

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

X-Linked Adrenoleukodystrophy

Volume 2, No. 3

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INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 3, 2016. 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 11, 2016, a panel of five dried blood spot (DBS) specimens prepared with different enrichments of two biomarkers for X-linked Adrenoleukodystrophy (X-ALD) was distributed to six domestic laboratories and seven foreign laboratories. DBS specimens were prepared at 50% hematocrit.

We processed data from seven participants. Laboratories were asked to report concentrations of 24:0-Lysophosphatidylcholine (24LPC) and 26:0-Lysophosphatidylcholine (26LPC) results in $\mu\text{mol/L}$ 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 methods (Table 3) were combined so as to not identify an individual laboratory. Two participants reported using Flow Injection Analysis (FIA) MS/MS non-kit and five reported using LC-MS/MS. Six laboratories reported quantitative results for 24LPC, with one not reporting a clinical assessment. Seven reported quantitative

results and clinical assessments for 26LPC. One participant reported cutoffs for 24LPC 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-negative and no False-positive results.

All data are presented in units of $\mu\text{mol/L}$ blood. In order to expedite the issuance of this report, data that are not submitted in the requested units ($\mu\text{mol/L}$ blood) will not be accepted. The conversion factor from $\mu\text{g/mL}$ to $\mu\text{mol/L}$ blood is provided on the XALDPT Data Report Form. Please contact us for guidance on conversion factors if needed.

NSQAP will ship the next XALDPT specimens on October 3, 2016. If you have any comments or questions about XALDPT MS/MS quality assurance issues, contact Dr. Christopher A. Haynes at 770-488-7019 or by e-mail at cph7@cdc.gov. ❖

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

Quarter 3 – August 2016

Table 1. Specimen Certification

Specimen Number	Expected 24LPC ($\mu\text{mol/L}$)	24LPC Assessment Code*
31621	1.52	2
31622	0.02	1
31623	0.02	1
31624	0.02	1
31625	3.02	2
Specimen Number	Expected 26LPC ($\mu\text{mol/L}$)	26LPC Assessment Code
31621	1.56	2
31622	0.06	1
31623	0.06	1
31624	0.06	1
31625	3.06	2

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

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

Specimen Number	Within Normal Limits	Outside Normal Limits
31621	0	5
31622	5	0
31623	5	0
31624	5	0
31625	0	5

* One participant did not report assessments for 24LPC

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

Specimen Number	Within Normal Limits	Outside Normal Limits
31621	0	7
31622	7	0
31623	7	0
31624	7	0
31625	0	7

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OVERALL STATISTICS

Table 3a. 24LPC

Specimen	N	Mean ($\mu\text{mol/L}$ whole blood)	SD
31621	6	1.79	1.22
31622	6	0.17	0.10
31623	6	0.18	0.12
31624	6	0.18	0.13
31625	6	3.82	2.67

Table 3b. 26LPC

Specimen	N	Mean ($\mu\text{mol/L}$ whole blood)	SD
31621	7	2.69	2.81
31622	7	0.20	0.15
31623	7	0.20	0.15
31624	7	0.21	0.15
31625	7	5.69	6.39

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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