

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Second Tier LC-MS/MS for CAH
Quarterly Report

February 2014

INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 1, 2014. 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 January 13, 2014, 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). Eight 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 four false-positive and no false-negative results. Specimen number 114A1 was not enriched and therefore had analyte levels at or near the limit of detection for most methods.

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 July 14, 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. ❖

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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%)
114A1	7	0.7	1.8	0.0
114A2	8	106.1	150.9	61.3
114A3	8	94.9	154.6	35.3
114A4	8	57.3	80.4	34.2
114A5	8	61.5	81.2	41.8

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%)
114A1	10	1.1	2.9	0.0
114A2	15	105.1	154.1	56.0
114A3	15	94.1	138.2	49.9
114A4	15	59.0	86.4	31.6
114A5	15	55.9	81.9	29.9

OVERALL STATISTICS - 4-ANDROSTENEDIONE (ng/mL Serum)

LC-MS/MS SCREENING RESULTS

Specimen	N	Mean	UL (95%)	LL (95%)
114A1	9	0.6	1.5	0.0
114A2	15	39.5	64.1	15.0
114A3	15	25.3	42.6	7.9
114A4	15	24.6	41.2	8.0
114A5	15	24.3	41.8	6.9

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

Specimen	N	Mean	UL (95%)	LL (95%)
114A1	9	1.4	5.5	0.0
114A2	15	18.9	30.4	7.4
114A3	15	163.0	257.0	69.0
114A4	15	97.8	153.1	42.6
114A5	15	93.1	144.6	41.7

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

Specimen	N	Mean	UL (95%)	LL (95%)
114A1	7	1.3	6.0	0.0
114A2	10	26.3	43.0	9.7
114A3	10	5.5	10.4	0.5
114A4	10	9.4	16.3	2.5
114A5	10	9.1	14.9	3.2

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

Specimen	N	Mean	UL (95%)	LL (95%)
114A1	6	0.9	3.8	0.0
114A2	10	8.6	15.1	2.1
114A3	6	0.9	3.6	0.0
114A4	6	0.8	3.5	0.0
114A5	7	0.9	3.2	0.0

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

Specimen	Within Normal Limits (WNL)	Outside Normal Limits (ONL)	Not Reported
114A1	11	1	3
114A2	0	15	0
114A3	14	1	0
114A4	14	1	0
114A5	14	1	0

*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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