1.5	1.1
Bio-Rad Quantase						
MP Biomed (ICN) Enzyme	20	15.2	1.6	1.6	1.5	1.3
	20 49 54	15.2 13.9 14.8	1.6 1.2 1.7	1.6 3.4 3.0	1.5 1.5 2.3	

<sup>\*</sup>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
ot 325 - Enriched 0 mg/dL who	e blood					
Fluorometric Manual	87	1.7	0.3	0.4	1.6	1.1
Bacterial Inhibition (Guthrie)	99	1.8	0.4	0.5	1.8	1.0
Fluor Cont Flo, In house	28	2.0	0.2	0.4	1.9	1.3
Fluor Cont Flo, Kit	150	2.1	0.5	0.8	2.0	1.2
Colorimetric	79	2.1	0.4	0.6	1.9	1.3
PerkinElmer Neonatal Fluor	334	1.5	0.2	0.3	1.5	1.0
HPLC	68	1.5	0.1	0.2	1.4	1.0
MS/MS Non-Kit	379	1.5	0.2	0.3	1.5	1.0
MS/MS PE Neogram MS2 Kit	60	1.5	0.2	0.2	1.5	1.0
Neometrics Accuwell	30	2.0	0.3	0.5	1.9	1.3
Bio-Rad Quantase	117	1.5	0.3	0.5	1.4	1.1
MP Biomed (ICN) Enzyme	8	1.7	0.6	0.6	1.5	1.2
Interscientific Enzyme	49	1.7	0.4	0.6	1.5	1.2
Other	40	2.4	0.4	0.6	2.3	1.1
ot 326 - Nonenriched 3 mg/dL v	whole blo	od 4.9	0.5	0.7	1.6	1.1
Bacterial Inhibition (Guthrie)	120	4.9	0.5	1.1	1.8	1.0
Fluor Cont Flo, In house	28	4.6 5.6	0.6	0.9	1.9	1.0
Fluor Cont Flo, Kit	146	5.4	0.4	1.2	2.0	1.2
Colorimetric	80	6.0	0.5	1.2	1.9	1.2
PerkinElmer Neonatal Fluor	337	4.5	0.5	0.6	1.5	1.0
HPLC	80	4.5	0.3	0.4	1.4	1.0
MS/MS Non-Kit	385	4.7	0.4	0.7	1.5	1.0
MS/MS PE Neogram MS2 Kit	59	4.5	0.5	0.5	1.5	1.0
Neometrics Accuwell	30	5.8	0.4	0.9	1.9	1.3
Bio-Rad Quantase	118	4.7	0.6	0.7	1.4	1.1
MP Biomed (ICN) Enzyme	20	5.0	0.8	0.8	1.5	1.2
Interscientific Enzyme	49	5.0	0.6	1.3	1.5	1.2
Other	40	5.5	0.6	0.6	2.3	1.1
	.0	5.0	5.5	3.0	0	

<sup>\*</sup>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
						•
ot 327 - Enriched 7 mg/dL whol	le blood					
Fluorometric Manual	90	9.3	0.8	1.1	1.6	1.1
Bacterial Inhibition (Guthrie)	119	8.6	1.0	1.5	1.8	1.0
Fluor Cont Flo, In house	28	10.4	1.0	1.4	1.9	1.3
Fluor Cont Flo, Kit	145	9.9	0.8	2.1	2.0	1.2
Colorimetric	80	10.8	0.9	2.5	1.9	1.3
PerkinElmer Neonatal Fluor	336	8.5	0.9	1.2	1.5	1.0
HPLC	70	8.8	0.5	0.6	1.4	1.0
MS/MS Non-Kit	384	8.7	0.8	1.4	1.5	1.0
MS/MS PE Neogram MS2 Kit	59	8.4	0.9	1.0	1.5	1.0
Neometrics Accuwell	30	11.0	0.8	1.6	1.9	1.3
Bio-Rad Quantase	118	9.0	1.2	1.4	1.4	1.1
MP Biomed (ICN) Enzyme	20	9.8	1.1	1.4	1.5	1.2
Interscientific Enzyme	50	9.6	0.9	2.2	1.5	1.2
Other	49	9.8	1.5	1.9	2.3	1.1
_ot 328 - Nonenriched 11 mg/dL						
Fluorometric Manual	90	13.8	1.0	1.4	1.6	1.1
Bacterial Inhibition (Guthrie)	115	12.9	1.6	2.3	1.8	1.0
Fluor Cont Flo, In house	28	16.0	1.2	2.1	1.9	1.3
Fluor Cont Flo, Kit	148	14.9	1.6	3.0	2.0	1.2
Colorimetric	77	16.8	1.8	3.7	1.9	1.3
PerkinElmer Neonatal Fluor	335	12.7	1.2	1.8	1.5	1.0
HPLC	78	12.9	8.0	1.3	1.4	1.0
MS/MS Non-Kit	387	13.1	1.1	2.0	1.5	1.0
MS/MS PE Neogram MS2 Kit	60	12.4	1.1	1.3	1.5	1.0
Neometrics Accuwell	30	16.7	1.2	2.5	1.9	1.3
Bio-Rad Quantase	109	13.9	1.1	1.6	1.4	1.1
MP Biomed (ICN) Enzyme	20	14.7	1.4	1.6	1.5	1.2
Interscientific Enzyme	50	14.8	1.4	2.9	1.5	1.2 1.1

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

### 2004 Quality Control Data Summaries of Statistical Analyses

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

	_		Average Within		Y-	
Method	N	Mean	Lab SD	Total SD	Intercept*	Slope
Lot 321 - Nonenriched 0 mg/dL v	vhole bloo	od				
Bacterial Inhibition Assays	30	2.1	0.6	1.2	1.9	0.9
HPLC	40	2.3	0.3	0.3	2.4	1.1
MS/MS Non-Kit	300	2.7	0.3	0.7	2.7	0.9
MS/MS PE Neogram MS2 Kit	48	2.8	0.4	0.5	2.7	0.9
Other	20	5.0	0.5	2.5	4.5	1.5
Lot 322 - Enriched 3 mg/dL whol	e blood					
Bacterial Inhibition Assays	40	4.6	1.0	1.5	1.9	0.9
HPLC	39	5.5	0.6	0.6	2.4	1.1
MS/MS Non-Kit	300	5.3	0.6	1.3	2.7	0.9
MS/MS PE Neogram MS2 Kit	49	5.1	0.5	0.7	2.7	0.9
Other	20	8.4	0.5	3.5	4.5	1.5
Lot 323 - Enriched 7 mg/dL whol	o blood					
Bacterial Inhibition Assays	39	8.5	1.2	1.9	1.9	0.9
HPLC	39	10.0	2.1	2.1	2.4	1.1
MS/MS Non-Kit	292	9.4	1.0	2.3 1.2	2.7 2.7	0.9
MS/MS PE Neogram MS2 Kit	49	8.9	0.9 0.9			0.9 1.5
Other	19	14.5	0.9	6.0	4.5	1.5
Lot 324 - Enriched 11 mg/dL who	ole blood					
Bacterial Inhibition Assays	37	12.2	2.5	3.8	1.9	0.9
HPLC	39	13.8	1.2	2.3	2.4	1.1
MS/MS Non-Kit	303	13.0	1.3	3.0	2.7	0.9
MS/MS PE Neogram MS2 Kit	51	12.0	1.3	1.4	2.7	0.9
Other	20	21.0	1.3	9.8	4.5	1.5
JJ.	_0			5.0		

<sup>\*</sup>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 325 - Nonenriched 0 mg/dL v	vhole bloc	od				
Bacterial Inhibition Assays	30	2.2	0.7	1.1	2.1	0.8
HPLC	40	2.1	0.3	0.4	2.1	1.1
MS/MS Non-Kit	336	2.4	0.2	0.5	2.4	0.9
MS/MS PE Neogram MS2 Kit	58	2.4	0.3	0.5	2.4	0.9
Other	19	4.1	0.6	1.2	3.8	1.3
Lot 326 - Enriched 3 mg/dL whol	e blood					
Bacterial Inhibition Assays	48	4.6	0.7	1.0	2.1	8.0
HPLC	39	5.4	0.4	0.5	2.1	1.1
MS/MS Non-Kit	332	5.1	0.5	0.9	2.4	0.9
MS/MS PE Neogram MS2 Kit Other	59	4.9	0.6	0.7	2.4	0.9
	19	7.5	1.2	2.7	3.8	1.3
Lot 327 - Enriched 7 mg/dL whole	e blood					
Bacterial Inhibition Assays	47	7.6	0.9	1.3	2.1	8.0
HPLC	39	9.7	0.8	0.9	2.1	1.1
MS/MS Non-Kit	330	8.7	0.9	1.5	2.4	0.9
MS/MS PE Neogram MS2 Kit	59	8.4	0.9	1.1	2.4	0.9
Other	20	12.7	1.5	4.7	3.8	1.3
Lot 328 - Enriched 11 mg/dL who	le blood					
Bacterial Inhibition Assays	49	11.2	2.0	2.6	2.1	0.8
HPLC	39	14.1	1.6	2.1	2.1	1.1
MS/MS Non-Kit	333	12.6	1.2	2.2	2.4	0.9
MS/MS PE Neogram MS2 Kit	57	11.9	1.2	1.5	2.4	0.9
Other	20	18.3	2.6	7.0	3.8	1.3

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

### 2004 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
					<u> </u>	
Lot 321 - Nonenriched 0 mg/dL v	vhole bloc	od				
Bacterial Inhibition Assays	30	0.5	0.3	0.6	0.8	1.3
HPLC	39	0.2	0.1	0.1	0.2	0.9
MS/MS Non-Kit	307	0.4	0.1	0.2	0.4	0.9
MS/MS PE Neogram MS2 Kit	38	0.5	0.2	0.3	0.5	0.9
Lot 322 - Enriched 1 mg/dL whol	e blood					
Bacterial Inhibition Assays	40	2.2	8.0	1.2	8.0	1.3
HPLC	40	1.1	0.1	0.2	0.2	0.9
MS/MS Non-Kit	306	1.3	0.2	0.2	0.4	0.9
MS/MS PE Neogram MS2 Kit	40	1.3	0.1	0.2	0.5	0.9
Lot 323 - Enriched 3 mg/dL whol						
Bacterial Inhibition Assays	40	5.2	1.3	2.0	8.0	1.3
HPLC	39	3.2	0.3	0.6	0.2	0.9
MS/MS Non-Kit	301	3.1	0.4	0.6	0.4	0.9
MS/MS PE Neogram MS2 Kit	40	3.2	0.4	0.4	0.5	0.9
Lot 324 - Enriched 6 mg/dL whol	e blood					
Bacterial Inhibition Assays	39	8.3	1.7	2.9	8.0	1.3
HPLC	40	5.8	0.5	0.8	0.2	0.9
MS/MS Non-Kit	307	5.8	0.5	1.0	0.4	0.9
MS/MS PE Neogram MS2 Kit	40	5.9	0.7	0.7	0.5	0.9

<sup>\*</sup>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 325 - Nonenriched 0 mg/dL v	whole bloc	od				
Bacterial Inhibition Assays	20	0.6	0.1	8.0	8.0	1.2
HPLC	40	0.3	0.1	0.1	0.2	0.9
MS/MS Non-Kit	342	0.4	0.1	0.1	0.4	0.9
MS/MS PE Neogram MS2 Kit	48	0.5	0.1	0.1	0.5	0.9
Lot 326 - Enriched 1 mg/dL whol	e blood					
Bacterial Inhibition Assays	30	2.2	0.6	1.2	0.8	1.2
HPLC	40	1.2	0.2	0.3	0.2	0.9
MS/MS Non-Kit	342	1.3	0.1	0.2	0.4	0.9
MS/MS PE Neogram MS2 Kit	50	1.4	0.2	0.2	0.5	0.9
Lot 327 - Enriched 3 mg/dL who	e blood					
Bacterial Inhibition Assays	30	4.2	1.1	2.2	0.0	
		7.2	1.1	2.2	0.8	1.2
HPLC	40	2.9	0.3	0.5	0.8	1.2 0.9
		2.9 3.0				
HPLC	40	2.9	0.3	0.5	0.2	0.9
HPLC MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	40 343 50	2.9 3.0	0.3 0.3	0.5 0.5	0.2 0.4	0.9 0.9
HPLC MS/MS Non-Kit MS/MS PE Neogram MS2 Kit  Lot 328 - Enriched 6 mg/dL whole	40 343 50 e blood	2.9 3.0 3.2	0.3 0.3 0.4	0.5 0.5 0.4	0.2 0.4 0.5	0.9 0.9 0.9
HPLC MS/MS Non-Kit MS/MS PE Neogram MS2 Kit  Lot 328 - Enriched 6 mg/dL whole Bacterial Inhibition Assays	40 343 50 e blood 29	2.9 3.0 3.2	0.3 0.3 0.4	0.5 0.5 0.4	0.2 0.4 0.5	0.9 0.9 0.9
HPLC MS/MS Non-Kit MS/MS PE Neogram MS2 Kit  Lot 328 - Enriched 6 mg/dL whole	40 343 50 e blood	2.9 3.0 3.2	0.3 0.3 0.4	0.5 0.5 0.4	0.2 0.4 0.5	0.9 0.9 0.9

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

### 2004 Quality Control Data Summaries of Statistical Analyses

TYROSINE (mg Tyr/dL whole blood)

			Average Within		Υ-	
Method	N	Mean	Lab SD	Total SD	Intercept*	Slope
Lot 321 - Nonenriched 0 mg/dL	whole bloc	od				
HPLC	58	1.2	0.2	0.4	1.3	1.0
MS/MS Non-Kit	308	1.2	0.1	0.3	1.2	0.9
MS/MS PE Neogram MS2 Kit	49	1.3	0.2	0.3	1.3	0.9
Other	39	1.8	0.3	0.5	1.9	1.0
Lot 322 - Enriched 2 mg/dL who	la blood					
HPLC	70	2.2	0.3	0.5	1.3	1.0
Tandem Mass Spec	319	2.1	0.2	0.5	1.2	0.9
Thin-Layer Chromatography	48	2.1	0.3	0.4	1.3	0.9
Other	39	2.9	0.3	0.6	1.9	1.0
Lot 323 - Enriched 3 mg/dL who	le blood					
HPLC	61	4.3	0.4	0.9	1.3	1.0
Tandem Mass Spec	340	4.0	0.5	0.8	1.2	0.9
Thin-Layer Chromatography	50	4.3	0.5	0.7	1.3	0.9
Other	40	5.0	0.4	0.9	1.9	1.0
Lot 324 - Enriched 8 mg/dL who	le blood					
HPLC	70	8.9	0.7	1.5	1.3	1.0
Tandem Mass Spec	320	8.5	0.9	1.9	1.2	0.9
Thin-Layer Chromatography	49	8.6	1.3	1.6	1.3	0.9
Other	40	10.0	0.9	1.9	1.9	1.0
Other	70	10.0	0.9	1.9	1.9	1.0

<sup>\*</sup>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 325 - Nonenriched 0 mg/dL v	vhole bloc	od				
HPLC	59	1.4	0.2	0.5	1.4	1.0
MS/MS Non-Kit	343	1.3	0.1	0.3	1.3	0.9
MS/MS PE Neogram MS2 Kit	57	1.3	0.2	0.2	1.3	0.9
Other	40	1.9	0.2	0.5	1.9	1.1
Lot 326 - Enriched 1 mg/dL whol	e blood					
HPLC	70	2.4	0.2	0.5	1.4	1.0
MS/MS Non-Kit	352	2.2	0.2	0.5	1.3	0.9
MS/MS PE Neogram MS2 Kit	57	2.3	0.3	0.4	1.3	0.9
Other	40	3.0	0.3	0.8	1.9	1.1
Lot 327 - Enriched 3 mg/dL whol	e blood					
HPLC	58	4.3	0.3	0.8	1.4	1.0
MS/MS Non-Kit	331	4.0	0.4	8.0	1.3	0.9
MS/MS PE Neogram MS2 Kit	57	4.2	0.5	0.6	1.3	0.9
Other	40	4.9	0.5	0.9	1.9	1.1
Lot 328 - Enriched 8 mg/dL whol	e blood					
	70	9.1	0.6	1.7	1.4	1.0
HPLC	70	0.1	0.0			
HPLC MS/MS Non-Kit	348	8.5	0.9	1.7	1.3	0.9

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

### 2004 Quality Control Data Summaries of Statistical Analyses

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

Lot 321 - Nonenriched 0 mg/dL whole blood	Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
HPLC 30 2.1 0.2 0.5 2.0 1 MS/MS Non-Kit 262 2.0 0.2 0.6 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.0 0.3 0.3 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.0 0.3 0.3 1.9 0 MS/MS Non-Kit 272 2.6 0.3 0.8 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0 MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0 MS/MS Non-Kit 276 6.6 0 MS/MS Non-Kit 276 0 MS/MS Non-Ki	Metriod	IN	IVICALI	Lab 3D		ппесері	Siope
HPLC 30 2.1 0.2 0.5 2.0 1 MS/MS Non-Kit 262 2.0 0.2 0.6 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.0 0.3 0.3 1.9 0  Lot 322 - Enriched 1 mg/dL whole blood  HPLC 30 2.5 0.3 0.8 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.8 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0  Lot 323 - Enriched 3 mg/dL whole blood  HPLC 30 5.0 0.3 0.8 2.0 1 MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0 MS/MS Non-Kit 40 4.4 0.5 0.7 1.9 0  Lot 324 - Enriched 6 mg/dL whole blood  HPLC 30 7.9 0.4 1.3 2.0 0 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0			_				
MS/MS Non-Kit 262 2.0 0.2 0.6 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.0 0.3 0.3 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.0 0.3 0.3 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.0 0.5 2.0 1 MS/MS Non-Kit 272 2.6 0.3 0.8 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0 MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0 MS/MS Non-Kit 276 6.6 0 MS/MS No	Lot 321 - Nonenriched 0 mg/dL v	whole blo	od				
Lot 322 - Enriched 1 mg/dL whole blood  HPLC 30 2.9 0.2 0.5 2.0 1 MS/MS Non-Kit 272 2.6 0.3 0.8 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0  Lot 323 - Enriched 3 mg/dL whole blood  HPLC 30 5.0 0.3 0.8 2.0 1 MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0  Lot 324 - Enriched 6 mg/dL whole blood  HPLC 30 7.9 0.4 1.3 2.0 0 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0							1.0
Lot 322 - Enriched 1 mg/dL whole blood  HPLC 30 2.9 0.2 0.5 2.0 1 MS/MS Non-Kit 272 2.6 0.3 0.8 1.9 0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0  Lot 323 - Enriched 3 mg/dL whole blood  HPLC 30 5.0 0.3 0.8 2.0 1 MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0  Lot 324 - Enriched 6 mg/dL whole blood  HPLC 30 7.9 0.4 1.3 2.0 0 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0							0.8
HPLC 30 2.9 0.2 0.5 2.0 11 MS/MS Non-Kit 272 2.6 0.3 0.8 1.9 0.0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0.0  Lot 323 - Enriched 3 mg/dL whole blood HPLC 30 5.0 0.3 0.8 2.0 11 MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0.0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0.0  Lot 324 - Enriched 6 mg/dL whole blood HPLC 30 7.9 0.4 1.3 2.0 0.0 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0.0	MS/MS PE Neogram MS2 Kit	40	2.0	0.3	0.3	1.9	0.8
HPLC 30 2.9 0.2 0.5 2.0 11 MS/MS Non-Kit 272 2.6 0.3 0.8 1.9 0.0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0.0  Lot 323 - Enriched 3 mg/dL whole blood  HPLC 30 5.0 0.3 0.8 2.0 11 MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0.0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0.0  Lot 324 - Enriched 6 mg/dL whole blood  HPLC 30 7.9 0.4 1.3 2.0 0.0 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0.0	Lat 222 Equiph ad 4 mag/dl whal						
MS/MS Non-Kit 272 2.6 0.3 0.8 1.9 0.0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0.0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0.0 MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.8 2.0 1 MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0.0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0.0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0.0 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0.0 MS/MS Non-Kit 276 0.0 MS/MS Non-Kit 27							
MS/MS PE Neogram MS2 Kit 40 2.5 0.3 0.4 1.9 0  Lot 323 - Enriched 3 mg/dL whole blood  HPLC 30 5.0 0.3 0.8 2.0 1  MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0  MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0  Lot 324 - Enriched 6 mg/dL whole blood  HPLC 30 7.9 0.4 1.3 2.0 0  MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0							1.0
Lot 323 - Enriched 3 mg/dL whole blood  HPLC 30 5.0 0.3 0.8 2.0 1  MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0  MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0  Lot 324 - Enriched 6 mg/dL whole blood  HPLC 30 7.9 0.4 1.3 2.0 0  MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0							0.8 0.8
HPLC 30 5.0 0.3 0.8 2.0 1 MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0  Lot 324 - Enriched 6 mg/dL whole blood  HPLC 30 7.9 0.4 1.3 2.0 0 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0							
MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0.5 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0.5	Lot 323 - Enriched 3 mg/dL whol	e blood					
MS/MS Non-Kit 272 4.2 0.5 1.2 1.9 0.5 MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0.5 0.7 1.9 0.4 1.3 2.0 0.5 MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0.5 0.7 1.9 0.4 0.5 0.7 0.7 0.9 0.4 0.7 0.9 0.9 0.9 0.9 0.9 0.9 0.9 0.9 0.9 0.9	HPLC	30	5.0	0.3	0.8	2.0	1.0
MS/MS PE Neogram MS2 Kit 40 4.4 0.5 0.7 1.9 0  Lot 324 - Enriched 6 mg/dL whole blood  HPLC 30 7.9 0.4 1.3 2.0 0  MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0.9							0.8
Lot 324 - Enriched 6 mg/dL whole blood         HPLC       30       7.9       0.4       1.3       2.0       0.0         MS/MS Non-Kit       276       6.6       0.7       1.9       1.9       0.0			4.4				0.8
HPLC         30         7.9         0.4         1.3         2.0         0           MS/MS Non-Kit         276         6.6         0.7         1.9         1.9         0		e blood					
MS/MS Non-Kit 276 6.6 0.7 1.9 1.9 0			7.0	0.4	1 2	2 0	0.8
							0.8
MS/MS PE Negaram MS2 Kit 30 66 08 10 10 10	MS/MS PE Neogram MS2 Kit	39	6.6	0.8	1.9	1.9	0.8

<sup>\*</sup>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 325 - Nonenriched 0 mg/dL v	vhole blo	nd				
HPLC	29	2.3	0.2	0.6	2.4	1.0
MS/MS Non-Kit	305	2.0	0.2	0.5	2.0	0.7
MS/MS PE Neogram MS2 Kit	48	2.0	0.2	0.3	2.0	0.8
Lot 326 - Enriched 1 mg/dL whol	e blood					
HPLC	30	3.5	0.2	0.6	2.4	1.0
MS/MS Non-Kit	303	2.8	0.3	0.7	2.0	0.7
MS/MS PE Neogram MS2 Kit	49	2.8	0.3	0.5	2.0	0.8
Lot 327 - Enriched 3 mg/dL whol	e blood					
HPLC	30	5.3	0.3	0.9	2.4	1.0
MS/MS Non-Kit	300	4.1	0.5	1.0	2.0	0.7
MS/MS PE Neogram MS2 Kit	50	4.4	0.5	0.9	2.0	0.8
Lot 328 - Enriched 6 mg/dL whol	e blood					
HPLC	30	8.2	0.7	1.6	2.4	1.0
MS/MS Non-Kit	300	6.5	0.7	1.5	2.0	0.7
MS/MS PE Neogram MS2 Kit	49	6.5	0.8	1.4	2.0	0.8

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

#### 2004 Quality Control Data Summaries of Statistical Analyses

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

Lot 321 - Nonenriched 0 mg/dL w MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	rhole bloo 257 40	0.4 0.5	0.1 0.0	0.3	0.5	
MS/MS Non-Kit	257	0.4			0.5	
					0 -	
MS/MS PE Neogram MS2 Kit	40	0.5	()()	0.4	0.5	0.8
			0.0	0.1	0.5	0.9
Lot 322 - Enriched 0.5 mg/dL who	ole blood 257	0.8	0.3	0.5	0.5	0.8
MS/MS PE Neogram MS2 Kit	40	1.0	0.1	0.2	0.5	0.9
Lot 323 - Enriched 1 mg/dL whole						
MS/MS Non-Kit	259	1.3	0.4	0.8	0.5	0.8
MS/MS PE Neogram MS2 Kit  Lot 324 - Enriched 2.5 mg/dL who	40	1.5	0.2	0.2	0.5	0.9
<del>_</del>			0.5	4.0	0.5	0.0
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	256	2.4 2.8	0.5 0.2	1.3 0.5	0.5 0.5	0.8 0.9

<sup>\*</sup>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 -

MS/MS PE Neogram MS2 Kit  Lot 326 - Enriched 0.5 mg/dL whole  MS/MS Non-Kit 2  MS/MS PE Neogram MS2 Kit  Lot 327 - Enriched 1 mg/dL whole black  MS/MS Non-Kit 2	90 0.5 50 0.6	0.1 0.0 0.2 0.1	0.4 0.1 0.6 0.2	0.5 0.6 0.5 0.6	0.8 1.0 0.8 1.0
MS/MS Non-Kit 2 MS/MS PE Neogram MS2 Kit  Lot 326 - Enriched 0.5 mg/dL whole MS/MS Non-Kit 2 MS/MS PE Neogram MS2 Kit  Lot 327 - Enriched 1 mg/dL whole black MS/MS Non-Kit 2	90 0.5 50 0.6 blood 89 0.9	0.0	0.1	0.6	0.8
MS/MS PE Neogram MS2 Kit  Lot 326 - Enriched 0.5 mg/dL whole  MS/MS Non-Kit 2  MS/MS PE Neogram MS2 Kit  Lot 327 - Enriched 1 mg/dL whole black to the second secon	50 0.6 blood 89 0.9	0.0	0.1	0.6	0.8
MS/MS Non-Kit 2 MS/MS PE Neogram MS2 Kit  Lot 327 - Enriched 1 mg/dL whole black MS/MS Non-Kit 2	89 0.9				
MS/MS Non-Kit 2 MS/MS PE Neogram MS2 Kit  Lot 327 - Enriched 1 mg/dL whole black MS/MS Non-Kit 2	89 0.9				
MS/MS PE Neogram MS2 Kit  Lot 327 - Enriched 1 mg/dL whole blue MS/MS Non-Kit 2					
_ot 327 - Enriched 1 mg/dL whole bl MS/MS Non-Kit 2	50 1.1	0.1	0.2	0.6	1.0
	ood				
MS/MS PE Neogram MS2 Kit	39 1.3	0.4	1.0	0.5	0.8
	49 1.6	0.1	0.2	0.6	1.0
Lot 328 - Enriched 2.5 mg/dL whole	blood				
	90 2.5	0.5	1.8	0.5	0.8
MS/MS PE Neogram MS2 Kit	ชบ 2.ถ	0.5	0.5	0.5	1.0

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

### 2004 Quality Control Data Summaries of Statistical Analyses

#### $\boldsymbol{ACETYLCARNITINE} \; (\mu mol \; C2/L \; whole \; blood)$

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
					<u> </u>	
Lot 361 - Nonenriched 0 μmol/L	whole blo	od				
MS/MS Non-Kit	351	12.07	2.82	5.21	11.72	1.13
MS/MS PE Neogram MS2 Kit	50	13.79	1.75	5.22	13.60	0.83
Lot 362 - Enriched 5 μmol/L who	le blood					
MS/MS Non-Kit	351	16.94	3.07	5.98	11.72	1.13
MS/MS PE Neogram MS2 Kit	50	17.38	1.68	4.56	13.60	0.83
Lot 363 - Enriched 10 μmol/L wh	ole blood					
Non-Kit MS/MS Non-KIt	354	22.95	3.73	7.09	11.72	1.13
MS/MS PE Neogram MS2 Kit	50	22.01	2.86	4.32	13.60	0.83
Lot 364 - Enriched 20 μmol/L wh	ole blood	l .				
MS/MS Non-Kit	360	34.44	5.13	9.63	11.72	1.13
MS/MS PE Neogram MS2 Kit	50	30.12	2.78	5.77	13.60	0.83

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

### $\boldsymbol{ACETYLCARNITINE} \; (\mu mol \; C2/L \; whole \; blood)$

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
					·	
Lot 365 - Nonenriched 0 μmol/L						
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	400 50	22.67 21.13	3.04 3.14	7.48 4.04	23.12 21.56	0.84 0.71
Lot 366 - Enriched 5 μmol/L who						
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	392 50	27.31 25.25	3.43 3.58	8.63 4.39	23.12 21.56	0.84 0.71
Lot 367 - Enriched 10 μmol/L wh	ole blood	ı				
MS/MS Non-Kit	395	32.51	4.33	9.00	23.12	0.84
MS/MS PE Neogram MS2 Kit	49	29.31	2.57	5.24	21.56	0.71
Lot 368 - Enriched 20 μmol/L wh	ole blood	1				
MS/MS Non-Kit	391	39.50	4.98	11.55	23.12	0.84
MS/MS PE Neogram MS2 Kit	50	35.38	3.57	7.78	21.56	0.71

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

#### 2004 Quality Control Data Summaries of Statistical Analyses

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

			Average			
Method	N	Mean	Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 361 - Nonenriched 0 μmol/L	whole blo	od				
MS/MS Non-Kit	379	0.80	0.16	0.23	0.65	1.14
MS/MS PE Neogram MS2 Kit	49	0.79	0.08	0.10	0.55	1.13
Lat 200 Farished 2 was all who	له ماط ما					
Lot 362 - Enriched 3 μmol/L who MS/MS Non-Kit	380	3.89	0.58	0.84	0.65	1.14
MS/MS PE Neogram MS2 Kit	50	3.69	0.33	0.64	0.65	1.14
Lot 363 - Enriched 7.5 μmol/L wl	nole blood	d				
MS/MS Non-Kit	395	9.14	1.50	2.08	0.65	1.14
MS/MS PE Neogram MS2 Kit	49	8.91	0.88	1.14	0.55	1.13
Lot 364 - Enriched 12 μmol/L wh	ole blood					
MS/MS Non-Kit	390	14.38	2.23	3.02	0.65	1.14
MS/MS PE Neogram MS2 Kit	49	14.30	1.36	1.86	0.55	1.13

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

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

- continued -

vhole blo 439 49	nod 1.64 1.55	0.34 0.19	0.42 0.28	1.77 1.66	1.16 1.17
439	1.64				
·		****			
e blood					
	5.31	0.68	0.99	1 77	1.16
50		0.47			1.17
ole bloo	1				
		2 73	3 37	1 77	1.16
49					1.17
ole blood					
		2.57	2.62	1 77	1.16
434			1.86	1.77	1.16
	ole blood 424 49 ble blood 434	ole blood  424 10.64 49 10.52  ble blood  434 15.50	ole blood  424	ole blood       424     10.64     2.73     3.37       49     10.52     0.95     1.33         ole blood       434     15.50     2.57     3.62	50     5.23     0.47     0.58     1.66       ole blood       424     10.64     2.73     3.37     1.77       49     10.52     0.95     1.33     1.66       ole blood       434     15.50     2.57     3.62     1.77

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

#### 2004 Quality Control Data Summaries of Statistical Analyses

#### BUTYRYLCARNITINE (µmol C4/L whole blood)

			Average Within	Total SD	Y-	Clama
Method	N	Mean	Lab SD	- Iotal 3D	Intercept*	Slope
Lot 361 - Nonenriched 0 μmol/L	whole blo	od				
MS/MS Non-Kit	399	0.16	0.11	0.17	0.08	1.02
MS/MS PE Neogram MS2 Kit	50	0.15	0.03	0.05	0.04	1.04
Lot 362 - Enriched 1 μmol/L who	le blood					
MS/MS Non-Kit	392	0.98	0.19	0.35	0.08	1.02
MS/MS PE Neogram MS2 Kit	50	0.96	0.12	0.17	0.04	1.04
Lot 363 - Enriched 2.5 μmol/L wh	nole blood	k				
MS/MS Non-Kit	399	2.67	1.56	1.72	0.08	1.02
MS/MS PE Neogram MS2 Kit	49	2.60	0.44	0.63	0.04	1.04
Lot 364 - Enriched 5 μmol/L who	le blood					
MS/MS Non-Kit	385	5.19	0.66	1.40	0.08	1.02
MS/MS PE Neogram MS2 Kit	54	5.28	0.67	0.87	0.04	1.04

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

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

			Average			
Method	N	Mean	Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 365 - Nonenriched 0 μmol/L v	whole blo	od				
MS/MS Non-Kit	424	0.23	0.12	0.19	0.29	0.93
MS/MS PE Neogram MS2 Kit	49	0.24	0.07	0.07	0.32	0.91
Lot 366 - Enriched 1 μmol/L whol		4.04	0.00	2.27		0.00
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	438 49	1.24 1.19	0.22 0.17	0.37 0.19	0.29 0.32	0.93 0.91
Lot 367 - Enriched 2.5 μmol/L wh	ole blood	I				
MS/MS Non-Kit	439	2.67	0.43	0.79	0.29	0.93
•			0.43 0.40	0.79 0.48	0.29 0.32	0.93 0.91
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	439 50	2.67				
	439 50	2.67				

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

#### 2004 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
						<u> </u>
Lot 361 - Nonenriched 0 μmol/L ν	whole blo	od				
MS/MS Non-Kit	392	0.12	0.05	0.14	0.09	1.00
MS/MS PE Neogram MS2 Kit	50	0.15	0.05	0.09	0.12	0.97
Lot 362 - Enriched 0.5 μmol/L wh	ole blood	l				
MS/MS Non-Kit	379	0.57	0.12	0.24	0.09	1.00
MS/MS PE Neogram MS2 Kit	48	0.56	0.12	0.17	0.12	0.97
_ot 363 - Enriched 1.5 μmol/L wh	ole blood	I				
MS/MS Non-Kit	404	1.57	0.27	0.53	0.09	1.00
MS/MS PE Neogram MS2 Kit	50	1.58	0.25	0.27	0.12	0.97
_ot 364 - Enriched 3 μmol/L whol	e blood					
MS/MS Non-Kit	396	3.12	0.41	0.91	0.09	1.00
MS/MS PE Neogram MS2 Kit	46	3.12	0.46	0.57	0.09	0.97
Monto i L Noogiam Moz Mit	70	0.00	0.70	0.01	0.12	0.01

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

#### ISOVALERYLCARNITINE (µmol C5/L whole blood)

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 365 - Nonenriched 0 μmol/L	whole blo	od				
Non-Kit MS/MS Non-Klt	442	0.17	0.29	0.33	0.18	1.05
MS/MS PE Neogram MS2 Kit	50	0.17	0.29	0.33	0.18	1.03
at 2000. Enrished O.E. was all with	aala bissa					
Lot 366 - Enriched 0.5 μmol/L wh						
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	438 49	0.70 0.71	0.12 0.13	0.22 0.13	0.18 0.19	1.05 1.03
Lot 367 - Enriched 1.5 μmol/L wh	nole blood	Ŀ				
MS/MS Non-Kit	426	1.76	0.31	0.55	0.18	1.05
MS/MS PE Neogram MS2 Kit	50	1.76	0.39	0.41	0.19	1.03
_ot 368 - Enriched 3 μmol/L who	le blood					
MS/MS Non-Kit	432	3.32	0.47	0.92	0.18	1.05
MS/MS PE Neogram MS2 Kit	50	3.28	0.49	0.59	0.19	1.03

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

#### 2004 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
Let 204 New confet and Oursell Let	ماما ماماد	I				
Lot 361 - Nonenriched 0 μmol/L MS/MS Non-Kit	384	0.04	0.06	0.09	0.01	0.91
MS/MS PE Neogram MS2 Kit	49	0.13	0.06	0.27	0.09	0.86
Lot 362 - Enriched 0.5 μmol/L wh	nole blood	d				
MS/MS Non-Kit	380	0.44	0.10	0.16	0.01	0.91
MS/MS PE Neogram MS2 Kit	49	0.50	0.11	0.18	0.09	0.86
Lot 363 - Enriched 1 μmol/L who						
MS/MS Non-Kit	383	0.91	0.14	0.28	0.01	0.91
MS/MS PE Neogram MS2 Kit	49	0.92	0.29	0.32	0.09	0.86
Lot 364 - Enriched 2.5 μmol/L wh	nole blood	d				
MS/MS Non-Kit	391	2.29	0.31	0.56	0.01	0.91
MS/MS PE Neogram MS2 Kit	47	2.26	0.43	0.51	0.09	0.86

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

### $\boldsymbol{HEXANOYLCARNITINE} \; (\mu mol \; C6/L \; whole \; blood)$

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lat 005 New York at 0 and 10					•	
Lot 365 - Nonenriched 0 μmol/L v MS/MS Non-Kit	whole blo 423	0.06	0.13	0.15	0.06	0.89
MS/MS PE Neogram MS2 Kit	423	0.06	0.13	0.13	0.12	0.89
_ot 366 - Enriched 0.5 μmol/L wh	nole bloor	4				
MS/MS Non-Kit	419	0.51	0.12	0.17	0.06	0.89
MS/MS PE Neogram MS2 Kit	48	0.49	0.09	0.18	0.12	0.81
_ot 367 - Enriched 1 μmol/L who	le blood					
			0.40		0.00	
MS/MS Non-Kit	416	0.95	0.19	0.31	0.06	0.89
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	416 49	0.95 0.93	0.19 0.14	0.31 0.23	0.06	0.89 0.81
MS/MS PE Neogram MS2 Kit	49	0.93				
	49	0.93				

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

#### 2004 Quality Control Data Summaries of Statistical Analyses

## $\boldsymbol{OCTANOYLCARNITINE} \; (\mu mol \; C8/L \; whole \; blood)$

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 361 - Nonenriched 0 μmol/L	whole blo	od				
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	399 65	0.05 0.05	0.04 0.04	0.06 0.06	0.02 0.01	1.03 1.00
Lot 362 - Enriched 0.5 μmol/L wl	nole blood	d				
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	400 65	0.49 0.44	0.09 0.11	0.12 0.14	0.02 0.01	1.03 1.00
			·	·		
Lot 363 - Enriched 1 μmol/L who	le blood					
Non-Kit MS/MS Non-Klt MS/MS PE Neogram MS2 Kit	398 63	1.04 1.05	0.23 0.25	0.31 0.29	0.02 0.01	1.03 1.00
MIS/MIS PE Neogram MISZ KII	63	1.05	0.25	0.29	0.01	1.00
Lot 364 - Enriched 2.5 μmol/L wl	nole blood	d				
MS/MS Non-Kit	396	2.59	0.29	0.45	0.02	1.03
MS/MS PE Neogram MS2 Kit	66	2.52	0.44	0.51	0.01	1.00

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

### $\boldsymbol{OCTANOYLCARNITINE} \; (\mu mol \; C8/L \; whole \; blood)$

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
_ot 365 - Nonenriched 0 μmol/L v	whole blo	od				
MS/MS Non-Kit	439	0.07	0.05	0.06	0.07	1.10
MS/MS PE Neogram MS2 Kit	59	0.07	0.04	0.05	0.08	0.97
_ot 366 - Enriched 0.5 μmol/L wh	nole blood	d				
MS/MS Non-Kit	441	0.63	0.11	0.14	0.07	1.10
MS/MS PE Neogram MS2 Kit	58	0.60	0.11	0.14	0.08	0.97
umol/L Lot 367 - Enriched 1 μmo	I/L whole	blood				
MS/MS Non-Kit	446	1.16	0.20	0.25	0.07	1.10
umol/L Lot 367 - Enriched 1 μmo MS/MS Non-Kit MS/MS PE Neogram MS2 Kit			0.20 0.17	0.25 0.19	0.07 0.08	1.10 0.97
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	446 59	1.16 1.04				
MS/MS Non-Kit	446 59	1.16 1.04				

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

### 2004 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 blo	od				
MS/MS Non-Kit	390	0.08	0.07	0.09	0.05	0.98
MS/MS PE Neogram MS2 Kit	50	0.08	0.03	0.04	0.04	0.85
Lot 362 - Enriched 0.5 μmol/L wh	nole blood	i				
MS/MS Non-Kit	391	0.53	0.13	0.19	0.05	0.98
MS/MS PE Neogram MS2 Kit	49	0.46	0.07	0.10	0.04	0.85
Lot 363 - Enriched 1.5 μmol/L wh	nole blood	ı				
MS/MS Non-Kit	408	1.47	0.32	0.52	0.05	0.98
MS/MS PE Neogram MS2 Kit	48	1.28	0.19	0.23	0.04	0.85
_ot 364 - Enriched 3.0 μmol/L wh	nole blood	I				
MS/MS Non-Kit	415	3.00	0.50	0.87	0.05	0.98
MS/MS PE Neogram MS2 Kit	50	2.62	0.33	0.43	0.04	0.85

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

## $\boldsymbol{MYRISTOYLCARNITINE} \; (\mu mol \; C14/L \; whole \; blood)$

- continued -

			Average Within		Y-		
Method	N	Mean	Lab SD	Total SD	Intercept*	Slope	
_ot 365 - Nonenriched 0 μmol/L \	whole blo	od					
MS/MS Non-Kit	438	0.15	0.23	0.25	0.14	0.98	
MS/MS PE Neogram MS2 Kit	49	0.11	0.06	0.07	0.12	0.85	
_ot 366 - Enriched 0.5 μmol/L wh	ole blood	d					
Non-Kit MS/MS Non-KIt	432	0.60	0.19	0.25	0.14	0.98	
MS/MS PE Neogram MS2 Kit	50	0.51	0.10	0.11	0.12	0.85	
_ot 367 - Enriched 1.5 μmol/L wh	ole blood	d					
MS/MS Non-Kit	406	1.63	0.30	0.49	0.14	0.98	
MS/MS PE Neogram MS2 Kit	50	1.46	0.21	0.28	0.12	0.85	
_ot 368 - Enriched 3.0 μmol/L wh	ole blood	d					
MS/MS Non-Kit	406	3.06	0.49	0.81	0.14	0.98	
MS/MS PE Neogram MS2 Kit	49	2.63	0.32	0.39	0.12	0.85	

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

#### 2004 Quality Control Data Summaries of Statistical Analyses

## $\label{eq:palmitoylcarnitine} \textbf{PALMITOYLCARNITINE} \; (\mu\text{mol C16/L whole blood})$

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 361 - Nonenriched 0 μmol/L	whole blo	od				
MS/MS Non-Kit	396	0.63	0.15	0.27	0.43	0.91
MS/MS PE Neogram MS2 Kit	49	0.66	0.10	0.13	0.39	0.93
Lot 362 - Enriched 4 μmol/L who						
MS/MS Non-Kit MS/MS PE Neogram MS2 Kit	390 49	3.84 3.62	0.53 0.56	1.10 0.70	0.43 0.39	0.91 0.93
Lot 363 - Enriched 8 μmol/L who	le blood					
MS/MS Non-Kit	390	7.59	0.96	2.23	0.43	0.91
MS/MS PE Neogram MS2 Kit	50	7.98	0.98	1.64	0.39	0.93
Lot 364 - Enriched 12 μmol/L wh	ole blood					
MS/MS Non-Kit	394	11.54	1.40	3.36	0.43	0.91

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

### $\label{eq:palmitoylcarnitine} \textbf{PALMITOYLCARNITINE} \; (\mu mol \; C16/L \; whole \; blood)$

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Wethou	IN .	IVICALI	Lab OD		intercept	Оюрс
Lot 365 - Nonenriched 0 μmol/L v	whole blo	od				
MS/MS Non-Kit	430	1.16	0.35	0.49	1.13	0.93
MS/MS PE Neogram MS2 Kit	49	1.08	0.17	0.24	1.03	0.91
Lot 366 - Enriched 4 μmol/L who	le blood					
MS/MS Non-Kit	432	4.80	0.56	1.24	1.13	0.93
MS/MS PE Neogram MS2 Kit	49	4.63	0.66	0.92	1.03	0.91
Lot 367 - Enriched 8 μmol/L who						
MS/MS Non-Kit	435	8.50	1.11	2.39	1.13	0.93
MS/MS PE Neogram MS2 Kit	49	8.33	1.07	1.61	1.03	0.91
Lot 368 - Enriched 12 μmol/L wh	ole blood					
MS/MS Non-Kit	434	12.27	1.54	3.09	1.13	0.93
MS/MS PE Neogram MS2 Kit	47	12.04	1.28	1.95	1.03	0.91

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

#### 2004 Quality Control Data Summaries of Statistical Analyses

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

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope		
					<del>-</del>			
Lot 365 - CDC Assayed 0.07 μmol/L whole blood								
MS/MS Non-Kit	396	0.04	0.04	0.05	-0.04	1.08		
MS/MS PE Neogram MS2 Kit	30	0.04	0.02	0.02	-0.06	1.34		
_ot 366 - CDC Assayed 0.16 μm	ol/L whol	e blood						
MS/MS Non-Kit	389	0.13	0.05	0.07	-0.04	1.08		
MS/MS PE Neogram MS2 Kit	30	0.15	0.04	0.04	-0.06	1.34		
Lot 367 - CDC Assayed 0.25 μm	ol/L whol	e blood						
MS/MS Non-Kit	384	0.23	0.06	0.10	-0.04	1.08		
MS/MS PE Neogram MS2 Kit	30	0.28	0.04	0.06	-0.06	1.34		
_ot 368 - CDC Assayed 0.41 μm	ol/L whol	e blood						
MS/MS Non-Kit	369	0.40	0.12	0.19	-0.04	1.08		
MS/MS PE Neogram MS2 Kit	309	0.40	0.12	0.19	-0.04	1.34		
	30	0.00	0.00	<b>U.11</b>	0.00			

Note the calculation of concentrations for specimens varied for both kit and *non-kit users* with type of internal standard. Most non-kit users calculated concentrations using the D3/C8 internal standard. The *kit users* calculated with D3/C12, D3/C10, D9/C5, or D6/C5DC internal standard (see text). Data are not sorted by internal standard type.

<sup>\*</sup>Estimated by performing a weighted linear regression analysis of mean reported concentrations versus CDC assayed concentrations and extrapolating the regression to the Y-axis.

#### 2004 Quality Control Data Summaries of Statistical Analyses

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

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope		
						•		
Lot 365 - Nonenriched 0 μmol/L whole blood								
MS/MS Non-Kit	441	0.08	1.48	1.48	0.09	1.20		
MS/MS PE Neogram MS2 Kit	59	0.06	0.03	0.05	0.09	0.96		
World I L Neogram Woz Kit	33	0.00	0.00	0.00	0.00	0.50		
Lot 366 - Enriched 0.25 μmol/L whole blood								
MS/MS Non-Kit	426	0.39	0.09	0.13	0.09	1.20		
MS/MS PE Neogram MS2 Kit	59	0.33	0.10	0.12	0.08	0.96		
		•						
_ot 367 - Enriched 0.75 μmol/L w	thole bloc	od						
MS/MS Non-Kit	415	1.01	0.22	0.34	0.09	1.20		
MS/MS PE Neogram MS2 Kit	60	0.84	0.16	0.24	0.08	0.96		
Lot 368 - Enriched 1.5 μmol/L whole blood								
MS/MS Non-Kit	422	1.88	0.38	0.64	0.09	1.20		
MS/MS PE Neogram MS2 Kit	59	1.51	0.26	0.39	0.08	0.96		
WO/WO I L Neogram Woz Kit	33	1.01	0.20	0.00	0.00	0.90		

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