

Newborn Screening Quality Assurance Program

Hormones Quality Control Specimen Certification
Set 2– July 8, 2013

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 ₄ µg/dL serum)	1301	2	1302	7	1303	11
Thyroid-Stimulating Hormone (TSH µIU/mL serum)	1311	25	1312	40	1313	80
17 α-Hydroxyprogesterone (17-OHP ng/mL serum)	251	25	252	50	253	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 ₄		$\bar{x} = 1.6$		$\bar{x} = 6.1$		$\bar{x} = 9.5$
	1301	CL = 0.9-2.2	1302	CL = 5.1-7.1	1303	CL = 7.2-11.8
TSH		$\bar{x} = 22.8$		$\bar{x} = 36.9$		$\bar{x} = 77.5$
	1311	CL = 17.8 - 27.7	1312	CL = 28.5 - 45.4	1313	CL = 62.0 - 93.0
17-OHP		$\bar{x} = 25.1$		$\bar{x} = 48.7$		$\bar{x} = 109.2$
	251	CL = 17.0 - 33.2	252	CL = 35.1 – 62.3	253	CL = 79.9 – 138.5

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.

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.

Newborn Screening Quality Assurance Program

Hormones Quality Control Specimen Certification
Set 2 – July 8, 2013

Previous Lot Transition Materials (parallel testing)

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 ₄ μg/dL serum)	101	2	102	7	103	11
Thyroid-Stimulating Hormone (TSH μIU/mL serum)	211	25	212	40	213	80

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 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

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.