Newborn Screening Quality Assurance Program

Amino Acids Quality Control Specimen Certification

Set 2 – July 2016

Amino Acids Analysis Method: Derivatized – MS/MS non-kit

Total Galactose Analysis Method: PerkinElmer Neonatal Kit

Material Expiration Date: February 2017

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	*Lot*	*Base/Low*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Alanine (µmol/L blood)	1525	0.0	1526	200.0	1527	400.0	1528	600.0
Arginine (µmol/L blood)	1525	0.0	1526	100.0	1527	200.0	1528	300.0
Citrulline (µmol/L blood)	1525	0.0	1526	25.0	1527	100.0	1528	250.0
Leucine (µmol/L blood)	1525	0.0	1526	100.0	1527	250.0	1528	500.0
Methionine (µmol/L blood)	1525	0.0	1526	50.0	1527	150.0	1528	250.0
Phenylalanine (µmol/L blood)	1525	0.0	1526	100.0	1527	200.0	1528	300.0
Succinylacetone (µmol/L blood)	1525	0.0	1526	2.5	1527	7.5	1528	15.0
Tyrosine (µmol/L blood)	1525	0.0	1526	200.0	1527	400.0	1528	600.0
Valine (µmol/L blood)	1525	0.0	1526	200.0	1527	350.0	1528	500.0
Total Galactose (mg/dL blood)	1525	5.0	1526	10.0	1527	15.0	1528	30.0

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*
Ala	1525	$\bar{x}$ = 458.6 CL = 416.5–500.8	1526	$\bar{x}$ = 623.2 CL = 542.7–703.7	1527	$\bar{x}$ = 802.3 CL = 701.5–903.2	1528	$\bar{x}$ = 1012.1 CL = 843.6–1180.7
Arg	1525	$\bar{x}$ = 11.0 CL = 7.6–14.4	1526	$\bar{x}$ = 94.1 CL = 79.7–108.5	1527	$\bar{x}$ = 177.0 CL = 139.1–214.9	1528	$\bar{x}$ = 265.3 CL = 211.6–319.1
Cit	1525	$\bar{x}$ = 28.4 CL = 24.2–32.6	1526	$\bar{x}$ = 50.8 CL = 44.8–56.8	1527	$\bar{x}$ = 117.3 CL = 97.4–137.3	1528	$\bar{x}$ = 257.1 CL = 209.4–304.8
Leu	1525	$\bar{x}$ = 145.3 CL = 128.7–161.8	1526	$\bar{x}$ = 232.1 CL = 202.2–261.9	1527	$\bar{x}$ = 360.4 CL = 320.1–400.7	1528	$\bar{x}$ = 592.2 CL= 493.0–691.3
Met	1525	$\bar{x}$ = 23.4 CL = 21.3–25.6	1526	$\bar{x}$ = 67.8 CL = 59.2–76.3	1527	$\bar{x}$ = 154.7 CL = 134.8–174.6	1528	$\bar{x}$ = 252.7 CL = 213.0–292.4
Phe	1525	$\bar{x}$ = 80.5 CL = 71.0–90.0	1526	$\bar{x}$ = 178.0 CL = 155.4–200.5	1527	$\bar{x}$ = 268.6 CL = 233.3–303.8	1528	$\bar{x}$ = 379.4 CL = 319.1–439.7
SUAC	1525	$\bar{x}$ = 0.9 CL = 0.7–1.1	1526	$\bar{x}$ = 1.9 CL = 1.6–2.3	1527	$\bar{x}$ = 3.8 CL = 3.2–4.4	1528	$\bar{x}$ = 7.2 CL = 5.6–8.8
Tyr	1525	$\bar{x}$ = 58.2 CL = 51.6–64.8	1526	$\bar{x}$ = 233.5 CL = 208.1–258.8	1527	$\bar{x}$ = 403.6 CL = 348.6–458.6	1528	$\bar{x}$ = 598.8 CL = 506.4–691.3
Val	1525	$\bar{x}$ = 168.3 CL = 141.5–195.0	1526	$\bar{x}$ = 321.1 CL = 284.6–357.6	1527	$\bar{x}$ = 439.3 CL = 394.8–483.8	1528	$\bar{x}$ = 573.5 CL = 482.1–665.0
TGal	1525	$\bar{x}$ = 5.9 CL = 4.8–7.1	1526	$\bar{x}$ = 9.8 CL = 8.2–11.5	1527	$\bar{x}$ = 15.5 CL = 12.6–18.4	1528	$\bar{x}$ = 27.5 CL = 22.9–32.0

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 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.*