Newborn Screening
Quality Assurance Program

Quality Control Specimen Certification
Set 1: January 9, 2012

Enrichment Levels (endogenous not included)

Analyte	*Units*	*Lot*	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Total Galactose	mg / dL blood	125	5	126	10	127	15	128	30
Phenylalanine	µmol / L blood	125	0	126	150	127	400	128	600
Leucine	µmol / L blood	125	0	126	200	127	500	128	800
Methionine	µmol / L blood	125	0	126	100	127	250	128	500
Tyrosine	µmol / L blood	125	0	126	250	127	500	128	750
Valine	µmol / L blood	125	0	126	250	127	600	128	1000
Citrulline	µmol / L blood	125	0	126	50	127	150	128	300
Arginine	µmol / L blood	125	0	126	65	127	130	128	200
Succinylacetone	µmol / L blood	125	0	126	2.5	127	5	128	10

Analytical Information

Lot Numbers, Mean Values (X) and 95% Confidence Limits (CL)											
Analyte	*Lot*	*Mean and 95% CL*		*Lot*	*Mean and 95% CL*		*Lot*	*Mean and 95% CL*		*Lot*	*Mean and 95% CL*
Total Gal	125	$\bar{X}$ =	4.7	126	$\bar{X}$ =	9.0	127	$\bar{X}$ =	14.6	128	$\bar{X}$ = 30.3
		CL=	3.5 - 5.9		CL=	7.7 - 10.3		CL=	12.9 - 16.3		CL= 25.4 - 35.1
Phe*	125	$\bar{X}$ =	61.0	126	$\bar{X}$ =	171.0	127	$\bar{X}$ =	367.0	128	$\bar{X}$ = 528.2
		CL=	55.7 - 66.2		CL=	153.2 - 188.9		CL=	326.2 - 407.8		CL= 457.7 - 598.6
Leu*	125	$\bar{X}$ =	129.6	126	$\bar{X}$ =	279.4	127	$\bar{X}$ =	527.8	128	$\bar{X}$ = 781.0
		CL=	110.7 - 148.5		CL=	252.3 - 306.4		CL=	474.9 - 580.6		CL= 676.6 - 885.5
Met*	125	$\bar{X}$ =	18.1	126	$\bar{X}$ =	89.3	127	$\bar{X}$ =	199.5	128	$\bar{X}$ = 392.7
		CL=	13.9 - 22.2		CL=	76.2 - 102.5		CL=	179.2 - 219.8		CL= 344.3 - 441.2
Tyr*	125	$\bar{X}$ =	46.0	126	$\bar{X}$ =	224.1	127	$\bar{X}$ =	407.4	128	$\bar{X}$ = 593.9
		CL=	39.8 - 52.2		CL=	200.3 - 247.9		CL=	355.7 - 459.0		CL= 500.0 - 687.8
Val*	125	$\bar{X}$ =	126.7	126	$\bar{X}$ =	284.8	127	$\bar{X}$ =	531.1	128	$\bar{X}$ = 826.0
		CL=	106.7 - 146.7		CL=	250.9 - 318.8		CL=	465.0 - 597.3		CL= 705.8 - 946.2
Cit*	125	$\bar{X}$ =	26.6	126	$\bar{X}$ =	64.0	127	$\bar{X}$ =	145.0	128	$\bar{X}$ = 269.4
		CL=	23.8 - 29.4		CL=	58.1 - 69.9		CL=	130.0 - 160.0		CL= 229.7 - 309.0
Arg*	125	$\bar{X}$ =	17.3	126	$\bar{X}$ =	27.1	127	$\bar{X}$ =	48.2	128	$\bar{X}$ = 109.1
		CL=	5.7 - 29.0		CL=	15.3 - 38.8		CL=	28.7 - 67.8		CL= 74.4 - 143.7
SUAC*	125	$\bar{X}$ =	0.7	126	$\bar{X}$ =	1.4	127	$\bar{X}$ =	2.2	128	$\bar{X}$ = 3.4
		CL=	0.5 - 0.9		CL=	1.2 - 1.7		CL=	1.7 - 2.7		CL= 2.6 - 4.3

* **Analysis Method: MSMS Derivatized- MSMS 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 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
Transition (parallel testing) Materials
Set 1: January 9, 2012

Enrichment Levels (endogenous not included)

Analyte	*Units*	*Lot*	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Total Galactose	mg / dL blood	121	5	122	10	123	15	124	30
Phenylalanine	umol / L blood	121	0	122	150	123	400	124	600
Leucine	umol / L blood	121	0	122	200	123	500	124	800
Methionine	umol / L blood	121	0	122	100	123	250	124	500
Tyrosine	umol / L blood	121	0	122	250	123	500	124	750
Valine	umol / L blood	121	0	122	250	123	600	124	1000
Citrulline	umol / L blood	121	0	122	50	123	150	124	300
Arginine	umol / L blood	121	0	122	65	123	130	124	200
Succinylacetone	umol / L blood	121	0	122	2.5	123	5	124	10

Analytical Information

Lot Numbers, Mean Values (X) and 95% Confidence Limits (CL)									
Analyte	*Lot*	*Mean and 95% CL*	*Lot*	*Mean and 95% CL*	*Lot*	*Mean and 95% CL*	*Lot*	*Mean and 95% CL*	
Total Gal	121	$\bar{X}$ =	4.53	122 $\bar{X}$ =	8.88	123 $\bar{X}$ =	15.22	124 $\bar{X}$ =	31.48
		CL=	3.59 - 5.47	CL=	7.52 - 10.24	CL=	12.78 - 17.65	CL=	26.68 - 36.27
Phe*	121	$\bar{X}$ =	52.60	122 $\bar{X}$ =	161.72	123 $\bar{X}$ =	342.40	124 $\bar{X}$ =	487.21
		CL=	39.91 - 65.28	CL=	135.82 - 187.63	CL=	292.71 - 392.10	CL=	400.09 - 574.33
Leu*	121	$\bar{X}$ =	128.84	122 $\bar{X}$ =	287.74	123 $\bar{X}$ =	514.23	124 $\bar{X}$ =	760.56
		CL=	98.92 - 158.76	CL=	248.05 - 327.43	CL=	430.04 - 598.43	CL=	623.14 - 897.98
Met*	121	$\bar{X}$ =	17.24	122 $\bar{X}$ =	85.86	123 $\bar{X}$ =	191.49	124 $\bar{X}$ =	364.12
		CL=	12.24 - 22.24	CL=	71.61 - 100.10	CL=	160.30 - 222.68	CL=	300.99 - 427.26
Tyr*	121	$\bar{X}$ =	39.64	122 $\bar{X}$ =	199.71	123 $\bar{X}$ =	365.71	124 $\bar{X}$ =	543.05
		CL=	32.31 - 46.98	CL=	162.33 - 237.09	CL=	304.62 - 426.79	CL=	427.67 - 658.42
Val*	121	$\bar{X}$ =	128.38	122 $\bar{X}$ =	298.38	123 $\bar{X}$ =	530.03	124 $\bar{X}$ =	813.42
		CL=	91.79 - 164.98	CL=	248.94 - 347.82	CL=	459.50 - 600.56	CL=	647.57 - 979.28
Cit*	121	$\bar{X}$ =	15.54	122 $\bar{X}$ =	41.89	123 $\bar{X}$ =	94.64	124 $\bar{X}$ =	173.18
		CL=	11.82 - 19.26	CL=	33.74 - 50.04	CL=	75.30 - 113.98	CL=	129.41 - 216.95
Arg*	121	$\bar{X}$ =	3.74	122 $\bar{X}$ =	9.18	123 $\bar{X}$ =	19.89	124 $\bar{X}$ =	32.70
		CL=	2.15 - 5.34	CL=	6.94 - 11.41	CL=	14.48 - 25.30	CL=	23.10 - 42.30
SUAC*	121	$\bar{X}$ =	0.07	122 $\bar{X}$ =	2.50	123 $\bar{X}$ =	4.74	124 $\bar{X}$ =	9.30
		CL=	0.00 - 0.29	CL=	1.95 - 3.05	CL=	3.88 - 5.60	CL=	7.60 - 11.00

* **Analysis Method: MSMS Derivatized- MSMS 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 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.*