Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Set 2 – July 8, 2013

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)	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	$\bar{x}$ = 66.1 CL = 58.1-74.1	1322	$\bar{x}$ = 157.0 CL = 139.9-174.1	1323	$\bar{x}$ = 245.1 CL = 211.6-278.6	1324	$\bar{x}$ = 330.5 CL = 283.7-377.3
Leu	1321	$\bar{x}$ = 131.6 CL = 115.5-147.6	1322	x = 221.2 CL = 193.9-248.5	1323	x = 345.3 CL = 288.6-402.0	1324	x = 552.8 CL = 477.6-627.9
Met	1321	$\bar{x}$ = 15.9 CL = 12.0-19.8	1322	$\bar{x}$ = 52.2 CL = 40.7-63.8	1323	$\bar{x}$ = 123.8 CL = 97.5-150.2	1324	$\bar{x}$ = 192.5 CL = 153.0-232.0
Tyr	1321	$\bar{x}$ =49.1 CL = 41.9-56.2	1322	$\bar{x}$ = 211.0 CL = 183.0-238.9	1323	$\bar{x}$ = 375.5 CL = 311.7-439.3	1324	$\bar{x}$ = 516.9 CL = 421.0-612.7
Val	1321	$\bar{x}$ = 127.2 CL = 105.1-149.3	1322	$\bar{x}$ = 262.2 CL = 217.5-306.8	1323	$\bar{x}$ = 360.2 CL = 278.1-442.3	1324	$\bar{x}$ = 464.4 CL = 386.8-542.0
Cit	1321	$\bar{x}$ = 26.2 CL = 22.0-30.4	1322	$\bar{x}$ = 52.5 CL = 43.7-61.3	1323	$\bar{x}$ = 118.7 CL = 95.6-141.8	1324	$\bar{x}$ = 237.1 CL = 187.6-286.6
Arg	1321	$\bar{x}$ = 15.0 CL = 5.1-24.9	1322	$\bar{x}$ = 97.4 CL = 77.4-117.5	1323	$\bar{x}$ = 184.2 CL = 141.2-227.1	1324	$\bar{x}$ = 260.5 CL = 196.6-324.5
Ala	1321	$\bar{x}$ = 179.1 CL = 130.6-227.6	1322	$\bar{x}$ = 261.0 CL = 190.6-331.5	1323	$\bar{x}$ = 348.6 CL = 268.7-428.6	1324	$\bar{x}$ = 422.2 CL = 304.3-540.0
SUAC	1321	$\bar{x}$ = 0.7 CL = 0.5-0.9	1322	$\bar{x}$ = 1.9 CL = 1.6-2.1	1323	$\bar{x}$ = 4.6 CL = 3.6-5.6	1324	$\bar{x}$ = 8.5 CL = 7.0-10.0

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. *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 8, 2013

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)	1225	5.0	1226	10.0	1227	15.0	1228	30.0
Phenylalanine (µmol/L whole blood)	1225	0.0	1226	100.0	1227	200.0	1228	300.0
Leucine (µmol /L whole blood)	1225	0.0	1226	150.0	1227	250.0	1228	500.0
Methionine (µmol /L whole blood)	1225	0.0	1226	50.0	1227	150.0	1228	250.0
Tyrosine (µmol /L whole blood)	1225	0.0	1226	200.0	1227	400.0	1228	600.0
Valine (µmol /L whole blood)	1225	0.0	1226	250.0	1227	350.0	1228	500.0
Citrulline (µmol /L whole blood)	1225	0.0	1226	25.0	1227	100.0	1228	250.0
Arginine (µmol /L whole blood)	1225	0.0	1226	100.0	1227	200.0	1228	300.0
Alanine (µmol /L whole blood)	1225	0.0	1226	200.0	1227	400.0	1228	600.0
Succinylacetone (µmol /L whole blood)	1225	0.0	1226	2.5	1227	7.5	1228	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	1225	$\bar{x}$ = 4.7 CL = 3.4-6.1	1226	$\bar{x}$ = 10.0 CL = 7.5-12.4	1227	$\bar{x}$ = 15.5 CL = 12.6-18.5	1228	$\bar{x}$ = 31.9 CL = 27.1-36.7
Phe	1225	$\bar{x}$ = 64.3 CL = 58.2-70.4	1226	$\bar{x}$ = 150.6 CL = 129.2-172.0	1227	$\bar{x}$ = 247.1 CL = 222.7-271.6	1228	$\bar{x}$ = 333.4 CL = 292.4-374.4
Leu	1225	$\bar{x}$ = 146.6 CL = 124.9-168.3	1226	x = 234.4 CL = 201.6-267.2	1227	x = 384.3 CL = 344.0-424.6	1228	x = 594.3 CL = 520.8-667.8
Met	1225	$\bar{x}$ = 18.7 CL = 15.1-22.2	1226	$\bar{x}$ = 52.0 CL = 44.5-59.5	1227	$\bar{x}$ = 127.6 CL = 108.7-146.4	1228	$\bar{x}$ = 199.9 CL = 166.0-233.9
Tyr	1225	$\bar{x}$ =47.4 CL = 40.7-54.1	1226	$\bar{x}$ = 196.7 CL = 161.7-231.8	1227	$\bar{x}$ = 366.1 CL = 313.9-418.3	1228	$\bar{x}$ = 510.3 CL = 434.0-586.6
Val	1225	$\bar{x}$ = 123.8 CL = 105.1-142.6	1226	$\bar{x}$ = 261.8 CL = 231.1-292.4	1227	$\bar{x}$ = 385.4 CL = 326.1-444.6	1228	$\bar{x}$ = 480.0 CL = 396.6-563.4
Cit	1225	$\bar{x}$ = 26.0 CL = 21.9-30.0	1226	$\bar{x}$ = 48.3 CL = 39.6-57.0	1227	$\bar{x}$ = 116.7 CL = 97.5-135.9	1228	$\bar{x}$ = 225.3 CL = 178.8-271.7
Arg	1225	$\bar{x}$ = 9.4 CL = 3.3-15.5	1226	$\bar{x}$ = 42.3 CL = 28.1-56.4	1227	$\bar{x}$ = 103.4 CL = 74.5-132.3	1228	$\bar{x}$ = 132.8 CL = 69.3-196.4
Ala	1225	$\bar{x}$ = 170.7 CL = 134.1-207.2	1226	$\bar{x}$ = 250.3 CL = 194.9-305.8	1227	$\bar{x}$ = 357.1 CL = 286.1-428.1	1228	$\bar{x}$ = 410.3 CL = 317.9-502.8
SUAC	1225	$\bar{x}$ = 0.5 CL = 0.2-0.7	1226	$\bar{x}$ = 1.2 CL = 0.9-1.6	1227	$\bar{x}$ = 3.0 CL = 2.6-3.5	1228	$\bar{x}$ = 5.5 CL = 4.4-6.6

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. *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.*