Newborn Screening Quality Assurance Program 2018 Quality Control Report

In co-sponsorship with Association of Public Health Laboratories (APHL) Provided by the Newborn Screening and Molecular Biology Branch Centers for Disease Control and Prevention 4770 Buford Highway NE, MS/F19 Atlanta, GA 30341-3724 Email: <u>NSQAPDMT@cdc.gov</u>

Quality Control Report for QC Set 2 – Issued November 5, 2018 Volume 29, No. 2

Report Authorization

This report has been reviewed and authorized by Dr. Joanne Mei, Laboratory Chief, Newborn Screening Quality Assurance Program.

Introduction

The Newborn Screening Quality Assurance Program (NSQAP) Quality Control (QC) dried blood spot materials provide participants with external controls to assess method performance over time. The controls provide continuity and transcend changes in production lots of routinely used method- or kit-control materials. The external QC materials are intended to supplement the participants' method- or kit-control materials at periodic intervals to allow participants to monitor the long-term stability of their assays. NSQAP QC material is not a replacement for manufacturer kit controls or other daily QC, and should not be used for routine analysis. This report contains a summary of the 2018 Set 2 QC data submitted during the second half of the year by state, contract, and private laboratories in the United States; international participants; and manufacturers of screening test products.

QC Material Production

QC specimen lots were provided as 6-month supplies of DBS on filter paper. DBS QC lots were prepared from lysed whole blood of 50% hematocrit. The materials were enriched with predetermined quantities of selected analytes and dispensed in 100 µL aliquots on Grade 903 filter paper (GE Healthcare Bio-Sciences Corporation (Westborough, MA)).

NSQAP provides QC materials for analysis of thyroxine (T₄), thyroid-stimulating hormone (TSH), 17 α hydroxyprogesterone (17OHP), total galactose (TGal), galactose-1-phosphate uridyltransferase (GALT), immunoreactive trypsinogen (IRT), phenylalanine (Phe), leucine (Leu), methionine (Met), tyrosine (Tyr), valine (Val), citrulline (Cit), alanine (Ala), arginine (Arg), ornithine (Orn), glycine (Gly), succinylacetone (SUAC), free carnitine (C0), acetylcarnitine (C2), propionylcarnitine (C3), malonylcarnitine (C3DC), butyrylcarnitine (C4), hydroxybutyrylcarnitine (C4OH), isovalerylcarnitine (C5), glutarylcarnitine (C5DC), hydroxyisovalerylcarnitine (C5OH), hexanoylcarnitine (C6), octanoylcarnitine (C8), decanoylcarnitine (C10), dodecanoylcarnitine (C12), myristoylcarnitine (C14), palmitoylcarnitine (C16), hydroxypalmitoylcarnitine (C16OH), stearoylcarnitine (C18), hydroxystearoylcarnitine (C18OH), 20:0-, 22:0-, 24:0and 26:0-lysophosphatidylcholine for the detection of X-linked adrenoleukodystrophy (XALD) and galactocerebrosidase (GALC), acid α -glucosidase (GAA), α -L-iduronidase (IDUA), α -galactosidase (GLA), β -glucocerebrosidase (ABG), and acid sphingomyelinase (ASM) for the detection of lysosomal storage disorder (LSD). T4, TSH, 17OHP and TGal, GALT and XALD consisted of blood spot materials from three lots per analyte, with each lot containing a different concentration of analyte. The shipment for IRT, TGal, amino acids, SUAC, acylcarnitines, and LSD consisted of blood spot cards from four lots.

NSQAP also distributed certified QC materials for newborn screening analytes and disorders designed for second-tier testing by tandem mass spectrometry (MS/MS). These programs include second-tier congenital adrenal hyperplasia

QC Material Production (cont.)

(CAHQC) by LC-MS/MS for the analytes 17 α-hydroxyprogesterone (17OHP2), 4-androstenedione (4AD2), cortisol (CORT2), 11-deoxycortisol (11D2), and 21-deoxycortisol (21D2); second-tier maple syrup urine disease and phenylketonuria (MSUD-PKUQC) by LC-MS/MS for the analytes alloisoleucine (ALE2), isoleucine (ILE2), leucine (LEU2), phenylalanine (PHE2), tyrosine (TYR2), and valine (VAL2); second-tier methylmalonic/propionic acidemia and homocystinuria (MMA-tHCY) by LC-MS/MS for the analytes malonic acid (MA2), methylmalonic acid (MMA2), ethylmalonic acid (EMA2), 2-methylcitric acid (MCA2), and total homocysteine (tHCY2); and guanidinoacetate methyltransferase (GAMT) by FIA-MS/MS for the analytes guanidinoacetic acid (GAA2), and creatine (CRE2).

QC Material Distribution

On July 10, 2018 we distributed dried blood spot (DBS) QC materials to 524 participanting laboratories.

QC Data Reporting Requirements

Participants used the QC Data Report forms located at <u>https://www.cdc.gov/labstandards/nsqap_resources.html</u> to report results. NSQAP required the following information for each QC analyte; 1) laboratory information (contact name, laboratory code number, email address, 2) analyte kit or method, 3) results of duplicate sample analysis from five independent runs in the analytic units and decimal places requested, and 4) at least nine data points for each lot of analyte. If these minimum requirements were not met, the data was not accepted.

Participant Results

For this Set 2 QC materials, we compiled the participant results from five analytic runs from each QC lot, and calculated mean values and standard deviations (SD). Data values outside 4SD limits were reviewed, and if considered to be "blunders", removed from the data set. For linear regression analysis, we excluded qualitative data, data submitted as inequalities or ranges, data submitted in unidentified units, or data from less than five analytic runs per specimen lot per analyte.

To ensure that all results are appropriately entered in the CDC database, participants must convert their results to the requested units before entering them on the data report forms. For GALT analysis, where no conversion factor exists between methods using units of U/g Hb and other reportable units, we included a separate table to provide participants with peer-group method statistics. For LSD analysis, where mean activities differ based on method, we provided separate tables if sufficient data was submitted.

The reported QC data are summarized in tables on pages **4—90** 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 (aggregated) versus enriched concentrations. Methods with less than three participants reporting data were not included in the tables.

Discussion

The enriched values of the QC specimen lots do not take into account the endogenous levels of the analytes. For Phe, Leu, Met, Tyr, Val, Cit, Ala, Arg, Orn,Gly, SUAC, acylcarnitines, 20:0-, 22:0-, 24:0- and 26:0lysophosphatidylcholine,GALC,GAA, IDUA, GAL, ABG, ASM, and all Second-tier analytes, the non-enriched base pools were distributed as the first QC specimen lot in each series so that participants could measure the endogenous concentration of the series.

Summary tables show data sorted by method, method-related differences in analytic recoveries and method bias. Because we prepared each QC lot series from a single batch of hematocrit-adjusted, non-enriched blood, the endogenous concentration was the same for all specimens across the lot series and 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. A method with no analytical bias will have a slope of 1.0, with an acceptable range from 0.8 to 1.2.

Calculations of concentrations for the QC lots may vary with type of MS/MS internal standard used. Data are not sorted by internal standard type. QC materials are provided as sets of three to five analyte concentrations. A bias error in any one pool can influence the slope and intercept for a method.

Discussion (cont.)

For our assessment, we first calculated the within-laboratory SD component of the total SD and used the reported QC data from multiple analytic runs for regression analyses. We then calculated the Y-intercept and slope listed in each table using all analyte concentrations within a lot series (e.g., lots A1801, B1801, and C1801). The Y-intercept is estimated by performing a weighted linear regression analysis on mean reported concentrations versus either 1) enriched concentrations, 2) assayed values (GALT, IRT), or 3) mean activity (LSD), and extrapolating the regression to the Y-axis. This parameter provides one measure of the endogenous concentration level for an analyte. For Phe, Leu, Met, Tyr, Val, Cit, Ala, Arg, Orn, Gly, SUAC, acylcarnitines, 20:0-, 22:0-, 24:0-, and 26:0-lysophosphatidylcholine, GALC,GAA, IDUA, GAL, ABG, ASM, and all Second-tier analytes, participants measured the endogenous concentration or activity levels by analyzing the non-enriched QC lots.

We found the majority of analytes as demonstrating acceptable performance, with slopes falling near or within the range of acceptability (range from 0.8 to 1.2). Analytes which demonstrated low slopes included Orn, SUAC, C3DC + C4OH, C4OH, and C18OH, but were historically consistent with previous sets.

Submit changes in QC enrollment using the correct form at:

<u>https://www.cdc.gov/labstandards/nsqap_resources.html</u> Send forms to <u>NSQAPDMT@cdc.gov</u> and observe deadlines for enrollment. Include your laboratory code number on the form and on all correspondence with NSQAP.

2018 Quality Control Data Summaries of Statistical Analyses 17 α-HYDROXYPROGESTERONE (170HP ng/mL serum)

Lot A1705 – Enriched 25 ng/mL serum

			Average	Tatal	V	
METHOD	Ν	Mean	Lab SD	SD	۲- Intercept	Slope
Delfia	209	21.9	3.4	7.9	-2.3	0.9
AutoDelfia	280	21.1	2.1	2.8	1.0	0.8
Labsystems Diagnostics	40	20.4	1.6	5.8	2.7	0.8
Bio-Rad Quantase	40	34.0	4.1	10.0	-1.2	1.4
TecnoSuma UMELISA	40	39.4	7.5	13.7	1.5	1.5
Delfia Neonatal 17-OHP (A024)	180	20.8	2.7	4.6	1.2	0.8
AutoDelfia Neonatal 17-OHP (B024)	340	22.2	2.5	4.2	0.9	0.9
PerkinElmer GSP Neonatal	543	22.4	2.0	3.3	2.1	0.8
Zentech	60	23.9	2.9	3.9	1.3	0.9

Lot B1705 – Enriched 50 ng/mL serum

			Average	Total	V	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Delfia	208	43.7	6.2	17.5	-2.3	0.9
AutoDelfia	280	42.4	3.9	5.3	1.0	0.8
Labsystems Diagnostics	40	41.4	2.8	13.7	2.7	0.8
Bio-Rad Quantase	40	63.8	13.3	18.1	-1.2	1.4
TecnoSuma UMELISA	40	75.9	13.1	29.1	1.5	1.5
Delfia Neonatal 17-OHP (A024)	180	41.6	5.1	8.5	1.2	0.8
AutoDelfia Neonatal 17-OHP (B024)	340	43.4	3.9	7.8	0.9	0.9
PerkinElmer GSP Neonatal	545	43.0	3.4	5.8	2.1	0.8
Zentech	60	46.9	3.6	10.0	1.3	0.9
Delfia	208	43.7	6.2	17.5	-2.3	0.9

Lot C1705 – Enriched 100 ng/mL serum

			Average	Total	V	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Delfia	210	92.0	13.3	36.1	-2.3	0.9
AutoDelfia	280	82.6	7.2	10.2	1.0	0.8
Labsystems Diagnostics	40	76.8	5.4	22.4	2.7	0.8
Bio-Rad Quantase	40	134.2	21.9	45.5	-1.2	1.4
TecnoSuma UMELISA	40	151.8	19.3	51.0	1.5	1.5
Delfia Neonatal 17-OHP (A024)	180	80.9	9.1	15.3	1.2	0.8
AutoDelfia Neonatal 17-OHP (B024)	339	85.9	9.2	16.0	0.9	0.9
PerkinElmer GSP Neonatal	545	83.7	7.0	11.8	2.1	0.8
Zentech	60	92.0	8.5	17.8	1.3	0.9
Delfia	210	92.0	13.3	36.1	-2.3	0.9

2018 Quality Control Data Summaries of Statistical Analyses THYROXINE (T₄ µg/dL serum)

Lot A1700 – Enriched 2 µg/dL serum

	Average								
			Within	Total	Y-				
METHOD	N	Mean	Lab SD	SD	Intercept	Slope			
Delfia	93	1.8	0.3	0.6	-0.3	1.0			
AutoDelfia	180	1.7	0.4	0.6	-0.5	1.1			
PerkinElmer GSP Neonatal	173	1.8	0.3	0.3	-0.3	1.0			

Lot B1700 – Enriched 7 µg/dL serum

			Average			
			Within	Total	Y-	
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
Delfia	100	6.8	0.7	1.7	-0.3	1.0
AutoDelfia	177	7.0	0.8	2.0	-0.5	1.1
PerkinElmer GSP Neonatal	190	6.7	0.7	0.9	-0.3	1.0

Lot C1700 – Enriched 11 µg/dL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
Delfia	100	11.1	1.2	2.15	-0.3	1.0
AutoDelfia	176	11.5	0.9	3.3	-0.5	1.1
PerkinElmer GSP Neonatal	190	11.2	1.1	1.2	-0.3	1.0

2018 Quality Control Data Summaries of Statistical Analyses THYROID-STIMULATING HORMONE (TSH µIU/mL serum)

Lot A1801 – Enriched 25 µIU/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Delfia	510	26.2	3.0	6.8	-1.8	1.1
In House	40	25.2	2.3	4.7	1.3	1.0
AutoDelfia	830	25.8	2.4	5.3	-3.2	1.1
Labsystems Diagnostics	120	26.1	2.0	11.1	-6.0	1.3
Bio-Rad Quantase	30	30.8	2.5	10.1	1.5	1.2
TecnoSuma UMELISA	40	22.4	2.3	5.6	-2.7	1.0
PerkinElmer GSP Neonatal	688	23.6	2.0	4.3	-6.9	1.2
Zentech	90	21.4	3.2	6.2	-8.3	1.2
Trimaris Neonatal	30	28.3	1.9	3.5	6.0	0.9

Lot B1801 – Enriched 40 µIU/mL serum

			Average	Total	v	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Delfia	508	41.4	4.3	10.2	-1.8	1.1
In House	40	43.4	4.6	6.3	1.3	1.0
AutoDelfia	830	41.4	3.5	8.3	-3.2	1.1
Labsystems Diagnostics	120	44.8	3.3	16.8	-6.0	1.3
Bio-Rad Quantase	30	47.5	4.2	16.5	1.5	1.2
TecnoSuma UMELISA	40	39.0	4.5	10.7	-2.7	1.0
PerkinElmer GSP Neonatal	690	40.2	3.6	7.7	-6.9	1.2
Zentech	90	37.6	4.4	10.1	-8.3	1.2
Trimaris Neonatal	30	42.9	3.5	5.7	6.0	0.9

Lot C1801 – Enriched 80 µIU/mL serum

			Average Within	Total	v .	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Delfia	510	86.3	9.1	21.1	-1.8	1.1
In House	40	81.6	6.9	16.0	1.3	1.0
AutoDelfia	829	87.8	6.9	17.4	-3.2	1.1
Labsystems Diagnostics	120	96.2	6.0	31.6	-6.0	1.3
Bio-Rad Quantase	30	94.4	12.6	35.6	1.5	1.2
TecnoSuma UMELISA	40	79.0	7.9	20.0	-2.7	1.0
PerkinElmer GSP Neonatal	690	89.2	7.6	16.4	-6.9	1.2
Zentech	90	85.2	8.9	17.2	-8.3	1.2
Trimaris Neonatal	30	78.5	4.3	6.8	6.0	0.9

2018 Quality Control Data Summaries of Statistical Analyses GALACTOSE-1-PHOSPHATE URIDYLTRANSFERASE (GALT U/g Hb)

Lot A1803 – Assayed 1.5 U/g Hb

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
PerkinElmer Neonatal Kit	299	1.4	0.3	0.5	0.1	0.8
Astoria-Pacific Neonatal Microplate Reagent Kit U/g Hb	60	0.7	0.1	0.2	-0.4	0.7

Lot B1803 – Assayed 4.6 U/g Hb

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
PerkinElmer Neonatal Kit	306	3.7	0.5	0.6	0.1	0.8
Astoria-Pacific Neonatal Microplate Reagent Kit U/g Hb	60	2.5	0.2	0.6	-0.4	0.7

Lot C1803 – Assayed 10.7 U/g Hb

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
PerkinElmer Neonatal Kit	310	8.9	1.1	1.7	0.1	0.8
Astoria-Pacific Neonatal Microplate Reagent Kit U/g Hb	60	6.8	0.8	1.2	-0.4	0.7

2018 Quality Control Data Summaries of Statistical Analyses

GALACTOSE-1-PHOSPHATE URIDYLTRANSFERASE (cont.) METHODS REPORTED IN UNITS OTHER THAN U/g Hb (≥2 PARTICIPANTS)

Lot A1803

METHOD	N	Mean	Average Within Lab SD	All Lab SD	Min	Max
Astoria-Pacific 50 Hour Reagent Kit (µmol/L blood)	20	9.9	3.3	3.5	2.0	16.0
Perkin Elmer GSP Neonatal (U/dL blood)	145	1.3	0.2	1.5	0.0	10.5

Lot B1803

METHOD	N	Mean	Average Within Lab SD	All Lab SD	Min	Max
Astoria-Pacific 50 Hour Reagent Kit (µmol/L blood)	20	61.9	7.2	12.8	40.0	84.3
Perkin Elmer GSP Neonatal (U/dL blood)	224	3.6	0.4	1.5	1.5	12.1

Lot C1803

			Average Within	All Lab		
METHOD	Ν	Mean	Lab SD	SD	Min	Мах
Astoria-Pacific 50 Hour Reagent Kit (µmol/L blood)	20	211.5	25.3	29.0	160.0	264.3
Perkin Elmer GSP Neonatal (U/dL blood)	230	16.6	1.2	3.7	6.8	30.7

*Outlier data was removed based on the 99% confidence interval

Several laboratories reported their GALT results in either μ mol/L blood or U/dL blood according to their analytic method. NSQAP's certified units for GALT are U/g hemoglobin. Due to the lack of a conversion factor between U/g hemoglobin and μ mol/L blood or U/dL blood, the linear regression parameters cannot be calculated for these units of measure. Basic peer-group statistics are provided to assist in self-assessment.

2018 Quality Control Data Summaries of Statistical Analyses IMMUNOREACTIVE TRYPSINOGEN (IRT ng/mL blood)

Lot A1709 – Assayed 18.3 ng/mL blood

	Average							
			Within	Total	Y-			
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope		
Delfia	228	17.8	2.2	2.8	-0.2	0.9		
AutoDelfia	658	16.9	1.6	2.0	-0.8	0.9		
MP Biomedicals ELISA Assay	40	21.6	2.9	4.1	8.0	1.5		
PerkinElmer GSP Neonatal	418	17.3	1.5	1.7	-2.7	1.0		
Zentech	30	27.6	4.0	5.1	37.9	0.8		
Labsystems - FEIA	40	21.9	2.5	5.0	4.9	0.9		

Lot B1709 – Assayed 63.7 ng/mL blood

		Average				
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Delfia	229	57.0	7.0	10.4	-0.2	0.9
AutoDelfia	669	58.3	4.7	5.7	-0.8	0.9
MP Biomedicals ELISA Assay	40	108.1	18.8	19.1	8.0	1.5
PerkinElmer GSP Neonatal	440	60.1	4.4	5.2	-2.7	1.0
Zentech	30	108.8	13.1	13.1	37.9	0.8
Labsystems - FEIA	40	61.4	2.9	8.1	4.9	0.9

Lot C1709 – Assayed 132.9 ng/mL blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Delfia	229	113.5	12.0	19.3	-0.2	0.9
AutoDelfia	669	117.4	10.5	12.8	-0.8	0.9
MP Biomedicals ELISA Assay	40	236.4	47.3	57.7	8.0	1.5
PerkinElmer GSP Neonatal	438	119.0	8.5	10.4	-2.7	1.0
Zentech	30	175.8	17.5	18.4	37.9	0.8
Labsystems - FEIA	40	122.0	6.1	32.8	4.9	0.9

Lot D1709 – Assayed 227.1 ng/mL blood

			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Delfia	229	204.2	21.9	33.1	-0.2	0.9
AutoDelfia	670	209.0	17.9	23.0	-0.8	0.9
MP Biomedicals ELISA Assay	40	338.7	65.7	112.3	8.0	1.5
PerkinElmer GSP Neonatal	430	220.3	16.3	19.6	-2.7	1.0
Zentech	30	210.0	25.3	31.0	37.9	0.8
Labsystems - FEIA	40	207.6	9.6	39.1	4.9	0.9

2018 Quality Control Data Summaries of Statistical Analyses ALANINE (Ala µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	558	225.7	27.4	58.5	236.6	0.7
Derivatized - MS/MS PE NeoGram Kit	40	227.4	19.4	55.2	240.3	0.7
Non-derivatized - MS/MS non-kit	160	244.9	36.7	58.5	258.3	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	196.1	16.3	48.4	203.8	0.6
Non-derivatized - MS/MS PE NeoBase Kit	740	259.8	19.1	44.6	269.6	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	99	216.2	12.6	41.5	217.8	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	220.5	12.2	26.4	232.4	0.6

Lot B1715 – Enriched 200 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	558	374.3	40.7	90.2	236.6	0.7
Derivatized - MS/MS PE NeoGram Kit	40	381.5	33.2	68.3	240.3	0.7
Non-derivatized - MS/MS non-kit	160	413.6	51.9	97.0	258.3	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	159	318.7	27.9	78.9	203.8	0.6
Non-derivatized - MS/MS PE NeoBase Kit	738	431.5	29.2	63.3	269.6	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	371.5	28.8	77.8	217.8	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	370.9	23.0	52.1	232.4	0.6

Lot C1715 – Enriched 400 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	560	511.9	50.3	125.9	236.6	0.7
Derivatized - MS/MS PE NeoGram Kit	40	548.3	52.8	101.1	240.3	0.7
Non-derivatized - MS/MS non-kit	160	554.1	64.0	124.1	258.3	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	462.9	31.8	114.5	203.8	0.6
Non-derivatized - MS/MS PE NeoBase Kit	739	600.5	43.5	86.7	269.6	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	521.4	33.4	105.9	217.8	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	497.0	34.0	80.6	232.4	0.6

Lot D1715 – Enriched 600 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	560	611.8	62.1	150.8	236.6	0.7
Derivatized - MS/MS PE NeoGram Kit	40	631.5	56.0	130.2	240.3	0.7
Non-derivatized - MS/MS non-kit	160	670.1	83.1	149.1	258.3	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	536.3	38.3	143.4	203.8	0.6
Non-derivatized - MS/MS PE NeoBase Kit	738	724.4	48.6	106.0	269.6	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	671.5	36.6	171.3	217.8	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	600.2	41.3	81.8	232.4	0.6

2018 Quality Control Data Summaries of Statistical Analyses ARGININE (Arg µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	575	7.9	1.7	3.9	9.5	0.6
Derivatized - MS/MS PE NeoGram Kit	60	7.0	1.4	2.5	9.9	0.7
Non-derivatized - MS/MS non-kit	168	10.2	3.6	8.6	12.8	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	158	16.6	1.9	36.2	22.0	0.8
Non-derivatized - MS/MS PE NeoBase Kit	798	7.1	0.7	1.7	10.0	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	108	8.9	1.1	3.0	13.1	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	5.7	0.9	1.9	7.6	0.6

Lot B1715 – Enriched 100 µmol/L blood

			Average			
METHOD	N	Mean	Within Lab SD	Total SD	Y- Intercept	Slope
Derivatized - MS/MS non-kit	580	69.4	7.3	24.0	9.5	0.6
Derivatized - MS/MS PE NeoGram Kit	60	78.8	9.7	11.9	9.9	0.7
Non-derivatized - MS/MS non-kit	170	78.0	14.7	25.2	12.8	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	159	95.2	9.7	51.4	22.0	0.8
Non-derivatized - MS/MS PE NeoBase Kit	798	80.3	5.3	10.2	10.0	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	84.8	5.7	20.9	13.1	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	61.5	4.2	20.2	7.6	0.6

Lot C1715 – Enriched 200 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	580	150.0	14.3	51.1	9.5	0.6
Derivatized - MS/MS PE NeoGram Kit	60	169.9	10.8	23.7	9.9	0.7
Non-derivatized - MS/MS non-kit	170	157.2	32.4	47.1	12.8	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	191.6	17.2	53.9	22.0	0.8
Non-derivatized - MS/MS PE NeoBase Kit	798	176.2	12.1	22.5	10.0	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	173.4	9.2	39.6	13.1	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	131.8	13.1	41.2	7.6	0.6

Lot D1715 – Enriched 300 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	578	193.9	21.1	71.4	9.5	0.6
Derivatized - MS/MS PE NeoGram Kit	60	217.5	13.2	30.2	9.9	0.7
Non-derivatized - MS/MS non-kit	170	206.5	42.2	60.2	12.8	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	234.7	21.3	59.5	22.0	0.8
Non-derivatized - MS/MS PE NeoBase Kit	797	223.5	14.8	27.5	10.0	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	222.4	12.7	51.6	13.1	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	171.2	11.8	46.8	7.6	0.6

2018 Quality Control Data Summaries of Statistical Analyses CITRULLINE (Cit µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	634	10.7	1.8	3.0	11.3	0.7
Derivatized - MS/MS PE NeoGram Kit	59	12.4	1.7	2.4	12.5	0.9
Non-derivatized - MS/MS non-kit	248	12.3	1.8	4.0	13.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	157	12.6	2.2	2.5	14.2	0.8
Non-derivatized - MS/MS PE NeoBase Kit	864	11.2	1.4	1.9	12.2	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	108	11.0	1.4	3.1	12.1	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	10.2	1.8	2.5	11.0	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	12.0	1.1	2.0	13.3	0.7

Lot B1715 – Enriched 25 µmol/L blood

			Average	Tatal	V	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	633	29.3	3.9	7.5	11.3	0.7
Derivatized - MS/MS PE NeoGram Kit	60	33.5	2.9	4.7	12.5	0.9
Non-derivatized - MS/MS non-kit	249	34.1	4.1	6.0	13.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	159	33.0	3.3	4.1	14.2	0.8
Non-derivatized - MS/MS PE NeoBase Kit	865	32.5	2.7	3.9	12.2	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	34.5	2.5	5.0	12.1	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	31.3	3.5	3.6	11.0	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	31.1	2.4	5.8	13.3	0.7

Lot C1715 – Enriched 100 µmol/L blood

			Average Within	Total	V	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	633	82.3	10.1	20.5	11.3	0.7
Derivatized - MS/MS PE NeoGram Kit	60	97.4	5.8	11.3	12.5	0.9
Non-derivatized - MS/MS non-kit	248	93.7	10.6	18.6	13.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	93.4	8.6	11.3	14.2	0.8
Non-derivatized - MS/MS PE NeoBase Kit	866	93.8	6.9	10.4	12.2	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	89.9	5.8	10.7	12.1	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	87.3	6.5	7.9	11.0	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	82.2	5.5	15.3	13.3	0.7

2018 Quality Control Data Summaries of Statistical Analyses CITRULLINE (Cit µmol/L blood) (cont.)

Lot D1715 – Enriched 250 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	634	187.5	22.0	44.0	11.3	0.7
Derivatized - MS/MS PE NeoGram Kit	60	223.7	21.6	44.3	12.5	0.9
Non-derivatized - MS/MS non-kit	248	214.8	22.8	41.8	13.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	203.7	22.3	26.0	14.2	0.8
Non-derivatized - MS/MS PE NeoBase Kit	864	212.4	14.6	23.7	12.2	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	212.0	14.5	24.5	12.1	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	202.5	15.0	18.5	11.0	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	182.7	9.1	28.7	13.3	0.7

2018 Quality Control Data Summaries of Statistical Analyses GLYCINE (Gly µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	489	286.4	26.2	66.7	296.8	0.7
Derivatized - MS/MS PE NeoGram Kit	30	386.8	98.7	159.4	398.9	0.9
Non-derivatized - MS/MS non-kit	130	244.7	52.2	96.7	244.9	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	150	271.4	21.1	47.6	283.7	0.7
Non-derivatized - MS/MS PE NeoBase Kit	568	303.0	28.3	53.5	309.2	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	98	232.6	17.1	35.0	243.3	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	292.9	19.3	36.7	301.1	0.8

Lot B1715 – Enriched 300 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	490	519.3	41.5	119.4	296.8	0.7
Derivatized - MS/MS PE NeoGram Kit	30	663.8	134.9	227.3	398.9	0.9
Non-derivatized - MS/MS non-kit	130	421.5	61.2	148.9	244.9	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	150	486.5	34.9	94.6	283.7	0.7
Non-derivatized - MS/MS PE NeoBase Kit	569	551.5	43.1	77.4	309.2	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	434.9	29.9	86.1	243.3	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	530.4	31.0	80.3	301.1	0.8

Lot C1715 – Enriched 600 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	490	767.1	59.5	179.2	296.8	0.7
Derivatized - MS/MS PE NeoGram Kit	30	970.9	193.6	305.3	398.9	0.9
Non-derivatized - MS/MS non-kit	130	611.9	69.8	197.5	244.9	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	150	721.0	102.6	168.8	283.7	0.7
Non-derivatized - MS/MS PE NeoBase Kit	569	836.1	66.1	120.5	309.2	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	644.4	33.0	120.1	243.3	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	779.2	52.7	111.3	301.1	0.8

Lot D1715 – Enriched 900 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	490	940.4	85.7	229.6	296.8	0.7
Derivatized - MS/MS PE NeoGram Kit	30	1172.5	209.2	309.7	398.9	0.9
Non-derivatized - MS/MS non-kit	130	781.2	103.9	271.4	244.9	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	150	865.2	66.6	177.9	283.7	0.7
Non-derivatized - MS/MS PE NeoBase Kit	569	1035.3	77.7	149.2	309.2	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	790.1	46.9	142.4	243.3	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	970.2	55.4	146.7	301.1	0.8

2018 Quality Control Data Summaries of Statistical Analyses LEUCINE (Leu µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	636	85.1	9.2	17.3	92.1	0.7
Derivatized - MS/MS PE NeoGram Kit	60	87.2	6.3	8.4	94.3	0.8
Non-derivatized - MS/MS non-kit	320	101.9	9.5	15.8	110.2	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	156	80.5	6.9	13.1	88.6	0.6
Non-derivatized - MS/MS PE NeoBase Kit	888	102.5	7.0	12.9	109.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	97.2	4.8	19.4	105.7	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	114.4	10.8	12.0	121.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	81.6	7.7	17.0	84.7	0.7

Lot B1715 – Enriched 100 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	638	162.6	16.8	29.6	92.1	0.7
Derivatized - MS/MS PE NeoGram Kit	60	168.3	13.1	16.1	94.3	0.8
Non-derivatized - MS/MS non-kit	320	186.3	13.5	29.0	110.2	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	159	150.1	13.8	26.5	88.6	0.6
Non-derivatized - MS/MS PE NeoBase Kit	887	186.2	11.9	19.7	109.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	179.1	9.9	28.5	105.7	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	205.6	14.1	15.5	121.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	155.6	15.4	22.7	84.7	0.7

Lot C1715 – Enriched 250 µmol/L blood

			Average			
METHOD	N	Mean	Within	Total	Y- Intercent	Slope
		Weall		30	ппенсері	Slope
Derivatized - MS/MS non-kit	638	279.2	26.2	46.1	92.1	0.7
Derivatized - MS/MS PE NeoGram Kit	59	306.4	17.8	21.9	94.3	0.8
Non-derivatized - MS/MS non-kit	319	309.1	22.4	54.9	110.2	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	258.6	18.5	40.5	88.6	0.6
Non-derivatized - MS/MS PE NeoBase Kit	890	315.3	20.8	33.4	109.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	289.3	12.0	35.8	105.7	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	336.4	23.3	38.3	121.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	275.2	22.4	38.5	84.7	0.7

2018 Quality Control Data Summaries of Statistical Analyses LEUCINE (Leu µmol/L blood) (cont.)

Lot D1715 – Enriched 500 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	640	434.3	45.2	78.1	92.1	0.7
Derivatized - MS/MS PE NeoGram Kit	60	470.8	33.9	42.3	94.3	0.8
Non-derivatized - MS/MS non-kit	320	473.7	35.7	88.4	110.2	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	389.0	26.5	62.5	88.6	0.6
Non-derivatized - MS/MS PE NeoBase Kit	889	488.4	31.3	52.0	109.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	446.8	24.2	51.5	105.7	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	525.9	35.9	63.2	121.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	443.6	26.3	63.2	84.7	0.7

2018 Quality Control Data Summaries of Statistical Analyses METHIONINE (Met µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	614	16.2	2.4	3.8	16.8	0.7
Derivatized - MS/MS PE NeoGram Kit	59	16.1	1.5	2.1	20.7	0.8
Non-derivatized - MS/MS non-kit	306	13.9	1.7	3.3	13.7	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	12.4	2.2	3.4	12.8	0.6
Non-derivatized - MS/MS PE NeoBase Kit	875	12.8	1.2	2.1	12.1	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	108	12.1	1.2	3.0	12.4	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	14.7	1.4	1.8	13.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	15.1	1.4	2.1	14.5	0.8

Lot B1715 – Enriched 50 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	620	54.1	6.0	9.8	16.8	0.7
Derivatized - MS/MS PE NeoGram Kit	60	62.6	18.0	24.9	20.7	0.8
Non-derivatized - MS/MS non-kit	310	49.9	3.9	9.3	13.7	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	42.4	6.4	14.3	12.8	0.6
Non-derivatized - MS/MS PE NeoBase Kit	878	46.7	3.1	5.0	12.1	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	47.0	4.2	9.8	12.4	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	51.8	3.3	3.4	13.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	52.7	3.7	5.7	14.5	0.8

Lot C1715 – Enriched 150 µmol/L blood

			Average	Total	v	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	619	123.3	12.1	21.5	16.8	0.7
Derivatized - MS/MS PE NeoGram Kit	60	139.6	17.0	22.4	20.7	0.8
Non-derivatized - MS/MS non-kit	310	116.7	9.7	27.4	13.7	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	100.6	12.4	27.8	12.8	0.6
Non-derivatized - MS/MS PE NeoBase Kit	879	111.7	7.0	11.9	12.1	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	105.2	6.0	16.9	12.4	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	120.1	6.6	8.9	13.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	123.3	8.1	15.8	14.5	0.8

2018 Quality Control Data Summaries of Statistical Analyses METHIONINE (Met µmol/L blood) (cont.)

Lot D1715 – Enriched 250 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	620	196.5	19.1	33.4	16.8	0.7
Derivatized - MS/MS PE NeoGram Kit	60	208.7	19.2	21.5	20.7	0.8
Non-derivatized - MS/MS non-kit	309	190.9	15.3	39.6	13.7	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	158.9	18.6	43.5	12.8	0.6
Non-derivatized - MS/MS PE NeoBase Kit	878	184.5	11.5	20.3	12.1	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	175.6	9.3	30.0	12.4	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	204.1	10.0	15.2	13.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	59	203.2	12.9	24.9	14.5	0.8

2018 Quality Control Data Summaries of Statistical Analyses ORNITHINE (Orn µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	487	81.7	12.9	37.5	83.9	0.5
Non-derivatized - MS/MS non-kit	138	96.3	12.3	37.3	98.5	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	149	118.4	13.1	25.5	124.0	0.7
Non-derivatized - MS/MS PE NeoBase Kit	599	99.7	7.6	17.3	102.5	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	99	96.8	10.6	32.6	99.7	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	85.3	9.2	20.3	88.5	0.5

Lot B1715 – Enriched 100 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Non-derivatized - MS/MS non-kit	140	160.7	16.1	53.3	98.5	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	150	196.4	21.6	46.1	124.0	0.7
Non-derivatized - MS/MS PE NeoBase Kit	600	169.0	11.2	25.7	102.5	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	174.7	12.5	35.1	99.7	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	148.0	19.3	33.3	88.5	0.5

Lot C1715 – Enriched 200 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	488	181.8	21.3	78.7	83.9	0.5
Non-derivatized - MS/MS non-kit	140	204.9	19.3	62.4	98.5	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	149	256.0	25.1	55.9	124.0	0.7
Non-derivatized - MS/MS PE NeoBase Kit	599	225.9	14.7	34.0	102.5	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	218.5	14.7	39.4	99.7	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	185.9	16.8	39.7	88.5	0.5

Lot D1715 – Enriched 300 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	488	236.0	30.6	103.9	83.9	0.5
Non-derivatized - MS/MS non-kit	140	268.3	20.6	85.8	98.5	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	149	315.2	30.7	70.2	124.0	0.7
Non-derivatized - MS/MS PE NeoBase Kit	600	287.1	18.3	43.5	102.5	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	299.0	18.3	50.2	99.7	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	244.9	17.4	42.8	88.5	0.5

2018 Quality Control Data Summaries of Statistical Analyses PHENYLALANINE (Phe µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
PerkinElmer Neonatal Kit	169	40.3	10.2	14.1	42.7	0.9
Derivatized - MS/MS non-kit	675	34.2	3.3	6.2	37.6	0.8
Labsystems Diagnostics	80	32.2	6.1	18.7	27.6	1.1
Bio-Rad Quantase	40	46.9	20.1	23.6	47.3	1.1
Interscientific Enzyme	30	59.0	3.2	15.9	45.2	0.7
Derivatized - MS/MS PE NeoGram Kit	60	37.3	2.8	4.5	40.3	0.9
Non-derivatized - MS/MS non-kit	346	35.7	3.2	5.3	39.3	0.9
Fluorometric Manual	90	53.5	9.9	18.2	55.3	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	150	33.2	3.7	6.4	36.8	0.8
Non-derivatized - MS/MS PE NeoBase Kit	897	34.4	2.6	4.2	37.0	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	37.9	3.1	5.2	41.8	0.9
PerkinElmer GSP Neonatal	59	25.5	8.6	12.6	31.6	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	38.2	2.7	3.3	41.9	0.9
Zentech	30	33.8	13.3	27.6	40.6	0.7
Trimaris Neonatal	30	30.9	5.9	12.0	30.5	1.1
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	35.2	2.6	7.6	37.2	0.8

Lot B1715 – Enriched 100 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
PerkinElmer Neonatal Kit	170	128.8	14.6	18.1	42.7	0.9
Derivatized - MS/MS non-kit	678	118.5	10.6	19.7	37.6	0.8
Labsystems Diagnostics	80	127.3	10.6	28.6	27.6	1.1
Bio-Rad Quantase	40	159.6	21.4	26.9	47.3	1.1
Interscientific Enzyme	30	96.4	6.3	9.9	45.2	0.7
Derivatized - MS/MS PE NeoGram Kit	60	129.2	9.4	15.8	40.3	0.9
Non-derivatized - MS/MS non-kit	350	129.8	8.4	15.7	39.3	0.9
Fluorometric Manual	90	161.6	14.5	31.2	55.3	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	149	112.7	7.9	16.0	36.8	0.8
Non-derivatized - MS/MS PE NeoBase Kit	897	122.0	7.8	12.2	37.0	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	133.1	7.2	16.4	41.8	0.9
PerkinElmer GSP Neonatal	70	131.6	11.2	12.6	31.6	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	135.5	10.1	15.0	41.9	0.9
Zentech	30	119.5	14.9	47.9	40.6	0.7
Trimaris Neonatal	30	145.6	12.9	14.6	30.5	1.1
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	117.3	7.8	11.2	37.2	0.8

2018 Quality Control Data Summaries of Statistical Analyses **PHENYLALANINE (Phe µmol/L blood) (cont.)**

Lot C1715 – Enriched 200 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
PerkinElmer Neonatal Kit	170	228.2	22.2	28.7	42.7	0.9
Derivatized - MS/MS non-kit	678	208.0	16.8	35.9	37.6	0.8
Labsystems Diagnostics	80	254.2	16.6	39.0	27.6	1.1
Bio-Rad Quantase	40	258.8	25.7	28.7	47.3	1.1
Interscientific Enzyme	30	172.2	9.3	24.4	45.2	0.7
Derivatized - MS/MS PE NeoGram Kit	60	235.5	15.6	24.2	40.3	0.9
Non-derivatized - MS/MS non-kit	349	228.3	14.2	30.7	39.3	0.9
Fluorometric Manual	90	285.9	23.0	49.9	55.3	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	150	196.4	14.3	27.8	36.8	0.8
Non-derivatized - MS/MS PE NeoBase Kit	899	218.3	13.6	22.5	37.0	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	225.5	10.4	24.6	41.8	0.9
PerkinElmer GSP Neonatal	70	244.4	22.3	25.3	31.6	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	232.1	10.7	23.9	41.9	0.9
Zentech	30	177.6	20.3	53.8	40.6	0.7
Trimaris Neonatal	30	256.9	18.8	28.6	30.5	1.1
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	204.8	18.3	25.0	37.2	0.8

Lot D1715 – Enriched 300 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
PerkinElmer Neonatal Kit	169	299.4	28.2	38.6	42.7	0.9
Derivatized - MS/MS non-kit	680	272.9	23.0	48.1	37.6	0.8
Labsystems Diagnostics	80	356.3	29.6	47.7	27.6	1.1
Bio-Rad Quantase	40	376.3	26.2	39.0	47.3	1.1
Interscientific Enzyme	30	259.6	11.9	22.7	45.2	0.7
Derivatized - MS/MS PE NeoGram Kit	60	305.4	24.7	32.2	40.3	0.9
Non-derivatized - MS/MS non-kit	350	302.5	20.8	40.6	39.3	0.9
Fluorometric Manual	90	376.9	33.4	58.0	55.3	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	150	255.5	20.4	40.8	36.8	0.8
Non-derivatized - MS/MS PE NeoBase Kit	899	288.6	19.0	30.4	37.0	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	302.9	16.1	37.6	41.8	0.9
PerkinElmer GSP Neonatal	70	319.9	31.4	36.3	31.6	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	311.2	15.3	27.3	41.9	0.9
Zentech	30	242.9	22.1	47.1	40.6	0.7
Trimaris Neonatal	30	375.3	22.2	22.4	30.5	1.1
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	274.1	20.2	29.4	37.2	0.8

2018 Quality Control Data Summaries of Statistical Analyses SUCCINYLACETONE (SUAC µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	190	0.6	0.2	0.4	0.6	0.5
Non-derivatized - MS/MS non-kit	149	0.9	0.3	1.0	0.9	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	120	0.4	0.2	0.4	0.5	0.3
Non-derivatized - MS/MS PE NeoBase Kit	533	0.5	0.1	0.3	0.5	0.2

Lot B1715 – Enriched 2.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	208	1.8	0.3	1.2	0.6	0.5
Non-derivatized - MS/MS non-kit	149	2.1	0.3	1.4	0.9	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	120	1.4	0.2	0.4	0.5	0.3
Non-derivatized - MS/MS PE NeoBase Kit	548	1.0	0.2	0.3	0.5	0.2

Lot C1715 – Enriched 7.5 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	209	3.9	0.5	2.8	0.6	0.5
Non-derivatized - MS/MS non-kit	149	4.2	0.5	2.4	0.9	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	120	2.8	0.4	0.7	0.5	0.3
Non-derivatized - MS/MS PE NeoBase Kit	550	1.9	0.3	0.5	0.5	0.2

Lot D1715 – Enriched 15 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	209	7.4	1.0	5.7	0.6	0.5
Non-derivatized - MS/MS non-kit	149	7.9	1.3	4.6	0.9	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	120	5.4	0.8	1.8	0.5	0.3
Non-derivatized - MS/MS PE NeoBase Kit	550	3.5	0.5	0.9	0.5	0.2

2018 Quality Control Data Summaries of Statistical Analyses TYROSINE (Tyr µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	647	32.7	3.6	6.6	37.1	0.7
Derivatized - MS/MS PE NeoGram Kit	60	33.4	3.5	4.0	35.2	0.8
Non-derivatized - MS/MS non-kit	315	36.0	4.7	9.8	39.7	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	158	37.9	5.2	8.0	45.2	0.8
Non-derivatized - MS/MS PE NeoBase Kit	892	36.1	3.4	5.4	39.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	41.8	4.8	16.2	45.6	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	33.7	2.6	2.6	37.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	30.3	1.9	3.1	30.6	0.7

Lot B1715 – Enriched 200 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	648	183.6	16.6	34.0	37.1	0.7
Derivatized - MS/MS PE NeoGram Kit	60	183.4	18.0	20.1	35.2	0.8
Non-derivatized - MS/MS non-kit	316	199.6	14.5	31.2	39.7	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	202.3	21.0	32.2	45.2	0.8
Non-derivatized - MS/MS PE NeoBase Kit	898	201.7	14.5	23.3	39.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	203.9	10.7	36.9	45.6	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	195.9	13.5	13.5	37.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	171.5	9.7	14.7	30.6	0.7

Lot C1715 – Enriched 400 µmol/L blood

			Average	Tatal	V	
METHOD	N	Mean	Lab SD	l otal SD	r- Intercept	Slope
Derivatized - MS/MS non-kit	646	349.9	31.2	67.8	37.1	0.7
Derivatized - MS/MS PE NeoGram Kit	60	366.3	33.2	33.8	35.2	0.8
Non-derivatized - MS/MS non-kit	319	384.1	28.8	66.0	39.7	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	394.4	33.9	60.0	45.2	0.8
Non-derivatized - MS/MS PE NeoBase Kit	898	393.2	26.8	44.1	39.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	377.0	18.4	65.5	45.6	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	371.0	17.9	21.6	37.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	336.8	18.0	34.6	30.6	0.7

2018 Quality Control Data Summaries of Statistical Analyses TYROSINE (Tyr µmol/L blood) (cont.)

Lot D1715 – Enriched 600 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	647	471.4	42.0	90.6	37.1	0.7
Derivatized - MS/MS PE NeoGram Kit	60	490.9	49.1	57.2	35.2	0.8
Non-derivatized - MS/MS non-kit	318	518.7	36.5	82.6	39.7	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	509.0	43.8	89.4	45.2	0.8
Non-derivatized - MS/MS PE NeoBase Kit	897	531.0	34.9	59.2	39.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	514.5	28.8	85.1	45.6	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	508.9	27.2	27.4	37.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	464.4	26.9	49.1	30.6	0.7

2018 Quality Control Data Summaries of Statistical Analyses VALINE (Val µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	609	91.4	10.9	20.5	94.9	0.7
Derivatized - MS/MS PE NeoGram Kit	50	84.9	8.5	12.4	88.5	0.7
Non-derivatized - MS/MS non-kit	240	75.6	6.6	14.1	79.1	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	77.4	10.7	17.6	81.7	0.6
Non-derivatized - MS/MS PE NeoBase Kit	859	88.3	8.0	13.4	91.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	74.8	5.4	22.4	78.7	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	89.4	7.8	8.9	93.5	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	71.8	9.5	17.6	73.3	0.7

Lot B1715 – Enriched 200 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	610	231.2	24.8	43.2	94.9	0.7
Derivatized - MS/MS PE NeoGram Kit	50	223.8	21.2	27.6	88.5	0.7
Non-derivatized - MS/MS non-kit	240	217.1	15.9	38.5	79.1	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	200.9	20.5	38.1	81.7	0.6
Non-derivatized - MS/MS PE NeoBase Kit	860	255.1	20.3	34.9	91.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	211.5	10.1	51.3	78.7	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	259.8	22.5	27.4	93.5	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	199.9	18.6	45.4	73.3	0.7

Lot C1715 – Enriched 350 µmol/L blood

			Average	T = 4 = 1	V	
METHOD	N	Mean	Within Lab SD	I otal SD	Y- Intercent	Slone
Derivatized - MS/MS non-kit	610	343.0	31.6	63.0		0.7
Derivatized MS/MS RE NooCram Kit	50	249.6	32.0	12.0	94.9	0.7
	0.10	340.0	32.0	42.0	70.4	0.7
Non-derivatized - MS/MS non-kit	240	329.1	22.2	61.8	79.1	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	309.4	26.9	54.2	81.7	0.6
Non-derivatized - MS/MS PE NeoBase Kit	860	395.2	29.4	51.4	91.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	314.2	13.7	65.0	78.7	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	386.2	29.4	48.5	93.5	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	309.3	43.0	76.2	73.3	0.7

2018 Quality Control Data Summaries of Statistical Analyses VALINE (Val µmol/L blood) (cont.)

Lot D1715 – Enriched 500 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	610	426.7	37.7	80.5	94.9	0.7
Derivatized - MS/MS PE NeoGram Kit	50	422.8	32.5	58.4	88.5	0.7
Non-derivatized - MS/MS non-kit	240	414.4	28.3	76.4	79.1	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	371.7	34.0	74.7	81.7	0.6
Non-derivatized - MS/MS PE NeoBase Kit	859	497.7	37.4	68.4	91.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	397.9	21.9	80.0	78.7	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	495.2	45.1	58.2	93.5	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	390.3	41.6	89.6	73.3	0.7

2018 Quality Control Data Summaries of Statistical Analyses

TOTAL GALACTOSE (TGal mg/dL blood)

Lot A1705 – Enriched 5 mg/dL blood

		Average	Total	V_	
Ν	Mean	Lab SD	SD	Intercept	Slope
30	5.5	0.4	0.4	2.3	0.8
40	6.8	1.3	1.9	0.4	1.3
319	5.0	0.6	1.0	1.0	0.8
50	5.5	0.5	0.9	0.9	0.9
120	6.5	1.2	2.0	-0.1	1.3
40	5.3	0.4	0.6	1.1	0.8
40	6.6	0.5	0.9	2.1	0.9
50	7.0	1.5	1.9	1.2	1.2
140	5.6	0.9	1.5	0.7	1.0
248	5.9	0.6	0.9	1.4	0.9
30	5.4	0.5	0.7	-0.7	1.2
70	5.6	1.1	1.3	2.5	0.8
	N 30 40 319 50 120 40 40 40 50 140 248 30 70	NMean305.5406.83195.0505.51206.5405.3406.6507.01405.62485.9305.4705.6	NMeanLab SD305.50.4406.81.33195.00.6505.50.51206.51.2405.30.4406.60.5507.01.51405.60.92485.90.6305.40.5705.61.1	NMeanLab SDTotal SD305.50.40.4406.81.31.93195.00.61.0505.50.50.91206.51.22.0405.30.40.6406.60.50.91206.51.22.0405.30.40.6406.60.50.9507.01.51.91405.60.91.52485.90.60.9305.40.50.7705.61.11.3	Average Within Lab SDTotal SDY- Intercept305.50.40.42.3406.81.31.90.43195.00.61.01.0505.50.50.90.91206.51.22.0-0.1405.30.40.61.1405.60.50.92.1507.01.51.91.21405.60.91.50.72485.90.60.91.4305.40.50.7-0.7705.61.11.32.5

Lot B1705 – Enriched 10 mg/dL blood

		Average			
		Within	Total	Y-	
Ν	Mean	Lab SD	SD	Intercept	Slope
30	10.7	0.8	0.9	2.3	0.8
40	13.0	2.2	3.8	0.4	1.3
319	9.3	0.9	1.5	1.0	0.8
50	10.0	0.9	1.7	0.9	0.9
119	13.3	1.7	2.7	-0.1	1.3
40	9.5	0.5	0.6	1.1	0.8
40	11.3	1.0	1.6	2.1	0.9
50	13.9	1.8	2.3	1.2	1.2
140	10.1	1.1	1.5	0.7	1.0
247	10.5	0.8	1.3	1.4	0.9
30	10.6	0.5	0.9	-0.7	1.2
70	11.2	1.4	2.3	2.5	0.8
	N 30 40 319 50 119 40 40 50 140 247 30 70	NMean3010.74013.03199.35010.011913.3409.54011.35013.914010.124710.53010.67011.2	NMeanLab SD3010.70.84013.02.23199.30.95010.00.911913.31.7409.50.54011.31.05013.91.814010.11.124710.50.83010.60.57011.21.4	NMeanLab SDTotal SD3010.70.80.94013.02.23.83199.30.91.55010.00.91.711913.31.72.7409.50.50.64011.31.01.65013.91.82.314010.11.11.524710.50.81.33010.60.50.97011.21.42.3	Average Within Lab SDTotal SDY- Intercept3010.70.80.92.34013.02.23.80.43199.30.91.51.05010.00.91.70.911913.31.72.7-0.1409.50.50.61.14011.31.01.62.15013.91.82.31.214010.11.11.50.724710.50.81.31.43010.60.50.9-0.77011.21.42.32.5

Lot C1705 – Enriched 30 mg/dL blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Siemens Healthcare Diagnostics	30	24.9	1.3	4.7	2.3	0.8
Colorimetric	40	38.5	4.9	11.5	0.4	1.3
PerkinElmer Neonatal Kit	319	25.6	2.2	3.3	1.0	0.8
Labsystems Diagnostics	50	28.4	2.0	7.1	0.9	0.9
Bio-Rad Quantase	120	39.9	5.9	8.7	-0.1	1.3
Interscientific Enzyme	40	26.3	2.0	2.0	1.1	0.8
Astoria-Pacific 50 Hour Reagent Kit	40	29.4	2.3	4.4	2.1	0.9
TecnoSuma UMTEST	50	37.8	4.9	7.0	1.2	1.2
Fluorometric Manual	140	29.4	2.4	3.4	0.7	1.0
PerkinElmer GSP Neonatal	246	28.5	2.9	4.1	1.4	0.9
Astoria-Pacific Neonatal Microplate Reagent Kit U/g Hb	30	34.2	1.9	1.9	-0.7	1.2
Zentech	70	25.5	2.5	2.8	2.5	0.8

2018 Quality Control Data Summaries of Statistical Analyses FREE CARNITINE (C0 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	669	15.81	1.69	2.99	15.66	1.4
Derivatized - MS/MS PE NeoGram Kit	60	18.88	2.20	4.23	18.75	1.7
Non-derivatized - MS/MS non-kit	259	14.07	1.28	2.71	14.14	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	167	12.82	1.64	3.37	12.97	1.1
Non-derivatized - MS/MS PE NeoBase Kit	869	13.20	1.09	1.84	13.03	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	108	12.73	1.00	2.32	12.59	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	13.81	1.36	1.85	13.89	1.0
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	15.69	1.43	2.95	15.52	1.3

Lot B1715 – Enriched 10 µmol/L blood

			Average			
METHOD	N	Maan	Within	Total	Y-	Slana
METHOD	IN	wean	Lab SD	30	intercept	Slope
Derivatized - MS/MS non-kit	670	29.12	2.95	5.65	15.66	1.4
Derivatized - MS/MS PE NeoGram Kit	60	35.50	3.94	7.14	18.75	1.7
Non-derivatized - MS/MS non-kit	260	24.97	2.29	4.74	14.14	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	169	23.85	2.25	5.57	12.97	1.1
Non-derivatized - MS/MS PE NeoBase Kit	870	22.88	1.72	3.09	13.03	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	108	22.23	1.69	3.74	12.59	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	24.58	1.84	2.06	13.89	1.0
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	59	28.80	4.51	5.94	15.52	1.3

Lot C1715 – Enriched 20 µmol/L blood

			Average	T . (.)	V	
METHOD	Ν	Mean	Lab SD	SD	۲- Intercept	Slope
Derivatized - MS/MS non-kit	670	42.14	4.15	8.36	15.66	1.4
Derivatized - MS/MS PE NeoGram Kit	60	53.21	6.11	10.48	18.75	1.7
Non-derivatized - MS/MS non-kit	259	34.91	2.96	6.80	14.14	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	170	35.00	2.80	7.80	12.97	1.1
Non-derivatized - MS/MS PE NeoBase Kit	869	32.71	2.36	4.43	13.03	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	31.82	1.98	5.20	12.59	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	34.46	2.11	3.34	13.89	1.0
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	40.41	3.53	6.29	15.52	1.3

2018 Quality Control Data Summaries of Statistical Analyses FREE CARNITINE (C0 µmol/L blood) (cont.)

Lot D1715 – Enriched 30 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	669	56.34	5.50	11.53	15.66	1.4
Derivatized - MS/MS PE NeoGram Kit	60	69.92	7.58	12.46	18.75	1.7
Non-derivatized - MS/MS non-kit	258	45.95	4.48	9.50	14.14	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	170	45.21	4.25	9.81	12.97	1.1
Non-derivatized - MS/MS PE NeoBase Kit	869	43.19	3.05	5.62	13.03	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	41.98	2.47	6.62	12.59	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	45.26	2.95	3.71	13.89	1.0
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	55.10	5.38	7.87	15.52	1.3

2018 Quality Control Data Summaries of Statistical Analyses ACETYLCARNITINE (C2 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	636	12.39	1.46	3.11	12.62	0.9
Derivatized - MS/MS PE NeoGram Kit	50	12.70	0.81	2.12	12.90	0.6
Non-derivatized - MS/MS non-kit	219	9.50	0.71	1.57	9.58	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	169	9.68	1.15	2.20	10.01	0.8
Non-derivatized - MS/MS PE NeoBase Kit	857	8.23	0.63	0.89	8.28	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	119	8.18	0.92	1.86	7.93	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	9.11	0.51	0.99	9.23	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	59	9.51	0.59	1.49	9.46	0.8

Lot B1715 – Enriched 10 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	639	21.73	2.15	4.46	12.62	0.9
Derivatized - MS/MS PE NeoGram Kit	50	18.92	1.28	2.49	12.90	0.6
Non-derivatized - MS/MS non-kit	220	19.00	1.48	2.96	9.58	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	169	17.83	1.30	2.77	10.01	0.8
Non-derivatized - MS/MS PE NeoBase Kit	860	16.32	1.07	1.77	8.28	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	120	15.92	0.87	2.73	7.93	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	18.53	1.33	1.44	9.23	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	17.24	1.27	2.43	9.46	0.8

Lot C1715 – Enriched 20 µmol/L blood

			Average	Tatal	v	
METHOD	Ν	Mean	Lab SD	SD	r- Intercept	Slope
Derivatized - MS/MS non-kit	637	30.27	2.53	5.80	12.62	0.9
Derivatized - MS/MS PE NeoGram Kit	50	24.51	1.46	2.27	12.90	0.6
Non-derivatized - MS/MS non-kit	220	27.98	1.98	4.95	9.58	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	25.22	1.74	3.49	10.01	0.8
Non-derivatized - MS/MS PE NeoBase Kit	858	24.47	1.53	2.43	8.28	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	120	23.69	1.40	4.48	7.93	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	26.75	1.29	2.07	9.23	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	24.94	1.72	4.02	9.46	0.8

2018 Quality Control Data Summaries of Statistical Analyses ACETYLCARNITINE (C2 µmol/L blood) (cont.)

Lot D1715 – Enriched 30 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	637	38.84	3.38	7.27	12.62	0.9
Derivatized - MS/MS PE NeoGram Kit	50	30.06	1.75	2.62	12.90	0.6
Non-derivatized - MS/MS non-kit	219	37.31	3.02	6.85	9.58	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	32.11	2.36	4.88	10.01	0.8
Non-derivatized - MS/MS PE NeoBase Kit	859	32.31	2.03	3.37	8.28	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	120	32.66	2.03	6.39	7.93	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	36.21	1.69	2.44	9.23	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	32.92	2.27	4.76	9.46	0.8

2018 Quality Control Data Summaries of Statistical Analyses **PROPIONYLCARNITINE (C3 µmol/L blood)**

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	656	1.01	0.13	0.23	1.07	0.9
Derivatized - MS/MS PE NeoGram Kit	60	0.79	0.10	0.11	0.80	0.7
Non-derivatized - MS/MS non-kit	259	0.91	0.11	0.20	0.95	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	168	0.86	0.21	0.26	0.95	0.7
Non-derivatized - MS/MS PE NeoBase Kit	875	0.79	0.07	0.11	0.80	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	0.84	0.11	0.21	0.84	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.84	0.06	0.07	0.87	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.83	0.08	0.14	0.83	0.8

Lot B1715 – Enriched 4 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	659	4.61	0.53	0.92	1.07	0.9
Derivatized - MS/MS PE NeoGram Kit	60	3.62	0.31	0.39	0.80	0.7
Non-derivatized - MS/MS non-kit	258	4.32	0.37	0.74	0.95	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	170	3.79	0.45	0.63	0.95	0.7
Non-derivatized - MS/MS PE NeoBase Kit	879	3.73	0.24	0.44	0.80	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	3.77	0.29	0.73	0.84	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	4.09	0.27	0.28	0.87	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	4.12	0.30	0.46	0.83	0.8

Lot C1715 – Enriched 8 µmol/L blood

			Average	Tatal	v	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	658	8.17	0.89	1.59	1.07	0.9
Derivatized - MS/MS PE NeoGram Kit	60	6.47	0.50	0.61	0.80	0.7
Non-derivatized - MS/MS non-kit	258	7.56	0.61	1.44	0.95	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	170	7.03	0.68	1.29	0.95	0.7
Non-derivatized - MS/MS PE NeoBase Kit	878	6.68	0.44	0.73	0.80	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	6.52	0.37	1.24	0.84	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	7.13	0.35	0.44	0.87	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	7.28	0.55	0.89	0.83	0.8

2018 Quality Control Data Summaries of Statistical Analyses **PROPIONYLCARNITINE (C3 µmol/L blood) (cont.)**

Lot D1715 – Enriched 12 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	659	11.51	1.19	2.20	1.07	0.9
Derivatized - MS/MS PE NeoGram Kit	60	9.22	0.96	1.10	0.80	0.7
Non-derivatized - MS/MS non-kit	258	10.84	1.06	1.94	0.95	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	169	9.32	1.10	1.61	0.95	0.7
Non-derivatized - MS/MS PE NeoBase Kit	880	9.57	0.65	1.07	0.80	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	9.51	0.68	1.84	0.84	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	10.38	0.61	0.66	0.87	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	10.66	0.89	1.07	0.83	0.8

2018 Quality Control Data Summaries of Statistical Analyses MALONYLCARNITINE (C3DC µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
NETHOD			Within	Total	Y-	.
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	570	0.04	0.02	0.04	0.05	0.6
Derivatized - MS/MS PE NeoGram Kit	60	0.04	0.01	0.02	0.08	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	144	0.04	0.02	0.04	0.04	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	59	0.01	0.01	0.01	0.01	0.5

Lot B1715 – Enriched 0.5 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	597	0.34	0.07	0.14	0.05	0.6
Derivatized - MS/MS PE NeoGram Kit	60	0.64	0.09	0.10	0.08	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	149	0.42	0.09	0.19	0.04	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.25	0.03	0.09	0.01	0.5

Lot C1715 – Enriched 1.5 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	593	0.92	0.16	0.35	0.05	0.6
Derivatized - MS/MS PE NeoGram Kit	60	1.85	0.20	0.25	0.08	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	149	1.15	0.21	0.45	0.04	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.70	0.05	0.25	0.01	0.5

Lot D1715 – Enriched 3 µmol/L blood

			Average			
METHOD	N	Mean	Within Lab SD	Total SD	Y- Intercept	Slope
Derivatized - MS/MS non-kit	595	1.74	0.28	0.69	0.05	0.6
Derivatized - MS/MS PE NeoGram Kit	60	3.38	0.33	0.42	0.08	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	150	2.31	0.38	1.02	0.04	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.41	0.14	0.55	0.01	0.5

2018 Quality Control Data Summaries of Statistical Analyses MALONYLCARNITINE + HYDROXYBUTYRYLCARNITINE

(C3DC+C4OH µmol/L blood)

Lot A1715 - Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
Non-derivatized - MS/MS non-kit	146	0.07	0.03	0.05	0.08	0.4
Non-derivatized - MS/MS PE NeoBase Kit	687	0.05	0.01	0.02	0.05	0.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	30	0.14	0.02	0.16	0.17	0.6

Lot B1715 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
Non-derivatized - MS/MS non-kit	150	0.54	0.17	0.38	0.08	0.4
Non-derivatized - MS/MS PE NeoBase Kit	696	0.37	0.03	0.11	0.05	0.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.86	0.11	1.14	0.17	0.6

Lot C1715 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
Non-derivatized - MS/MS non-kit	150	1.11	0.21	0.79	0.08	0.4
Non-derivatized - MS/MS PE NeoBase Kit	694	0.77	0.06	0.22	0.05	0.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.62	0.09	2.1	0.17	0.6

Lot D1715 – Enriched 5.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
Non-derivatized - MS/MS non-kit	150	2.42	0.52	1.81	0.08	0.4
Non-derivatized - MS/MS PE NeoBase Kit	699	1.73	0.16	0.52	0.05	0.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	3.55	0.51	4.41	0.17	0.6

2018 Quality Control Data Summaries of Statistical Analyses BUTYRYLCARNITINE (C4 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	643	0.12	0.03	0.06	0.13	0.8
Derivatized - MS/MS PE NeoGram Kit	60	0.10	0.04	0.04	0.12	0.7
Non-derivatized - MS/MS non-kit	227	0.10	0.02	0.04	0.11	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	165	0.10	0.03	0.03	0.11	0.7
Non-derivatized - MS/MS PE NeoBase Kit	865	0.10	0.01	0.03	0.10	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	98	0.09	0.02	0.05	0.11	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.08	0.01	0.01	0.06	0.8

Lot B1715 – Enriched 1 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	658	0.93	0.13	0.21	0.13	0.8
Derivatized - MS/MS PE NeoGram Kit	60	0.82	0.12	0.15	0.12	0.7
Non-derivatized - MS/MS non-kit	228	0.94	0.08	0.16	0.11	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	168	0.77	0.09	0.11	0.11	0.7
Non-derivatized - MS/MS PE NeoBase Kit	868	0.83	0.06	0.10	0.10	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	0.83	0.05	0.16	0.11	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	0.96	0.07	0.09	0.03	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.83	0.06	0.11	0.06	0.8

Lot C1715 – Enriched 3 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	659	2.57	0.29	0.52	0.13	0.8
Derivatized - MS/MS PE NeoGram Kit	60	2.25	0.25	0.31	0.12	0.7
Non-derivatized - MS/MS non-kit	230	2.60	0.22	0.52	0.11	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	169	2.25	0.36	0.43	0.11	0.7
Non-derivatized - MS/MS PE NeoBase Kit	868	2.34	0.15	0.27	0.10	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	2.22	0.13	0.38	0.11	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	2.62	0.17	0.20	0.03	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	2.35	0.20	0.36	0.06	0.8
2018 Quality Control Data Summaries of Statistical Analyses BUTYRYLCARNITINE (C4 µmol/L blood) (cont.)

Lot D1715 – Enriched 5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	659	4.11	0.44	0.82	0.13	0.8
Derivatized - MS/MS PE NeoGram Kit	60	3.55	0.65	0.80	0.12	0.7
Non-derivatized - MS/MS non-kit	230	4.20	0.36	0.78	0.11	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	170	3.49	0.51	0.62	0.11	0.7
Non-derivatized - MS/MS PE NeoBase Kit	868	3.80	0.24	0.48	0.10	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	3.63	0.20	0.52	0.11	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	4.53	0.23	0.28	0.03	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	3.93	0.34	0.51	0.06	0.8

2018 Quality Control Data Summaries of Statistical Analyses HYDROXYBUTYRYLCARNITINE (C4OH µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	563	0.09	0.03	0.05	0.09	0.7
Derivatized - MS/MS PE NeoGram Kit	50	0.08	0.02	0.03	0.10	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	129	0.07	0.02	0.03	0.08	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.04	0.01	0.01	0.04	0.5

Lot B1715 – Enriched 0.5 µmol/L blood

			Average	Tatal	V	
METHOD	Ν	Mean	Lab SD	SD	r- Intercept	Slope
Derivatized - MS/MS non-kit	565	0.42	0.08	0.15	0.09	0.7
Derivatized - MS/MS PE NeoGram Kit	50	0.42	0.06	0.07	0.10	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	130	0.38	0.07	0.09	0.08	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.30	0.03	0.06	0.04	0.5

Lot C1715 – Enriched 1 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	564	0.79	0.13	0.27	0.09	0.7
Derivatized - MS/MS PE NeoGram Kit	50	0.82	0.09	0.11	0.10	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	130	0.73	0.09	0.16	0.08	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.58	0.06	0.12	0.04	0.5

Lot D1715 – Enriched 2.5 µmol/L blood

			Average			
METHOD	N	Mean	Within Lab SD	Total SD	Y- Intercent	Slope
Derivatized - MS/MS non-kit	569	1.79	0.23	0.57	0.09	0.7
Derivatized - MS/MS PE NeoGram Kit	50	1.77	0.20	0.22	0.10	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	130	1.60	0.26	0.39	0.08	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.38	0.13	0.28	0.04	0.5

2018 Quality Control Data Summaries of Statistical Analyses ISOVALERYLCARNITINE (C5 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	662	0.08	0.02	0.04	0.09	0.8
Derivatized - MS/MS PE NeoGram Kit	60	0.07	0.02	0.03	0.06	0.8
Non-derivatized - MS/MS non-kit	295	0.06	0.01	0.03	0.08	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	168	0.08	0.03	0.03	0.10	0.8
Non-derivatized - MS/MS PE NeoBase Kit	882	0.06	0.01	0.02	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	0.06	0.02	0.03	0.06	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.06	0.01	0.01	0.06	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.06	0.01	0.02	0.06	0.8

Lot B1715 – Enriched 0.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	676	0.51	0.07	0.11	0.09	0.8
Derivatized - MS/MS PE NeoGram Kit	60	0.46	0.07	0.07	0.06	0.8
Non-derivatized - MS/MS non-kit	298	0.51	0.04	0.08	0.08	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	168	0.48	0.07	0.08	0.10	0.8
Non-derivatized - MS/MS PE NeoBase Kit	889	0.45	0.03	0.05	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	0.46	0.03	0.08	0.06	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.51	0.05	0.06	0.06	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.47	0.05	0.07	0.06	0.8

Lot C1715 – Enriched 1.5 µmol/L blood

			Average	Total	v	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	677	1.36	0.14	0.26	0.09	0.8
Derivatized - MS/MS PE NeoGram Kit	60	1.21	0.13	0.19	0.06	0.8
Non-derivatized - MS/MS non-kit	300	1.35	0.12	0.23	0.08	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	169	1.32	0.21	0.26	0.10	0.8
Non-derivatized - MS/MS PE NeoBase Kit	900	1.26	0.09	0.14	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	1.28	0.11	0.25	0.06	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.36	0.09	0.16	0.06	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	59	1.29	0.10	0.13	0.06	0.8

2018 Quality Control Data Summaries of Statistical Analyses ISOVALERYLCARNITINE (C5 µmol/L blood) (cont.)

Lot D1715 – Enriched 3 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	679	2.58	0.28	0.48	0.09	0.8
Derivatized - MS/MS PE NeoGram Kit	60	2.42	0.25	0.35	0.06	0.8
Non-derivatized - MS/MS non-kit	299	2.61	0.28	0.46	0.08	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	2.40	0.31	0.41	0.10	0.8
Non-derivatized - MS/MS PE NeoBase Kit	898	2.44	0.17	0.28	0.06	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	2.53	0.15	0.46	0.06	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.72	0.21	0.31	0.06	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	2.56	0.21	0.25	0.06	0.8

2018 Quality Control Data Summaries of Statistical Analyses GLUTARYLCARNITINE (C5DC µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	640	0.02	0.02	0.02	0.03	0.6
Derivatized - MS/MS PE NeoGram Kit	58	0.03	0.02	0.02	0.05	0.9
Non-derivatized - MS/MS non-kit	266	0.05	0.01	0.07	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	162	0.05	0.03	0.07	0.05	1.2
Non-derivatized - MS/MS PE NeoBase Kit	810	0.05	0.01	0.02	0.05	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	98	0.13	0.05	0.19	0.20	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.05	0.01	0.01	0.06	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	40	0.03	0.01	0.01	0.04	1.5

Lot B1715 – Enriched 0.5 µmol/L blood

			Average			
NETUOD			Within	Total	Y-	0 1
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	680	0.35	0.06	0.16	0.03	0.6
Derivatized - MS/MS PE NeoGram Kit	60	0.52	0.05	0.07	0.05	0.9
Non-derivatized - MS/MS non-kit	280	0.52	0.09	0.17	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	169	0.65	0.15	0.21	0.05	1.2
Non-derivatized - MS/MS PE NeoBase Kit	819	0.52	0.04	0.07	0.05	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	98	0.84	0.16	0.68	0.20	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.50	0.05	0.06	0.06	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	0.79	0.10	0.19	0.04	1.5

Lot C1715 – Enriched 1 µmol/L blood

			Average			
			Within	lotal	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	675	0.68	0.10	0.29	0.03	0.6
Derivatized - MS/MS PE NeoGram Kit	60	1.02	0.10	0.14	0.05	0.9
Non-derivatized - MS/MS non-kit	280	0.99	0.16	0.32	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	169	1.30	0.23	0.39	0.05	1.2
Non-derivatized - MS/MS PE NeoBase Kit	819	1.01	0.08	0.13	0.05	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	108	1.69	0.48	1.73	0.20	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.91	0.10	0.10	0.06	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	1.57	0.21	0.40	0.04	1.5

2018 Quality Control Data Summaries of Statistical Analyses GLUTARYLCARNITINE (C5DC µmol/L blood) (cont.)

Lot D1715 – Enriched 2.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	674	1.62	0.22	0.69	0.03	0.6
Derivatized - MS/MS PE NeoGram Kit	59	2.38	0.21	0.25	0.05	0.9
Non-derivatized - MS/MS non-kit	280	2.27	0.22	0.70	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	3.13	0.45	0.93	0.05	1.2
Non-derivatized - MS/MS PE NeoBase Kit	820	2.39	0.18	0.32	0.05	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	105	3.51	0.73	2.56	0.20	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.19	0.21	0.26	0.06	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	3.79	0.46	1.07	0.04	1.5

2018 Quality Control Data Summaries of Statistical Analyses HYDROXYISOVALERYLCARNITINE (C5OH µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	678	0.45	0.07	0.10	0.45	0.7
Derivatized - MS/MS PE NeoGram Kit	59	0.43	0.06	0.08	0.42	0.7
Non-derivatized - MS/MS non-kit	220	0.66	0.06	0.14	0.66	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	158	0.46	0.08	0.11	0.45	0.6
Non-derivatized - MS/MS PE NeoBase Kit	670	0.49	0.04	0.09	0.49	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.46	0.05	0.26	0.46	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.70	0.05	0.08	0.70	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.32	0.03	0.07	0.31	0.5

Lot B1715 – Enriched 1 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	679	1.13	0.14	0.22	0.45	0.7
Derivatized - MS/MS PE NeoGram Kit	60	1.08	0.13	0.17	0.42	0.7
Non-derivatized - MS/MS non-kit	220	1.38	0.12	0.31	0.66	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	157	1.05	0.15	0.22	0.45	0.6
Non-derivatized - MS/MS PE NeoBase Kit	672	0.98	0.07	0.19	0.49	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.97	0.06	0.32	0.46	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.52	0.11	0.13	0.70	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.85	0.09	0.18	0.31	0.5

Lot C1715 – Enriched 2 µmol/L blood

			Average		N/	
METHOD	Ν	Mean	Within Lab SD	l otal SD	۲- Intercept	Slope
Derivatized - MS/MS non-kit	678	1.82	0.21	0.36	0.45	0.7
Derivatized - MS/MS PE NeoGram Kit	60	1.77	0.22	0.26	0.42	0.7
Non-derivatized - MS/MS non-kit	220	2.06	0.14	0.46	0.66	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	158	1.68	0.20	0.35	0.45	0.6
Non-derivatized - MS/MS PE NeoBase Kit	672	1.45	0.11	0.29	0.49	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	1.46	0.09	0.49	0.46	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.23	0.12	0.26	0.70	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.35	0.15	0.30	0.31	0.5

2018 Quality Control Data Summaries of Statistical Analyses HYDROXYISOVALERYLCARNITINE (C5OH µmol/L blood) (cont.)

Lot D1715 – Enriched 3 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	679	2.49	0.30	0.51	0.45	0.7
Derivatized - MS/MS PE NeoGram Kit	60	2.44	0.29	0.48	0.42	0.7
Non-derivatized - MS/MS non-kit	220	2.76	0.26	0.63	0.66	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	159	2.29	0.31	0.55	0.45	0.6
Non-derivatized - MS/MS PE NeoBase Kit	673	1.93	0.14	0.39	0.49	0.5
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	1.99	0.13	0.63	0.46	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	3.09	0.15	0.30	0.70	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.92	0.20	0.40	0.31	0.5

2018 Quality Control Data Summaries of Statistical Analyses HEXANOYLCARNITINE (C6 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	607	0.03	0.01	0.04	0.05	0.7
Derivatized - MS/MS PE NeoGram Kit	60	0.02	0.02	0.02	0.07	0.6
Non-derivatized - MS/MS non-kit	236	0.02	0.02	0.03	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	166	0.05	0.02	0.03	0.08	0.5
Non-derivatized - MS/MS PE NeoBase Kit	872	0.01	0.01	0.01	0.03	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	100	0.02	0.02	0.03	0.03	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	0.01	0.00	0.00	0.02	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	0.01	0.01	0.01	0.03	0.6

Lot B1715 – Enriched 0.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	655	0.42	0.07	0.11	0.05	0.7
Derivatized - MS/MS PE NeoGram Kit	60	0.37	0.09	0.09	0.07	0.6
Non-derivatized - MS/MS non-kit	248	0.43	0.05	0.10	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	168	0.35	0.06	0.07	0.08	0.5
Non-derivatized - MS/MS PE NeoBase Kit	879	0.38	0.03	0.04	0.03	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	0.39	0.03	0.08	0.03	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	0.43	0.03	0.03	0.02	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.32	0.04	0.05	0.03	0.6

Lot C1715 – Enriched 1 µmol/L blood

			Average Within	Total	V-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	655	0.79	0.10	0.17	0.05	0.7
Derivatized - MS/MS PE NeoGram Kit	60	0.65	0.09	0.10	0.07	0.6
Non-derivatized - MS/MS non-kit	248	0.82	0.09	0.21	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	170	0.64	0.10	0.14	0.08	0.5
Non-derivatized - MS/MS PE NeoBase Kit	880	0.74	0.05	0.08	0.03	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	0.72	0.04	0.14	0.03	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	0.83	0.05	0.06	0.02	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.61	0.04	0.07	0.03	0.6

2018 Quality Control Data Summaries of Statistical Analyses HEXANOYLCARNITINE (C6 µmol/L blood) (cont.)

Lot D1715 – Enriched 2.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	658	1.86	0.22	0.39	0.05	0.7
Derivatized - MS/MS PE NeoGram Kit	60	1.42	0.14	0.23	0.07	0.6
Non-derivatized - MS/MS non-kit	246	1.94	0.21	0.43	0.04	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	170	1.35	0.15	0.29	0.08	0.5
Non-derivatized - MS/MS PE NeoBase Kit	880	1.77	0.12	0.19	0.03	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	1.79	0.10	0.37	0.03	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	2.06	0.09	0.15	0.02	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.45	0.08	0.13	0.03	0.6

2018 Quality Control Data Summaries of Statistical Analyses OCTANOYLCARNITINE (C8 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	633	0.03	0.02	0.03	0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	59	0.02	0.01	0.02	0.03	0.8
Non-derivatized - MS/MS non-kit	290	0.02	0.01	0.02	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	165	0.02	0.01	0.02	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	864	0.01	0.00	0.01	0.01	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	108	0.01	0.00	0.01	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.01	0.00	0.01	0.00	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	0.01	0.01	0.01	0.00	0.7

Lot B1715 – Enriched 0.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	675	0.49	0.07	0.12	0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	60	0.44	0.09	0.10	0.03	0.8
Non-derivatized - MS/MS non-kit	297	0.48	0.04	0.10	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	167	0.39	0.06	0.08	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	878	0.43	0.03	0.06	0.01	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	120	0.38	0.05	0.08	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.44	0.03	0.04	0.00	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.36	0.04	0.06	0.00	0.7

Lot C1715 – Enriched 1 µmol/L blood

			Average	Total	v	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	677	0.98	0.12	0.21	0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	60	0.87	0.11	0.12	0.03	0.8
Non-derivatized - MS/MS non-kit	298	0.95	0.09	0.22	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	167	0.79	0.17	0.17	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	879	0.86	0.06	0.11	0.01	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	120	0.75	0.05	0.13	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.85	0.05	0.07	0.00	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.72	0.06	0.11	0.00	0.7

2018 Quality Control Data Summaries of Statistical Analyses OCTANOYLCARNITINE (C8 µmol/L blood) (cont.)

Lot D1715 – Enriched 2.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	679	2.33	0.28	0.48	0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	60	2.07	0.27	0.31	0.03	0.8
Non-derivatized - MS/MS non-kit	296	2.29	0.23	0.52	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	1.81	0.24	0.31	0.04	0.7
Non-derivatized - MS/MS PE NeoBase Kit	883	2.13	0.15	0.26	0.01	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	120	1.91	0.13	0.36	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.17	0.14	0.16	0.00	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.81	0.14	0.30	0.00	0.7

2018 Quality Control Data Summaries of Statistical Analyses DECANOYLCARNITINE (C10 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	596	0.03	0.01	0.03	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	60	0.02	0.01	0.02	0.01	0.7
Non-derivatized - MS/MS non-kit	276	0.04	0.01	0.04	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	163	0.02	0.01	0.02	0.02	0.5
Non-derivatized - MS/MS PE NeoBase Kit	870	0.02	0.01	0.01	0.01	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	99	0.02	0.01	0.02	0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.01	0.00	0.01	0.00	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.01	0.00	0.01	-0.01	0.7

Lot B1715 – Enriched 0.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	647	0.51	0.09	0.14	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	60	0.39	0.06	0.08	0.01	0.7
Non-derivatized - MS/MS non-kit	288	0.53	0.07	0.15	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	0.27	0.06	0.10	0.02	0.5
Non-derivatized - MS/MS PE NeoBase Kit	896	0.42	0.03	0.06	0.01	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	0.40	0.04	0.09	0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.43	0.04	0.05	0.00	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.38	0.05	0.06	-0.01	0.7

Lot C1715 – Enriched 1 µmol/L blood

			Average	Total	v	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	647	0.91	0.12	0.22	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	60	0.71	0.10	0.12	0.01	0.7
Non-derivatized - MS/MS non-kit	288	0.92	0.10	0.25	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	0.49	0.06	0.16	0.02	0.5
Non-derivatized - MS/MS PE NeoBase Kit	897	0.75	0.06	0.10	0.01	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	0.70	0.05	0.17	0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.75	0.06	0.09	0.00	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.67	0.06	0.09	-0.01	0.7

2018 Quality Control Data Summaries of Statistical Analyses DECANOYLCARNITINE (C10 µmol/L blood) (cont.)

Lot D1715 – Enriched 2.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	647	2.36	0.30	0.54	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	60	1.86	0.24	0.34	0.01	0.7
Non-derivatized - MS/MS non-kit	287	2.40	0.27	0.58	0.03	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	1.26	0.15	0.39	0.02	0.5
Non-derivatized - MS/MS PE NeoBase Kit	897	1.99	0.15	0.25	0.01	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	1.87	0.14	0.42	0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.02	0.13	0.22	0.00	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.85	0.22	0.26	-0.01	0.7

2018 Quality Control Data Summaries of Statistical Analyses DODECANOYLCARNITINE (C12 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	549	0.04	0.02	0.03	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	59	0.03	0.02	0.02	0.01	1.0
Non-derivatized - MS/MS non-kit	220	0.02	0.01	0.02	0.01	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	169	0.05	0.03	0.04	0.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	816	0.01	0.01	0.01	0.00	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	99	0.01	0.01	0.01	0.00	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	0.01	0.00	0.00	0.01	1.1
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	59	0.02	0.01	0.01	0.01	0.9

Lot B1715 – Enriched 1 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	588	1.03	0.18	0.29	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	60	0.99	0.13	0.15	0.01	1.0
Non-derivatized - MS/MS non-kit	226	1.07	0.12	0.38	0.01	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	170	0.89	0.12	0.20	0.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	836	0.92	0.07	0.10	0.00	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	0.89	0.07	0.17	0.00	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.09	0.10	0.15	0.01	1.1
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	59	0.90	0.10	0.11	0.01	0.9

Lot C1715 – Enriched 2 µmol/L blood

			Average		N/	
METHOD	N	Mean	Within Lab SD	l otal SD	Y- Intercept	Slope
Derivatized - MS/MS non-kit	589	2.01	0.30	0.51	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	60	1.95	0.26	0.31	0.01	1.0
Non-derivatized - MS/MS non-kit	225	2.12	0.23	0.84	0.01	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	169	1.74	0.22	0.44	0.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	839	1.85	0.14	0.19	0.00	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	1.72	0.12	0.34	0.00	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.11	0.14	0.41	0.01	1.1
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.76	0.14	0.18	0.01	0.9

2018 Quality Control Data Summaries of Statistical Analyses DODECANOYLCARNITINE (C12 µmol/L blood) (cont.)

Lot D1715 – Enriched 3 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	587	3.01	0.46	0.76	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	60	3.03	0.32	0.46	0.01	1.0
Non-derivatized - MS/MS non-kit	226	3.20	0.35	1.24	0.01	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	169	2.46	0.30	0.54	0.07	0.8
Non-derivatized - MS/MS PE NeoBase Kit	837	2.79	0.21	0.30	0.00	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	2.66	0.18	0.51	0.00	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	3.25	0.24	0.55	0.01	1.1
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	2.72	0.28	0.31	0.01	0.9

2018 Quality Control Data Summaries of Statistical Analyses MYRISTOYLCARNITINE (C14 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	643	0.07	0.02	0.03	0.08	0.9
Derivatized - MS/MS PE NeoGram Kit	60	0.05	0.02	0.02	0.07	0.8
Non-derivatized - MS/MS non-kit	247	0.05	0.01	0.03	0.06	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	0.07	0.02	0.04	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	849	0.04	0.01	0.01	0.04	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	98	0.03	0.01	0.02	0.04	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.05	0.00	0.00	0.05	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.03	0.01	0.01	0.03	0.6

Lot B1715 – Enriched 0.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	657	0.52	0.08	0.13	0.08	0.9
Derivatized - MS/MS PE NeoGram Kit	60	0.49	0.06	0.07	0.07	0.8
Non-derivatized - MS/MS non-kit	248	0.53	0.06	0.10	0.06	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	168	0.40	0.06	0.08	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	868	0.45	0.03	0.05	0.04	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	0.42	0.04	0.08	0.04	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.50	0.04	0.04	0.05	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.35	0.05	0.07	0.03	0.6

Lot C1715 – Enriched 1.5 µmol/L blood

			Average	Total	v	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	658	1.42	0.17	0.32	0.08	0.9
Derivatized - MS/MS PE NeoGram Kit	60	1.33	0.15	0.18	0.07	0.8
Non-derivatized - MS/MS non-kit	250	1.41	0.16	0.27	0.06	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	165	1.06	0.12	0.18	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	867	1.27	0.09	0.13	0.04	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	1.13	0.09	0.19	0.04	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.36	0.08	0.12	0.05	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.95	0.07	0.19	0.03	0.6

2018 Quality Control Data Summaries of Statistical Analyses MYRISTOYLCARNITINE (C14 µmol/L blood) (cont.)

Lot D1715 – Enriched 3 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	655	2.71	0.32	0.58	0.08	0.9
Derivatized - MS/MS PE NeoGram Kit	60	2.55	0.26	0.34	0.07	0.8
Non-derivatized - MS/MS non-kit	249	2.79	0.28	0.57	0.06	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	169	2.05	0.25	0.37	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	868	2.51	0.18	0.26	0.04	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	2.26	0.18	0.36	0.04	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.71	0.20	0.23	0.05	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.92	0.16	0.32	0.03	0.6

2018 Quality Control Data Summaries of Statistical Analyses PALMITOYLCARNITINE (C16 µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	<u>.</u>
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	655	0.79	0.11	0.17	0.81	0.8
Derivatized - MS/MS PE NeoGram Kit	60	0.72	0.08	0.08	0.72	0.8
Non-derivatized - MS/MS non-kit	268	0.77	0.08	0.12	0.80	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	168	0.68	0.11	0.14	0.71	0.8
Non-derivatized - MS/MS PE NeoBase Kit	865	0.72	0.07	0.10	0.69	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	108	0.68	0.06	0.14	0.70	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.74	0.06	0.16	0.75	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.77	0.07	0.11	0.75	0.9

Lot B1715 – Enriched 4 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	656	4.18	0.43	0.69	0.81	0.8
Derivatized - MS/MS PE NeoGram Kit	60	3.94	0.43	0.50	0.72	0.8
Non-derivatized - MS/MS non-kit	270	4.43	0.38	0.67	0.80	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	3.79	0.39	0.59	0.71	0.8
Non-derivatized - MS/MS PE NeoBase Kit	867	3.99	0.29	0.47	0.69	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	3.87	0.27	0.62	0.70	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	4.23	0.32	0.70	0.75	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	4.34	0.40	0.82	0.75	0.9

Lot C1715 – Enriched 8 µmol/L blood

			Average	Total	v	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	659	7.42	0.71	1.18	0.81	0.8
Derivatized - MS/MS PE NeoGram Kit	60	6.92	0.55	0.66	0.72	0.8
Non-derivatized - MS/MS non-kit	270	7.76	0.59	1.26	0.80	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	168	6.84	0.74	0.95	0.71	0.8
Non-derivatized - MS/MS PE NeoBase Kit	870	7.21	0.51	0.85	0.69	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	6.70	0.45	1.09	0.70	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	7.36	0.42	1.44	0.75	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	7.71	0.56	1.52	0.75	0.9

2018 Quality Control Data Summaries of Statistical Analyses PALMITOYLCARNITINE (C16 µmol/L blood) (cont.)

Lot D1715 – Enriched 12 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	658	10.77	1.00	1.77	0.81	0.8
Derivatized - MS/MS PE NeoGram Kit	60	10.26	0.96	1.21	0.72	0.8
Non-derivatized - MS/MS non-kit	270	11.42	1.01	1.94	0.80	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	169	9.84	0.93	1.25	0.71	0.8
Non-derivatized - MS/MS PE NeoBase Kit	870	10.68	0.79	1.24	0.69	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	9.97	0.65	1.53	0.70	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	10.95	0.75	1.98	0.75	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	11.45	0.84	2.19	0.75	0.9

2018 Quality Control Data Summaries of Statistical Analyses HYDROXYPALMITOYLCARNITINE (C16OH µmol/L blood)

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	590	0.02	0.01	0.02	0.02	0.7
Derivatized - MS/MS PE NeoGram Kit	60	0.02	0.02	0.02	0.02	0.7
Non-derivatized - MS/MS non-kit	227	0.01	0.00	0.01	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	157	0.02	0.01	0.01	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	829	0.01	0.00	0.01	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	89	0.05	0.02	0.15	0.07	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.00	0.00	0.00	0.01	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	0.01	0.00	0.01	0.01	0.6

Lot B1715 – Enriched 0.25 µmol/L blood

			Average	Total	v	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	638	0.21	0.04	0.06	0.02	0.7
Derivatized - MS/MS PE NeoGram Kit	60	0.18	0.03	0.04	0.02	0.7
Non-derivatized - MS/MS non-kit	240	0.22	0.03	0.07	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	170	0.18	0.04	0.06	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	870	0.16	0.01	0.03	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	89	0.29	0.03	0.37	0.07	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.18	0.03	0.03	0.01	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.16	0.03	0.06	0.01	0.6

Lot C1715 – Enriched 1 µmol/L blood

			Average			
METHOD	N	Mean	Within Lab SD	Total SD	Y- Intercept	Slope
Derivatized - MS/MS non-kit	640	0.75	0.09	0.19	0.02	0.7
Derivatized - MS/MS PE NeoGram Kit	60	0.68	0.09	0.13	0.02	0.7
Non-derivatized - MS/MS non-kit	240	0.81	0.09	0.26	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	170	0.65	0.09	0.19	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	869	0.61	0.05	0.12	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	89	0.76	0.06	0.66	0.07	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.69	0.07	0.10	0.01	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.62	0.07	0.20	0.01	0.6

2018 Quality Control Data Summaries of Statistical Analyses HYDROXYPALMITOYLCARNITINE (C16OH µmol/L blood) (cont.)

Lot D1715 – Enriched 1.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	640	1.09	0.14	0.28	0.02	0.7
Derivatized - MS/MS PE NeoGram Kit	60	0.99	0.11	0.22	0.02	0.7
Non-derivatized - MS/MS non-kit	240	1.21	0.13	0.40	0.01	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	169	0.93	0.12	0.25	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	870	0.90	0.07	0.18	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	90	1.18	0.08	1.04	0.07	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.02	0.15	0.19	0.01	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.94	0.12	0.31	0.01	0.6

2018 Quality Control Data Summaries of Statistical Analyses **STEAROYLCARNITINE (C18 µmol/L blood)**

Lot A1715 – Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	617	0.59	0.10	0.15	0.60	0.8
Derivatized - MS/MS PE NeoGram Kit	60	0.60	0.09	0.09	0.61	0.9
Non-derivatized - MS/MS non-kit	228	0.63	0.10	0.18	0.62	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	170	0.52	0.08	0.12	0.52	0.7
Non-derivatized - MS/MS PE NeoBase Kit	869	0.54	0.04	0.06	0.53	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	0.54	0.06	0.13	0.55	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.53	0.03	0.06	0.52	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.57	0.05	0.24	0.55	0.9

Lot B1715 – Enriched 1 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	619	1.42	0.17	0.31	0.60	0.8
Derivatized - MS/MS PE NeoGram Kit	60	1.49	0.13	0.17	0.61	0.9
Non-derivatized - MS/MS non-kit	228	1.58	0.15	0.31	0.62	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	169	1.27	0.13	0.27	0.52	0.7
Non-derivatized - MS/MS PE NeoBase Kit	868	1.40	0.10	0.14	0.53	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	109	1.35	0.09	0.22	0.55	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.38	0.10	0.12	0.52	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	1.46	0.17	0.63	0.55	0.9

Lot C1715 – Enriched 3 µmol/L blood

			Average			
METHOD	N	Mean	Within Lab SD	Total SD	Y- Intercent	Slope
Derivatized - MS/MS non-kit	620	2.99	0.32	0.58	0.60	0.8
Derivatized - MS/MS PE NeoGram Kit	60	3.22	0.29	0.32	0.61	0.9
Non-derivatized - MS/MS non-kit	229	3.33	0.30	0.60	0.62	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	165	2.75	0.28	0.45	0.52	0.7
Non-derivatized - MS/MS PE NeoBase Kit	870	3.02	0.23	0.32	0.53	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	2.82	0.17	0.47	0.55	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.91	0.19	0.29	0.52	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	3.12	0.30	1.42	0.55	0.9

2018 Quality Control Data Summaries of Statistical Analyses STEAROYLCARNITINE (C18 µmol/L blood) (cont.)

Lot D1715 – Enriched 5 µmol/L blood

			Average	Tatal	V	
METHOD	N	Mean	Lab SD	SD	r- Intercept	Slope
Derivatized - MS/MS non-kit	619	4.63	0.49	0.91	0.60	0.8
Derivatized - MS/MS PE NeoGram Kit	60	5.00	0.54	0.63	0.61	0.9
Non-derivatized - MS/MS non-kit	227	5.31	0.49	1.19	0.62	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	169	4.22	0.38	0.65	0.52	0.7
Non-derivatized - MS/MS PE NeoBase Kit	868	4.79	0.35	0.49	0.53	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	110	4.41	0.29	0.71	0.55	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	4.68	0.33	0.39	0.52	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	5.03	0.47	2.30	0.55	0.9

2018 Quality Control Data Summaries of Statistical Analyses HYDROXYSTEAROYLCARNITINE (C18OH µmol/L blood)

Lot A1715 - Non-enriched 0 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	470	0.02	0.01	0.02	0.02	0.6
Derivatized - MS/MS PE NeoGram Kit	59	0.02	0.01	0.02	0.02	0.7
Non-derivatized - MS/MS non-kit	148	0.00	0.01	0.01	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	142	0.01	0.01	0.01	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	730	0.00	0.00	0.00	0.00	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	79	0.00	0.00	0.01	0.00	0.5
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	50	0.01	0.00	0.01	0.01	0.6

Lot B1715 – Enriched 0.25 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	499	0.18	0.03	0.07	0.02	0.6
Derivatized - MS/MS PE NeoGram Kit	60	0.18	0.04	0.04	0.02	0.7
Non-derivatized - MS/MS non-kit	160	0.17	0.03	0.07	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	149	0.16	0.04	0.07	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	765	0.15	0.01	0.02	0.00	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	0.13	0.01	0.05	0.00	0.5
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.16	0.04	0.08	0.01	0.6

Lot C1715 – Enriched 1 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	493	0.63	0.08	0.23	0.02	0.6
Derivatized - MS/MS PE NeoGram Kit	60	0.67	0.09	0.13	0.02	0.7
Non-derivatized - MS/MS non-kit	160	0.62	0.13	0.27	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	150	0.59	0.10	0.22	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	769	0.57	0.06	0.09	0.00	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	90	0.51	0.03	0.14	0.00	0.5
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.60	0.09	0.35	0.01	0.6

Lot D1715 – Enriched 1.5 µmol/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	493	0.94	0.14	0.35	0.02	0.6
Derivatized - MS/MS PE NeoGram Kit	60	0.99	0.15	0.22	0.02	0.7
Non-derivatized - MS/MS non-kit	159	0.95	0.17	0.41	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	150	0.87	0.16	0.33	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	767	0.87	0.07	0.12	0.00	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	90	0.77	0.07	0.19	0.00	0.5
Derivatized - RECIPE ClinSpot® LC-MS/MS Complete Kit	60	0.91	0.17	0.56	0.01	0.6

2018 Quality Control Data Summaries of Statistical Analyses GALACTOCEREBROSIDASE (GALC µmol/hr/L blood)

Lot A1708 – Mean Activity 0.33 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	90	0.25	0.06	0.09	0.03	0.8
FIA-MS/MS non-kit multiplexed enzyme reaction	70	0.42	0.12	0.30	0.15	0.9

Lot B1708 - Mean Activity 0.67 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	90	0.50	0.08	0.14	0.03	0.8
FIA-MS/MS non-kit multiplexed enzyme reaction	70	0.70	0.12	0.30	0.15	0.9

Lot C1708 – Mean Activity 3.52 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	90	2.75	0.39	0.94	0.03	0.8
FIA-MS/MS non-kit multiplexed enzyme reaction	70	3.47	0.39	0.45	0.15	0.9

Lot D1708 – Mean Activity 6.68 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	90	4.97	0.43	1.61	0.03	0.8
FIA-MS/MS non-kit multiplexed enzyme reaction	70	6.08	0.51	0.72	0.15	0.9

2018 Quality Control Data Summaries of Statistical Analyses ACID α-GLUCOSIDASE (GAA μmol/hr/L blood)

Lot A1708 – Mean Activity 0.15 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	119	0.17	0.06	0.10	-0.12	1.3
FIA-MS/MS non-kit multiplexed enzyme reaction	79	0.20	0.19	0.33	0.07	0.9

Lot B1708 – Mean Activity 0.87 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	119	0.93	0.16	0.30	-0.12	1.3
FIA-MS/MS non-kit multiplexed enzyme reaction	89	0.80	0.17	0.26	0.07	0.9

Lot C1708 – Mean Activity 5.66 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	120	7.03	1.36	2.33	-0.12	1.3
FIA-MS/MS non-kit multiplexed enzyme reaction	90	5.56	1.10	1.35	0.07	0.9

Lot D1708 – Mean Activity 9.02 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	120	11.53	1.27	4.03	-0.12	1.3
FIA-MS/MS non-kit multiplexed enzyme reaction	90	8.36	0.72	1.49	0.07	0.9

GAA FLUOROMETRIC METHOD

Level	Ν	All Lab Mean	Total SD	Avg Within Lab SD
A1708	30	0.41	0.38	0.07
B1708	30	0.71	0.69	0.08
C1708	40	3.04	2.41	0.79
D1708	40	5.48	4.08	0.79

2018 Quality Control Data Summaries of Statistical Analyses

ACID α-GLUCOSIDASE* (GAA µmol/hr/L blood) (cont.) METHOD REPORT FOR DIGITAL MICROFLUIDICS

Lot B1708 – Mean Activity 2.00 µmol/hr/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Digital Microfluidics	30	3.10	0.37	0.46	0.74	1.2

Lot C1708 – Mean Activity 14.64 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Digital Microfluidics	30	18.36	3.66	3.66	0.74	1.2

Lot D1708 – Mean Activity 24.65 µmol/hr/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Digital Microfluidics	30	30.20	3.03	4.05	0.74	1.2

*Note: Lot A1708 is not shown due to insufficient data.

2018 Quality Control Data Summaries of Statistical Analyses α-L-IDURONIDASE* (IDUA μmol/hr/L blood)

Lot A1708 – Mean Activity 0.12 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	108	0.13	0.07	0.10	-0.08	1.3
FIA-MS/MS non-kit multiplexed enzyme reaction	85	0.14	0.09	0.11	0.07	1.0

Lot B1708 - Mean Activity 0.60 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	110	0.66	0.11	0.27	-0.08	1.3
FIA-MS/MS non-kit multiplexed enzyme reaction	90	0.59	0.09	0.12	0.07	1.0

Lot C1708 – Mean Activity 4.38 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	110	5.47	0.79	2.22	-0.08	1.3
FIA-MS/MS non-kit multiplexed enzyme reaction	90	4.50	0.63	0.77	0.07	1.0

Lot D1708 – Mean Activity 8.04 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	110	10.28	1.07	5.03	-0.08	1.3
FIA-MS/MS non-kit multiplexed enzyme reaction	90	7.67	0.67	1.16	0.07	1.0

*Note: The Digital Microfluidics method is not shown for IDUA due to insufficient data.

2018 Quality Control Data Summaries of Statistical Analyses α-GALACTOSIDASE* (GLA μmol/hr/L blood)

Lot A1708 – Mean Activity 1.11 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	109	0.88	0.17	0.30	-0.19	1.0
FIA-MS/MS non-kit multiplexed enzyme reaction	60	1.06	0.21	0.38	0.04	0.9

Lot B1708 - Mean Activity 1.78 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	109	1.58	0.13	0.41	-0.19	1.0
FIA-MS/MS non-kit multiplexed enzyme reaction	60	1.65	0.24	0.37	0.04	0.9

Lot C1708 – Mean Activity 7.44 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	110	7.29	0.47	1.42	-0.19	1.0
FIA-MS/MS non-kit multiplexed enzyme reaction	60	7.19	0.34	0.47	0.04	0.9

Lot D1708 – Mean Activity 13.52 µmol/hr/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	110	13.24	0.97	2.64	-0.19	1.0
FIA-MS/MS non-kit multiplexed enzyme reaction	60	12.63	0.64	1.08	0.04	0.9

*Note: The Digital Microfluidics method is not shown for GLA due to insufficient data.

GLA FLUOROMETRIC METHOD

Level	N	All Lab Mean	Total SD	Avg Within Lab SD
A1708	30	0.96	0.65	0.09
B1708	30	1.59	0.70	0.15
C1708	40	5.43	2.14	0.46
D1708	40	10.53	3.60	1.24

2018 Quality Control Data Summaries of Statistical Analyses **ß-GLUCOCEREBROSIDASE* (ABG µmol/hr/L blood)**

Lot A1708 - Mean Activity 0.68 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	119	0.77	0.27	0.49	0.21	0.9
FIA-MS/MS non-kit multiplexed enzyme reaction	59	0.84	0.28	0.40	0.33	0.9

Lot B1708 - Mean Activity 1.26 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	119	1.39	0.36	0.87	0.21	0.9
FIA-MS/MS non-kit multiplexed enzyme reaction	60	1.29	0.23	0.38	0.33	0.9

Lot C1708 – Mean Activity 5.88 µmol/hr/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	119	5.67	0.89	2.75	0.21	0.9
FIA-MS/MS non-kit multiplexed enzyme reaction	60	5.84	0.73	0.88	0.33	0.9

Lot D1708 - Mean Activity 10.91 µmol/hr/L blood

METHOD		Maan	Average Within	Total	Y-	Olama
METHOD	N	wean	Lab SD	5D	Intercept	Slope
LC-MS/MS	120	10.15	1.13	4.53	0.21	0.9
FIA-MS/MS non-kit multiplexed enzyme reaction	60	9.60	0.92	1.62	0.33	0.9

*Note: The Digital Microfluidics method is not shown for ABG due to insufficient data.

2018 Quality Control Data Summaries of Statistical Analyses

ACID SPHINGOMYELINASE (ASM µmol/hr/L blood)

Lot A1708 – Mean Activity 0.08 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	50	0.08	0.08	0.18	-0.06	1.1
FIA-MS/MS non-kit multiplexed enzyme reaction	51	0.07	0.05	0.12	-0.02	1.0

Lot B1708 – Mean Activity 0.22 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	50	0.18	0.02	0.03	-0.06	1.1
FIA-MS/MS non-kit multiplexed enzyme reaction	52	0.19	0.03	0.04	-0.02	1.0

Lot C1708 – Mean Activity 1.21 µmol/hr/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	50	1.23	0.11	0.31	-0.06	1.1
FIA-MS/MS non-kit multiplexed enzyme reaction	60	1.27	0.18	0.24	-0.02	1.0

Lot D1708 – Mean Activity 2.04 µmol/hr/L blood

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	50	2.32	0.24	0.71	-0.06	1.1
FIA-MS/MS non-kit multiplexed enzyme reaction	60	2.06	0.20	0.27	-0.02	1.0

2018 Quality Control Data Summaries of Statistical Analyses 20:0-LYSOPHOSPHATIDYLCHOLINE (20LPC µmol/L blood)

Lot A1710 - Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
FIA-MS/MS	39	0.26	0.03	0.10	0.26	0.6

Lot B1710 – Enriched 1µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
FIA-MS/MS	40	0.88	0.10	0.37	0.26	0.6

Lot C1710 – Enriched 5µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
FIA-MS/MS	40	3.43	0.31	1.49	0.26	0.6

2018 Quality Control Data Summaries of Statistical Analyses 22:0-LYSOPHOSPHATIDYLCHOLINE (22LPC µmol/L blood)

Lot A1710 - Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
FIA-MS/MS	30	0.12	0.01	0.04	0.12	0.6
Positive Ion Mode LC-MSMS	30	0.12	0.08	0.13	0.12	1.1

Lot B1710 – Enriched 1µmol/L blood

METHOD	N	Moan	Average Within	Total	Y-	Slope
WEIHOD	IN	Wear	Lab 3D	30	intercept	Slope
FIA-MS/MS	30	0.72	0.09	0.24	0.12	0.6
Positive Ion Mode LC-MSMS	30	1.23	0.25	0.39	0.12	1.1

Lot C1710 – Enriched 5 µmol/L blood

			Average Within	Total	Y-	
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
FIA-MS/MS	30	3.14	0.29	1.10	0.12	0.6
Positive Ion Mode LC-MSMS	30	5.66	0.45	1.80	0.12	1.1

2018 Quality Control Data Summaries of Statistical Analyses 24:0-LYSOPHOSPHATIDYLCHOLINE (24LPC µmol/L blood)

Lot A1710 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
FIA-MS/MS	79	0.32	0.04	0.06	0.29	0.9
Positive Ion Mode LC-MSMS	40	0.22	0.18	0.31	0.24	0.9
Negative Ion Mode LC-MSMS	30	0.07	0.02	0.02	0.08	0.9

Lot B1710 – Enriched 1µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
FIA-MS/MS	80	1.19	0.18	0.26	0.29	0.9
Positive Ion Mode LC-MSMS	40	1.19	0.28	0.60	0.24	0.9
Negative Ion Mode LC-MSMS	30	1.01	0.20	0.33	0.08	0.9

Lot C1710 – Enriched 5µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
FIA-MS/MS	80	4.96	0.79	1.28	0.29	0.9
Positive Ion Mode LC-MSMS	40	4.87	0.78	2.41	0.24	0.9
Negative Ion Mode LC-MSMS	30	4.68	0.80	1.59	0.08	0.9

2018 Quality Control Data Summaries of Statistical Analyses 26:0 LYSOPHOSPHATIDYLCHOLINE (26LPC µmol/L blood)

Lot A1710 - Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
FIA-MS/MS	70	0.28	0.04	0.09	0.25	1.0
Positive Ion Mode LC-MSMS	69	0.09	0.03	0.15	0.10	1.0
Negative Ion Mode LC-MSMS	40	0.04	0.01	0.04	0.01	0.9

Lot B1710 – Enriched 1µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
FIA-MS/MS	70	1.21	0.19	0.23	0.25	1.0
Positive Ion Mode LC-MSMS	69	1.10	0.22	0.27	0.10	1.0
Negative Ion Mode LC-MSMS	49	0.85	0.09	0.17	0.01	0.9

Lot C1710 – Enriched 5µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
FIA-MS/MS	70	5.25	0.79	1.18	0.25	1.0
Positive Ion Mode LC-MSMS	69	5.01	0.47	1.02	0.10	1.0
Negative Ion Mode LC-MSMS	50	4.41	0.50	0.85	0.01	0.9
2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER 17 α-HYDROXYPROGESTERONE (170HP2 ng/mL serum)

Lot A1811 – Non-enriched 0 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	150	1.0	0.7	1.2	1.7	1.0

Lot B1811 – Enriched 10 ng/mL serum

			Average Within	Total	Y-	
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	10.8	1.2	2.5	1.7	1.0

Lot C1811 – Enriched 50 ng/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	51.6	4.5	10.5	1.7	1.0

Lot D1811 – Enriched 100 ng/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	103.2	9.6	21.9	1.7	1.0

			Average Within	Total	V -	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	209	500.0	46.4	104.1	1.7	1.0

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER 4-ANDROSTENEDIONE (4AD2 ng/mL serum)

Lot A1811 – Non-enriched 0 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	151	0.6	0.5	0.7	0.7	1.0

Lot B1811 – Enriched 10 ng/mL serum

NETUOD			Average Within	Total	Y-	0
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	10.7	1.2	2.8	0.7	1.0

Lot C1811 – Enriched 50 ng/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	53.4	4.4	13.0	0.7	1.0

Lot D1811 – Enriched 100 ng/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	105.1	9.4	26.9	0.7	1.0

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	522.0	48.4	132.9	0.7	1.0

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER CORTISOL (CORT2 ng/mL serum)

Lot A1811 – Non-enriched 0 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	155	1.4	1.0	1.4	-2.7	1.0

Lot B1811 – Enriched 10 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	197	2.8	0.8	2.4	-2.7	1.0

Lot C1811 – Enriched 50 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	210	52.1	4.2	11.5	-2.7	1.0

Lot D1811 – Enriched 100 ng/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	95.5	7.3	20.1	-2.7	1.0

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	503.7	39.2	108.8	-2.7	1.0

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER 11-DEOXYCORTISOL (11D2 ng/mL serum)

Lot A1811 – Non-enriched 0 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	102	0.6	1.2	1.3	5.4	1.0

Lot B1811 – Enriched 10 ng/mL serum

			Average Within	Total	Y-	<u>.</u>
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	140	10.5	1.2	4.0	5.4	1.0

Lot C1811 – Enriched 50 ng/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	140	55.5	3.7	15.8	5.4	1.0

Lot D1811 – Enriched 100 ng/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	140	108.4	7.7	32.4	5.4	1.0

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	140	482.2	35.1	163.8	5.4	1.0

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER 21-DEOXYCORTISOL (21D2 ng/mL serum)

Lot A1811 – Non-enriched 0 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	97	0.4	0.6	0.7	0.9	0.9

Lot B1811 – Enriched 10 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	139	8.9	1.2	2.5	0.9	0.9

Lot C1811 – Enriched 50 ng/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	140	46.3	4.1	10.5	0.9	0.9

Lot D1811 – Enriched 100 ng/mL serum

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	140	94.9	8.6	23.5	0.9	0.9

			Average			
			Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	140	459.5	44.1	107.6	0.9	0.9

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER ALLO-ISOLEUCINE (ALE2 µmol/L blood)

Lot A1813 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	110	1.2	0.3	2.6	2.9	1.0
UPLC	39	0.1	0.2	0.2	3.3	0.9

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	118	102.6	6.6	28.9	2.9	1.0
UPLC	50	98.3	8.7	13.6	3.3	0.9

Lot C1813 – Enriched 200 µmol/L blood

			Average Within	Total	Y-	0
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	119	202.5	17.8	45.8	2.9	1.0
UPLC	50	191.3	32.0	39.0	3.3	0.9

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	120	419.6	37.9	100.3	2.9	1.0
UPLC	50	381.3	57.9	81.1	3.3	0.9

			Average Within	Total	Y-	0
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	119	810.3	60.9	162.2	2.9	1.0
UPLC	50	752.7	111.6	159.0	3.3	0.9

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER ISOLEUCINE (ILE2 µmol/L blood)

Lot A1813 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	100	13.0	2.2	6.6	14.2	1.0
UPLC	50	10.0	2.0	2.4	5.4	0.9

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	100	112.1	9.6	17.7	14.2	1.0
UPLC	50	99.4	7.3	26.0	5.4	0.9

Lot C1813 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	100	209.1	17.0	34.2	14.2	1.0
UPLC	50	174.4	18.4	73.2	5.4	0.9

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	100	402.0	32.2	74.3	14.2	1.0
UPLC	50	348.4	38.6	137.1	5.4	0.9

			Average Within	Total	Υ.	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	100	790.6	63.3	146.7	14.2	1.0
UPLC	50	715.2	63.2	179.9	5.4	0.9

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER LEUCINE (LEU2 µmol/L blood)

Lot A1813 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	120	32.9	5.2	10.5	36.5	1.3
UPLC	39	26.1	5.2	5.7	16.8	0.9

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	120	167.8	14.0	72.2	36.5	1.3
UPLC	40	107.6	5.7	33.9	16.8	0.9

Lot C1813 – Enriched 200 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	120	298.2	28.9	138.1	36.5	1.3
UPLC	40	178.9	16.1	81.7	16.8	0.9

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	120	563.6	61.9	290.0	36.5	1.3
UPLC	40	339.0	34.2	147.0	16.8	0.9

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	120	1078.4	89.5	555.9	36.5	1.3
UPLC	40	705.4	57.9	184.4	16.8	0.9

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER PHENYLALANINE (PHE2 µmol/L blood)

Lot A1813 - Non-enriched 0 µmol/L blood

METHOD		Maan	Average Within	Total	Y-	Classe
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	110	16.0	2.0	6.1	19.7	0.9
UPLC	40	14.3	4.5	5.5	15.3	1.1

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	120	110.1	8.0	14.9	19.7	0.9
UPLC	40	128.4	43.8	52.6	15.3	1.1

Lot C1813 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	120	199.9	13.5	26.8	19.7	0.9
UPLC	40	265.1	94.2	141.4	15.3	1.1

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	120	382.6	24.8	45.7	19.7	0.9
UPLC	40	442.8	137.3	151.8	15.3	1.1

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	120	734.6	44.8	98.5	19.7	0.9
UPLC	40	936.6	288.3	378.5	15.3	1.1

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER TYROSINE (TYR2 µmol/L blood)

Lot A1813 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	100	21.8	2.5	4.3	20.3	0.9
UPLC	40	18.9	4.4	4.5	28.6	1.0

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	110	112.1	11.4	22.7	20.3	0.9
UPLC	40	122.6	26.6	31.9	28.6	1.0

Lot C1813 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	110	200.6	17.8	38.2	20.3	0.9
UPLC	40	224.1	70.4	75.4	28.6	1.0

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	110	383.0	30.1	67.2	20.3	0.9
UPLC	40	435.6	89.2	112.8	28.6	1.0

			Average Within	Total	Υ.	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	110	749.7	54.5	134.5	20.3	0.9
UPLC	40	790.8	150.9	158.3	28.6	1.0

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER VALINE (VAL2 µmol/L blood)

Lot A1813 - Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	110	50.9	6.3	27.6	50.9	0.9
UPLC	40	38.0	4.1	15.6	39.1	1.0

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	120	145.6	14.7	29.4	50.9	0.9
UPLC	40	143.7	24.6	27.3	39.1	1.0

Lot C1813 – Enriched 200 µmol/L blood

NETHOD			Average Within	Total	Y-	01
METHOD	N	wean	Lab SD	5D	Intercept	Slope
LC-MS/MS	120	238.7	29.7	45.8	50.9	0.9
UPLC	40	234.3	63.9	67.6	39.1	1.0

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	120	424.6	50.5	84.4	50.9	0.9
UPLC	40	420.0	89.0	105.4	39.1	1.0

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	120	802.7	84.5	162.2	50.9	0.9
UPLC	40	824.3	119.9	143.8	39.1	1.0

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER MALONIC ACID (MA2 µmol/L blood)

Lot A1714 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	20	5.26	1.21	1.47	5.06	0.8

Lot B1714 – Enriched 5 µmol/L blood

			Average Within	Total	Y-	
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	20	9.15	1.63	2.01	5.06	0.8

Lot C1714 – Enriched 10 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	20	13.55	2.19	2.45	5.06	0.8

Lot D1714 – Enriched 25 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	20	24.67	2.62	4.38	5.06	0.8

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	20	46.4	3.55	5.28	5.06	0.8

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER METHYLMALONIC ACID (MMA2 µmol/L blood)

Lot A1714 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	198	0.46	0.42	0.68	0.49	0.8

Lot B1714 – Enriched 5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
	••	moun			morepr	0.000
LC-MS/MS	208	4.54	0.52	1.28	0.49	0.8

Lot C1714 – Enriched 10 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	208	8.59	0.96	2.09	0.49	0.8

Lot D1714 – Enriched 25 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	208	20.63	2.14	4.62	0.49	0.8

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	207	40.85	4.19	9.04	0.49	0.8

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER ETHYLMALONIC ACID (EMA2 µmol/L blood)

Lot A1714 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	90	0.32	0.15	0.32	0.28	0.9

Lot B1714 – Enriched 5 µmol/L blood

			Average Within	Total	Y-	
METHOD	N	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	90	4.92	0.6	0.93	0.28	0.9

Lot C1714 – Enriched 10 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	90	9.46	1.21	2.26	0.28	0.9

Lot D1714 – Enriched 25 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	90	22.56	1.91	4.25	0.28	0.9

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	90	45.9	4.33	7.51	0.28	0.9

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER 2-METHYLCITRIC ACID (MCA2 µmol/L blood)

Lot A1714 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	148	0.23	0.17	0.26	0.31	0.9

Lot B1714 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	160	2.58	0.39	0.94	0.31	0.9

Lot C1714 – Enriched 5 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	160	4.89	0.63	1.48	0.31	0.9

Lot D1714 – Enriched 12.5 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	160	11.32	1.34	2.3	0.31	0.9

Lot E1714 – Enriched 25 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	160	22.58	2.75	4.7	0.31	0.9

2018 Quality Control Data Summaries of Statistical Analyses 2ND TIER TOTAL HOMOCYSTEINE (tHCY2 µmol/L blood)

Lot A1714 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
LC-MS/MS	210	6.36	1.15	3.34	5.74	0.9

Lot B1714 – Enriched 10 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	14.46	1.86	6.84	5.74	0.9

Lot C1714 – Enriched 20 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	23.03	3.11	10.74	5.74	0.9

Lot D1714 – Enriched 50 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	47.07	6.85	23.2	5.74	0.9

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
LC-MS/MS	210	92.48	12.64	48.95	5.74	0.9

2018 Quality Control Data Summaries of Statistical Analyses GUANIDINOACETIC ACID (GAA2 µmol/L blood)

Lot A1812 - Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
Derivatized MS/MS non-kit	50	1.00	0.15	0.27	0.87	0.8

Lot B1812 – Enriched 5 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized MS/MS non-kit	50	4.87	0.75	1.00	0.87	0.8

Lot C1812 – Enriched 10 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized MS/MS non-kit	49	8.78	0.81	1.25	0.87	0.8

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept	Slope
Derivatized MS/MS non-kit	50	17.17	1.35	2.35	0.87	0.8

2018 Quality Control Data Summaries of Statistical Analyses CREATINE (CRE2 µmol/L blood)

Lot A1812 - Non-enriched 0 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	30	184.68	10.08	15.99	181.23	0.8

Lot B1812 – Enriched 50 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	30	220.91	17.66	27.49	181.23	0.8

Lot C1812 – Enriched 200 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	30	338.06	14.6	20.08	181.23	0.8

Lot D1812 – Enriched 450 µmol/L blood

			Average Within	Total	Y-	
METHOD	Ν	Mean	Lab SD	SD	Intercept	Slope
Derivatized - MS/MS non-kit	30	547.58	31.17	39.7	181.23	0.8

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