

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Second Tier LC-MS/MS CAH
Quarterly Report

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INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 1, 2015. 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 12, 2015, 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 ten foreign laboratories. DBS specimens were prepared at 50% hematocrit.

PARTICIPANT RESULTS

We processed data from 16 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.

Sixteen laboratories reported results using tandem mass spectrometry (LC-MS/MS). Nine of these labs also reported enzyme immunoassay (EIA) results. The expected analyte concentration values were based on CDC expected 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 two 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 July 13, 2015. 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. ❖

CDC/APHL

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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%)
115A1	9	7.45	11.29	3.62
115A2	9	46.20	58.45	33.94
115A3	9	75.21	97.92	52.50
115A4	9	110.19	138.24	82.13
115A5	9	7.31	10.70	3.91

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%)
115A1	14	7.81	13.32	2.30
115A2	16	45.57	60.09	31.05
115A3	16	75.02	98.66	51.38
115A4	16	107.86	141.04	74.68
115A5	14	8.46	13.64	3.28

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

LC-MS/MS SCREENING RESULTS

Specimen	N	Mean	UL (95%)	LL (95%)
115A1	14	20.58	31.51	9.65
115A2	16	24.93	38.89	10.97
115A3	16	26.01	39.82	12.19
115A4	16	39.77	59.72	19.82
115A5	14	20.69	31.58	9.81

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

Specimen	N	Mean	UL (95%)	LL (95%)
115A1	14	37.25	59.98	14.53
115A2	16	111.04	166.50	55.59
115A3	16	127.44	187.50	67.38
115A4	16	22.38	40.08	4.68
115A5	14	39.68	64.50	14.86

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

Specimen	N	Mean	UL (95%)	LL (95%)
115A1	8	0.58	1.81	0.00
115A2	8	0.72	2.11	0.00
115A3	8	0.68	1.84	0.00
115A4	10	7.02	12.31	1.73
115A5	8	0.67	2.26	0.00

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

Specimen	N	Mean	UL (95%)	LL (95%)
115A1	7	0.69	2.68	0.00
115A2	9	0.70	2.52	0.00
115A3	7	0.67	2.87	0.00
115A4	8	0.87	3.43	0.00
115A5	7	0.58	3.03	0.00

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

Specimen	Within Normal Limits (WNL)	Outside Normal Limits (ONL)	Not Evaluated
115A1	14	0	2
115A2	15	1	0
115A3	15	1	0
115A4	0	16	0
115A5	14	0	2

*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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