Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Set 2 – July 14, 2014

Amino Acids Analysis 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*
Total Galactose (mg/dL whole blood)	1421	5.0	1422	10.0	1423	15.0	1424	30.0
Phenylalanine (µmol/L whole blood)	1421	0.0	1422	100.0	1423	200.0	1424	300.0
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
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
Citrulline (µmol /L whole blood)	1421	0.0	1422	25.0	1423	100.0	1424	250.0
Arginine (µmol /L whole blood)	1421	0.0	1422	100.0	1423	200.0	1424	300.0
Alanine (µmol /L whole blood)	1421	0.0	1422	200.0	1423	400.0	1424	600.0
Succinylacetone (µmol /L whole blood)	1421	0.0	1422	2.5	1423	7.5	1424	15.0

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*
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
Phe	1421	$\bar{x}$ = 71.8 CL = 56.8–86.8	1422	$\bar{x}$ = 160.0 CL = 138.8–181.2	1423	$\bar{x}$ = 247.6 CL = 214.7–280.6	1424	$\bar{x}$ = 325.4 CL = 278.4–372.4
Leu	1421	$\bar{x}$ = 116.0 CL = 90.9–141.0	1422	$\bar{x}$ = 190.4 CL = 162.9–218.0	1423	$\bar{x}$ = 293.1 CL = 249.1–337.0	1424	$\bar{x}$ = 445.7 CL = 374.7–516.8
Met	1421	$\bar{x}$ = 19.9 CL = 16.1–23.8	1422	$\bar{x}$ = 60.0 CL = 52.5–67.6	1423	$\bar{x}$ = 140.2 CL = 122.7–157.7	1424	$\bar{x}$ = 214.2 CL = 188.3–240.1
Tyr	1421	$\bar{x}$ = 49.7 CL = 39.1–60.2	1422	$\bar{x}$ = 205.3 CL = 174.8–235.8	1423	$\bar{x}$ = 351.6 CL = 295.5–407.6	1424	$\bar{x}$ = 489.4 CL = 417.2–561.6
Val	1421	$\bar{x}$ = 121.4 CL = 93.5–149.4	1422	$\bar{x}$ = 239.4 CL = 205.8–273.0	1423	$\bar{x}$ = 342.1 CL = 284.8–399.4	1424	$\bar{x}$ = 428.6 CL = 366.8–490.3
Cit	1421	$\bar{x}$ = 26.3 CL = 21.5–31.2	1422	$\bar{x}$ = 47.9 CL = 40.3–55.4	1423	$\bar{x}$ = 111.7 CL = 94.6–128.8	1424	$\bar{x}$ = 232.7 CL = 195.2–270.2
Arg	1421	$\bar{x}$ = 10.0 CL = 7.1–12.9	1422	$\bar{x}$ = 96.1 CL = 76.0–116.3	1423	$\bar{x}$ = 183.7 CL = 151.4–216.0	1424	$\bar{x}$ = 266.1 CL = 215.1–317.0
Ala	1421	$\bar{x}$ = 292.8 CL = 238.1–347.5	1422	$\bar{x}$ = 410.6 CL = 351.8–469.5	1423	$\bar{x}$ = 534.7 CL = 454.4–615.0	1424	$\bar{x}$ = 625.5 CL = 542.3–708.7
SUAC	1421	$\bar{x}$ = 0.5 CL = 0.3–0.6	1422	$\bar{x}$ = 1.7 CL = 1.4–2.0	1423	$\bar{x}$ = 4.0 CL = 3.5–4.6	1424	$\bar{x}$ = 8.1 CL = 6.9–9.4

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 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.*

Newborn Screening Quality Assurance Program

Quality Control Specimen Certification

Set 2 – July 14, 2014

Previous Lot Transition Materials (parallel testing)

Amino Acid Analysis Method: MSMS 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*
Total Galactose (mg/dL whole blood)	1325	5.0	1326	10.0	1327	15.0	1328	30.0
Phenylalanine (µmol/L whole blood)	1325	0.0	1326	100.0	1327	200.0	1328	300.0
Leucine (µmol /L whole blood)	1325	0.0	1326	100.0	1327	250.0	1328	500.0
Methionine (µmol /L whole blood)	1325	0.0	1326	50.0	1327	150.0	1328	250.0
Tyrosine (µmol /L whole blood)	1325	0.0	1326	200.0	1327	400.0	1328	600.0
Valine (µmol /L whole blood)	1325	0.0	1326	200.0	1327	350.0	1328	500.0
Citrulline (µmol /L whole blood)	1325	0.0	1326	25.0	1327	100.0	1328	250.0
Arginine (µmol /L whole blood)	1325	0.0	1326	100.0	1327	200.0	1328	300.0
Alanine (µmol /L whole blood)	1325	0.0	1326	200.0	1327	400.0	1328	600.0
Succinylacetone (µmol /L whole blood)	1325	0.0	1326	2.5	1327	7.5	1328	15.0

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*
Total Gal	1325	$\bar{x}$ = 4.6 CL = 3.3–5.8	1326	$\bar{x}$ = 9.5 CL = 7.7–11.3	1327	$\bar{x}$ = 14.5 CL = 12.0–17.0	1328	$\bar{x}$ = 29.4 CL = 25.1–33.6
Phe	1325	$\bar{x}$ = 64.8 CL = 57.4–72.1	1326	$\bar{x}$ = 156.2 CL = 137.2–175.2	1327	$\bar{x}$ = 260.9 CL = 230.0–291.9	1328	$\bar{x}$ = 337.5 CL = 302.9–372.2
Leu	1325	$\bar{x}$ = 119.7 CL = 104.7–134.8	1326	$\bar{x}$ = 210.4 CL = 183.4–237.4	1327	$\bar{x}$ = 334.4 CL = 296.4–372.3	1328	$\bar{x}$ = 538.4 CL = 471.9–604.9
Met	1325	$\bar{x}$ = 18.3 CL = 0.0–36.6	1326	$\bar{x}$ = 57.8 CL = 50.3–65.2	1327	$\bar{x}$ = 135.8 CL = 118.4–153.1	1328	$\bar{x}$ = 216.2 CL = 186.2–246.3
Tyr	1325	$\bar{x}$ = 48.3 CL = 40.5–56.2	1326	$\bar{x}$ = 210.0 CL = 177.5–242.4	1327	$\bar{x}$ = 364.3 CL = 311.8–416.9	1328	$\bar{x}$ = 528.3 CL = 443.4–613.2
Val	1325	$\bar{x}$ = 116.3 CL = 98.5–134.1	1326	$\bar{x}$ = 261.6 CL = 228.3–294.9	1327	$\bar{x}$ = 357.2 CL = 297.0–417.4	1328	$\bar{x}$ = 466.6 CL = 380.4–552.7
Cit	1325	$\bar{x}$ = 28.2 CL = 23.6–32.9	1326	$\bar{x}$ = 57.9 CL = 48.5–67.3	1327	$\bar{x}$ = 126.9 CL = 107.6–146.2	1328	$\bar{x}$ = 256.6 CL = 221.4–291.8
Arg	1325	$\bar{x}$ = 12.3 CL = 5.1–19.4	1326	$\bar{x}$ = 90.6 CL = 74.4–106.8	1327	$\bar{x}$ = 171.0 CL = 142.2–199.8	1328	$\bar{x}$ = 251.3 CL = 215.5–287.1
Ala	1325	$\bar{x}$ = 201.3 CL = 142.6–260.0	1326	$\bar{x}$ = 294.9 CL = 203.9–385.8	1327	$\bar{x}$ = 378.0 CL = 264.1–491.8	1328	$\bar{x}$ = 441.9 CL = 334.4–549.3
SUAC	1325	$\bar{x}$ = 0.7 CL = 0.5–0.8	1326	$\bar{x}$ = 1.6 CL = 1.3–1.9	1327	$\bar{x}$ = 3.5 CL = 3.0–4.1	1328	$\bar{x}$ = 6.3 CL = 5.3–7.2

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 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.*