Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Set 1 – January 12, 2015

Amino Acids Method: MSMS Non-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*
Alanine (µmol /L whole blood)	1425	0.0	1426	200.0	1427	400.0	1428	600.0
Arginine (µmol /L whole blood)	1425	0.0	1426	100.0	1427	200.0	1428	300.0
Citrulline (µmol /L whole blood)	1425	0.0	1426	25.0	1427	100.0	1428	250.0
Leucine (µmol /L whole blood)	1425	0.0	1426	100.0	1427	250.0	1428	500.0
Methionine (µmol /L whole blood)	1425	0.0	1426	50.0	1427	150.0	1428	250.0
Phenylalanine (µmol/L whole blood)	1425	0.0	1426	100.0	1427	200.0	1428	300.0
Succinylacetone (µmol /L whole blood)	1425	0.0	1426	2.5	1427	7.5	1428	15.0
Tyrosine (µmol /L whole blood)	1425	0.0	1426	200.0	1427	400.0	1428	600.0
Valine (µmol /L whole blood)	1425	0.0	1426	200.0	1427	350.0	1428	500.0
Total Galactose (mg/dL whole blood)	1425	5.0	1426	10.0	1427	15.0	1428	30.0

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*
Ala	1425	$\bar{x}$ = 403.9 CL = 330.3–477.5	1426	$\bar{x}$ = 556.7 CL = 480.4–632.9	1427	$\bar{x}$ = 698.9 CL = 589.4–808.4	1428	$\bar{x}$ = 882.3 CL = 716.2–1048.4
Arg	1425	$\bar{x}$ = 9.3 CL = 7.2–11.3	1426	$\bar{x}$ = 91.4 CL = 79.3–103.5	1427	$\bar{x}$ = 171.2 CL = 144.1–198.4	1428	$\bar{x}$ = 248.2 CL = 199.3–297.1
Cit	1425	$\bar{x}$ = 29.9 CL = 18.9–40.9	1426	$\bar{x}$ = 53.1 CL = 33.3–73.0	1427	$\bar{x}$ = 123.0 CL = 71.0–174.9	1428	$\bar{x}$ = 264.1 CL = 187.7–340.5
Leu	1425	$\bar{x}$ = 167.7 CL = 138.7–196.7	1426	$\bar{x}$ = 256.2 CL = 226.8–285.7	1427	$\bar{x}$ = 385.4 CL = 315.7–455.2	1428	$\bar{x}$ = 607.8 CL = 502.1–713.5
Met	1425	$\bar{x}$ = 17.6 CL = 14.4–20.8	1426	$\bar{x}$ = 52.9 CL = 45.2–60.6	1427	$\bar{x}$ = 123.9 CL = 88.5–159.3	1428	$\bar{x}$ = 199.8 CL = 172.8–226.8
Phe	1425	$\bar{x}$ = 76.4 CL = 59.8–92.9	1426	$\bar{x}$ = 171.1 CL = 139.2–203.0	1427	$\bar{x}$ = 262.2 CL = 214.6–309.8	1428	$\bar{x}$ = 364.2 CL = 288.4–440.1
SUAC	1425	$\bar{x}$ = 0.5 CL = 0.4–0.7	1426	$\bar{x}$ = 1.4 CL = 1.2–1.6	1427	$\bar{x}$ = 3.2 CL = 2.7–3.7	1428	$\bar{x}$ = 6.0 CL = 5.0–7.0
Tyr	1425	$\bar{x}$ = 49.2 CL = 31.0–67.4	1426	$\bar{x}$ = 207.8 CL = 129.1–286.5	1427	$\bar{x}$ = 350.8 CL = 225.2–476.4	1428	$\bar{x}$ = 514.9 CL = 324.8–705.0
Val	1425	$\bar{x}$ = 144.9 CL = 120.2–169.6	1426	$\bar{x}$ = 294.7 CL = 241.8–347.5	1427	$\bar{x}$ = 394.6 CL = 324.6–464.6	1428	$\bar{x}$ = 497.5 CL = 395.3–599.7
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

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 1 – January 12, 2015

Previous Lot Transition Materials (parallel testing)

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

Total Galactose Analysis Method: Fluorometric Manual

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	*Lot*	*Base/Low*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Alanine (µmol /L whole blood)	1421	0.0	1422	200.0	1423	400.0	1424	600.0
Arginine (µmol /L whole blood)	1421	0.0	1422	100.0	1423	200.0	1424	300.0
Citrulline (µmol /L whole blood)	1421	0.0	1422	25.0	1423	100.0	1424	250.0
Leucine (µmol /L whole blood)	1421	0.0	1422	100.0	1423	250.0	1424	500.0
Methionine (µmol /L whole blood)	1421	0.0	1422	50.0	1423	150.0	1424	250.0
Phenylalanine (µmol/L whole blood)	1421	0.0	1422	100.0	1423	200.0	1424	300.0
Succinylacetone (µmol /L whole blood)	1421	0.0	1422	2.5	1423	7.5	1424	15.0
Tyrosine (µmol /L whole blood)	1421	0.0	1422	200.0	1423	400.0	1424	600.0
Valine (µmol /L whole blood)	1421	0.0	1422	200.0	1423	350.0	1424	500.0
Total Galactose (mg/dL whole blood)	1421	5.0	1422	10.0	1423	15.0	1424	30.0

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*
Ala	1421	$\bar{x}$ = 305.0 CL = 236.5–373.5	1422	$\bar{x}$ = 424.8 CL = 346.7–503.0	1423	$\bar{x}$ = 569.9 CL = 455.6–684.2	1424	$\bar{x}$ = 668.9 CL = 529.9–807.9
Arg	1421	$\bar{x}$ = 12.7 CL = 8.5–16.9	1422	$\bar{x}$ = 112.7 CL = 89.0–136.4	1423	$\bar{x}$ = 213.3 CL = 152.0–274.6	1424	$\bar{x}$ = 292.9 CL = 233.8–352.1
Cit	1421	$\bar{x}$ = 23.9 CL = 19.4–28.5	1422	$\bar{x}$ = 43.5 CL = 34.9–52.2	1423	$\bar{x}$ = 99.9 CL = 79.0–120.8	1424	$\bar{x}$ = 206.4 CL = 175.0–237.8
Leu	1421	$\bar{x}$ = 136.8 CL = 118.8–154.8	1422	$\bar{x}$ = 216.7 CL = 183.1–250.3	1423	$\bar{x}$ = 321.4 CL = 275.1–367.7	1424	$\bar{x}$ = 471.1 CL = 414.3–527.9
Met	1421	$\bar{x}$ = 16.7 CL = 13.3–20.0	1422	$\bar{x}$ = 51.3 CL = 40.2–62.4	1423	$\bar{x}$ = 119.3 CL = 103.8–134.8	1424	$\bar{x}$ = 187.1 CL = 155.9–218.3
Phe	1421	$\bar{x}$ = 70.4 CL = 57.6–83.2	1422	$\bar{x}$ = 164.0 CL = 138.6–189.5	1423	$\bar{x}$ = 254.3 CL = 208.7–300.0	1424	$\bar{x}$ = 333.7 CL = 286.3–381.1
SUAC	1421	$\bar{x}$ = 0.4 CL = 0.3–0.5	1422	$\bar{x}$ = 1.6 CL = 1.3–1.9	1423	$\bar{x}$ = 3.8 CL = 2.9–4.7	1424	$\bar{x}$ = 7.6 CL = 5.9–9.4
Tyr	1421	$\bar{x}$ = 48.5 CL = 36.4–60.6	1422	$\bar{x}$ = 196.7 CL = 162.9–230.4	1423	$\bar{x}$ = 342.2 CL = 259.0–425.4	1424	$\bar{x}$ = 484.8 CL = 388.1–581.5
Val	1421	$\bar{x}$ = 153.2 CL = 127.3–179.1	1422	$\bar{x}$ = 311.4 CL = 265.6–357.3	1423	$\bar{x}$ = 417.7 CL = 350.1–485.2	1424	$\bar{x}$ = 514.5 CL = 446.8–582.2
Total Gal	1421	$\bar{x}$ = 5.8 CL = 4.3–7.3	1422	$\bar{x}$ = 10.5 CL = 8.1–12.9	1423	$\bar{x}$ = 14.9 CL = 12.1–17.6	1424	$\bar{x}$ = 27.4 CL = 22.6–32.2

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.*