Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Lot 1325-1328 January 13, 2014

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*
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	$\bar{x}$ = 65.5 CL = 49.4–81.5	1326	$\bar{x}$ = 154.8 CL = 123.0–186.7	1327	$\bar{x}$ = 244.7 CL = 158.2–331.2	1328	$\bar{x}$ = 337.7 CL = 271.0–404.4
Leu	1325	$\bar{x}$ = 147.7 CL = 115.8–179.7	1326	$\bar{x}$ = 243.3 CL = 202.6–284.0	1327	$\bar{x}$ = 350.4 CL = 227.8–473.0	1328	$\bar{x}$ = 583.5 CL = 464.8–702.2
Met	1325	$\bar{x}$ = 13.2 CL = 7.9–18.6	1326	$\bar{x}$ = 47.9 CL = 36.5–59.3	1327	$\bar{x}$ = 114.4 CL = 69.2–159.6	1328	$\bar{x}$ = 197.1 CL = 149.3–245.0
Tyr	1325	$\bar{x}$ = 46.6 CL = 22.2–71.1	1326	$\bar{x}$ = 197.0 CL = 99.1–295.0	1327	$\bar{x}$ = 329.3 CL = 160.9–497.7	1328	$\bar{x}$ = 503.4 CL = 211.1–795.7
Val	1325	$\bar{x}$ = 125.2 CL = 102.0–148.4	1326	$\bar{x}$ = 273.3 CL = 215.7–331.0	1327	$\bar{x}$ = 357.6 CL = 220.0–495.2	1328	$\bar{x}$ = 485.6 CL = 357.4–613.8
Cit	1325	$\bar{x}$ = 25.1 CL = 17.1–33.2	1326	$\bar{x}$ = 49.8 CL = 30.0–69.7	1327	$\bar{x}$ = 99.8 CL = 56.1–143.4	1328	$\bar{x}$ = 235.7 CL = 144.9–326.5
Arg	1325	$\bar{x}$ = 8.2 CL = 4.8–11.6	1326	$\bar{x}$ = 92.3 CL = 74.0–110.5	1327	$\bar{x}$ = 168.4 CL = 109.5–227.3	1328	$\bar{x}$ = 268.7 CL = 229.2–308.1
Ala	1325	$\bar{x}$ = 207.3 CL = 92.5–322.1	1326	$\bar{x}$ = 329.3 CL = 122.5–536.1	1327	$\bar{x}$ = 420.2 CL = 135.0–705.5	1328	$\bar{x}$ = 472.2 CL = 181.3–763.1
SUAC	1325	$\bar{x}$ = 0.5 CL = 0.3–0.7	1326	$\bar{x}$ = 1.4 CL = 1.0–1.8	1327	$\bar{x}$ = 3.1 CL = 2.0–4.3	1328	$\bar{x}$ = 6.1 CL = 4.8–7.3

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 20 successive, independent measurements.

Reference: *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

Lot 1321-1324 January 13, 2014

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*
Total Galactose (mg/dL whole blood)	1321	5.0	1322	10.0	1323	15.0	1324	30.0
Phenylalanine (µmol/L whole blood)	1321	0.0	1322	100.0	1323	200.0	1324	300.0
Leucine (µmol /L whole blood)	1321	0.0	1322	100.0	1323	250.0	1324	500.0
Methionine (µmol /L whole blood)	1321	0.0	1322	50.0	1323	150.0	1324	250.0
Tyrosine (µmol /L whole blood)	1321	0.0	1322	200.0	1323	400.0	1324	600.0
Valine (µmol /L whole blood)	1321	0.0	1322	200.0	1323	350.0	1324	500.0
Citrulline (µmol /L whole blood)	1321	0.0	1322	25.0	1323	100.0	1324	250.0
Arginine (µmol /L whole blood)	1321	0.0	1322	100.0	1323	200.0	1324	300.0
Alanine (µmol /L whole blood)	1321	0.0	1322	200.0	1323	400.0	1324	600.0
Succinylacetone (µmol /L whole blood)	1321	0.0	1322	2.5	1323	7.5	1324	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	1321	$\bar{x}$ = 5.2 CL = 3.7–6.7	1322	$\bar{x}$ = 10.4 CL = 9.1–11.8	1323	$\bar{x}$ = 16.3 CL = 13.4–19.2	1324	$\bar{x}$ = 33.4 CL = 29.1–37.6
Phe	1321	$\bar{x}$ = 67.5 CL = 56.1–79.0	1322	$\bar{x}$ = 154.0 CL = 134.1–173.8	1323	$\bar{x}$ = 238.1 CL = 194.6–281.6	1324	$\bar{x}$ = 342.3 CL = 293.5–391.2
Leu	1321	$\bar{x}$ = 166.1 CL = 136.6–195.7	1322	$\bar{x}$ = 253.6 CL = 219.1–288.1	1323	$\bar{x}$ = 364.4 CL = 325.1–403.8	1324	$\bar{x}$ = 618.0 CL = 489.4–746.7
Met	1321	$\bar{x}$ = 18.0 CL = 9.0–27.0	1322	$\bar{x}$ = 60.7 CL = 39.7–81.6	1323	$\bar{x}$ = 133.6 CL = 90.5–176.7	1324	$\bar{x}$ = 221.3 CL = 142.1–300.4
Tyr	1321	$\bar{x}$ = 46.8 CL = 33.2–60.5	1322	$\bar{x}$ = 193.1 CL = 144.2–242.0	1323	$\bar{x}$ = 346.1 CL = 269.8–422.4	1324	$\bar{x}$ = 505.0 CL = 394.2–616.0
Val	1321	$\bar{x}$ = 126.4 CL = 100.0–152.9	1322	$\bar{x}$ = 268.6 CL = 218.9–318.2	1323	$\bar{x}$ = 364.2 CL = 307.6–420.8	1324	$\bar{x}$ = 474.5 CL = 381.5–567.5
Cit	1321	$\bar{x}$ = 21.6 CL = 14.0–29.2	1322	$\bar{x}$ = 39.2 CL = 25.3–53.1	1323	$\bar{x}$ = 97.0 CL = 57.9–136.0	1324	$\bar{x}$ = 199.3 CL = 141.1–257.4
Arg	1321	$\bar{x}$ = 7.9 CL = 5.1–10.8	1322	$\bar{x}$ = 94.0 CL = 67.7–120.2	1323	$\bar{x}$ = 187.3 CL = 134.1–240.6	1324	$\bar{x}$ = 276.2 CL = 211.2–341.2
Ala	1321	$\bar{x}$ = 199.3 CL = 99.5–299.2	1322	$\bar{x}$ = 292.9 CL = 70.9–515.0	1323	$\bar{x}$ = 366.4 CL = 176.8–556.0	1324	$\bar{x}$ = 474.0 CL = 225.7–722.4
SUAC	1321	$\bar{x}$ = 0.4 CL = 0.3–0.5	1322	$\bar{x}$ = 1.6 CL = 1.4–1.9	1323	$\bar{x}$ = 4.3 CL = 3.5–5.0	1324	$\bar{x}$ = 9.2 CL = 7.4–11.1

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 20 successive, independent measurements.

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