



# Newborn Screening Quality Assurance Program

## Quality Control Hormones Specimen Certification Set 1 – January 9, 2012

### ENRICHMENT LEVELS (endogenous levels not included)

<i>Analyte</i>	<i>Lot</i>	<i>Low</i>	<i>Lot</i>	<i>Intermediate</i>	<i>Lot</i>	<i>High</i>
Thyroxine (T <sub>4</sub> µg/dL serum)	101	2	102	7	103	11
Thyroid-Stimulating Hormone (TSH µIU/mL serum)	111	25	112	40	113	80
17 α-Hydroxyprogesterone (17-OHP ng/mL serum)	151	25	152	50	153	100

### ANALYTICAL INFORMATION

<i>Analyte</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>
T <sub>4</sub>		$\bar{x} = 1.8$ CL = 1.1 – 2.6		$\bar{x} = 7.1$ CL = 5.5 – 8.7		$\bar{x} = 11.2$ CL = 8.7 – 13.6
TSH		$\bar{x} = 24.8$ CL = 21.9 - 27.8		$\bar{x} = 38.7$ CL = 31.4 - 46.0		$\bar{x} = 81.9$ CL = 70.3 - 93.5
17-OHP		$\bar{x} = 28.9$ CL = 21.5 - 36.4		$\bar{x} = 53.3$ CL = 45.4 – 61.3		$\bar{x} = 110.1$ CL = 87.3 – 133.0

**\*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.*



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**Transition (parallel testing) Materials**

ENRICHMENT LEVELS (endogenous levels not included)

<i>Analyte</i>	Lot	<i>Low</i>	Lot	<i>Intermediate</i>	Lot	<i>High</i>
T <sub>4</sub>	901	2	902	7	903	11
TSH						
17-OHP						

**ANALYTICAL INFORMATION**

<i>Analyte</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>
T <sub>4</sub>		$\bar{x} = 1.3$		$\bar{x} = 5.5$		$\bar{x} = 10.5$
	901	CL = 0.6 - 2.0	902	CL = 3.1 - 7.8	903	CL = 6.4 - 14.6
TSH						
17-OHP						

**\*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.*