Newborn Screening
Quality Assurance Program

Quality Control Specimen Certification
Set 2 – July 11, 2011

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	Lot	*Base/Low*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Total Galactose (Gal mg/dL whole blood)	121	5.00	122	10.00	123	15.00	124	30.00
Phenylalanine umol/L blood	121	0.00	122	150.00	123	400.00	124	600.00
Leucine umol/L blood	121	0.00	122	200.00	123	500.00	124	800.00
Methionine umol/L blood	121	0.00	122	100.00	123	250.00	124	500.00
Tyrosine umol/L blood	121	0.00	122	250.00	123	500.00	124	750.00
Valine umol/L blood	121	0.00	122	250.00	123	600.00	124	1000.00
Citrulline umol/L blood	121	0.00	122	50.00	123	150.00	124	300.00
Arginine umol/L blood	121	0.00	122	65.00	123	130.00	124	200.00
Succinylacetone umol/L blood	121	0.00	122	2.50	123	5.00	124	10.00

ANALYTICAL INFORMATION

Lot Numbers, Mean Values (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	121	X = 4.53 CL = 3.59-5.47	122	X = 8.88 CL = 7.52-10.24	123	X = 15.22 CL = 12.78-17.65	124	X = 31.48 CL = 26.68-36.27
Phe*	121	X = 52.60 CL = 39.91-65.28	122	X = 161.72 CL =135.82-187.63	123	X = 342.40 CL = 292.71-392.10	124	X = 487.21 CL = 400.09-574.33
Leu*	121	X = 128.84 CL = 98.92-158.76	122	X = 287.74 CL = 248.05-327.43	123	X = 514.23 CL = 430.04-598.43	124	X = 760.56 CL = 623.14-897.98
Met*	121	X = 17.24 CL = 12.24-22.24	122	X = 85.86 CL = 71.61-100.10	123	X = 191.49 CL = 160.30-222.68	124	X = 364.12 CL = 300.99-427.26
Tyr*	121	X = 39.64 CL = 32.31-46.98	122	X = 199.71 CL = 162.33-237.09	123	X = 365.71 CL = 304.62-426.79	124	X = 543.05 CL = 427.67-658.42
Val*	121	X = 128.38 CL = 91.79-164.98	122	X = 298.38 CL = 248.92-347.82	123	X = 530.03 CL = 459.50-600.56	124	X = 813.42 CL = 647.57-979.28
Cit*	121	X = 15.54 CL = 11.82-19.26	122	X = 41.89 CL = 33.74-50.04	123	X = 94.64 CL = 75.30-113.98	124	X = 173.18 CL = 129.41-216.95
Arg*	121	X = 3.74 CL = 2.15-5.34	122	X = 9.18 CL = 6.94-11.41	123	X = 19.89 CL = 14.48-25.30	124	X = 32.70 CL = 23.10-42.30
SUAC*	121	X = 0.07 CL = 0.00-0.29	122	X = 2.50 CL = 1.95-3.05	123	X = 4.74 CL = 3.88-5.60	124	X = 9.30 CL = 7.60-11.00

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

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 11, 2011
Transition (parallel testing) Materials

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	Lot	*Base/Low*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Total Galactose (Gal mg/dL whole blood)	025	5.00	026	10.00	027	15.00	028	30.00
Phenylalanine umol/L blood	025	0.00	026	150.00	027	400.00	028	600.00
Leucine umol/L blood	025	0.00	026	200.00	027	500.00	028	800.00
Methionine umol/L blood	025	0.00	026	100.00	027	250.00	028	500.00
Tyrosine umol/L blood	025	0.00	026	250.00	027	500.00	028	750.00
Valine umol/L blood	025	0.00	026	250.00	027	600.00	028	1000.00
Citrulline umol/L blood	025	0.00	026	50.00	027	150.00	028	300.00
Arginine umol/L blood	025	0.00	026	65.00	027	130.00	028	200.00
Succinylacetone umol/L blood	025	0.00	026	2.50	027	5.00	028	10.00

ANALYTICAL INFORMATION

Lot Numbers, Mean Values (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	025	x = 4.8 CL = 4.4-5.3	026	x = 10.0 CL = 9.2-10.9	027	x = 16.1 CL = 14.6-17.6	028	x = 31.4 CL = 27.7-35.2
Phe*	025	$\bar{x}$ = 70.32 CL = 63.41-77.24	026	$\bar{x}$ = 180.64 CL = 160.13-201.16	027	$\bar{x}$ = 366.93 CL = 331.45-402.41	028	$\bar{x}$ = 534.27 CL = 469.60-598.94
Leu*	025	$\bar{x}$ = 148.66 CL = 133.14-164.18	026	x = 290.24 CL = 256.92-323.57	027	x = 518.11 CL = 460.86-575.37	028	x = 738.04 CL = 635.63-840.46
Met*	025	$\bar{x}$ = 19.93 CL = 15.28-24.59	026	$\bar{x}$ = 80.74 CL = 64.35-97.13	027	$\bar{x}$ = 171.56 CL = 149.14-193.98	028	$\bar{x}$ = 343.07 CL = 310.22-375.93
Tyr*	025	$\bar{x}$ =43.87 CL = 38.90-48.83	026	$\bar{x}$ = 199.86 CL = 177.75-221.97	027	$\bar{x}$ = 357.46 CL = 321.13-393.78	028	$\bar{x}$ = 532.32 CL = 453.16-611.48
Val*	025	$\bar{x}$ = 239.63 CL = 139.29-339.97	026	$\bar{x}$ = 404.60 CL = 315.04-494.16	027	$\bar{x}$ = 653.51 CL = 553.31-753.71	028	$\bar{x}$ = 972.26 CL = 873.28-1071.24
Cit*	025	$\bar{x}$ = 19.09 CL = 16.78-21.39	026	$\bar{x}$ = 42.69 CL = 37.13-48.25	027	$\bar{x}$ = 93.85 CL = 82.19-105.51	028	$\bar{x}$ = 174.44 CL = 147.64-201.23
Arg*	025	$\bar{x}$ = 4.62 CL = 3.51-5.72	026	$\bar{x}$ = 11.27 CL = 6.23-16.30	027	$\bar{x}$ = 24.71 CL = 17.67-31.75	028	$\bar{x}$ = 43.20 CL = 25.57-60.82
SUAC*	025	$\bar{x}$ = 0.12 CL = 0-0.39	026	$\bar{x}$ = 2.84 CL = 2.36-3.32	027	$\bar{x}$ = 5.05 CL = 4.32-5.78	028	$\bar{x}$ = 10.42 CL = 8.70-12.15

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

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.*