Newborn Screening Quality Assurance Program

Quality Control Specimen Certification

Set 2 – July 13, 2015

Amino Acids Method: MSMS Derivatized – MS/MS non-kit

Total Galactose Analysis Method: PerkinElmer Neonatal Kit

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	*Lot*	*Base/Low*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*	*Expiration Date*
Alanine (µmol /L whole blood)	1521	0.0	1522	200.0	1523	400.0	1524	600.0	April 10, 2016
Arginine (µmol /L whole blood)	1521	0.0	1522	100.0	1523	200.0	1524	300.0	April 10, 2016
Citrulline (µmol /L whole blood)	1521	0.0	1522	25.0	1523	100.0	1524	250.0	April 10, 2016
Leucine (µmol /L whole blood)	1521	0.0	1522	100.0	1523	250.0	1524	500.0	April 10, 2016
Methionine (µmol /L whole blood)	1521	0.0	1522	50.0	1523	150.0	1524	250.0	April 10, 2016
Phenylalanine (µmol/L whole blood)	1521	0.0	1522	100.0	1523	200.0	1524	300.0	April 10, 2016
Succinylacetone (µmol /L whole blood)	1521	0.0	1522	2.5	1523	7.5	1524	15.0	April 10, 2016
Tyrosine (µmol /L whole blood)	1521	0.0	1522	200.0	1523	400.0	1524	600.0	April 10, 2016
Valine (µmol /L whole blood)	1521	0.0	1522	200.0	1523	350.0	1524	500.0	April 10, 2016
Total Galactose (mg/dL whole blood)	1521	5.0	1522	10.0	1523	15.0	1524	30.0	April 10, 2016

ANALYTICAL INFORMATION

Lot Numbers, Mean Values ($\bar{x}$), and 95% Confidence Limits (CL)									
Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Expiration Date*
Ala	1521	$\bar{x}$ = 462.7 CL = 399.7–525.7	1522	$\bar{x}$ = 645.1 CL = 548.0–742.2	1523	$\bar{x}$ = 858.1 CL = 692.5–1023.7	1524	$\bar{x}$ = 1035.7 CL = 857.3–1214.1	April 10, 2016
Arg	1521	$\bar{x}$ = 7.2 CL = 3.6–10.7	1522	$\bar{x}$ = 93.9 CL = 78.9–108.9	1523	$\bar{x}$ = 186.3 CL = 151.3–221.2	1524	$\bar{x}$ = 264.6 CL = 202.4–326.8	April 10, 2016
Cit	1521	$\bar{x}$ = 29.3 CL = 25.0–33.6	1522	$\bar{x}$ = 51.4 CL = 43.2–59.7	1523	$\bar{x}$ = 124.0 CL = 101.6–146.4	1524	$\bar{x}$ = 250.2 CL = 200.3–300.2	April 10, 2016
Leu	1521	$\bar{x}$ = 138.6 CL = 117.1–160.2	1522	$\bar{x}$ = 232.0 CL = 194.5–269.6	1523	$\bar{x}$ = 382.0 CL = 305.7–458.4	1524	$\bar{x}$ = 617.3 CL = 510.4–724.1	April 10, 2016
Met	1521	$\bar{x}$ = 22.9 CL = 19.5–26.2	1522	$\bar{x}$ = 68.0 CL = 56.1–79.8	1523	$\bar{x}$ = 166.4 CL = 129.4–203.5	1524	$\bar{x}$ = 257.7 CL = 210.0–305.5	April 10, 2016
Phe	1521	$\bar{x}$ = 77.3 CL = 65.0–89.7	1522	$\bar{x}$ = 179.9 CL = 150.8–209.0	1523	$\bar{x}$ = 289.1 CL = 232.8–345.4	1524	$\bar{x}$ = 390.2 CL = 325.8–454.6	April 10, 2016
SUAC	1521	$\bar{x}$ = 0.6 CL = 0.4–0.8	1522	$\bar{x}$ = 1.6 CL = 1.3–1.9	1523	$\bar{x}$ = 3.6 CL = 2.8–4.5	1524	$\bar{x}$ = 6.3 CL = 5.0–7.5	April 10, 2016
Tyr	1521	$\bar{x}$ = 55.5 CL = 47.5–63.4	1522	$\bar{x}$ = 229.8 CL = 195.0–264.6	1523	$\bar{x}$ = 415.4 CL = 345.0–485.8	1524	$\bar{x}$ = 585.8 CL = 486.7–685.0	April 10, 2016
Val	1521	$\bar{x}$ = 177.1 CL = 151.7–202.5	1522	$\bar{x}$ = 342.1 CL = 287.4–396.9	1523	$\bar{x}$ = 492.5 CL = 387.5–597.4	1524	$\bar{x}$ = 618.3 CL = 511.0–725.6	April 10, 2016
Total Gal	1521	$\bar{x}$ = 6.5 CL = 5.5–7.4	1522	$\bar{x}$ = 10.0 CL = 9.0–11.1	1523	$\bar{x}$ = 14.7 CL = 13.0–16.5	1524	$\bar{x}$ = 27.9 CL = 23.8–32.1	April 10, 2016

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimate s of mean values and CL can be determined after 10 successive, independent measurements. *Slazyk WE, Hannon WH. Quality Assurance in the newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.*

Newborn Screening Quality Assurance Program

Quality Control Specimen Certification

Set 2 – July 13, 2015

Previous Lot Transition Materials (parallel testing)

Amino Acids Method: MSMS Derivatized – MS/MS non-kit

Total Galactose Analysis Method: PerkinElmer Neonatal Kit

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	*Lot*	*Base/Low*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*	*Expiration Date*
Total Galactose (mg/dL whole blood)	1425	5.0	1426	10.0	1427	15.0	1428	30.0	August 31, 2015
Phenylalanine (µmol/L whole blood)	1425	0.0	1426	100.0	1427	200.0	1428	300.0	August 31, 2015
Leucine (µmol /L whole blood)	1425	0.0	1426	100.0	1427	250.0	1428	500.0	August 31, 2015
Methionine (µmol /L whole blood)	1425	0.0	1426	50.0	1427	150.0	1428	250.0	August 31, 2015
Tyrosine (µmol /L whole blood)	1425	0.0	1426	200.0	1427	400.0	1428	600.0	August 31, 2015
Valine (µmol /L whole blood)	1425	0.0	1426	200.0	1427	350.0	1428	500.0	August 31, 2015
Citrulline (µmol /L whole blood)	1425	0.0	1426	25.0	1427	100.0	1428	250.0	August 31, 2015
Arginine (µmol /L whole blood)	1425	0.0	1426	100.0	1427	200.0	1428	300.0	August 31, 2015
Alanine (µmol /L whole blood)	1425	0.0	1426	200.0	1427	400.0	1428	600.0	August 31, 2015
Succinylacetone (µmol /L whole blood)	1425	0.0	1426	2.5	1427	7.5	1428	15.0	August 31, 2015

ANALYTICAL INFORMATION

Lot Numbers, Mean Values ($\bar{x}$), and 95% Confidence Limits (CL)									
Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Expiration Date*
Total Gal	1425	$\bar{x}$ = 5.2 CL = 4.1–6.4	1426	$\bar{x}$ = 9.7 CL = 7.4–12.1	1427	$\bar{x}$ = 14.1 CL = 11.3–16.9	1428	$\bar{x}$ = 25.6 CL = 20.8–30.4	August 31, 2015
Phe	1425	$\bar{x}$ = 76.3 CL = 69.0–83.6	1426	$\bar{x}$ = 171.6 CL = 151.6–191.6	1427	$\bar{x}$ = 260.6 CL = 228.0–293.2	1428	$\bar{x}$ = 367.5 CL = 330.3–404.7	August 31, 2015
Leu	1425	$\bar{x}$ = 142.7 CL = 120.8–164.6	1426	$\bar{x}$ = 229.0 CL = 203.7–254.2	1427	$\bar{x}$ = 357.5 CL = 307.7–407.3	1428	$\bar{x}$ = 585.2 CL = 512.0–658.4	August 31, 2015
Met	1425	$\bar{x}$ = 21.4 CL = 18.9–23.9	1426	$\bar{x}$ = 60.6 CL = 54.5–66.8	1427	$\bar{x}$ = 136.2 CL = 118.4–154.1	1428	$\bar{x}$ = 221.6 CL = 201.1–242.2	August 31, 2015
Tyr	1425	$\bar{x}$ = 57.4 CL = 50.2–64.7	1426	$\bar{x}$ = 227.9 CL = 200.0–255.8	1427	$\bar{x}$ = 393.0 CL = 341.2–444.9	1428	$\bar{x}$ = 571.8 CL = 491.2–652.5	August 31, 2015
Val	1425	$\bar{x}$ = 155.6 CL = 127.3–183.9	1426	$\bar{x}$ = 315.4 CL = 264.8–365.9	1427	$\bar{x}$ = 419.5 CL = 358.6–480.3	1428	$\bar{x}$ = 544.6 CL = 461.8–627.3	August 31, 2015
Cit	1425	$\bar{x}$ = 28.5 CL = 25.8–31.3	1426	$\bar{x}$ = 50.3 CL = 44.4–56.1	1427	$\bar{x}$ = 114.0 CL = 102.0–126.0	1428	$\bar{x}$ = 243.2 CL = 222.1–264.3	August 31, 2015
Arg	1425	$\bar{x}$ = 11.1 CL = 8.2–13.9	1426	$\bar{x}$ = 95.8 CL = 82.1–109.5	1427	$\bar{x}$ = 177.1 CL = 154.5–199.8	1428	$\bar{x}$ = 258.6 CL = 232.7–284.4	August 31, 2015
Ala	1425	$\bar{x}$ = 413.1 CL = 346.2–480.0	1426	$\bar{x}$ = 572.1 CL = 498.7–645.5	1427	$\bar{x}$ = 726.9 CL = 614.6–839.2	1428	$\bar{x}$ = 915.5 CL = 805.5–1025.6	August 31, 2015
SUAC	1425	$\bar{x}$ = 0.8 CL = 0.4–1.1	1426	$\bar{x}$ = 1.6 CL = 1.2–1.9	1427	$\bar{x}$ = 3.5 CL = 3.0–4.1	1428	$\bar{x}$ = 6.5 CL = 5.7–7.3	August 31, 2015

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements. *Slazyk WE, Hannon WH. Quality Assurance in the newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.*