

Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Set 1 – January 11, 2016

T4, TSH and 17-OHP METHOD: FIA

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	Lot	Low	Lot	Intermediate	Lot	High	Expiration Date
Thyroxine (T ₄ µg/dL serum)	1401	2	1402	7	1403	11	October 2016
Thyroid-Stimulating Hormone (TSH µIU/mL serum)	1511	25	1512	40	1513	80	March 2017
17 α-Hydroxyprogesterone (17-OHP 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	1401	$\bar{x} = 1.8$ CL = 1.4 - 2.2	1402	$\bar{x} = 6.4$ CL = 5.5 - 7.2	1403	$\bar{x} = 11.0$ CL = 9.3-12.7
TSH	1511	$\bar{x} = 27.1$ CL = 23.5 - 30.6	1512	$\bar{x} = 48.9$ CL = 42.1 - 55.6	1513	$\bar{x} = 90.5$ CL = 75.0 - 106.1
17-OHP	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.