Newborn Screening Quality Assurance Program

2019 Quality Control Report

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Introduction

The NSQAP Quality Control (QC) dried blood spot (DBS) 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 materials are 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 2019 Set 2 QC data submitted 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 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 Life Sciences Corporation (Marlborough, 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). The QC pool for Tandem Mass Spectrometry (MSMS1QC) included enrichments for twenty acylcarnitines - free carnitine (C0), acetylcarnitine (C2), propionylcarnitine (C3), malonylcarnitine (C3DC), butyrylcarnitine (C4), hydroxybutyrylcarnitine (C4OH), isovalerylcarnitine (C5), tiglylcarnitine (C5:1), glutarylcarnitine (C5DC), hydroxyisovalerylcarnitine (C5OH), hexanoylcarnitine (C6), octanoylcarnitine (C8), decanoylcarnitine (C10), dodecanoylcarnitine (C12), myristoylcarnitine (C14), tetradecenoylcarnitine (C14:1), palmitoylcarnitine (C16), hydroxypalmitoylcarnitine (C16OH), stearoylcarnitine (C18), hydroxystearoylcarnitine (C18OH), 20:0-, 22:0-, 24:0- and 26:0-lysophosphatidylcholine for the detection of X-linked Adrenoleukodystrophy (XALD), creatine (CRE), guanidinoacetic acid (GUAC), creatinine (CRN). We also provided materials for 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 Disorders (LSD).

T4, TSH, 17OHP and TGal, GALT consisted of QC materials from three lots per analyte, with each lot containing a different concentration of analyte. QC materials for IRT, TGal, amino acids, SUAC, acylcarnitines, XALD, GAMT, and LSD consisted of four lots.

NSQAP also distributed certified QC materials for newborn screening analytes and disorders tested by second-tier methods for tandem mass spectrometry (MS/MS). These programs include Second-tier Congenital Adrenal Hyperplasia (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

QC Material Production (cont.)

Homocystinuria (MMA-tHCY) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) for the analytes malonic acid (MA2), methylmalonic acid (MMA2), ethylmalonic acid (EMA2), 2-methylcitric acid (MCA2), and total homocysteine (tHCY2). QC materials for these analytes consisted of four to five lots.

QC Material Distribution

On June 25, we distributed DBS QC materials to 502 participanting laboratories worldwide.

QC Data Reporting Requirements

Participants used the QC Data Report forms located at https://www.cdc.gov/labstandards/nsqap_resources.html to report results. NSQAP required the following information for each QC analyte; 1) laboratory information (contact name, laboratory code number, email, 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 and analyte. If these minimum requirements were not met, the data was not accepted unless the participant corrected their submission.

Participant Results

For 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, 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 was excluded.

Several participants were required to resubmit their data because either the method was not entered from the drop-down menu as requested or data was reported in the incorrect units. 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 units of U/g Hb and other reportable units, we included a separate table to provide participants with peer-group statistics. For LSDQC 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—104 which show the analyte by series of QC lots, the number of measurements (N), the mean values, and the 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 where less than three participants reported data were not included in the tables.

Discussion

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 lot can influence the slope and intercept for a method.

Discussion (cont.)

For the purpose of 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 using all analyte concentrations within a lot series **(e.g., lots A1901, B1901, and C1901).** 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, CRE, GALC, GALC, GAA, IDUA, GAL, ABG, ASM. The endogenous concentration or activity levels of QC materials for second-tier analytes is represented by the non-enriched QC lots. For CRN and MA, no data are shown due to insufficient data.

The majority of analytes demonstrated 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 Request for Participation Form at:

https://www.cdc.gov/labstandards/nsqap_resources.html Send forms to NSQAPDMT@ cdc.gov

Domestic laboratories must submit changes no later than November 1, 2020 to receive materials in January 2021. International laboratories must submit changes no later than August 31, 2020 to receive materials in January 2021. Include your laboratory code number on the form and all correspondence with NSQAP.

2019 Quality Control Data Summaries of Statistical Analyses

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

Lot A1905 – Enriched 25 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	399	18.0	1.7	4.0	-4.5	0.9
AutoDelfia	560	20.8	1.6	3.3	-1.5	0.9
Ani Labsystems	70	23.8	2.3	3.7	4.1	0.9
LC-MS/MS	50	20.8	1.6	3.3	-0.4	0.9
PerkinElmer GSP Neonatal	580	20.6	1.7	3.0	0.7	0.8
Zentech	60	23.7	6.8	11.1	-1.0	1.1

Lot B1905 – Enriched 50 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	398	41.5	3.7	10.6	-4.5	0.9
AutoDelfia	560	44.3	3.1	6.9	-1.5	0.9
Ani Labsystems	70	50.2	3.9	11.0	4.1	0.9
LC-MS/MS	50	42.0	3.0	6.7	-0.4	0.9
PerkinElmer GSP Neonatal	580	43.5	2.7	5.1	0.7	0.8
Zentech	60	58.5	14.1	19.1	-1.0	1.1

Lot C1905 – Enriched 100 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	399	86.6	7.9	21.0	-4.5	0.9
AutoDelfia	560	88.9	7.0	13.9	-1.5	0.9
Ani Labsystems	70	89.6	12.9	21.7	4.1	0.9
LC-MS/MS	50	84.4	5.0	11.9	-0.4	0.9
PerkinElmer GSP Neonatal	580	83.2	5.2	9.2	0.7	0.8
Zentech	60	107.9	20.7	31.7	-1.0	1.1

2019 Quality Control Data Summaries of Statistical Analyses

THYROXINE (T_4 µg/dL serum)

Lot A1700 – Enriched 2 µg/dL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	100	1.7	0.4	0.8	-0.1	1.0
AutoDelfia	131	1.7	0.2	0.3	-0.5	1.0
PerkinElmer GSP Neonatal	104	2.3	0.3	1.6	0.0	1.1

Lot B1700 – Enriched 7 µg/dL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	100	6.6	0.8	1.4	-0.1	1.0
AutoDelfia	139	6.3	0.5	0.7	-0.5	1.0
PerkinElmer GSP Neonatal	130	7.6	0.8	4.0	0.0	1.1

Lot C1700 – Enriched 11 µg/dL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	100	10.2	0.9	1.8	-0.1	1.0
AutoDelfia	139	10.8	0.8	0.9	-0.5	1.0
PerkinElmer GSP Neonatal	130	12.4	1.2	5.2	0.0	1.1

2019 Quality Control Data Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE (TSH µIU/mL serum)

Lot A1901 – Enriched 25 µIU/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	459	26.1	2.7	7.0	-0.2	1.1
AutoDelfia	789	28.5	2.0	5.9	0.2	1.1
Ani Labsystems	160	28.0	2.7	6.2	-5.0	1.4
DiaSorin	70	30.9	2.8	3.9	2.7	1.1
PerkinElmer GSP Neonatal	720	25.7	2.0	4.7	-3.4	1.2
Zentech	110	19.9	2.7	8.9	-1.7	0.9
Trimaris Neonatal	30	25.1	2.4	3.7	1.7	1.0

Lot B1901 – Enriched 40 µIU/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	459	43.8	3.7	11.2	-0.2	1.1
AutoDelfia	789	46.4	3.0	9.2	0.2	1.1
Ani Labsystems	160	49.9	4.2	6.9	-5.0	1.4
DiaSorin	70	48.6	6.1	7.4	2.7	1.1
PerkinElmer GSP Neonatal	720	43.7	3.3	8.0	-3.4	1.2
Zentech	110	33.6	3.9	14.6	-1.7	0.9
Trimaris Neonatal	30	42.1	3.5	5.1	1.7	1.0

Lot C1901 – Enriched 80 µIU/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	459	85.8	7.9	22.8	-0.2	1.1
AutoDelfia	788	91.6	5.7	18.5	0.2	1.1
Ani Labsystems	160	102.6	7.6	14.9	-5.0	1.4
DiaSorin	70	93.7	9.3	12.1	2.7	1.1
PerkinElmer GSP Neonatal	720	90.1	6.4	16.1	-3.4	1.2
Zentech	110	68.2	9.7	31.3	-1.7	0.9
Trimaris Neonatal	30	79.4	4.6	8.7	1.7	1.0

2019 Quality Control Data Summaries of Statistical Analyses

GALACTOSE-1-PHOSPHATE URIDYLTRANSFERASE (GALT U/g Hb)

Lot A1903 – Assayed 1.3 U/g Hb

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
PerkinElmer Neonatal Kit U/g Hb	310	1.4	0.2	0.4	0.3	0.7
Astoria-Pacific Neonatal Microplate Reagent Kit	30	0.6	0.1	0.1	-0.3	0.6

Lot B1903 – Assayed 4.0 U/g Hb

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
PerkinElmer Neonatal Kit U/g Hb	350	2.9	0.3	0.7	0.3	0.7
Astoria-Pacific Neonatal Microplate Reagent Kit	30	2.1	0.2	0.3	-0.3	0.6

Lot C1903 – Assayed 9.4 U/g Hb

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
PerkinElmer Neonatal Kit U/g Hb	350	6.8	0.6	1.8	0.3	0.7
Astoria-Pacific Neonatal Microplate Reagent Kit	30	5.5	0.4	0.7	-0.3	0.6

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

Lot A1903

METHOD	N	Mean	Average Within Lab SD	All Lab SD	Min	Max
Astoria-Pacific 50 Hour Reagent Kit (µmol/L blood)	20	7.3	1.3	1.4	5.0	10.0
Perkin Elmer GSP Neonatal (U/dL blood)	72	0.9	0.4	1.3	0.0	8.2

Lot B1903

METHOD	N	Mean	Average Within Lab SD	All Lab SD	Min	Max
Astoria-Pacific 50 Hour Reagent Kit (µmol/L blood)	20	55.0	4.6	5.1	46.0	64.0
Perkin Elmer GSP Neonatal (U/dL blood)	146	1.7	0.3	1.5	0.5	8.8

Lot C1903

METHOD	N	Mean	Average Within Lab SD	All Lab SD	Min	Max
Astoria-Pacific 50 Hour Reagent Kit (µmol/L blood)	20	156.4	28.5	38.5	75.0	216.7
Perkin Elmer GSP Neonatal (U/dL blood)	220	10.2	0.8	5.3	5.8	41.5

Several laboratories reported their GALT results in either µmol/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 µmol/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 under those curcumstances.

2019 Quality Control Data Summaries of Statistical Analyses

IMMUNOREACTIVE TRYPSINOGEN (IRT ng/mL blood)

Lot A1809 – Assayed 16.6 ng/mL blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	169	17.5	1.8	3.3	0.0	1.0
AutoDelfia	579	17.3	1.3	2.0	1.5	1.0
PerkinElmer GSP Neonatal	499	16.5	1.5	2.9	-1.0	1.0
ZenTech	40	23.9	2.7	2.8	42.4	0.8
Labsystems - FEIA	80	21.5	3.9	7.3	1.6	1.1

Lot B1809 – Assayed 66.9 ng/mL blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	169	64.9	6.3	11.5	0.0	1.0
AutoDelfia	589	68.4	4.6	6.6	1.5	1.0
PerkinElmer GSP Neonatal	519	66.4	4.4	8.2	-1.0	1.0
ZenTech	30	114.0	8.6	13.9	42.4	0.8
Labsystems - FEIA	80	68.3	8.7	15.6	1.6	1.1

Lot C1809 – Assayed 122.0 ng/mL blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	169	124.0	12.6	28.1	0.0	1.0
AutoDelfia	589	127.3	9.3	12.2	1.5	1.0
PerkinElmer GSP Neonatal	519	122.7	7.8	18.9	-1.0	1.0
ZenTech	40	170.9	15.7	23.9	42.4	0.8
Labsystems - FEIA	79	132.9	15.5	28.5	1.6	1.1

IMMUNOREACTIVE TRYPSINOGEN (IRT ng/mL blood) cont.

Lot D1809 – Assayed 234.7 ng/mL blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Delfia	169	235.3	25.7	43.3	0.0	1.0
AutoDelfia	589	237.1	16.2	23.9	1.5	1.0
PerkinElmer GSP Neonatal	520	237.9	15.9	23.6	-1.0	1.0
ZenTech	40	206.9	18.3	37.4	42.4	0.8
Labsystems - FEIA	80	250.6	32.0	52.8	1.6	1.1

2019 Quality Control Data Summaries of Statistical Analyses

ALANINE (Ala µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	530	257.9	23.7	60.3	251.4	0.7
Derivatized - MS/MS PerkinElme	40	271.0	15.0	39.2	268.2	0.7
Non-derivatized - MS/MS non-kit	180	273.6	21.9	55.9	267.7	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	140	231.3	18.7	44.2	222.2	0.6
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	800	285.0	17.4	44.3	276.7	0.8
Non-derivatized - MS/MS Chromsystems	60	238.6	10.0	39.8	233.9	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	243.3	14.1	32.9	228.9	0.7

Lot B1815 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	530	378.7	34.0	90.7	251.4	0.7
Derivatized - MS/MS PerkinElme	40	399.0	19.4	68.1	268.2	0.7
Non-derivatized - MS/MS non-kit	180	409.2	41.0	93.1	267.7	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	140	324.2	23.6	61.8	222.2	0.6
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	800	423.9	27.3	73.7	276.7	0.8
Non-derivatized - MS/MS Chromsystems	60	342.2	15.1	58.2	233.9	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	338.0	23.8	57.2	228.9	0.7

Lot C1815 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	530	560.6	54.6	141.2	251.4	0.7
Derivatized - MS/MS PerkinElme	40	564.7	32.5	87.4	268.2	0.7
Non-derivatized - MS/MS non-kit	180	587.2	39.6	116.4	267.7	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	140	485.0	35.3	100.6	222.2	0.6
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	800	625.2	36.8	105.1	276.7	0.8
Non-derivatized - MS/MS Chromsystems	60	521.8	16.9	94.1	233.9	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	515.3	38.9	82.8	228.9	0.7

ALANINE (Ala µmol/L blood) cont.

Lot D1815 – Enriched 600 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	530	683.1	62.8	166.5	251.4	0.7
Derivatized - MS/MS PerkinElme	40	688.2	36.5	115.3	268.2	0.7
Non-derivatized - MS/MS non-kit	180	731.2	51.3	154.3	267.7	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	140	589.7	42.8	127.9	222.2	0.6
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	800	774.5	45.8	130.0	276.7	0.8
Non-derivatized - MS/MS Chromsystems	60	610.9	26.8	101.9	233.9	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	640.5	50.5	91.2	228.9	0.7

2019 Quality Control Data Summaries of Statistical Analyses

ARGININE (Arg µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	570	8.8	1.5	5.2	7.1	0.7
Derivatized - MS/MS PerkinElme	60	6.7	0.4	1.1	5.8	0.9
Non-derivatized - MS/MS non-kit	180	7.9	1.4	5.8	6.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	140	9.3	1.8	3.3	11.4	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	870	6.1	0.6	1.4	5.2	0.8
Non-derivatized - MS/MS Chromsystems	70	6.9	1.2	2.7	11.1	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	5.9	1.0	2.1	4.0	0.7

Lot B1815 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	570	76.9	6.4	28.4	7.1	0.7
Derivatized - MS/MS PerkinElme	60	91.8	5.3	6.9	5.8	0.9
Non-derivatized - MS/MS non-kit	179	87.7	6.6	26.5	6.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	140	92.1	10.5	26.2	11.4	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	870	86.2	5.0	10.8	5.2	0.8
Non-derivatized - MS/MS Chromsystems	70	87.5	5.3	8.2	11.1	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	68.9	5.7	15.5	4.0	0.7

Lot C1815 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	570	150.7	13.8	57.7	7.1	0.7
Derivatized - MS/MS PerkinElme	60	174.9	10.0	11.8	5.8	0.9
Non-derivatized - MS/MS non-kit	180	167.7	12.8	46.3	6.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	140	168.0	19.2	50.1	11.4	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	870	166.2	9.8	20.3	5.2	0.8
Non-derivatized - MS/MS Chromsystems	70	163.6	8.3	21.9	11.1	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	137.1	14.8	36.9	4.0	0.7

ARGININE (Arg µmol/L blood) cont.

Lot D1815 – Enriched 300 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	570	224.6	19.7	93.3	7.1	0.7
Derivatized - MS/MS PerkinElme	60	265.7	19.2	22.8	5.8	0.9
Non-derivatized - MS/MS non-kit	180	254.8	19.3	72.8	6.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	140	243.7	30.8	74.9	11.4	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	870	251.1	14.6	30.1	5.2	0.8
Non-derivatized - MS/MS Chromsystems	70	225.4	13.1	33.8	11.1	0.7
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	207.3	17.5	51.8	4.0	0.7

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CITRULLINE (Cit µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	14.9	1.5	3.1	15.5	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	16.2	1.6	2.8	16.2	0.9
Non-derivatized - MS/MS non-kit	260	15.9	2.2	6.3	16.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	16.0	2.1	3.5	16.3	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	919	15.2	1.6	2.3	15.7	0.9
Non-derivatized - MS/MS Chromsystems	80	15.2	1.6	3.5	16.9	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	14.4	1.2	1.9	15.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	17.3	1.8	2.2	18.4	0.7

Lot B1815 – Enriched 25 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	579	35.0	3.2	7.4	15.5	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	58	38.8	2.5	5.0	16.2	0.9
Non-derivatized - MS/MS non-kit	260	38.0	3.6	7.0	16.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	36.2	3.4	5.9	16.3	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	919	38.0	2.7	4.2	15.7	0.9
Non-derivatized - MS/MS Chromsystems	80	35.5	2.6	6.8	16.9	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	35.5	2.1	2.8	15.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	35.3	2.2	3.4	18.4	0.7

Lot C1815 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	94.3	8.2	19.5	15.5	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	108.1	6.1	15.1	16.2	0.9
Non-derivatized - MS/MS non-kit	260	100.2	9.0	18.9	16.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	159	98.3	8.6	15.4	16.3	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	918	102.9	6.6	11.0	15.7	0.9
Non-derivatized - MS/MS Chromsystems	80	102.3	6.1	14.7	16.9	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	96.3	6.6	9.4	15.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	88.2	4.7	11.0	18.4	0.7

CITRULLINE (Cit µmol/L blood) (cont.)

Lot D1815 – Enriched 250 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	210.0	17.8	40.5	15.5	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	244.5	16.8	38.0	16.2	0.9
Non-derivatized - MS/MS non-kit	260	226.4	18.7	42.2	16.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	218.5	19.0	33.9	16.3	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	920	233.2	13.9	22.9	15.7	0.9
Non-derivatized - MS/MS Chromsystems	80	215.9	14.7	37.5	16.9	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	215.2	12.5	16.7	15.2	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	187.3	12.5	26.2	18.4	0.7

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GLYCINE (Gly µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	500	331.9	26.4	74.3	318.7	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	348.8	19.0	29.4	341.8	0.8
Non-derivatized - MS/MS non-kit	130	278.5	32.2	83.1	268.8	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	140	289.1	22.5	92.4	277.8	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	720	343.0	25.7	61.5	329.2	0.8
Non-derivatized - MS/MS Chromsystems	60	226.3	12.8	36.6	220.3	0.5
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	349.3	20.8	37.4	330.8	0.8

Lot B1815 – Enriched 300 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	500	526.1	38.5	113.6	318.7	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	564.6	29.9	60.2	341.8	0.8
Non-derivatized - MS/MS non-kit	130	435.5	49.1	138.3	268.8	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	140	452.1	32.8	145.3	277.8	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	720	549.4	35.9	92.2	329.2	0.8
Non-derivatized - MS/MS Chromsystems	60	345.7	24.3	52.6	220.3	0.5
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	546.4	32.2	56.9	330.8	0.8

Lot C1815 – Enriched 600 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	500	794.3	57.9	174.7	318.7	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	832.9	46.6	78.4	341.8	0.8
Non-derivatized - MS/MS non-kit	130	640.0	58.5	206.9	268.8	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	140	675.6	54.4	221.0	277.8	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	720	833.7	57.8	143.9	329.2	0.8
Non-derivatized - MS/MS Chromsystems	60	524.7	24.5	86.7	220.3	0.5
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	826.6	46.1	83.7	330.8	0.8

GLYCINE (Gly µmol/L blood) cont.

Lot D1815 – Enriched 900 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	500	1017.9	77.9	250.1	318.7	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	1057.4	75.5	124.3	341.8	0.8
Non-derivatized - MS/MS non-kit	130	822.1	78.7	268.4	268.8	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	140	864.8	56.6	273.7	277.8	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	720	1070.4	74.0	188.2	329.2	0.8
Non-derivatized - MS/MS Chromsystems	60	644.1	47.1	90.0	220.3	0.5
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1074.6	84.0	140.1	330.8	0.8

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LEUCINE (Leu µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	84.9	6.6	14.8	86.8	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	88.5	5.6	10.0	90.5	0.8
Non-derivatized - MS/MS non-kit	320	98.5	7.1	15.3	98.3	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	150	85.2	7.8	21.9	85.5	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	99.5	6.3	12.4	99.2	0.9
Non-derivatized - MS/MS Chromsystems	80	100.2	5.3	23.4	107.6	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	117.2	6.0	9.3	117.3	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	80.0	4.1	8.8	75.2	0.8

Lot B1815 – Enriched 150 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	197.4	14.9	30.6	86.8	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	212.9	14.2	19.4	90.5	0.8
Non-derivatized - MS/MS non-kit	320	217.1	14.0	31.7	98.3	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	150	181.1	11.1	36.5	85.5	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	220.2	12.8	21.7	99.2	0.9
Non-derivatized - MS/MS Chromsystems	80	207.0	9.0	36.4	107.6	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	243.6	13.5	14.2	117.3	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	186.1	10.5	22.2	75.2	0.8

Lot C1815 – Enriched 300 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	333.8	25.0	52.4	86.8	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	353.7	22.2	27.8	90.5	0.8
Non-derivatized - MS/MS non-kit	320	356.7	21.9	52.2	98.3	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	297.2	23.9	71.1	85.5	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	366.8	22.6	38.6	99.2	0.9
Non-derivatized - MS/MS Chromsystems	80	339.0	12.9	41.9	107.6	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	399.4	18.3	21.3	117.3	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	324.9	21.0	42.3	75.2	0.8

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LEUCINE (Leu µmol/L blood) (cont.)

Lot D1815 – Enriched 600 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	549.1	42.7	89.6	86.8	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	592.3	37.0	46.8	90.5	0.8
Non-derivatized - MS/MS non-kit	320	594.9	40.4	102.9	98.3	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	487.7	35.6	116.4	85.5	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	939	609.9	33.9	59.1	99.2	0.9
Non-derivatized - MS/MS Chromsystems	80	515.7	23.3	61.1	107.6	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	651.5	33.2	50.8	117.3	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	560.9	44.0	77.7	75.2	0.8

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METHIONINE (Met µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	14.6	2.0	4.3	13.6	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	13.6	1.6	2.0	17.0	0.8
Non-derivatized - MS/MS non-kit	310	12.5	1.4	4.3	11.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	11.5	3.9	9.1	10.6	0.5
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	11.2	1.0	1.7	9.3	0.8
Non-derivatized - MS/MS Chromsystems	80	9.8	0.9	1.6	9.6	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	13.3	0.8	0.8	11.5	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	12.9	1.0	1.4	10.5	0.8

Lot B1815 – Enriched 50 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	52.3	4.5	7.6	13.6	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	60.2	10.7	25.6	17.0	0.8
Non-derivatized - MS/MS non-kit	310	48.3	4.2	9.4	11.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	36.3	5.1	13.6	10.6	0.5
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	45.5	3.2	5.5	9.3	0.8
Non-derivatized - MS/MS Chromsystems	80	41.3	2.7	4.6	9.6	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	51.5	2.6	3.7	11.5	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	50.5	3.0	5.3	10.5	0.8

Lot C1815 – Enriched 150 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	133.2	10.9	19.4	13.6	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	141.6	14.1	30.4	17.0	0.8
Non-derivatized - MS/MS non-kit	310	124.5	8.6	24.6	11.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	93.0	11.0	34.4	10.6	0.5
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	120.0	7.9	15.7	9.3	0.8
Non-derivatized - MS/MS Chromsystems	80	111.5	5.2	15.2	9.6	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	138.4	8.8	13.8	11.5	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	132.9	10.3	14.7	10.5	0.8

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METHIONINE (Met µmol/L blood) (cont.)

Lot D1815 – Enriched 250 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	213.2	16.8	32.5	13.6	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	216.9	16.0	24.4	17.0	0.8
Non-derivatized - MS/MS non-kit	310	203.1	13.3	37.6	11.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	160	146.4	15.7	51.2	10.6	0.5
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	198.5	12.7	23.5	9.3	0.8
Non-derivatized - MS/MS Chromsystems	80	173.9	9.7	23.0	9.6	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	223.1	11.7	12.8	11.5	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	220.9	15.7	27.8	10.5	0.8

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ORNITHINE (Orn µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	490	112.4	12.0	50.7	106.2	0.4
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	138.0	8.7	10.4	133.5	0.5
Non-derivatized - MS/MS non-kit	160	127.3	13.6	35.3	120.3	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	140	138.8	11.1	39.8	130.4	0.5
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	730	137.9	8.8	25.4	129.8	0.6
Non-derivatized - MS/MS Chromsystems	60	154.7	9.6	16.9	144.9	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	117.0	9.9	10.4	108.5	0.5

Lot B1815 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	490	139.8	12.9	62.2	106.2	0.4
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	176.8	11.3	17.5	133.5	0.5
Non-derivatized - MS/MS non-kit	160	157.2	17.5	47.8	120.3	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	140	168.7	14.9	49.8	130.4	0.5
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	730	171.4	10.0	31.8	129.8	0.6
Non-derivatized - MS/MS Chromsystems MassChrom	60	184.2	11.3	19.5	144.9	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	138.8	13.3	15.2	108.5	0.5

Lot C1815 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	490	198.0	19.2	87.5	106.2	0.4
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	230.4	16.5	24.3	133.5	0.5
Non-derivatized - MS/MS non-kit	160	218.7	23.2	58.6	120.3	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	139	236.5	17.9	73.0	130.4	0.5
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	730	242.2	14.7	42.7	129.8	0.6
Non-derivatized - MS/MS Chromsystems	60	267.3	12.4	26.0	144.9	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	204.9	23.7	25.6	108.5	0.5

2019 Quality Control Data Summaries of Statistical Analyses

ORNITHINE (Orn µmol/L blood)(cont.)

Lot D1815 – Enriched 300 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	490	240.7	25.3	108.1	106.2	0.4
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	284.4	27.9	33.0	133.5	0.5
Non-derivatized - MS/MS non-kit	160	267.5	23.0	67.0	120.3	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	140	289.8	21.1	84.9	130.4	0.5
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	730	297.8	17.6	50.7	129.8	0.6
Non-derivatized - MS/MS Chromsystems	60	319.2	17.8	38.3	144.9	0.6
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	246.9	25.1	26.8	108.5	0.5

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PHENYLALANINE (Phe µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
PerkinElmer Neonatal Kit	99	46.5	12.3	18.2	44.2	0.8
Derivatized - MS/MS non-kit	600	37.1	3.2	6.6	37.6	0.9
Ani Labsystems	130	33.2	6.1	15.6	30.4	1.1
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	38.1	2.8	4.3	37.4	0.9
Non-derivatized - MS/MS non-kit	320	35.4	2.6	4.5	34.0	0.9
Fluorometric manual (e.g. Hill or Misuma)	81	61.1	8.5	16.6	61.9	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	150	36.8	3.5	6.4	35.8	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	37.4	2.2	21.7	36.2	0.9
Non-derivatized - MS/MS Chromsystems	90	38.9	2.2	6.2	43.2	0.8
PerkinElmer GSP Neonatal	60	31.7	10.3	20.0	29.2	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	42.8	2.1	5.5	44.7	1.0
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	34.8	2.9	4.3	31.1	0.8

Lot B1815 – Enriched 150 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
PerkinElmer Neonatal Kit	100	162.8	16.0	19.0	44.2	0.8
Derivatized - MS/MS non-kit	599	164.2	11.4	23.9	37.6	0.9
Ani Labsystems	130	195.6	17.7	24.8	30.4	1.1
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	176.1	9.9	19.7	37.4	0.9
Non-derivatized - MS/MS non-kit	320	165.0	10.5	21.0	34.0	0.9
Fluorometric manual (e.g. Hill or Misuma)	90	225.3	15.7	33.2	61.9	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	150	151.7	11.0	21.0	35.8	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	166.7	9.1	25.7	36.2	0.9
Non-derivatized - MS/MS Chromsystems	90	168.4	8.5	21.4	43.2	0.8
PerkinElmer GSP Neonatal	70	149.7	12.1	66.7	29.2	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	188.1	9.5	18.6	44.7	1.0
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	153.7	11.0	18.3	31.1	0.8

PHENYLALANINE (Phe µmol/L blood) (cont.)

Lot C1815 – Enriched 300 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
PerkinElmer Neonatal Kit	100	290.9	25.2	34.8	44.2	0.8
Derivatized - MS/MS non-kit	600	296.2	20.1	43.1	37.6	0.9
Ani Labsystems	129	369.9	20.6	38.1	30.4	1.1
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	316.2	15.8	28.2	37.4	0.9
Non-derivatized - MS/MS non-kit	320	293.8	18.5	46.4	34.0	0.9
Fluorometric manual (e.g. Hill or Misuma)	90	395.0	31.9	53.1	61.9	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	150	274.4	18.9	48.1	35.8	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	303.1	17.2	40.3	36.2	0.9
Non-derivatized - MS/MS Chromsystems	90	299.5	13.9	31.7	43.2	0.8
PerkinElmer GSP Neonatal	70	276.7	15.6	114.9	29.2	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	334.3	15.4	31.4	44.7	1.0
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	279.0	24.0	30.2	31.1	0.8

Lot D1815 – Enriched 450 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
PerkinElmer Neonatal Kit	100	412.9	37.2	52.5	44.2	0.8
Derivatized - MS/MS non-kit	600	418.3	30.6	64.9	37.6	0.9
Ani Labsystems	130	540.5	31.0	60.3	30.4	1.1
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	456.8	27.0	46.6	37.4	0.9
Non-derivatized - MS/MS non-kit	320	431.0	30.8	65.7	34.0	0.9
Fluorometric manual (e.g. Hill or Misuma)	90	552.9	36.3	61.7	61.9	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	149	390.5	25.4	74.2	35.8	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	929	435.1	23.8	50.8	36.2	0.9
Non-derivatized - MS/MS Chromsystems	90	406.8	21.4	55.1	43.2	0.8
PerkinElmer GSP Neonatal	70	402.8	28.8	169.0	29.2	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	469.5	21.1	26.8	44.7	1.0
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	413.0	36.0	56.5	31.1	0.8

2019 Quality Control Data Summaries of Statistical Analyses

SUCCINYLACETONE (SUAC µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	208	0.8	0.2	0.5	0.8	0.5
Non-derivatized - MS/MS non-kit	100	1.1	0.2	1.0	1.0	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	140	0.5	0.2	0.5	0.4	0.4
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	583	0.5	0.1	0.3	0.5	0.2

Lot B1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	210	2.2	0.3	1.0	0.8	0.5
Non-derivatized - MS/MS non-kit	100	2.5	0.3	1.7	1.0	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	140	1.5	0.3	0.6	0.4	0.4
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	590	1.1	0.2	0.4	0.5	0.2

Lot C1815 – Enriched 10 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	210	6.2	0.8	3.0	0.8	0.5
Non-derivatized - MS/MS non-kit	100	6.4	0.6	4.7	1.0	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	140	4.5	0.6	1.0	0.4	0.4
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	590	2.8	0.3	0.8	0.5	0.2

Lot D1815 – Enriched 20 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	210	11.6	1.2	6.1	0.8	0.5
Non-derivatized - MS/MS non-kit	100	12.5	1.4	9.8	1.0	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	140	9.2	1.3	4.3	0.4	0.4
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	590	5.2	0.5	1.4	0.5	0.2

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TYROSINE (Tyr µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	590	34.1	3.5	7.4	35.0	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	34.3	3.5	4.1	36.3	0.8
Non-derivatized - MS/MS non-kit	320	37.5	3.8	10.1	39.5	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	160	37.3	3.7	6.1	37.8	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	35.9	2.9	5.2	34.7	0.9
Non-derivatized - MS/MS Chromsystems	80	37.5	2.3	5.3	41.3	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	33.4	2.0	2.4	35.1	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	29.7	1.7	2.5	26.0	0.8

Lot B1815 – Enriched 300 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	590	282.4	21.7	52.4	35.0	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	290.6	22.1	26.6	36.3	0.8
Non-derivatized - MS/MS non-kit	320	296.8	20.7	56.0	39.5	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	160	287.1	21.7	42.8	37.8	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	305.9	18.2	36.3	34.7	0.9
Non-derivatized - MS/MS Chromsystems	80	302.5	16.0	36.1	41.3	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	283.3	12.5	16.0	35.1	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	258.9	12.2	24.0	26.0	0.8

Lot C1815 – Enriched 600 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	590	534.3	51.1	105.4	35.0	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	542.5	28.3	35.6	36.3	0.8
Non-derivatized - MS/MS non-kit	320	553.6	38.1	103.9	39.5	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	160	544.9	40.9	91.6	37.8	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	581.4	35.3	75.9	34.7	0.9
Non-derivatized - MS/MS Chromsystems	80	576.2	32.6	80.6	41.3	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	535.6	28.2	40.5	35.1	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	495.0	33.4	42.4	26.0	0.8

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TYROSINE (Tyr µmol/L blood) (cont.)

Lot D1815 – Enriched 900 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	590	776.1	65.0	151.5	35.0	0.8
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	790.7	55.0	60.8	36.3	0.8
Non-derivatized - MS/MS non-kit	320	804.4	51.4	156.0	39.5	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	160	788.1	56.4	132.7	37.8	0.8
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	939	854.7	49.2	107.6	34.7	0.9
Non-derivatized - MS/MS Chromsystems	80	817.9	56.0	83.1	41.3	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	776.0	35.1	40.2	35.1	0.8
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	739.1	51.8	74.3	26.0	0.8

2019 Quality Control Data Summaries of Statistical Analyses

VALINE (Val µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	570	86.5	8.5	21.5	88.9	0.7
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	88.5	7.0	11.4	90.1	0.8
Non-derivatized - MS/MS non-kit	250	74.6	5.4	11.9	77.6	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	75.1	8.3	15.3	74.0	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	919	83.9	6.1	13.4	84.9	0.9
Non-derivatized - MS/MS Chromsystems	70	68.0	3.3	8.5	72.8	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	89.6	4.6	10.5	93.0	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	66.4	4.3	7.6	65.1	0.7

Lot B1815 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	570	159.0	12.9	29.1	88.9	0.7
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	164.8	12.2	19.3	90.1	0.8
Non-derivatized - MS/MS non-kit	250	152.7	12.1	34.5	77.6	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	141.5	15.4	29.1	74.0	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	920	169.4	11.6	21.9	84.9	0.9
Non-derivatized - MS/MS Chromsystems	70	134.0	7.3	14.3	72.8	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	177.2	10.2	19.1	93.0	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	131.2	8.2	18.9	65.1	0.7

Lot C1815 – Enriched 300 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	570	308.5	25.2	56.5	88.9	0.7
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	325.1	19.4	28.2	90.1	0.8
Non-derivatized - MS/MS non-kit	250	302.3	21.8	57.1	77.6	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	287.9	25.6	65.6	74.0	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	919	349.3	25.5	46.3	84.9	0.9
Non-derivatized - MS/MS Chromsystems	70	270.9	13.4	21.6	72.8	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	363.2	20.4	33.8	93.0	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	272.4	21.6	31.6	65.1	0.7

VALINE (Val µmol/L blood) (cont.)

Lot D1815 – Enriched 500 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	570	438.3	36.4	82.7	88.9	0.7
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	466.6	30.8	47.9	90.1	0.8
Non-derivatized - MS/MS non-kit	250	442.2	32.4	85.0	77.6	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	160	424.2	38.8	104.5	74.0	0.7
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	919	512.8	34.1	65.4	84.9	0.9
Non-derivatized - MS/MS Chromsystems	70	373.7	24.0	55.4	72.8	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	516.2	27.3	30.1	93.0	0.9
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	407.1	36.5	60.8	65.1	0.7

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TOTAL GALACTOSE (TGal mg/dL blood)

Lot A1905 – Enriched 5 mg/dL blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Siemens Healthcare Diagnostics	30	5.4	0.3	0.5	2.0	0.8
Colorimetric	40	7.2	1.4	1.9	1.1	1.2
PerkinElmer Neonatal Kit	320	4.7	0.5	1.1	0.6	0.8
Bio-Rad Quantase	70	5.8	0.9	1.6	-1.4	1.5
Interscientific Enzyme	40	4.1	0.5	0.7	0.4	0.8
Astoria-Pacific 50 Hour Reagent Kit	40	6.4	0.6	0.8	1.7	1.0
TechnoSuma UMTEST	30	6.4	2.3	2.4	1.0	1.0
Fluorometric manual (e.g. Hill or Misuma)	150	5.5	0.5	1.1	0.7	1.0
PerkinElmer GSP Neonatal	240	5.7	0.6	1.0	0.9	1.0
Zentech	70	5.9	0.9	1.3	2.2	0.8

Lot B1905 – Enriched 10 mg/dL blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Siemens Healthcare Diagnostics	30	10.5	0.5	0.9	2.0	0.8
Colorimetric	40	13.4	2.1	3.7	1.1	1.2
PerkinElmer Neonatal Kit	320	8.9	0.7	1.7	0.6	0.8
Bio-Rad Quantase	70	13.1	2.4	3.5	-1.4	1.5
Interscientific Enzyme	40	8.1	0.5	0.9	0.4	0.8
Astoria-Pacific 50 Hour Reagent Kit	40	11.3	0.9	1.0	1.7	1.0
TechnoSuma UMTEST	30	10.7	2.1	3.1	1.0	1.0
Fluorometric manual (e.g. Hill or Misuma)	150	10.3	0.9	1.7	0.7	1.0
PerkinElmer GSP Neonatal	240	10.6	0.9	1.7	0.9	1.0
Zentech	70	11.0	1.0	2.4	2.2	0.8

Lot C1905 – Enriched 30 mg/dL blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Siemens Healthcare Diagnostics	30	25.4	1.2	3.8	2.0	0.8
Colorimetric	40	37.8	5.9	13.5	1.1	1.2
PerkinElmer Neonatal Kit	320	25.2	1.7	4.3	0.6	0.8
Bio-Rad Quantase	70	42.0	4.3	8.8	-1.4	1.5
Interscientific Enzyme	40	23.1	1.4	2.7	0.4	0.8
Astoria-Pacific 50 Hour Reagent Kit	40	30.2	2.7	3.4	1.7	1.0
TechnoSuma UMTEST	30	31.3	4.8	6.2	1.0	1.0
Fluorometric manual (e.g. Hill or Misuma)	150	29.2	1.9	3.7	0.7	1.0
PerkinElmer GSP Neonatal	240	30.0	2.9	4.9	0.9	1.0
Zentech	70	26.9	2.1	5.4	2.2	0.8

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FREE CARNITINE (C0 µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	17.82	1.44	3.48	17.49	1.50
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	20.23	1.39	4.28	19.68	1.83
Non-derivatized - MS/MS non-kit	250	15.73	1.19	2.86	15.63	1.14
Derivatized - MS/MS Chromsystems MassChrom Kit	160	14.09	1.68	3.86	13.70	1.25
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	939	15.43	1.09	2.01	15.21	1.16
Non-derivatized - MS/MS Chromsystems	60	15.32	0.95	2.88	15.25	1.03
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	16.65	0.94	1.58	16.74	1.18
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	19.18	1.47	2.22	18.50	1.61

Lot B1815 – Enriched 10 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	32.41	2.68	6.43	17.49	1.50
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	37.50	2.81	7.60	19.68	1.83
Non-derivatized - MS/MS non-kit	250	27.31	2.15	5.17	15.63	1.14
Derivatized - MS/MS Chromsystems MassChrom Kit	160	26.18	2.56	5.80	13.70	1.25
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	26.75	1.78	3.33	15.21	1.16
Non-derivatized - MS/MS Chromsystems	60	25.14	1.33	3.58	15.25	1.03
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	28.76	1.70	2.15	16.74	1.18
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	33.95	2.33	3.21	18.50	1.61

Lot C1815 – Enriched 20 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	46.77	3.96	9.78	17.49	1.50
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	55.51	3.95	12.16	19.68	1.83
Non-derivatized - MS/MS non-kit	250	37.55	2.53	7.37	15.63	1.14
Derivatized - MS/MS Chromsystems MassChrom Kit	160	37.75	3.19	7.64	13.70	1.25
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	37.80	2.63	4.77	15.21	1.16
Non-derivatized - MS/MS Chromsystems	60	36.41	1.74	4.88	15.25	1.03
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	40.21	2.46	3.53	16.74	1.18
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	49.89	4.81	7.04	18.50	1.61

FREE CARNITINE (C0 µmol/L blood) (cont.)

Lot D1815 – Enriched 30 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	63.14	5.05	13.64	17.49	1.50
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	75.18	4.30	17.54	19.68	1.83
Non-derivatized - MS/MS non-kit	250	50.30	3.46	9.86	15.63	1.14
Derivatized - MS/MS Chromsystems MassChrom Kit	160	52.05	5.12	13.96	13.70	1.25
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	50.37	3.62	6.51	15.21	1.16
Non-derivatized - MS/MS Chromsystems	60	45.88	2.63	6.99	15.25	1.03
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	52.18	2.54	3.33	16.74	1.18
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	67.44	5.12	6.77	18.50	1.61

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ACETYLCARNITINE (C2 µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	12.45	1.16	3.83	12.47	0.98
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	11.92	0.77	2.89	11.90	0.68
Non-derivatized - MS/MS non-kit	240	9.63	0.75	2.52	9.90	1.07
Derivatized - MS/MS Chromsystems MassChrom Kit	160	10.12	1.07	2.48	10.30	0.87
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	920	8.08	0.47	1.18	8.19	0.92
Non-derivatized - MS/MS Chromsystems	60	7.90	0.46	1.58	8.41	0.81
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	9.31	0.38	0.70	9.55	1.03
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	9.63	0.64	1.09	9.52	0.84

Lot B1815 – Enriched 10 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	22.32	1.71	4.75	12.47	0.98
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	18.74	1.16	2.26	11.90	0.68
Non-derivatized - MS/MS non-kit	240	21.16	1.56	5.56	9.90	1.07
Derivatized - MS/MS Chromsystems MassChrom Kit	160	19.27	1.72	3.05	10.30	0.87
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	920	17.68	1.01	2.63	8.19	0.92
Non-derivatized - MS/MS Chromsystems	60	16.91	0.93	2.90	8.41	0.81
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	20.18	1.21	1.50	9.55	1.03
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	17.99	1.17	2.46	9.52	0.84

Lot C1815 – Enriched 20 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	32.14	2.53	6.59	12.47	0.98
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	25.43	1.48	2.16	11.90	0.68
Non-derivatized - MS/MS non-kit	240	31.04	1.82	7.46	9.90	1.07
Derivatized - MS/MS Chromsystems MassChrom Kit	160	27.66	2.09	3.78	10.30	0.87
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	920	26.46	1.56	3.98	8.19	0.92
Non-derivatized - MS/MS Chromsystems	60	25.47	1.32	3.85	8.41	0.81
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	30.13	1.44	1.91	9.55	1.03
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	25.76	1.70	2.84	9.52	0.84

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ACETYLCARNITINE (C2 μmol/L blood) (cont.)

Lot D1815 – Enriched 30 μmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	41.92	3.19	9.31	12.47	0.98
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	32.38	2.58	3.41	11.90	0.68
Non-derivatized - MS/MS non-kit	238	42.06	2.77	10.60	9.90	1.07
Derivatized - MS/MS Chromsystems MassChrom Kit	160	36.31	2.78	5.17	10.30	0.87
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	920	35.94	1.97	5.05	8.19	0.92
Non-derivatized - MS/MS Chromsystems	60	32.14	1.79	5.06	8.41	0.81
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	40.24	1.92	3.26	9.55	1.03
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	34.97	2.46	4.69	9.52	0.84

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PROPIONYLCARNITINE (C3 µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	1.18	0.12	0.33	1.18	0.95
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.90	0.06	0.08	0.88	0.77
Non-derivatized - MS/MS non-kit	240	1.12	0.10	0.24	1.10	0.98
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.91	0.11	0.18	0.87	0.79
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	0.95	0.07	0.14	0.92	0.86
Non-derivatized - MS/MS Chromsystems	60	0.96	0.09	0.23	1.01	0.77
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	1.01	0.04	0.06	1.04	0.90
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.88	0.07	0.16	0.83	0.81

Lot B1815 – Enriched 4 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	639	5.01	0.43	0.93	1.18	0.95
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	3.97	0.27	0.34	0.88	0.77
Non-derivatized - MS/MS non-kit	240	5.10	0.42	1.03	1.10	0.98
Derivatized - MS/MS Chromsystems MassChrom Kit	160	4.01	0.34	0.66	0.87	0.79
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	4.38	0.25	0.60	0.92	0.86
Non-derivatized - MS/MS Chromsystems	60	4.12	0.25	0.64	1.01	0.77
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	4.68	0.29	0.30	1.04	0.90
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	4.09	0.27	0.74	0.83	0.81

Lot C1815 – Enriched 8 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	639	8.75	0.78	1.67	1.18	0.95
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	6.99	0.46	0.69	0.88	0.77
Non-derivatized - MS/MS non-kit	240	8.78	0.61	1.77	1.10	0.98
Derivatized - MS/MS Chromsystems MassChrom Kit	160	7.06	0.55	1.34	0.87	0.79
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	939	7.69	0.46	1.05	0.92	0.86
Non-derivatized - MS/MS Chromsystems	60	7.23	0.41	1.04	1.01	0.77
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	8.21	0.39	0.56	1.04	0.90
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	7.15	0.57	1.28	0.83	0.81

PROPIONYLCARNITINE (C3 µmol/L blood) (cont.)

Lot D1815 – Enriched 12 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	12.59	1.07	2.35	1.18	0.95
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	10.19	0.96	1.34	0.88	0.77
Non-derivatized - MS/MS non-kit	240	13.00	0.87	2.56	1.10	0.98
Derivatized - MS/MS Chromsystems MassChrom Kit	160	10.40	1.33	3.28	0.87	0.79
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	11.34	0.69	1.55	0.92	0.86
Non-derivatized - MS/MS Chromsystems	59	10.15	0.62	1.55	1.01	0.77
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	11.81	0.62	0.64	1.04	0.90
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	10.70	0.94	2.08	0.83	0.81

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MALONYLCARNITINE (C3DC µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	0.10	0.02	0.05	0.03	0.62
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.17	0.02	0.03	0.04	1.23
Derivatized - MS/MS Chromsystems MassChrom Kit	140	0.10	0.03	0.05	0.03	0.73
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.07	0.02	0.03	0.00	0.51

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	0.35	0.05	0.15	0.03	0.62
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.67	0.08	0.14	0.04	1.23
Derivatized - MS/MS Chromsystems MassChrom Kit	140	0.40	0.09	0.18	0.03	0.73
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.26	0.03	0.11	0.00	0.51

Lot C1815 – Enriched 1.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	0.96	0.12	0.43	0.03	0.62
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	1.83	0.16	0.49	0.04	1.23
Derivatized - MS/MS Chromsystems MassChrom Kit	140	1.13	0.21	0.48	0.03	0.73
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.73	0.07	0.27	0.00	0.51

Lot D1815 – Enriched 3 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	1.91	0.21	0.88	0.03	0.62
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	3.74	0.32	0.97	0.04	1.23
Derivatized - MS/MS Chromsystems MassChrom Kit	140	2.23	0.43	0.95	0.03	0.73
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.56	0.14	0.71	0.00	0.51

2019 Quality Control Data Summaries of Statistical Analyses

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

Lot A1815 – Non-enriched 0.2 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	120	0.20	0.04	0.14	0.10	0.49
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	820	0.14	0.02	0.09	0.06	0.36

Lot B1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	120	0.63	0.11	0.44	0.10	0.49
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	820	0.45	0.03	0.26	0.06	0.36

Lot C1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	120	1.24	0.19	0.85	0.10	0.49
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	820	0.92	0.06	0.54	0.06	0.36

Lot D1815 – Enriched 5.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	120	2.81	0.37	1.88	0.10	0.49
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	820	2.08	0.14	1.20	0.06	0.36

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BUTYRYLCARNITINE (C4 µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	610	0.14	0.03	0.12	0.14	0.81
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.12	0.03	0.05	0.09	0.73
Non-derivatized - MS/MS non-kit	230	0.10	0.02	0.06	0.11	0.79
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.10	0.02	0.04	0.08	0.67
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	0.10	0.02	0.05	0.08	0.76
Non-derivatized - MS/MS Chromsystems	60	0.09	0.02	0.02	0.15	0.68
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.09	0.01	0.01	0.08	0.88
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.10	0.02	0.02	0.05	0.78

Lot B1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	610	0.96	0.12	0.22	0.14	0.81
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.83	0.11	0.14	0.09	0.73
Non-derivatized - MS/MS non-kit	229	0.93	0.09	0.21	0.11	0.79
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.75	0.08	0.15	0.08	0.67
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	0.85	0.05	0.10	0.08	0.76
Non-derivatized - MS/MS Chromsystems	60	0.87	0.07	0.20	0.15	0.68
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.96	0.06	0.07	0.08	0.88
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.84	0.06	0.12	0.05	0.78

Lot C1815 – Enriched 3 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	610	2.53	0.26	0.46	0.14	0.81
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	2.21	0.24	0.34	0.09	0.73
Non-derivatized - MS/MS non-kit	230	2.47	0.18	0.50	0.11	0.79
Derivatized - MS/MS Chromsystems MassChrom Kit	159	2.05	0.22	0.51	0.08	0.67
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	2.33	0.14	0.28	0.08	0.76
Non-derivatized - MS/MS Chromsystems	60	2.28	0.14	0.33	0.15	0.68
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	2.72	0.12	0.18	0.08	0.88
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	2.27	0.16	0.36	0.05	0.78

2019 Quality Control Data Summaries of Statistical Analyses

BUTYRYLCARNITINE (C4 µmol/L blood) (cont.)

Lot D1815 – Enriched 5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	610	4.20	0.42	0.72	0.14	0.81
Derivatized - MS/MS PerkinElmer NeoGram Kit	59	3.79	0.42	0.52	0.09	0.73
Non-derivatized - MS/MS non-kit	230	4.09	0.29	0.83	0.11	0.79
Derivatized - MS/MS Chromsystems MassChrom Kit	160	3.44	0.37	0.89	0.08	0.67
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	3.93	0.23	0.44	0.08	0.76
Non-derivatized - MS/MS Chromsystems	60	3.52	0.24	0.55	0.15	0.68
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	4.49	0.23	0.34	0.08	0.88
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	4.04	0.42	0.62	0.05	0.78

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HYDROXYBUTYRYLCARNITINE (C4OH µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	530	0.16	0.03	0.06	0.09	0.70
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	0.16	0.02	0.03	0.08	0.77
Derivatized - MS/MS Chromsystems MassChrom Kit	120	0.14	0.03	0.05	0.09	0.64
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.12	0.02	0.02	0.04	0.62

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	530	0.43	0.06	0.14	0.09	0.70
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	0.46	0.05	0.07	0.08	0.77
Derivatized - MS/MS Chromsystems MassChrom Kit	120	0.42	0.14	0.22	0.09	0.64
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.35	0.03	0.06	0.04	0.62

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	530	0.80	0.09	0.26	0.09	0.70
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	0.85	0.09	0.10	0.08	0.77
Derivatized - MS/MS Chromsystems MassChrom Kit	120	0.74	0.13	0.23	0.09	0.64
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.65	0.07	0.12	0.04	0.62

Lot D1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	530	1.83	0.20	0.60	0.09	0.70
Derivatized - MS/MS PerkinElmer NeoGram Kit	40	2.00	0.15	0.19	0.08	0.77
Derivatized - MS/MS Chromsystems MassChrom Kit	119	1.68	0.29	0.55	0.09	0.64
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.60	0.17	0.30	0.04	0.62

ISOVALERYLCARNITINE (C5 µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	0.19	0.03	0.06	0.10	0.92
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.17	0.03	0.04	0.07	0.90
Non-derivatized - MS/MS non-kit	290	0.15	0.02	0.04	0.06	0.96
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.18	0.04	0.08	0.09	0.88
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	0.15	0.01	0.02	0.05	0.91
Non-derivatized - MS/MS Chromsystems	70	0.16	0.01	0.03	0.08	0.94
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.18	0.01	0.02	0.07	1.04
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.16	0.02	0.02	0.05	0.92

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	0.57	0.07	0.12	0.10	0.92
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.52	0.05	0.07	0.07	0.90
Non-derivatized - MS/MS non-kit	290	0.55	0.05	0.10	0.06	0.96
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.54	0.07	0.13	0.09	0.88
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	939	0.52	0.03	0.07	0.05	0.91
Non-derivatized - MS/MS Chromsystems	70	0.54	0.03	0.09	0.08	0.94
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.59	0.04	0.05	0.07	1.04
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.51	0.03	0.07	0.05	0.92

Lot C1815 – Enriched 1.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	1.47	0.14	0.27	0.10	0.92
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	1.39	0.17	0.21	0.07	0.90
Non-derivatized - MS/MS non-kit	290	1.47	0.11	0.24	0.06	0.96
Derivatized - MS/MS Chromsystems MassChrom Kit	160	1.40	0.21	0.40	0.09	0.88
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	1.40	0.09	0.20	0.05	0.91
Non-derivatized - MS/MS Chromsystems	70	1.51	0.08	0.21	0.08	0.94
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	1.63	0.10	0.17	0.07	1.04
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.40	0.11	0.18	0.05	0.92

ISOVALERYLCARNITINE (C5 µmol/L blood) (cont.)

Lot D1815 – Enriched 3 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	2.86	0.26	0.53	0.10	0.92
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	2.77	0.28	0.31	0.07	0.90
Non-derivatized - MS/MS non-kit	290	2.95	0.20	0.50	0.06	0.96
Derivatized - MS/MS Chromsystems MassChrom Kit	159	2.74	0.30	0.60	0.09	0.88
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	2.80	0.18	0.38	0.05	0.91
Non-derivatized - MS/MS Chromsystems	70	2.87	0.17	0.49	0.08	0.94
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	3.20	0.19	0.23	0.07	1.04
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	2.81	0.24	0.33	0.05	0.92

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TIGLYLCARNITINE (C5:1 µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	0.12	0.02	0.05	0.05	0.75
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	0.10	0.03	0.03	0.03	0.65
Non-derivatized - MS/MS non-kit	190	0.17	0.02	0.20	0.03	1.34
Derivatized - MS/MS Chromsystems MassChrom Kit	140	0.11	0.06	0.10	0.07	0.67
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	810	0.09	0.01	0.02	0.01	0.65
Non-derivatized - MS/MS Chromsystems	30	0.06	0.01	0.04	-0.01	0.55
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.09	0.01	0.02	0.01	0.71

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	0.42	0.05	0.12	0.05	0.75
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	0.36	0.05	0.06	0.03	0.65
Non-derivatized - MS/MS non-kit	190	0.71	0.08	0.85	0.03	1.34
Derivatized - MS/MS Chromsystems MassChrom Kit	140	0.42	0.17	0.39	0.07	0.67
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	810	0.34	0.03	0.06	0.01	0.65
Non-derivatized - MS/MS Chromsystems	30	0.25	0.05	0.14	-0.01	0.55
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.35	0.03	0.06	0.01	0.71

Lot C1815 – Enriched 1.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	1.18	0.15	0.35	0.05	0.75
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	0.99	0.12	0.17	0.03	0.65
Non-derivatized - MS/MS non-kit	190	2.02	0.16	2.31	0.03	1.34
Derivatized - MS/MS Chromsystems MassChrom Kit	140	1.08	0.22	0.54	0.07	0.67
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	810	0.98	0.07	0.18	0.01	0.65
Non-derivatized - MS/MS Chromsystems	30	0.83	0.16	0.36	-0.01	0.55
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.05	0.10	0.18	0.01	0.71

TIGLYLCARNITINE (C5:1 µmol/L blood) (cont.)

Lot D1815 – Enriched 3 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	580	2.31	0.26	0.67	0.05	0.75
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	1.99	0.27	0.34	0.03	0.65
Non-derivatized - MS/MS non-kit	190	4.07	0.32	4.63	0.03	1.34
Derivatized - MS/MS Chromsystems MassChrom Kit	140	2.06	0.36	0.84	0.07	0.67
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	810	1.97	0.14	0.36	0.01	0.65
Non-derivatized - MS/MS Chromsystems	30	1.65	0.26	0.47	-0.01	0.55
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	2.13	0.21	0.30	0.01	0.71

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GLUTARYLCARNITINE (C5DC µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	0.10	0.03	0.09	0.02	0.69
Derivatized - MS/MS PerkinElmer Neo	60	0.16	0.03	0.04	0.04	1.12
Non-derivatized - MS/MS non-kit	260	0.16	0.02	0.07	0.05	1.05
Derivatized - MS/MS Chromsystems Ma	160	0.17	0.04	0.07	0.04	1.23
Non-derivatized - MS/MS PerkinElmer	799	0.15	0.02	0.05	0.05	1.05
Non-derivatized - MS/MS Chromsystem	70	0.19	0.03	0.07	0.09	1.26
Non-derivatized - MS2 Screening Neo	30	0.14	0.01	0.02	0.06	0.88
Derivatized - RECIPE ClinSpot® LC-M	40	0.18	0.04	0.06	0.05	1.41

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	0.37	0.05	0.16	0.02	0.69
Derivatized - MS/MS PerkinElmer Neo	60	0.61	0.05	0.10	0.04	1.12
Non-derivatized - MS/MS non-kit	260	0.58	0.06	0.21	0.05	1.05
Derivatized - MS/MS Chromsystems Ma	160	0.66	0.09	0.19	0.04	1.23
Non-derivatized - MS/MS PerkinElmer	800	0.58	0.04	0.10	0.05	1.05
Non-derivatized - MS/MS Chromsystem	70	0.72	0.11	0.22	0.09	1.26
Non-derivatized - MS2 Screening Neo	30	0.50	0.03	0.05	0.06	0.88
Derivatized - RECIPE ClinSpot® LC-M	40	0.78	0.09	0.17	0.05	1.41

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	0.71	0.08	0.31	0.02	0.69
Derivatized - MS/MS PerkinElmer Neo	60	1.15	0.09	0.14	0.04	1.12
Non-derivatized - MS/MS non-kit	260	1.09	0.09	0.37	0.05	1.05
Derivatized - MS/MS Chromsystems Ma	159	1.26	0.15	0.35	0.04	1.23
Non-derivatized - MS/MS PerkinElmer	800	1.09	0.08	0.18	0.05	1.05
Non-derivatized - MS/MS Chromsystem	70	1.41	0.16	0.38	0.09	1.26
Non-derivatized - MS2 Screening Neo	30	0.95	0.07	0.11	0.06	0.88
Derivatized - RECIPE ClinSpot® LC-M	40	1.46	0.18	0.30	0.05	1.41

2019 Quality Control Data Summaries of Statistical Analyses

GLUTARYLCARNITINE (C5DC µmol/L blood) (cont.)

Lot D1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	1.76	0.18	0.79	0.02	0.69
Derivatized - MS/MS PerkinElmer Neo	60	2.85	0.22	0.33	0.04	1.12
Non-derivatized - MS/MS non-kit	260	2.68	0.25	0.90	0.05	1.05
Derivatized - MS/MS Chromsystems Ma	159	3.12	0.36	0.90	0.04	1.23
Non-derivatized - MS/MS PerkinElmer	799	2.68	0.17	0.40	0.05	1.05
Non-derivatized - MS/MS Chromsystem	70	3.23	0.39	0.85	0.09	1.26
Non-derivatized - MS2 Screening Neo	30	2.25	0.15	0.25	0.06	0.88
Derivatized - RECIPE ClinSpot® LC-M	40	3.58	0.38	0.80	0.05	1.41

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HYDROXYISOVALERYLCARNITINE (C5OH µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	0.38	0.05	0.09	0.48	0.62
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	0.39	0.05	0.06	0.49	0.63
Non-derivatized - MS/MS non-kit	210	0.56	0.05	0.13	0.66	0.65
Derivatized - MS/MS Chromsystems MassChrom Kit	150	0.37	0.07	0.12	0.47	0.55
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	720	0.48	0.03	0.17	0.57	0.51
Non-derivatized - MS/MS Chromsystems	50	0.41	0.02	0.11	0.50	0.45
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.70	0.04	0.10	0.83	0.84
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.29	0.03	0.04	0.35	0.50

Lot B1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	1.27	0.14	0.28	0.48	0.62
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	1.28	0.12	0.22	0.49	0.63
Non-derivatized - MS/MS non-kit	210	1.52	0.11	0.35	0.66	0.65
Derivatized - MS/MS Chromsystems MassChrom Kit	150	1.19	0.17	0.37	0.47	0.55
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	720	1.22	0.08	0.42	0.57	0.51
Non-derivatized - MS/MS Chromsystems	50	1.09	0.07	0.25	0.50	0.45
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	1.92	0.10	0.22	0.83	0.84
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.99	0.08	0.12	0.35	0.50

Lot C1815 – Enriched 2 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	1.67	0.19	0.38	0.48	0.62
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	1.73	0.18	0.28	0.49	0.63
Non-derivatized - MS/MS non-kit	210	1.87	0.13	0.44	0.66	0.65
Derivatized - MS/MS Chromsystems MassChrom Kit	150	1.51	0.18	0.48	0.47	0.55
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	720	1.53	0.10	0.53	0.57	0.51
Non-derivatized - MS/MS Chromsystems	50	1.39	0.08	0.29	0.50	0.45
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	2.41	0.14	0.33	0.83	0.84
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.27	0.11	0.19	0.35	0.50

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HYDROXYISOVALERYLCARNITINE (C5OH µmol/L blood) (cont.)

Lot D1815 – Enriched 3 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	2.33	0.22	0.51	0.48	0.62
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	2.35	0.24	0.33	0.49	0.63
Non-derivatized - MS/MS non-kit	210	2.61	0.18	0.59	0.66	0.65
Derivatized - MS/MS Chromsystems MassChrom Kit	140	2.09	0.29	0.78	0.47	0.55
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	720	2.07	0.16	0.75	0.57	0.51
Non-derivatized - MS/MS Chromsystems	50	1.82	0.13	0.39	0.50	0.45
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	3.32	0.17	0.32	0.83	0.84
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.88	0.15	0.32	0.35	0.50

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HEXANOYLCARNITINE (C6 µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	639	0.13	0.02	0.08	0.05	0.74
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.12	0.05	0.08	0.07	0.61
Non-derivatized - MS/MS non-kit	230	0.11	0.04	0.09	0.03	0.81
Derivatized - MS/MS Chromsystems MassChrom Kit	159	0.13	0.04	0.06	0.08	0.56
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	939	0.10	0.01	0.01	0.03	0.76
Non-derivatized - MS/MS Chromsystems	60	0.11	0.01	0.02	0.05	0.71
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.10	0.01	0.01	0.03	0.80
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.12	0.08	0.14	0.05	0.61

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	0.42	0.05	0.13	0.05	0.74
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.37	0.04	0.05	0.07	0.61
Non-derivatized - MS/MS non-kit	230	0.43	0.04	0.09	0.03	0.81
Derivatized - MS/MS Chromsystems MassChrom Kit	159	0.36	0.06	0.11	0.08	0.56
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	0.41	0.03	0.05	0.03	0.76
Non-derivatized - MS/MS Chromsystems	60	0.40	0.02	0.05	0.05	0.71
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.43	0.03	0.03	0.03	0.80
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.36	0.03	0.04	0.05	0.61

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	0.80	0.09	0.21	0.05	0.74
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.69	0.06	0.09	0.07	0.61
Non-derivatized - MS/MS non-kit	230	0.84	0.07	0.16	0.03	0.81
Derivatized - MS/MS Chromsystems MassChrom Kit	159	0.65	0.08	0.17	0.08	0.56
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	0.79	0.05	0.08	0.03	0.76
Non-derivatized - MS/MS Chromsystems	60	0.80	0.04	0.11	0.05	0.71
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.84	0.04	0.07	0.03	0.80
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.67	0.05	0.08	0.05	0.61

HEXANOYLCARNITINE (C6 µmol/L blood) (cont.)

Lot D1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	640	1.90	0.20	0.46	0.05	0.74
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	1.58	0.15	0.22	0.07	0.61
Non-derivatized - MS/MS non-kit	230	2.06	0.17	0.38	0.03	0.81
Derivatized - MS/MS Chromsystems MassChrom Kit	160	1.48	0.14	0.39	0.08	0.56
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	940	1.93	0.11	0.19	0.03	0.76
Non-derivatized - MS/MS Chromsystems	60	1.81	0.10	0.23	0.05	0.71
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	2.02	0.10	0.13	0.03	0.80
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.59	0.12	0.20	0.05	0.61

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OCTANOYLCARNITINE (C8 µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	0.14	0.03	0.06	0.06	0.92
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.12	0.02	0.02	0.03	0.87
Non-derivatized - MS/MS non-kit	280	0.16	0.02	0.05	0.07	0.98
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.11	0.03	0.04	0.05	0.75
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	950	0.14	0.01	0.02	0.04	0.89
Non-derivatized - MS/MS Chromsystems	70	0.13	0.02	0.04	0.05	0.82
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.13	0.01	0.01	0.04	0.93
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.12	0.02	0.03	0.02	0.80

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	0.51	0.06	0.10	0.06	0.92
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.46	0.05	0.06	0.03	0.87
Non-derivatized - MS/MS non-kit	279	0.56	0.05	0.19	0.07	0.98
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.42	0.05	0.07	0.05	0.75
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	950	0.48	0.03	0.05	0.04	0.89
Non-derivatized - MS/MS Chromsystems	70	0.45	0.03	0.10	0.05	0.82
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.50	0.03	0.04	0.04	0.93
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.42	0.03	0.06	0.02	0.80

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	0.98	0.11	0.17	0.06	0.92
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.89	0.09	0.11	0.03	0.87
Non-derivatized - MS/MS non-kit	280	1.06	0.08	0.35	0.07	0.98
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.81	0.09	0.14	0.05	0.75
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	950	0.92	0.06	0.10	0.04	0.89
Non-derivatized - MS/MS Chromsystems	70	0.88	0.05	0.21	0.05	0.82
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.97	0.05	0.07	0.04	0.93
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.81	0.06	0.11	0.02	0.80

OCTANOYLCARNITINE (C8 µmol/L blood) (cont.)

Lot D1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	2.35	0.24	0.41	0.06	0.92
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	2.20	0.26	0.32	0.03	0.87
Non-derivatized - MS/MS non-kit	280	2.52	0.18	0.83	0.07	0.98
Derivatized - MS/MS Chromsystems MassChrom Kit	160	1.91	0.24	0.41	0.05	0.75
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	950	2.27	0.13	0.23	0.04	0.89
Non-derivatized - MS/MS Chromsystems	70	2.11	0.14	0.56	0.05	0.82
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	2.35	0.12	0.12	0.04	0.93
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	2.04	0.16	0.27	0.02	0.80

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DECANOYLCARNITINE (C10 µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	0.12	0.02	0.05	0.01	0.97
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.10	0.04	0.06	0.00	0.84
Non-derivatized - MS/MS non-kit	269	0.16	0.02	0.07	0.03	1.13
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.07	0.03	0.05	0.00	0.56
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	950	0.12	0.04	0.29	0.00	0.90
Non-derivatized - MS/MS Chromsystems	70	0.12	0.01	0.03	0.03	0.84
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.11	0.01	0.01	0.00	0.95
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.10	0.07	0.12	-0.02	0.78

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	0.47	0.06	0.12	0.01	0.97
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.40	0.06	0.09	0.00	0.84
Non-derivatized - MS/MS non-kit	270	0.57	0.06	0.22	0.03	1.13
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.26	0.04	0.09	0.00	0.56
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	950	0.42	0.03	0.06	0.00	0.90
Non-derivatized - MS/MS Chromsystems	70	0.42	0.03	0.10	0.03	0.84
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.45	0.03	0.03	0.00	0.95
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.34	0.03	0.05	-0.02	0.78

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	1.00	0.12	0.25	0.01	0.97
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.83	0.08	0.10	0.00	0.84
Non-derivatized - MS/MS non-kit	270	1.15	0.10	0.42	0.03	1.13
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.57	0.06	0.17	0.00	0.56
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	950	0.90	0.06	0.12	0.00	0.90
Non-derivatized - MS/MS Chromsystems	70	0.90	0.05	0.19	0.03	0.84
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.96	0.05	0.07	0.00	0.95
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.73	0.06	0.12	-0.02	0.78

DECANOYLCARNITINE (C10 µmol/L blood) (cont.)

Lot D1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	2.44	0.27	0.58	0.01	0.97
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	2.09	0.20	0.27	0.00	0.84
Non-derivatized - MS/MS non-kit	270	2.85	0.24	1.04	0.03	1.13
Derivatized - MS/MS Chromsystems MassChrom Kit	160	1.39	0.12	0.45	0.00	0.56
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	950	2.25	0.14	0.27	0.00	0.90
Non-derivatized - MS/MS Chromsystems	69	2.13	0.13	0.50	0.03	0.84
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	2.39	0.13	0.15	0.00	0.95
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.95	0.19	0.28	-0.02	0.78

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DODECANOYLCARNITINE (C12 µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	0.12	0.03	0.04	0.01	0.91
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.11	0.02	0.02	0.01	0.93
Non-derivatized - MS/MS non-kit	230	0.13	0.03	0.07	0.01	1.02
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.13	0.04	0.07	0.03	0.86
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	900	0.10	0.01	0.01	-0.02	0.89
Non-derivatized - MS/MS Chromsystems	60	0.09	0.01	0.02	0.00	0.83
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.12	0.01	0.01	-0.01	1.08
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.10	0.02	0.03	0.01	0.78

Lot B1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	0.90	0.13	0.24	0.01	0.91
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.93	0.10	0.12	0.01	0.93
Non-derivatized - MS/MS non-kit	230	1.00	0.10	0.48	0.01	1.02
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.86	0.12	0.26	0.03	0.86
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	900	0.85	0.05	0.11	-0.02	0.89
Non-derivatized - MS/MS Chromsystems	60	0.79	0.04	0.13	0.00	0.83
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	1.04	0.07	0.10	-0.01	1.08
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.76	0.06	0.07	0.01	0.78

Lot C1815 – Enriched 2 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	1.82	0.23	0.43	0.01	0.91
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	1.88	0.21	0.24	0.01	0.93
Non-derivatized - MS/MS non-kit	230	2.06	0.21	0.97	0.01	1.02
Derivatized - MS/MS Chromsystems MassChrom Kit	160	1.74	0.16	0.47	0.03	0.86
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	900	1.78	0.11	0.18	-0.02	0.89
Non-derivatized - MS/MS Chromsystems	60	1.73	0.09	0.29	0.00	0.83
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	2.16	0.12	0.21	-0.01	1.08
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.55	0.10	0.20	0.01	0.78

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DODECANOYLCARNITINE (C12 µmol/L blood) (cont.)

Lot D1815 – Enriched 3 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	2.75	0.37	0.70	0.01	0.91
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	2.81	0.20	0.24	0.01	0.93
Non-derivatized - MS/MS non-kit	230	3.08	0.26	1.45	0.01	1.02
Derivatized - MS/MS Chromsystems MassChrom Kit	160	2.62	0.29	0.76	0.03	0.86
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	900	2.68	0.15	0.24	-0.02	0.89
Non-derivatized - MS/MS Chromsystems	60	2.45	0.15	0.41	0.00	0.83
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	3.25	0.18	0.21	-0.01	1.08
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	2.35	0.22	0.36	0.01	0.78

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MYRISTOYLCARNITINE (C14 µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	0.09	0.02	0.04	0.04	0.93
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.07	0.02	0.02	0.01	0.95
Non-derivatized - MS/MS non-kit	239	0.08	0.01	0.07	0.03	0.94
Derivatized - MS/MS Chromsystems MassChrom Kit	150	0.09	0.03	0.06	0.05	0.74
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	929	0.06	0.01	0.01	0.00	0.91
Non-derivatized - MS/MS Chromsystems	60	0.06	0.01	0.02	0.02	0.78
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.07	0.01	0.01	0.01	0.98
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.08	0.07	0.14	0.02	0.66

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	0.52	0.07	0.12	0.04	0.93
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.51	0.06	0.07	0.01	0.95
Non-derivatized - MS/MS non-kit	240	0.52	0.05	0.09	0.03	0.94
Derivatized - MS/MS Chromsystems MassChrom Kit	150	0.43	0.06	0.08	0.05	0.74
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	0.47	0.03	0.05	0.00	0.91
Non-derivatized - MS/MS Chromsystems	60	0.42	0.03	0.07	0.02	0.78
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.52	0.03	0.04	0.01	0.98
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.34	0.03	0.05	0.02	0.66

Lot C1815 – Enriched 1.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	1.48	0.16	0.27	0.04	0.93
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	1.46	0.14	0.15	0.01	0.95
Non-derivatized - MS/MS non-kit	239	1.49	0.12	0.27	0.03	0.94
Derivatized - MS/MS Chromsystems MassChrom Kit	150	1.21	0.10	0.23	0.05	0.74
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	1.40	0.09	0.14	0.00	0.91
Non-derivatized - MS/MS Chromsystems	60	1.25	0.10	0.17	0.02	0.78
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	1.53	0.09	0.13	0.01	0.98
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.03	0.07	0.15	0.02	0.66

MYRISTOYLCARNITINE (C14 µmol/L blood) (cont.)

Lot D1815 – Enriched 3 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	2.80	0.29	0.52	0.04	0.93
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	2.85	0.27	0.30	0.01	0.95
Non-derivatized - MS/MS non-kit	240	2.84	0.23	0.50	0.03	0.94
Derivatized - MS/MS Chromsystems MassChrom Kit	150	2.24	0.22	0.48	0.05	0.74
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	929	2.72	0.16	0.24	0.00	0.91
Non-derivatized - MS/MS Chromsystems	60	2.33	0.16	0.38	0.02	0.78
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	2.94	0.17	0.17	0.01	0.98
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.98	0.24	0.44	0.02	0.66

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TETRADECENOYLCARNITINE (C14:1 µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	590	0.10	0.02	0.05	0.02	0.99
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	0.08	0.02	0.03	-0.02	1.04
Non-derivatized - MS/MS non-kit	210	0.08	0.02	0.03	0.00	0.95
Derivatized - MS/MS Chromsystems MassChrom Kit	140	0.09	0.04	0.07	0.05	0.68
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	830	0.07	0.01	0.03	0.00	0.84
Non-derivatized - MS/MS Chromsystems	40	0.09	0.02	0.05	0.08	0.88
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.05	0.01	0.02	0.00	0.66

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	590	0.53	0.07	0.12	0.02	0.99
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	0.52	0.06	0.07	-0.02	1.04
Non-derivatized - MS/MS non-kit	210	0.49	0.05	0.13	0.00	0.95
Derivatized - MS/MS Chromsystems MassChrom Kit	140	0.42	0.11	0.23	0.05	0.68
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	830	0.43	0.03	0.06	0.00	0.84
Non-derivatized - MS/MS Chromsystems	40	0.53	0.09	0.32	0.08	0.88
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.35	0.03	0.05	0.00	0.66

Lot C1815 – Enriched 1.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	590	1.52	0.17	0.31	0.02	0.99
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	1.54	0.23	0.32	-0.02	1.04
Non-derivatized - MS/MS non-kit	210	1.43	0.12	0.33	0.00	0.95
Derivatized - MS/MS Chromsystems MassChrom Kit	140	1.07	0.16	0.34	0.05	0.68
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	830	1.25	0.09	0.17	0.00	0.84
Non-derivatized - MS/MS Chromsystems	40	1.51	0.28	0.99	0.08	0.88
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.98	0.10	0.19	0.00	0.66

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TETRADECENOYLCARNITINE (C14:1 µmol/L blood) (cont.)

Lot D1815 – Enriched 3 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	590	2.99	0.34	0.73	0.02	0.99
Derivatized - MS/MS PerkinElmer NeoGram Kit	50	3.12	0.31	0.49	-0.02	1.04
Non-derivatized - MS/MS non-kit	210	2.84	0.25	0.65	0.00	0.95
Derivatized - MS/MS Chromsystems MassChrom	140	2.10	0.27	0.66	0.05	0.68
Non-derivatized - MS/MS PerkinElmer NeoBase	830	2.50	0.15	0.33	0.00	0.84
Non-derivatized - MS/MS Chromsystems	40	2.66	0.44	1.48	0.08	0.88
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.99	0.20	0.39	0.00	0.66

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PALMITOYLCARNITINE (C16 µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	0.82	0.11	0.19	0.83	0.77
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.77	0.08	0.11	0.78	0.77
Non-derivatized - MS/MS non-kit	250	0.80	0.08	0.12	0.82	0.80
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.74	0.11	0.21	0.71	0.73
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	0.82	0.07	0.26	0.80	0.82
Non-derivatized - MS/MS Chromsystems	60	0.72	0.06	0.12	0.82	0.69
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.86	0.04	0.10	0.90	0.87
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.91	0.14	0.20	0.88	0.80

Lot B1815 – Enriched 4 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	3.85	0.35	0.53	0.83	0.77
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	3.87	0.32	0.47	0.78	0.77
Non-derivatized - MS/MS non-kit	250	4.03	0.33	0.58	0.82	0.80
Derivatized - MS/MS Chromsystems MassChrom Kit	160	3.60	0.35	0.71	0.71	0.73
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	4.02	0.24	0.52	0.80	0.82
Non-derivatized - MS/MS Chromsystems	60	3.60	0.25	0.44	0.82	0.69
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	4.41	0.29	0.51	0.90	0.87
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	4.04	0.26	0.65	0.88	0.80

Lot C1815 – Enriched 8 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	7.09	0.61	0.95	0.83	0.77
Derivatized - MS/MS PerkinElmer NeoGram Kit	59	6.97	0.50	0.73	0.78	0.77
Non-derivatized - MS/MS non-kit	250	7.34	0.55	1.00	0.82	0.80
Derivatized - MS/MS Chromsystems MassChrom Kit	160	6.54	0.52	1.30	0.71	0.73
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	7.43	0.46	0.86	0.80	0.82
Non-derivatized - MS/MS Chromsystems	60	6.63	0.46	0.64	0.82	0.69
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	8.01	0.43	0.98	0.90	0.87
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	7.32	0.56	1.47	0.88	0.80

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PALMITOYLCARNITINE (C16 µmol/L blood) (cont.)

Lot D1815 – Enriched 12 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	630	9.96	0.86	1.41	0.83	0.77
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	10.06	0.78	0.89	0.78	0.77
Non-derivatized - MS/MS non-kit	248	10.41	0.79	1.40	0.82	0.80
Derivatized - MS/MS Chromsystems MassChrom Kit	160	9.52	0.73	1.82	0.71	0.73
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	929	10.62	0.61	1.17	0.80	0.82
Non-derivatized - MS/MS Chromsystems	60	8.93	0.53	0.92	0.82	0.69
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	11.31	0.62	1.31	0.90	0.87
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	10.55	1.02	2.28	0.88	0.80

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HYDROXYPALMITOYLCARNITINE (C16OH µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	0.09	0.02	0.04	0.02	0.78
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.08	0.02	0.03	0.01	0.73
Non-derivatized - MS/MS non-kit	230	0.08	0.01	0.03	0.00	0.85
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.08	0.02	0.04	0.01	0.68
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	0.07	0.01	0.04	0.00	0.67
Non-derivatized - MS/MS Chromsystems	50	0.07	0.01	0.03	0.01	0.59
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.08	0.00	0.01	0.00	0.76
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.09	0.05	0.09	0.00	0.72

Lot B1815 – Enriched 0.25 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	0.21	0.03	0.07	0.02	0.78
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.19	0.03	0.03	0.01	0.73
Non-derivatized - MS/MS non-kit	230	0.21	0.03	0.06	0.00	0.85
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.18	0.04	0.08	0.01	0.68
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	0.17	0.01	0.05	0.00	0.67
Non-derivatized - MS/MS Chromsystems	50	0.16	0.02	0.04	0.01	0.59
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.19	0.01	0.02	0.00	0.76
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.18	0.02	0.04	0.00	0.72

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	0.81	0.10	0.26	0.02	0.78
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.72	0.11	0.16	0.01	0.73
Non-derivatized - MS/MS non-kit	230	0.85	0.08	0.24	0.00	0.85
Derivatized - MS/MS Chromsystems MassChrom Kit	160	0.69	0.08	0.25	0.01	0.68
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	0.68	0.05	0.18	0.00	0.67
Non-derivatized - MS/MS Chromsystems	50	0.62	0.08	0.13	0.01	0.59
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.77	0.06	0.07	0.00	0.76
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.71	0.09	0.20	0.00	0.72

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HYDROXYPALMITOYLCARNITINE (C16OH µmol/L blood) (cont.)

Lot D1815 – Enriched 1.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	620	1.18	0.13	0.38	0.02	0.78
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	1.11	0.12	0.18	0.01	0.73
Non-derivatized - MS/MS non-kit	230	1.27	0.12	0.35	0.00	0.85
Derivatized - MS/MS Chromsystems MassChrom Kit	160	1.03	0.12	0.36	0.01	0.68
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	1.01	0.07	0.28	0.00	0.67
Non-derivatized - MS/MS Chromsystems	50	0.88	0.08	0.16	0.01	0.59
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	1.14	0.07	0.07	0.00	0.76
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.10	0.11	0.29	0.00	0.72

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STEAROYLCARNITINE (C18 µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	0.58	0.07	0.16	0.63	0.75
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.58	0.08	0.09	0.64	0.83
Non-derivatized - MS/MS non-kit	220	0.58	0.05	0.10	0.64	0.80
Derivatized - MS/MS Chromsystems MassChrom Kit	150	0.54	0.10	0.17	0.57	0.71
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	0.56	0.04	0.07	0.61	0.83
Non-derivatized - MS/MS Chromsystems	60	0.51	0.05	0.09	0.62	0.72
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	0.59	0.03	0.05	0.65	0.84
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.53	0.05	0.06	0.57	0.71

Lot B1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	1.40	0.15	0.28	0.63	0.75
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	1.48	0.15	0.17	0.64	0.83
Non-derivatized - MS/MS non-kit	220	1.48	0.13	0.22	0.64	0.80
Derivatized - MS/MS Chromsystems MassChrom Kit	150	1.28	0.16	0.38	0.57	0.71
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	1.45	0.09	0.16	0.61	0.83
Non-derivatized - MS/MS Chromsystems	60	1.39	0.24	0.46	0.62	0.72
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	1.53	0.11	0.12	0.65	0.84
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	1.28	0.10	0.12	0.57	0.71

Lot C1815 – Enriched 3 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	2.95	0.30	0.56	0.63	0.75
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	3.23	0.25	0.27	0.64	0.83
Non-derivatized - MS/MS non-kit	220	3.14	0.24	0.44	0.64	0.80
Derivatized - MS/MS Chromsystems MassChrom Kit	150	2.77	0.26	0.80	0.57	0.71
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	3.18	0.20	0.35	0.61	0.83
Non-derivatized - MS/MS Chromsystems	60	2.93	0.20	0.36	0.62	0.72
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	3.28	0.19	0.27	0.65	0.84
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	2.78	0.20	0.29	0.57	0.71

STEAROYLCARNITINE (C18 µmol/L blood) (cont.)

Lot D1815 – Enriched 5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	600	4.31	0.43	0.81	0.63	0.75
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	4.70	0.40	0.51	0.64	0.83
Non-derivatized - MS/MS non-kit	220	4.58	0.37	0.69	0.64	0.80
Derivatized - MS/MS Chromsystems MassChrom Kit	150	4.09	0.39	1.16	0.57	0.71
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	930	4.68	0.30	0.49	0.61	0.83
Non-derivatized - MS/MS Chromsystems	60	4.10	0.31	0.49	0.62	0.72
Non-derivatized - MS2 Screening Neo (MS-Neo)	30	4.81	0.28	0.30	0.65	0.84
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	4.06	0.47	0.73	0.57	0.71

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HYDROXYSTEAROYLCARNITINE (C18OH µmol/L blood)

Lot A1815 – Non-enriched 0.1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	480	0.07	0.02	0.03	0.02	0.63
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.08	0.02	0.02	0.01	0.67
Non-derivatized - MS/MS non-kit	160	0.06	0.01	0.02	0.01	0.60
Derivatized - MS/MS Chromsystems MassChrom Kit	130	0.08	0.05	0.10	0.01	0.59
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	849	0.06	0.01	0.03	0.00	0.60
Non-derivatized - MS/MS Chromsystems	50	0.06	0.01	0.01	0.02	0.56
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.06	0.01	0.02	0.00	0.58

Lot B1815 – Enriched 0.25 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	480	0.18	0.03	0.06	0.02	0.63
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.18	0.03	0.04	0.01	0.67
Non-derivatized - MS/MS non-kit	160	0.17	0.02	0.06	0.01	0.60
Derivatized - MS/MS Chromsystems MassChrom Kit	130	0.15	0.03	0.08	0.01	0.59
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	850	0.16	0.01	0.04	0.00	0.60
Non-derivatized - MS/MS Chromsystems	50	0.15	0.01	0.02	0.02	0.56
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.15	0.02	0.04	0.00	0.58

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	480	0.64	0.07	0.22	0.02	0.63
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	0.67	0.07	0.11	0.01	0.67
Non-derivatized - MS/MS non-kit	160	0.60	0.06	0.19	0.01	0.60
Derivatized - MS/MS Chromsystems MassChrom Kit	130	0.60	0.09	0.33	0.01	0.59
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	850	0.59	0.05	0.16	0.00	0.60
Non-derivatized - MS/MS Chromsystems	50	0.61	0.07	0.11	0.02	0.56
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.57	0.07	0.17	0.00	0.58

HYDROXYSTEAROYLCARNITINE (C18OH µmol/L blood) cont.

Lot D1815 – Enriched 1.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	480	0.96	0.11	0.36	0.02	0.63
Derivatized - MS/MS PerkinElmer NeoGram Kit	60	1.02	0.12	0.19	0.01	0.67
Non-derivatized - MS/MS non-kit	159	0.92	0.11	0.29	0.01	0.60
Derivatized - MS/MS Chromsystems MassChrom Kit	130	0.89	0.15	0.53	0.01	0.59
Non-derivatized - MS/MS PerkinElmer NeoBase Kit	849	0.90	0.07	0.25	0.00	0.60
Non-derivatized - MS/MS Chromsystems	50	0.84	0.08	0.12	0.02	0.56
Derivatized - RECIPE ClinSpot® LC-MS/MS	40	0.88	0.11	0.28	0.00	0.58

2019 Quality Control Data Summaries of Statistical Analyses

20:0-LYSOPHOSPHATIDYLCHOLINE (20LPC µmol/L blood)

Lot A1815 – Enriched 0.25 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	40	0.31	0.03	0.08	0.12	0.74
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	120	0.47	0.08	0.27	0.21	1.02

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	40	0.49	0.04	0.11	0.12	0.74
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	120	0.72	0.10	0.34	0.21	1.02

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	40	0.84	0.06	0.19	0.12	0.74
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	120	1.21	0.15	0.52	0.21	1.02

Lot D1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	40	1.96	0.20	0.40	0.12	0.74
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	120	2.76	0.31	0.97	0.21	1.02

2019 Quality Control Data Summaries of Statistical Analyses

22:0-LYSOPHOSPHATIDYLCHOLINE (22LPC µmol/L blood)

Lot A1815 – Enriched 0.25 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	40	0.28	0.02	0.08	0.09	0.76
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	120	0.37	0.07	0.17	0.10	1.05

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	40	0.47	0.03	0.10	0.09	0.76
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	120	0.64	0.09	0.25	0.10	1.05

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	40	0.83	0.06	0.13	0.09	0.76
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	119	1.12	0.13	0.39	0.10	1.05

Lot D1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	40	1.98	0.14	0.26	0.09	0.76
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	120	2.74	0.34	0.91	0.10	1.05

2019 Quality Control Data Summaries of Statistical Analyses

24:0-LYSOPHOSPHATIDYLCHOLINE (24LPC µmol/L blood)

Lot A1815 – Enriched 0.25 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	60	0.35	0.04	0.12	0.12	0.90
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	160	0.44	0.08	0.19	0.16	1.14

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	60	0.55	0.05	0.16	0.12	0.90
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	159	0.68	0.09	0.26	0.16	1.14

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	60	1.05	0.24	0.32	0.12	0.90
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	159	1.38	0.39	0.65	0.16	1.14

Lot D1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	60	2.37	0.26	0.57	0.12	0.90
Non-derivatized - MS/MS PerkinElmer NeoBase2	159	3.00	0.46	1.05	0.16	1.14

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26:0-LYSOPHOSPHATIDYLCHOLINE (26LPC µmol/L blood)

Lot A1815 – Enriched 0.25 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	70	0.35	0.04	0.11	0.07	1.06
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	160	0.40	0.06	0.13	0.07	1.21

Lot B1815 – Enriched 0.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	70	0.58	0.04	0.15	0.07	1.06
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	160	0.62	0.08	0.18	0.07	1.21

Lot C1815 – Enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	70	1.15	0.18	0.40	0.07	1.06
Non-derivatized - MS/MS PerkinElmer NeoBase2 Kit	159	1.33	0.27	0.40	0.07	1.21

Lot D1815 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Non-derivatized - MS/MS non-kit	70	2.73	0.33	0.93	0.07	1.06
Non-derivatized - MS/MS PerkinElmer NeoBase2	160	3.09	0.40	0.69	0.07	1.21

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CREATINE (CRE µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	30	217.68	14.51	33.77	221.63	0.94

Lot B1815 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	30	321.68	16.65	33.93	221.63	0.94

Lot C1815 – Enriched 300 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	30	499.84	20.47	38.87	221.63	0.94

Lot D1815 – Enriched 500 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	30	690.51	35.81	51.23	221.63	0.94

2019 Quality Control Data Summaries of Statistical Analyses

GUANIDINOACETIC ACID (GUAC µmol/L blood)

Lot A1815 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	50	1.45	0.21	0.72	1.48	0.92

Lot B1815 – Enriched 5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	50	6.15	0.50	1.37	1.48	0.92

Lot C1815 – Enriched 10 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized - MS/MS non-kit	50	10.72	0.81	2.10	1.48	0.92

Lot D1815 – Enriched 20 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Derivatized – MS/MS non-kit	50	19.94	1.31	3.25	1.48	0.92

2019 Quality Control Data Summaries of Statistical Analyses

CREATININE (CRN µmol/L blood)

Creatinine is not shown due to insufficient data.

2019 Quality Control Data Summaries of Statistical Analyses

GALACTOCEREBROSIDASE (GALC µmol/hr/L blood)

Lot A1808 – Mean Activity 0.16 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	60	0.15	0.06	0.10	0.03	0.76
FIA-MS/MS multiplexed enzyme reaction	50	0.16	0.03	0.05	0.01	1.09
NeoLSD MSMS Kit	60	0.22	0.04	0.20	0.10	0.91

Lot B1808 – Mean Activity 0.39 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	59	0.33	0.08	0.11	0.03	0.76
FIA-MS/MS multiplexed enzyme reaction	50	0.42	0.04	0.06	0.01	1.09
NeoLSD MSMS Kit	60	0.45	0.06	0.21	0.10	0.91

Lot C1808 – Mean Activity 2.89 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	60	2.26	0.27	0.60	0.03	0.76
FIA-MS/MS multiplexed enzyme reaction	50	3.19	0.29	0.46	0.01	1.09
NeoLSD MSMS Kit	60	2.79	0.25	0.27	0.10	0.91

Lot D1808 – Mean Activity 5.58 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	60	4.29	0.35	1.23	0.03	0.76
FIA-MS/MS multiplexed enzyme reaction	50	6.05	0.40	0.60	0.01	1.09
NeoLSD MSMS Kit	60	5.16	0.38	0.48	0.10	0.91

2019 Quality Control Data Summaries of Statistical Analyses

ACID α-GLUCOSIDASE (GAA µmol/hr/L blood)

Lot A1808 – Mean Activity 0.16 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	69	0.28	0.09	0.19	-0.06	1.45
FIA-MS/MS multiplexed enzyme reaction	70	0.23	0.05	0.20	0.07	1.00
NeoLSD MSMS Kit	90	0.14	0.02	0.03	-0.09	1.01

Lot B1808 – Mean Activity 0.58 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	0.88	0.20	0.53	-0.06	1.45
FIA-MS/MS multiplexed enzyme reaction	70	0.62	0.10	0.30	0.07	1.00
NeoLSD MSMS Kit	90	0.52	0.11	0.14	-0.09	1.01

Lot C1808 – Mean Activity 4.98 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	6.66	1.02	1.76	-0.06	1.45
FIA-MS/MS multiplexed enzyme reaction	70	5.09	0.75	1.35	0.07	1.00
NeoLSD MSMS Kit	90	4.73	0.60	0.72	-0.09	1.01

Lot D1808 – Mean Activity 7.87 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	11.68	0.95	3.43	-0.06	1.45
FIA-MS/MS multiplexed enzyme reaction	70	7.87	0.69	1.31	0.07	1.00
NeoLSD MSMS Kit	90	7.99	0.68	0.91	-0.09	1.01

GAA Fluorometric Method

Level	N	All Lab Mean	Total SD	Avg Within Lab SD
A1808	40	0.57	0.29	0.7
B1808	40	1.11	0.39	1.15
C1808	60	7.07	1.01	8.64
D1808	60	11.65	1.15	13.78

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

Lot A1808 – Mean Activity 1.44 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	32	1.62	0.27	0.42	0.58	0.98

Lot B1808 – Mean Activity 2.43 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	55	2.61	0.72	0.92	0.58	0.98

Lot C1808 – Mean Activity 15.42 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	60	17.12	2.23	2.23	0.58	0.98

Lot D1808 – Mean Activity 28.23 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	60	27.43	2.61	3.10	0.58	0.98

2019 Quality Control Data Summaries of Statistical Analyses

α-L-IDURONIDASE (IDUA µmol/hr/L blood)

Lot A1808 – Mean Activity 0.12 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	69	0.14	0.06	0.12	-0.13	1.41
FIA-MS/MS multiplexed enzyme reaction	70	0.16	0.04	0.14	0.06	0.91
NeoLSD MSMS Kit	90	0.12	0.03	0.07	0.00	0.89

Lot B1808 – Mean Activity 0.45 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	69	0.49	0.13	0.20	-0.13	1.41
FIA-MS/MS multiplexed enzyme reaction	70	0.47	0.08	0.25	0.06	0.91
NeoLSD MSMS Kit	90	0.40	0.08	0.13	0.00	0.89

Lot C1808 – Mean Activity 4.36 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	5.84	0.85	2.00	-0.13	1.41
FIA-MS/MS multiplexed enzyme reaction	70	4.05	0.53	0.87	0.06	0.91
NeoLSD MSMS Kit	90	3.86	0.46	0.66	0.00	0.89

Lot D1808 – Mean Activity 8.03 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	69	11.32	1.38	3.93	-0.13	1.41
FIA-MS/MS multiplexed enzyme reaction	70	7.36	0.54	1.05	0.06	0.91
NeoLSD MSMS Kit	90	7.19	0.56	1.10	0.00	0.89

IDUA Fluorometric Method

Level	N	All Lab Mean	Total SD	Avg Within Lab SD
C1808	30	3.02	0.54	0.79
D1808	30	7.92	0.9	4.29

2019 Quality Control Data Summaries of Statistical Analyses

α-L-IDURONIDASE (IDUA µmol/hr/L blood)

Lot A1808 – Mean Activity 2.44 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	48	2.85	0.40	0.51	0.26	0.86

Lot B1808 – Mean Activity 4.23 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	55	3.33	0.46	0.52	0.26	0.86

Lot C1808 – Mean Activity 15.79 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	59	14.00	1.13	1.67	0.26	0.86

Lot D1808 – Mean Activity 30.52 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	60	26.59	2.29	2.91	0.26	0.86

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α-GALACTOSIDASE (GLA μmol/hr/L blood)

Lot A1808 – Mean Activity 0.72 μmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	1.00	0.29	0.67	0.21	1.06
FIA-MS/MS multiplexed enzyme reaction	40	0.64	0.07	0.12	-0.04	0.97
NeoLSD MSMS Kit	90	0.63	0.08	0.11	0.03	0.91

Lot B1808 – Mean Activity 1.31 μmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	1.63	0.21	0.71	0.21	1.06
FIA-MS/MS multiplexed enzyme reaction	40	1.16	0.09	0.11	-0.04	0.97
NeoLSD MSMS Kit	90	1.17	0.11	0.18	0.03	0.91

Lot C1808 – Mean Activity 7.88 μmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	69	8.44	0.67	2.14	0.21	1.06
FIA-MS/MS multiplexed enzyme reaction	40	7.73	0.48	0.84	-0.04	0.97
NeoLSD MSMS Kit	90	7.46	0.59	1.10	0.03	0.91

Lot D1808 – Mean Activity 14.98 μmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	16.15	1.43	3.65	0.21	1.06
FIA-MS/MS multiplexed enzyme reaction	40	14.37	0.73	1.35	-0.04	0.97
NeoLSD MSMS Kit	90	13.62	0.94	2.12	0.03	0.91

GLA Fluorometric Method

Level	N	All Lab Mean	Total SD	Avg Within Lab SD
A1808	40	0.87	0.11	0.24
B1808	40	1.33	0.16	0.57
C1808	50	7.66	0.56	3.53
D1808	50	14.44	1.19	5.86

2019 Quality Control Data Summaries of Statistical Analyses

α-GALACTOSIDASE (GLA µmol/hr/L blood)

Lot A1808 – Mean Activity 3.66 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	23	4.29	0.51	1.20	1.76	0.81

Lot B1808 – Mean Activity 5.59 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	37	5.65	0.96	1.19	1.76	0.81

Lot C1808 – Mean Activity 32.42 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	40	30.18	2.87	3.26	1.76	0.81

Lot D1808 – Mean Activity 64.28 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	40	53.00	4.33	6.35	1.76	0.81

2019 Quality Control Data Summaries of Statistical Analyses

ß-GLUCOCEREBROSIDASE (ABG µmol/hr/L blood)

Lot A1808 – Mean Activity 0.60 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	69	0.66	0.22	0.42	0.27	0.87
FIA-MS/MS multiplexed enzyme reaction	40	0.46	0.07	0.13	-0.02	0.80
NeoLSD MSMS Kit	90	0.53	0.07	0.27	0.11	0.67

Lot B1808 – Mean Activity 1.06 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	69	1.31	0.47	0.91	0.27	0.87
FIA-MS/MS multiplexed enzyme reaction	40	0.79	0.09	0.19	-0.02	0.80
NeoLSD MSMS Kit	90	0.83	0.13	0.30	0.11	0.67

Lot C1808 – Mean Activity 5.74 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	69	5.30	0.78	2.01	0.27	0.87
FIA-MS/MS multiplexed enzyme reaction	40	4.67	0.70	0.85	-0.02	0.80
NeoLSD MSMS Kit	90	3.89	0.52	1.02	0.11	0.67

Lot D1808 – Mean Activity 11.29 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	69	10.08	1.41	4.25	0.27	0.87
FIA-MS/MS multiplexed enzyme reaction	40	8.99	0.84	1.91	-0.02	0.80
NeoLSD MSMS Kit	90	7.70	0.83	2.19	0.11	0.67

ABG Fluorometric Method

Level	N	All Lab Mean	Total SD	Avg Within Lab SD
A1808	28	0.41	0.24	0.32
B1808	29	0.64	0.22	0.32
C1808	40	2.92	0.43	1.76
D1808	40	5.38	0.6	2.81

2019 Quality Control Data Summaries of Statistical Analyses

ß-GLUCOCEREBROSIDASE (ABG µmol/hr/L blood)

Lot A1808 – Mean Activity 2.17 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	36	2.77	0.34	0.48	0.97	0.84

Lot B1808 – Mean Activity 2.36 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	39	2.69	0.44	0.47	0.97	0.84

Lot C1808 – Mean Activity 6.61 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	40	7.11	0.71	0.82	0.97	0.84

Lot D1808 – Mean Activity 11.66 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
Digital Microfluidics	39	10.56	0.81	1.01	0.97	0.84

2019 Quality Control Data Summaries of Statistical Analyses

ACID SPHINGOMYELINASE (ASM µmol/hr/L blood)

Lot A1808 – Mean Activity 0.16 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	39	0.13	0.04	0.05	-0.06	1.14
FIA-MS/MS multiplexed enzyme reaction	40	0.14	0.03	0.05	-0.02	1.02
NeoLSD MSMS Kit	60	0.11	0.03	0.06	-0.02	0.89

Lot B1808 – Mean Activity 0.30 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	39	0.27	0.04	0.05	-0.06	1.14
FIA-MS/MS multiplexed enzyme reaction	40	0.27	0.05	0.06	-0.02	1.02
NeoLSD MSMS Kit	60	0.24	0.04	0.09	-0.02	0.89

Lot C1808 – Mean Activity 1.45 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	40	1.62	0.17	0.50	-0.06	1.14
FIA-MS/MS multiplexed enzyme reaction	40	1.48	0.15	0.18	-0.02	1.02
NeoLSD MSMS Kit	60	1.31	0.18	0.27	-0.02	0.89

Lot D1808 – Mean Activity 2.67 µmol/hr/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	40	2.97	0.31	0.81	-0.06	1.14
FIA-MS/MS multiplexed enzyme reaction	40	2.68	0.23	0.30	-0.02	1.02
NeoLSD MSMS Kit	60	2.34	0.30	0.43	-0.02	0.89

2019 Quality Control Data Summaries of Statistical Analyses

2ND TIER 17 α-HYDROXYPROGESTERONE (17OHP2 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	111	1.77	2.68	7.61	2.79	1.04

Lot B1811 – Enriched 10 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC MS/MS	168	12.34	1.51	3.09	2.79	1.04

Lot C1811 – Enriched 50 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC MS/MS	168	54.89	5.21	10.75	2.79	1.04

Lot D1811 – Enriched 100 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC MS/MS	168	109.41	8.88	23.53	2.79	1.04

Lot E1711 – Enriched 500 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC MS/MS	170	523.52	53.89	110.89	2.79	1.04

2019 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	104	1.07	0.51	1.21	1.1	1.04

Lot B1811 – Enriched 10 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	168	10.72	1.12	2.04	1.1	1.04

Lot C1811 – Enriched 50 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	168	52.89	4.29	9.62	1.1	1.04

Lot D1811 – Enriched 100 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	168	105.6	8.0	19.3	1.1	1.0

Lot E1811 – Enriched 500 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	170	518.7	53.72	101.71	1.1	1.04

2019 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	92	1.86	1.27	2.74	-1.29	1.01

Lot B1811 – Enriched 10 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	110	2.61	0.9	2.16	-1.29	1.01

Lot C1811 – Enriched 50 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	158	53.14	4.71	7.73	-1.29	1.01

Lot D1811 – Enriched 100 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	158	98.3	7.6	13.6	-1.29	1.01

Lot E1811 – Enriched 500 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	160	501.73	53.38	86.13	-1.29	1.01

2019 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	69	0.95	0.42	1.05	3.12	1.08

Lot B1811 – Enriched 10 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	108	10.98	1.39	2.32	3.12	1.08

Lot C1811 – Enriched 50 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	108	58.98	5.32	9.14	3.12	1.08

Lot D1811 – Enriched 100 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	108	115.6	8.6	19.3	3.12	1.08

Lot E1811 – Enriched 500 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	110	542.84	59.17	110.67	3.12	1.08

2019 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	61	0.46	0.34	0.53	1.7	0.94

Lot B1811 – Enriched 10 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	98	9.08	1.28	2.4	1.7	0.94

Lot C1811 – Enriched 50 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	98	48.43	4.7	8.52	1.7	0.94

Lot D1811 – Enriched 100 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	98	100.1	9.4	18.2	1.7	0.94

Lot E1811 – Enriched 500 ng/mL serum

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	100	471.07	59.95	102.53	1.7	0.94

2019 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	76	1.59	0.34	2.83	4.16	0.92

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	96.89	5.7	19.72	4.16	0.92

Lot C1813 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	189.31	10.23	40.5	4.16	0.92

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	372.3	19.7	78.5	4.16	0.92

Lot E1813 – Enriched 800 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	737.28	40.56	148.9	4.16	0.92

2019 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	80	9.56	1.21	3.42	11.51	0.83

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	95.8	6.35	19.91	11.51	0.83

Lot C1813 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	176.73	11.4	37.81	11.51	0.83

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	344.0	22.0	64.1	11.51	0.83

Lot E1813 – Enriched 800 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	672.5	44.49	116.3	11.51	0.83

2019 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	80	25.53	2.83	5.75	28.20	0.91
UPLC	30	35.82	6.35	14.85	32.48	1.03

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	121.13	6.27	16.30	28.20	0.91
UPLC	30	135.92	11.94	24.30	32.48	1.03

Lot C1813 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	213.33	11.27	29.05	28.20	0.91
UPLC	30	238.32	15.34	37.30	32.48	1.03

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	386.84	21.94	52.34	28.20	0.91
UPLC	30	434.22	27.96	61.65	32.48	1.03

Lot E1813 – Enriched 800 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	754.69	47.31	93.60	28.20	0.91
UPLC	30	857.89	60.39	116.8	32.48	1.03

2019 Quality Control Data Summaries of Statistical Analyses

2ND TIER PHENYLALANINE (PHE2 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	90	13.66	1.04	7.16	12.90	0.93

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	90	107.92	5.69	15.07	12.90	0.93

Lot C1813 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	90	196.34	10.41	23.37	12.90	0.93

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	90	381.48	22.75	47.07	12.90	0.93

Lot E1813 – Enriched 800 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	90	756.31	37.29	95.52	12.90	0.93

2019 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	80	19.84	1.45	3.95	20.33	0.88

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	110.83	5.89	14.15	20.33	0.88

Lot C1813 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	195.09	10.09	20.34	20.33	0.88

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	366.75	16.70	34.57	20.33	0.88

Lot E1813 – Enriched 800 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	722.2	38.12	84.29	20.33	0.88

2019 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	80	37.03	3.15	10.81	37.63	0.86
UPLC	30	51.31	3.95	6.60	49.32	1.02

Lot B1813 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	124.42	6.86	28.58	37.63	0.86
UPLC	30	153.20	8.79	15.83	49.32	1.02

Lot C1813 – Enriched 200 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	210.82	13.26	49.27	37.63	0.86
UPLC	30	254.60	14.43	25.08	49.32	1.02

Lot D1813 – Enriched 400 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	375.55	22.60	84.46	37.63	0.86
UPLC	30	449.82	25.41	44.23	49.32	1.02

Lot E1813 – Enriched 800 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	80	723.26	41.89	151.1	37.63	0.86
UPLC	30	870.52	64.10	89.26	49.32	1.02

2019 Quality Control Data Summaries of Statistical Analyses

2ND TIER MALONIC ACID (MA2 µmol/L blood)

MA is not shown due to insufficient data.

2019 Quality Control Data Summaries of Statistical Analyses

2ND TIER METHYLMALONIC ACID (MMA2 µmol/L blood)

Lot A1814 – Non-enriched 2 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	134	2.31	0.23	0.57	0.59	0.85

Lot B1814 – Enriched 5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	140	4.81	0.56	1.30	0.59	0.85

Lot C1814 – Enriched 20 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	140	17.68	1.32	3.96	0.59	0.85

Lot D1814 – Enriched 50 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	140	43.20	2.62	8.41	0.59	0.85

2019 Quality Control Data Summaries of Statistical Analyses

2ND TIER ETHYLMALONIC ACID (EMA2 µmol/L blood)

Lot A1814 – Non-enriched 2 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	61	2.36	0.41	0.70	0.16	0.95

Lot B1814 – Enriched 5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	5.19	0.66	1.31	0.16	0.95

Lot C1814 – Enriched 20 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	18.37	1.67	3.98	0.16	0.95

Lot D1814 – Enriched 50 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	70	48.15	3.61	10.53	0.16	0.95

2019 Quality Control Data Summaries of Statistical Analyses

2ND TIER 2-METHYLCITRIC ACID (MCA2 µmol/L blood)

Lot A1814 – Non-enriched 1 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	100	0.85	0.2	0.46	0.09	0.82

Lot B1814 – Enriched 2.5 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	103	2.26	0.41	1.23	0.09	0.82

Lot C1814 – Enriched 10 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	110	8.23	1.1	2.94	0.09	0.82

Lot D1814 – Enriched 25 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	110	20.65	2.02	6.64	0.09	0.82

2019 Quality Control Data Summaries of Statistical Analyses

2ND TIER TOTAL HOMOCYSTEINE (tHCY2 µmol/L blood)

Lot A1814 – Non-enriched 0 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	120	14.91	1.73	7.30	14.82	1.17

Lot B1814 – Enriched 10 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	120	26.66	2.51	12.53	14.82	1.17

Lot C1814 – Enriched 50 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	120	73.00	8.34	34.09	14.82	1.17

Lot D1814 – Enriched 100 µmol/L blood

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept	Slope
LC-MS/MS	120	132.17	11.99	62.49	14.82	1.17

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

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