

# Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Second Tier LC-MS/MS for CAH  
Quarterly Report

December 2013

## INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 4, 2013. The attached tables provide the certification profiles for the distributed specimens, the verification of your reported data, the statistical analysis of the quantitative data, and the frequency distribution summaries for expected interpretations. We distribute this proficiency testing (PT) report to all participants, and program colleagues by request.

On October 23, 2013, a panel of five unknown dried-blood spot (DBS) specimens prepared with different enrichments of five biomarkers for congenital adrenal hyperplasia (CAH) was distributed to six domestic laboratories and eleven foreign laboratories. DBS specimens were prepared at 50% hematocrit.

We processed data from fifteen participants. Laboratories were asked to report concentrations of 17-hydroxyprogesterone (17-OHP), 4-androstenedione (4AD), cortisol, 11-deoxycortisol and 21-deoxycortisol results in ng/mL serum. For the statistical summary analysis, we did not include data that were outside the 99% confidence interval.

Fifteen laboratories reported results using tandem mass spectrometry (LC-MS/MS). Five of these labs also reported enzyme immunoassay (EIA) results. The expected analyte concentration values were based on CDC enriched values. Overall statistics from EIA (Table 1) and LC-MS/MS (Table 2) methods were

combined as not to identify an individual laboratory. The frequency distribution of participants' interpretations for screening results is shown in Table 3; your laboratory's interpretations are shown on the Specimen Certification page.

Expected interpretations (qualitative assessments) may differ by participant because of specific assessment practices. When the reported clinical assessment differs from our expected clinical assessment, the grading algorithm is used to evaluate test performance. An explanation of the grading algorithm can be found on the NSQAP data reporting web site or in the annual summary report. Overall, participants reported one false-positive and no false-negative results.

All data are presented in units of ng/mL serum. Data reported in nM whole blood units were multiplied by the following factors for conversion to serum concentration: 0.66 (17-OHP), 0.57 (4-AD), 0.72 (cortisol), and 0.69 (11- and 21-deoxycortisol). In order to expedite the issuance of this report, data that are not submitted in the requested units (ng/mL serum) will not be accepted. Please contact us for guidance on conversion factors.

NSQAP will ship the next Second Tier Congenital Adrenal Hyperplasia PT specimens on January 13, 2014. If you have any comments or questions about CAH LC-MS/MS quality assurance issues, contact Dr. Joanne V. Mei at 770-488-7945, by fax at 770-488-7459, or by e-mail at [jvm0@cdc.gov](mailto:jvm0@cdc.gov). ❖

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CONGENITAL ADRENAL HYPERPLASIA  
SECOND TIER PILOT PT PROGRAM FOR LC-MS/MS

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Table 1. Overall Statistics for 17-Hydroxyprogesterone by EIA.

**OVERALL STATISTICS - 17-HYDROXYPROGESTERONE (ng/mL Serum)  
EIA SCREENING RESULTS**

Specimen	N	Mean	UL (95%)	LL (95%)
413A1	5	11.5	19.3	3.7
413A2	5	12.2	19.0	5.3
413A3	5	11.9	21.1	2.8
413A4	5	105.5	166.6	44.4
413A5	5	94.3	140.5	48.2

Table 2. Overall Statistics for 17-Hydroxyprogesterone, 4-Androstenedione, Cortisol, 11-Deoxycortisol and 21-Deoxycortisol by LC-MS/MS.

**OVERALL STATISTICS - 17-HYDROXYPROGESTERONE (ng/mL Serum)  
LC-MS/MS SCREENING RESULTS**

Specimen	N	Mean	UL (95%)	LL (95%)
413A1	14	13.5	21.8	5.3
413A2	14	12.7	17.7	7.6
413A3	14	11.7	17.7	5.6
413A4	15	100.0	134.0	66.0
413A5	15	91.8	122.3	61.3

**OVERALL STATISTICS - 4-ANDROSTENEDIONE (ng/mL Serum)  
LC-MS/MS SCREENING RESULTS**

Specimen	N	Mean	UL (95%)	LL (95%)
413A1	14	20.2	31.2	9.1
413A2	14	19.4	30.8	8.0
413A3	14	18.9	30.3	7.5
413A4	15	39.7	63.0	16.3
413A5	15	24.8	39.6	10.1

**OVERALL STATISTICS - CORTISOL (ng/mL Serum)  
LC-MS/MS SCREENING RESULTS**

<b>Specimen</b>	<b>N</b>	<b>Mean</b>	<b>UL (95%)</b>	<b>LL (95%)</b>
413A1	14	39.4	59.2	19.5
413A2	14	37.7	54.4	21.1
413A3	14	37.7	58.4	17.1
413A4	15	18.2	27.4	9.0
413A5	15	154.6	230.6	78.5

**OVERALL STATISTICS - 11-DEOXYCORTISOL (ng/mL Serum)  
LC-MS/MS SCREENING RESULTS**

<b>Specimen</b>	<b>N</b>	<b>Mean</b>	<b>UL (95%)</b>	<b>LL (95%)</b>
413A1	9	9.2	16.2	2.2
413A2	9	8.7	14.9	2.5
413A3	9	9.9	18.9	0.9
413A4	9	23.9	38.3	9.4
413A5	9	5.1	10.7	0.0

**OVERALL STATISTICS - 21-DEOXYCORTISOL (ng/mL Serum)  
LC-MS/MS SCREENING RESULTS**

<b>Specimen</b>	<b>N</b>	<b>Mean</b>	<b>UL (95%)</b>	<b>LL (95%)</b>
413A1	5	1.8	5.6	0.0
413A2	6	1.4	4.3	0.0
413A3	4	1.1	4.3	0.0
413A4	9	7.9	13.9	1.8
413A5	5	1.0	3.8	0.0

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Table 3. Frequency Distribution of Participant's Final Interpretations\*

<b>Specimen</b>	<b>Within Normal Limits (WNL)</b>	<b>Outside Normal Limits (ONL)</b>
<b>413A1</b>	14	0
<b>413A2</b>	14	0
<b>413A3</b>	14	0
<b>413A4</b>	0	15
<b>413A5</b>	14	1

\*LC-MS/MS METHOD

This **NEWBORN SCREENING QUALITY ASSURANCE PROGRAM** report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the **Centers for Disease Control and Prevention (CDC)** and the **Association of Public Health Laboratories**.

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