Newborn Screening
Quality Assurance Program

Quality Control Specimen Certification
Set 2 – July 9, 2012

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	Lot	*Base/Low*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Total Galactose (Gal mg/dL whole blood)	221	5.0	222	10.0	223	15.0	224	30.0
Phenylalanine (µmol/L whole blood)	221	0.0	222	150.0	223	400.0	224	600.0
Leucine (µmol/L whole blood)	221	0.0	222	200.0	223	500.0	224	800.0
Methionine (µmol/L whole blood)	221	0.0	222	100.0	223	250.0	224	500.0
Tyrosine (µmol/L whole blood)	221	0.0	222	250.0	223	500.0	224	750.0
Valine (µmol/L whole blood)	221	0.0	222	250.0	223	600.0	224	1000.0
Citrulline (µmol/L whole blood)	221	0.0	222	50.0	223	150.0	224	300.0
Alanine (µmol/L whole blood)	221	0.0	222	250.0	223	500.0	224	750.0
Succinylacetone (µmol/L whole blood)	221	0.0	222	2.5	223	5.0	224	10.0

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	221	$\bar{x}$ = 4.4 CL = 3.4-5.3	222	$\bar{x}$ = 9.2 CL = 7.7-10.8	223	$\bar{x}$ = 14.0 CL = 11.3-16.6	224	$\bar{x}$ = 29.7 CL = 25.6-33.7
Phe*	221	$\bar{x}$ = 69.9 CL = 60.9-79.0	222	$\bar{x}$ = 185.4 CL = 153.3-217.5	223	$\bar{x}$ = 381.9 CL = 322.2-441.6	224	$\bar{x}$ = 546.2 CL = 480.2-612.1
Leu*	221	$\bar{x}$ = 167.2 CL = 149.4-185.0	222	x = 329.8 CL = 280.8-378.8	223	x = 571.5 CL = 477.4-665.6	224	x = 821.1 CL = 692.5-949.7
Met*	221	$\bar{x}$ = 20.4 CL = 4.6-36.2	222	$\bar{x}$ = 89.9 CL = 68.2-111.5	223	$\bar{x}$ = 201.4 CL = 146.8-256.0	224	$\bar{x}$ = 398.0 CL = 327.0-469.0
Tyr*	221	$\bar{x}$ =52.4 CL = 43.2-61.6	222	$\bar{x}$ = 233.7 CL = 190.4-277.0	223	$\bar{x}$ = 413.4 CL = 325.5-501.2	224	$\bar{x}$ = 595.3 CL = 509.1-681.4
Val*	221	$\bar{x}$ = 151.7 CL = 123.8-179.6	222	$\bar{x}$ = 321.8 CL = 272.0-371.6	223	$\bar{x}$ = 561.4 CL = 460.3-662.4	224	$\bar{x}$ = 838.3 CL = 765.0-911.7
Cit*	221	$\bar{x}$ = 27.8 CL = 24.0-31.5	222	$\bar{x}$ = 69.0 CL = 57.4-80.7	223	$\bar{x}$ = 152.6 CL = 125.8-179.4	224	$\bar{x}$ = 278.0 CL = 235.1-320.9
Ala*	221	$\bar{x}$ = 228.3 CL = 192.0-264.6	222	$\bar{x}$ = 316.9 CL = 243.1-390.8	223	$\bar{x}$ = 420.5 CL = 350.4-490.6	224	$\bar{x}$ = 519.6 CL = 432.7-606.4
SUAC*	221	$\bar{x}$ = 1.0 CL = 0.4-1.7	222	$\bar{x}$ = 1.8 CL = 1.1-2.5	223	$\bar{x}$ = 2.8 CL = 1.8-3.8	224	$\bar{x}$ = 4.8 CL = 3.3-5.4

***Analysis Method: Derivatized - MS/MS non-kit**

Note: The values provided in the above table 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

Transition Specimen Certification
Set 2 – July 9, 2012

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	Lot	*Base/Low*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Total Galactose (Gal mg/dL whole blood)	125	5.0	126	10.0	127	15.0	128	30.0
Phenylalanine (µmol/L whole blood)	125	0.0	126	150.0	127	400.0	128	600.0
Leucine (µmol/L whole blood)	125	0.0	126	200.0	127	500.0	128	800.0
Methionine (µmol/L whole blood)	125	0.0	126	100.0	127	250.0	128	500.0
Tyrosine (µmol/L whole blood)	125	0.0	126	250.0	127	500.0	128	750.0
Valine (µmol/L whole blood)	125	0.0	126	250.0	127	600.0	128	1000.0
Citrulline (µmol/L whole blood)	125	0.0	126	50.0	127	150.0	128	300.0
Arginine (µmol/L whole blood)	125	0.0	126	65.0	127	130.0	128	200.0
Succinylacetone (µmol/L whole blood)	125	0.0	126	2.5	127	5.0	128	10.0

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	125	$\bar{x}$ = 4.7 CL = 3.5-5.9	126	$\bar{x}$ = 9.0 CL = 7.7-10.3	127	$\bar{x}$ = 14.6 CL = 12.9-16.3	128	$\bar{x}$ = 30.3 CL = 25.4-35.1
Phe*	125	$\bar{x}$ = 61.0 CL = 55.7-66.2	126	$\bar{x}$ = 171.0 CL = 153.2-188.9	127	$\bar{x}$ = 367.0 CL = 326.2-407.8	128	$\bar{x}$ = 528.2 CL = 457.7-598.6
Leu*	125	$\bar{x}$ = 129.6 CL = 110.7-148.5	126	x = 279.4 CL = 252.3-306.4	127	x = 527.8 CL = 474.9-580.6	128	x = 781.0 CL = 676.6-885.5
Met*	125	$\bar{x}$ = 18.1 CL = 13.9-22.2	126	$\bar{x}$ = 89.3 CL = 76.2-102.5	127	$\bar{x}$ = 199.5 CL = 179.2-219.8	128	$\bar{x}$ = 392.7 CL = 344.3-441.2
Tyr*	125	$\bar{x}$ = 46.0 CL = 39.8-52.2	126	$\bar{x}$ = 224.1 CL = 200.3-247.9	127	$\bar{x}$ = 407.4 CL = 355.7-459.0	128	$\bar{x}$ = 593.9 CL = 500.01-687.8
Val*	125	$\bar{x}$ = 126.7 CL = 106.7-146.7	126	$\bar{x}$ = 284.8 CL = 250.9-318.8	127	$\bar{x}$ = 531.1 CL = 465.0-597.3	128	$\bar{x}$ = 826.0 CL = 705.8-946.2
Cit*	125	$\bar{x}$ = 26.6 CL = 23.8-29.4	126	$\bar{x}$ = 64.0 CL = 58.1-69.9	127	$\bar{x}$ = 145.0 CL = 130.0-160.0	128	$\bar{x}$ = 269.4 CL = 229.7-309.0
Arg*	125	$\bar{x}$ = 17.3 CL = 5.7-29.0	126	$\bar{x}$ = 27.1 CL = 15.3-38.8	127	$\bar{x}$ = 48.2 CL = 28.7-67.8	128	$\bar{x}$ = 109.1 CL = 74.4-143.7
SUAC*	125	$\bar{x}$ = 0.7 CL = 0.5-0.9	126	$\bar{x}$ = 1.4 CL = 1.2-1.7	127	$\bar{x}$ = 2.2 CL = 1.7-2.7	128	$\bar{x}$ = 3.4 CL = 2.6-4.3

***Analysis Method: Derivatized - MS/MS non-kit**

Note: The values provided in the above table 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.*