Newborn Screening Quality Assurance Program

Quality Control Specimen Certification

Set 1 – January 2016

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

Total Galactose Analysis Method: PerkinElmer Neonatal Kit

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	*Lot*	*Base/Low*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*	*Expiration Date*
Alanine (µmol /L whole blood)	1525	0	1526	200.0	1527	400.0	1528	600.0	February 2017
Arginine (µmol /L whole blood)	1525	0	1526	100.0	1527	200.0	1528	300.0	February 2017
Citrulline (µmol /L whole blood)	1525	0	1526	25.0	1527	100.0	1528	250.0	February 2017
Leucine (µmol /L whole blood)	1525	0	1526	100.0	1527	250.0	1528	500.0	February 2017
Methionine (µmol /L whole blood)	1525	0	1526	50.0	1527	150.0	1528	250.0	February 2017
Phenylalanine (µmol/L whole blood)	1525	0	1526	100.0	1527	200.0	1528	300.0	February 2017
Succinylacetone (µmol /L whole blood)	1525	0	1526	2.5	1527	7.5	1528	15.0	February 2017
Tyrosine (µmol /L whole blood)	1525	0	1526	200.0	1527	400.0	1528	600.0	February 2017
Valine (µmol /L whole blood)	1525	0	1526	200.0	1527	350.0	1528	500.0	February 2017
Total Galactose (mg/dL whole blood)	1525	5.0	1526	10.0	1527	15.0	1528	30.0	February 2017

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*	*Expiration Date*
Ala	1525	$\bar{x}$ = 493.5 CL = 420.0–567.1	1526	$\bar{x}$ = 653.1 CL = 571.7–734.5	1527	$\bar{x}$ = 894.4 CL = 730.7–1058.4	1528	$\bar{x}$ = 1021.8 CL = 920.4–1123.2	February 2017
Arg	1525	$\bar{x}$ = 9.9 CL = 6.7–13.2	1526	$\bar{x}$ = 95.7 CL = 77.9–113.5	1527	$\bar{x}$ = 181.3 CL = 147.8–214.9	1528	$\bar{x}$ = 248.2 CL = 203.7–292.8	February 2017
Cit	1525	$\bar{x}$ = 27.8 CL = 18.7–36.9	1526	$\bar{x}$ = 53.5 CL = 36.4–70.6	1527	$\bar{x}$ = 123.0 CL = 91.4–154.6	1528	$\bar{x}$ = 242.9 CL = 184.4–301.4	February 2017
Leu	1525	$\bar{x}$ = 186.9 CL = 160.9–213.0	1526	$\bar{x}$ = 274.0 CL = 235.4–312.5	1527	$\bar{x}$ = 420.1 CL = 344.2–495.9	1528	$\bar{x}$ = 622.9 CL = 565.1–680.7	February 2017
Met	1525	$\bar{x}$ = 19.6 CL = 12.2–26.9	1526	$\bar{x}$ = 60.1 CL = 42.2–78.1	1527	$\bar{x}$ = 142.6 CL = 117.6–167.5	1528	$\bar{x}$ = 219.7 CL = 188.9–250.6	February 2017
Phe	1525	$\bar{x}$ = 77.5 CL = 66.7–88.4	1526	$\bar{x}$ = 167.4 CL = 146.1–188.6	1527	$\bar{x}$ = 261.4 CL = 209.4–313.4	1528	$\bar{x}$ = 341.7 CL = 307.1–376.3	February 2017
SUAC	1525	$\bar{x}$ = 0.6 CL = 0.2–0.9	1526	$\bar{x}$ = 1.5 CL = 1.1–1.9	1527	$\bar{x}$ = 3.6 CL = 2.6–4.5	1528	$\bar{x}$ = 6.1 CL = 4.8–7.5	February 2017
Tyr	1525	$\bar{x}$ = 53.5 CL = 42.3–64.7	1526	$\bar{x}$ = 216.3 CL = 182.9–249.6	1527	$\bar{x}$ = 374.7 CL = 305.8–443.6	1528	$\bar{x}$ = 522.6 CL = 447.7–597.5	February 2017
Val	1525	$\bar{x}$ = 170.6 CL = 147.5–193.8	1526	$\bar{x}$ = 332.9 CL = 288.0–377.9	1527	$\bar{x}$ = 475.7 CL = 387.2–564.1	1528	$\bar{x}$ = 581.7 CL = 525.9–637.5	February 2017
Total Gal	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	February 2017

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.*