

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

X-Linked Adrenoleukodystrophy

Volume 1, No. 4

November 2015

INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 4, 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 October 5, 2015, a panel of five unknown dried blood spot (DBS) specimens prepared with different enrichments of two biomarkers for x-linked adrenoleukodystrophy (X-ALD) was distributed to four domestic laboratories and four foreign laboratories. DBS specimens were prepared at 50% hematocrit.

We processed data from five participants. Laboratories were asked to report concentrations of 24:0-lysophosphatidylcholine (24:0-LPC) and 26:0-lysophosphatidylcholine (26:0-LPC) results in μM whole blood. For the statistical summary analysis, we did not include data that were outside the 99% confidence interval.

The analyte concentration values were based on CDC expected values, and are provided in Table 1.

The frequency distribution of participants' clinical assessments for screening results is shown in Tables 2a and 2b. Overall statistics from MS/MS (Table 3) methods were combined so as to not identify an individual laboratory. Two participants reported using Flow Injection Analysis (FIA) MS/MS non-kit and four reported using LC-MS/MS. Two laboratories reported results for 24:0-LPC and five reported results for 26:0-LPC. All five laboratories based their clinical assessments on 26:0-LPC. One participant reported cutoffs for 24:0-LPC using female, indeterminate, and male categories.

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 no false-positive and no false-negative results.

All data are presented in units of μM whole blood. In order to expedite the issuance of this report, data that are not submitted in the requested units (μM whole blood) will not be accepted. Please contact us for guidance on conversion factors.

NSQAP will ship the next X-ALD PT specimens on January 11, 2016. If you have any comments or questions about X-ALD MS/MS quality assurance issues, contact Dr. Christopher A. Haynes at 770-488-7019, by fax at 770-488-7459, or by e-mail at cph7@cdc.gov. ❖

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

X-linked Adrenoleukodystrophy (X-ALD)
IN Dried Blood Spots

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Table 1. Specimen Certification

Specimen Number	Expected 24:0-LPC (μmol/L)	24:0-LPC Assessment Code*
41521	0.04	1
41522	2.05	2
41523	0.85	2
41524	0.05	1
41525	0.04	1
Specimen Number	Expected 26:0-LPC (μmol/L)	26:0-LPC Assessment Code
41521	0.03	1
41522	2.04	2
41523	0.82	2
41524	0.03	1
41525	0.02	1

* 1 = Within Normal Limits 2 = Outside of Normal Limits

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Table 2a. Frequency of reported Clinical Assessments: 24:0-LPC*

Specimen Number	Within Normal Limits	Outside Normal Limits
41521	2	0
41522	0	2
41523	0	2
41524	2	0
41525	2	0

* Three participants did not report assessments for 24:0-LPC

Table 2a. Frequency of reported Clinical Assessments: 26:0-LPC

Specimen Number	Within Normal Limits	Outside Normal Limits
41521	5	0
41522	0	5
41523	0	5
41524	5	0
41525	5	0

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OVERALL STATISTICS

Table 3a. 24:0-LPC

Specimen	N	Mean (μM whole blood)	SD
41521	2	0.18	0.00
41522	2	3.25	0.21
41523	2	1.38	0.20
41524	2	0.25	0.02
41525	2	0.18	0.01

Table 3b. 26:0-LPC

Specimen	N	Mean (μM whole blood)	SD
41521	5	0.18	0.09
41522	5	3.51	2.51
41523	5	1.42	0.94
41524	5	0.23	0.13
41525	5	0.20	0.13

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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