Newborn Screening
Quality Assurance Program

Quality Control Hormones Specimen Certification
Set 1 – January 7, 2013

ENRICHMENT LEVELS (endogenous levels not included)

Analyte	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Thyroxine (T_4 μg/dL serum)	101	2	102	7	103	11
Thyroid-Stimulating Hormone (TSH μIU/mL serum)	211	25	212	40	213	80
17 α-Hydroxyprogesterone (17-OHP ng/mL serum)	251	25	252	50	253	100

ANALYTICAL INFORMATION

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*
T_4	101	$\bar{x}$ = 1.8 CL = 1.1 – 2.6	102	$\bar{x}$ = 7.1 CL = 5.5 – 8.7	103	$\bar{x}$ = 11.2 CL = 8.7 – 13.6
TSH	211	$\bar{x}$ = 24.3 CL = 19.2 - 29.5	212	$\bar{x}$ = 39.2 CL = 31.0 - 47.3	213	$\bar{x}$ = 69.3 CL = 56.6 - 81.9
17-OHP	251	$\bar{x}$ = 25.1 CL = 17.0 - 33.2	252	$\bar{x}$ = 48.7 CL = 35.1 – 62.3	253	$\bar{x}$ = 109.2 CL = 79.9 – 138.5

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