

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Second Tier LC-MS/MS for CAH
Quarterly Report

August 2013

INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 3, 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 July 8, 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 seven domestic laboratories and eleven foreign laboratories. DBS specimens were prepared at 50% hematocrit.

We processed data from sixteen 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). Three 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 three 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 October 7, 2013. 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

Direct inquiries to:
Centers for Disease Control and Prevention (CDC)
4770 Buford Highway, NE, MS/F43
Atlanta, GA 30341-3724

This program is cosponsored by the Centers for Disease Control and Prevention (CDC)
and the Association of Public Health Laboratories (APHL).

Phone: 770-488-7963
FAX: 770-488-7459
E-mail: VDejesus@cdc.gov

Editor: Victor DeJesus
Production: Irene Williams



CONGENITAL ADRENAL HYPERPLASIA
SECOND TIER PILOT PT PROGRAM FOR LC-MS/MS
Quarter 3 - August 2013

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%)
313A1	3	10.8	14.7	6.9
313A2	3	98.8	133.6	64.0
313A3	3	63.4	80.0	46.7
313A4	3	119.8	126.9	112.8
313A5	3	0.9	2.8	0.0

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%)
313A1	16	11.8	18.9	4.7
313A2	16	87.2	138.2	36.1
313A3	16	57.9	84.0	31.7
313A4	16	101.4	137.5	65.2
313A5	14	1.1	3.4	0.0

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

Specimen	N	Mean	UL (95%)	LL (95%)
313A1	16	20.2	32.3	8.1
313A2	16	26.6	42.5	10.8
313A3	16	26.2	41.9	10.4
313A4	16	41.4	62.9	19.8
313A5	15	0.8	2.9	0.0

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

Specimen	N	Mean	UL (95%)	LL (95%)
313A1	16	39.6	62.0	17.2
313A2	16	158.1	236.5	79.7
313A3	16	99.5	154.1	44.9
313A4	16	19.0	29.5	8.6
313A5	15	1.4	5.0	0.0

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

Specimen	N	Mean	UL (95%)	LL (95%)
313A1	10	7.5	12.5	2.4
313A2	10	4.8	7.8	1.9
313A3	10	8.3	14.2	2.4
313A4	10	23.5	38.3	8.6
313A5	9	0.5	2.1	0.0

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

Specimen	N	Mean	UL (95%)	LL (95%)
313A1	9	0.4	1.9	0.0
313A2	9	0.5	2.1	0.0
313A3	9	0.4	1.9	0.0
313A4	10	7.5	12.9	2.0
313A5	9	0.6	2.3	0.0

CONGENITAL ADRENAL HYPERPLASIA
SECOND TIER PILOT PT PROGRAM FOR LC-MS/MS
Quarter 3 - August 2013

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

Specimen	Within Normal Limits (WNL)	Outside Normal Limits (ONL)
313A1	16	0
313A2	15	1
313A3	15	1
313A4	0	16
313A5	13	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**.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GA 30341

Director

Thomas R. Frieden, M.D., M.P.H.

Acting Director

National Center for Environmental Health

Robin M. Ikeda, M.D., M.P.H., RADM, USPHS

Director

Division of Laboratory Sciences

James L. Pirkle, M.D., Ph.D.

Chief

Newborn Screening and Molecular Biology Branch

Carla Cuthbert, Ph.D.



Contributors: Barbara W. Adam
Paul Dantonio
Victor R. De Jesus, Ph.D.
Marie C. Earley, Ph.D.
Sharon Flores
Stephanie Foster
Elizabeth M. Hall
Christopher Haynes, Ph.D.
Sarah Klass
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Daniel Mandel, Ph.D.
Joanne Mei, Ph.D.
Nancy Meredith
Patrick Pickens
Kelsey Sheard
Jennifer Taylor, Ph.D.
Robert Vogt, Ph.D.
Irene Williams
Golriz Yazdanpanah
Hui Zhou, Ph.D.
Sherri Zobel

Production: Sarah Brown
Felicia Manning
Connie Singleton



ASSOCIATION OF PUBLIC HEALTH LABORATORIES
SILVER SPRING, MD 20910

President

Christine Bean, Ph.D., M.B.A., MT(ASCP)

Chairman, Newborn Screening and Genetics in Public Health Committee

Susan M. Tanksley, Ph.D.

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee

Patrick Hopkin, B.S.

INQUIRIES TO:

Irene Williams, Editor • Centers for Disease Control and Prevention (CDC)
Newborn Screening Quality Assurance Program • Mailstop F-43
4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • FAX (770) 488-4255 • E-mail: IWilliams1@cdc.gov