

Newborn Screening Quality Assurance Program
Quality Control Specimen Certification

Second-Tier Congenital Adrenal Hyperplasia by LC-MS/MS
January 2016

Method: LC-MS/MS

<i>Enrichment levels. Units are ng/mL serum.</i>						
<i>Lot</i>	17 α - Hydroxyprogesterone (17-OHP)	4-Androstenedione (4-AD)	Cortisol	11-Deoxycortisol (11-D)	21-Deoxycortisol (21-D)	Expiration Date
5000	0	0	0	0	0	September 2016
5010	10	10	10	10	10	September 2016
5050	50	50	50	50	50	September 2016
5100	100	100	100	100	100	September 2016
5500	500	500	500	500	500	September 2016

ANALYTICAL INFORMATION

<i>Lot Numbers, Mean Values (x), and 95% Confidence Limits (CL). Units are ng/mL serum.</i>						
<i>Lot</i>	<i>Analyte</i>					Expiration Date
	17 α - Hydroxyprogesterone (17-OHP)	4-Androstenedione (4-AD)	Cortisol	11-Deoxycortisol (11-D)	21-Deoxycortisol (21-D)	
	<i>Mean/ 95% CL</i>	<i>Mean/ 95% CL</i>	<i>Mean/ 95% CL</i>	<i>Mean/ 95% CL</i>	<i>Mean/ 95% CL</i>	September 2016
5000	\bar{x} = 3.3 CL = 0.0 - 9.0	\bar{x} = 1.1 CL = 0.0 - 3.2	\bar{x} = 1.5 CL = 0.2 - 2.8	\bar{x} = 3.8 CL = 2.1 - 5.6	\bar{x} = 3.3 CL = 2.0 - 4.6	September 2016
5010	\bar{x} = 10.9 CL = 8.5 - 13.3	\bar{x} = 12.9 CL = 11.6 - 14.2	\bar{x} = 10.5 CL = 7.1 - 13.9	\bar{x} = 11.3 CL = 10.2 - 12.5	\bar{x} = 14.4 CL = 12.4 - 16.4	September 2016
5050	\bar{x} = 43.5 CL = 34.8 - 52.2	\bar{x} = 60.7 CL = 52.0 - 69.4	\bar{x} = 45.5 CL = 36.0 - 55.0	\bar{x} = 41.4 CL = 35.7 - 47.1	\bar{x} = 52.3 CL = 43.7 - 60.9	September 2016
5100	\bar{x} = 88.6 CL = 73.5 - 103.6	\bar{x} = 125.3 CL = 113.0 - 137.6	\bar{x} = 90.5 CL = 77.0 - 104.0	\bar{x} = 81.5 CL = 61.2 - 101.7	\bar{x} = 94.4 CL = 72.9 - 116.0	September 2016
5500	\bar{x} = 425.3 CL = 357.5 - 493.0	\bar{x} = 626.5 CL = 531.0 - 722.0	\bar{x} = 471.3 CL = 386.8 - 555.7	\bar{x} = 408.8 CL = 344.2 - 473.4	\bar{x} = 524.8 CL = 451.4 - 598.1	September 2016

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.