Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Set 2 – July 12, 2016

T4, TSH and 17OHP METHOD: FIA

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*	*Expiration Date*
Thyroxine (T_4 μg/dL serum)	A1600	2	B1600	7	C1600	11	February 2018
Thyroid-Stimulating Hormone (TSH μIU/mL serum)	A1601	25	B1601	40	C1601	80	March 2018
17 α-Hydroxyprogesterone (17OHP ng/mL serum)	1551	25	1552	50	1553	100	March 2017

ANALYTICAL INFORMATION

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*
T_4	A1600	$\bar{x}$ = 1.4 CL = 0.9 -1.9	B1600	$\bar{x}$ = 6.9 CL = 5.5 – 8.4	C1600	$\bar{x}$ = 11.5 CL = 9.3 - 13.8
TSH	A1601	$\bar{x}$ = 27.0 CL = 22.9 – 31.2	B1601	$\bar{x}$ = 40.9 CL = 35.4 – 46.3	C1601	$\bar{x}$ = 85.3 CL = 71.2 – 99.3
17OHP	1551	$\bar{x}$ = 23.7 CL = 19.2 - 28.2	1552	$\bar{x}$ = 47.7 CL = 39.1 - 56.4	1553	$\bar{x}$ = 97.7 CL = 83.0 - 112.5

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.

Reference: *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.*