Newborn Screening Quality Assurance Program

anti-Toxoplasma Antibodies in Dried Blood Spots Proficiency Testing Program (TOXOPT)

Issued: November 4, 2017

Introduction

This report summarizes the data reported within the specified period for the Quarter 4, 2017, anti-Toxoplasma Antibody in dried blood spots (DBS) Proficiency Testing (PT) Program. It is distributed to all participants, state laboratory directors, and program colleagues by request. The tables within this report provide certification profiles for the distributed specimens, statistical analysis of the quantitative data, and frequency distribution summaries for expected interpretations. An evaluation of your laboratory’s data is attached to this summary.

Certification of PT Specimens

This DBS panel was prepared from serum samples positive for Toxoplasma IgG and IgM purchased from SeraCare (Medford, Massachusetts) and from human serum positive for exposure to Toxoplasma gondii from a CDC specimen bank. All serum samples were mixed with washed red blood cells and the final hematocrit was adjusted to 50%. Table 1 provides the anti-Toxoplasma IgM expected values based on the NSQAP assayed values determined for each specimen by fluoroimmunoassay. Expected Clinical Assessments were based on a cutoff of 10 EIU/mL.

Table 1. NSQAP anti-Toxoplasma IgM Expected Values

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Expected Value (EIU/mL)</th>
<th>SD</th>
<th>Clinical Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>417T1</td>
<td>0.0</td>
<td>3.1</td>
<td>1</td>
</tr>
<tr>
<td>417T2</td>
<td>0.0</td>
<td>3.0</td>
<td>1</td>
</tr>
<tr>
<td>417T3</td>
<td>33.8</td>
<td>5.8</td>
<td>2</td>
</tr>
<tr>
<td>417T4</td>
<td>212.5</td>
<td>20.8</td>
<td>2</td>
</tr>
<tr>
<td>417T5</td>
<td>0.0</td>
<td>3.2</td>
<td>1</td>
</tr>
</tbody>
</table>

1 = Toxoplasma antibody non-reactive  2 = Toxoplasma antibody reactive

Distribution of PT Specimens

On October 2, 2017, a panel of five unknown DBS specimens was distributed to three laboratories in the United States and 13 laboratories in other countries.
Participant Results

- Quantitative Screening Results

We processed data from 13 participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Seven laboratories reported using an enzyme immunoassay method with units reported in OD, two reported using an enzyme immunoassay with units reported in EIU/mL, one used a fluorometric enzyme immunoassay (EIU/mL) to detect IgM, two reported using a Multiplex platform to report IgG (UA/mL), and one lab reported IgM and IgG results using a chemiluminescent immunoassay (CLIA). Overall statistics and cutoff information for the various immunoassay methods are summarized in Table 2. Extreme outlier data was removed from these statistics.

Table 2. Overall Statistics—Screening Results for Immunoassay Methods (N>1)

<table>
<thead>
<tr>
<th>Method/Antibody</th>
<th>Specimen</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Mean Reported Cutoffs</th>
<th>Range Reported Cutoffs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzyme Immunoassay IgM (OD&lt;sup&gt;a&lt;/sup&gt;)</td>
<td>417T1</td>
<td>6</td>
<td>0.021</td>
<td>0.019</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T2</td>
<td>6</td>
<td>0.024</td>
<td>0.020</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T3</td>
<td>6</td>
<td>0.128</td>
<td>0.068</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T4</td>
<td>6</td>
<td>0.454</td>
<td>0.283</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T5</td>
<td>6</td>
<td>0.024</td>
<td>0.016</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enzyme Immunoassay IgM (EIU/mL&lt;sup&gt;b&lt;/sup&gt;)</td>
<td>417T1</td>
<td>2</td>
<td>30.5</td>
<td>1.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T2</td>
<td>2</td>
<td>58.7</td>
<td>25.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T3</td>
<td>2</td>
<td>235.5</td>
<td>7.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T4</td>
<td>2</td>
<td>366.7</td>
<td>37.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T5</td>
<td>2</td>
<td>93.5</td>
<td>9.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiplex Immunoassay IgG (UA/mL&lt;sup&gt;c&lt;/sup&gt;)</td>
<td>417T1</td>
<td>2</td>
<td>40.0</td>
<td>4.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T2</td>
<td>2</td>
<td>39.5</td>
<td>10.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T3</td>
<td>2</td>
<td>615.0</td>
<td>50.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T4</td>
<td>2</td>
<td>662.0</td>
<td>31.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>417T5</td>
<td>2</td>
<td>30.5</td>
<td>7.8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>OD = Absorbance Units  
<sup>b</sup>EIU/mL = Enzyme International Units/mL serum  
<sup>c</sup>UA/mL = Arbitrary Units/mL serum

- Quantitative Confirmatory Results

Participants were asked to confirm specimens that screened above their cutoff for sorting test results that were Toxoplasma-antibody reactive from those that were Toxoplasma-antibody non-reactive. Three laboratories provided confirmatory results using an enzyme immunoassay for IgG or IgM.
Qualitative Clinical Assessments

Qualitative assessments may differ by participant because of specific assessment practices. Laboratory results were evaluated on the basis of the final assessments provided (screening only or confirmatory results). The frequency distribution of participant screening and confirmatory Clinical Assessments for both IgM and IgG are shown in Table 3.

Table 3. Frequency Distribution of Reported Clinical Assessments—All Methods

<table>
<thead>
<tr>
<th>Type of Testing</th>
<th>Specimen</th>
<th>Toxoplasma antibody Non-reactive</th>
<th>Toxoplasma antibody Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>417T1</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>417T2</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>417T3*</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>417T4</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>417T5</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Confirmatory</td>
<td>417T1</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>417T2</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>417T3*</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>417T4</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>417T5</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

*Specimen 417T3 was considered “Not Evaluated” due to lack of 80% consensus.

Evaluations

Overall, participants reported two False-negative and no False-positive final Clinical Assessments.
Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter’s TOXOPT specimens in January 2018.

The content of this report may also be located on our website at: http://www.cdc.gov/labstandards/nsqap_reports.html

This program is co-sponsored by the Centers for Disease Control and Prevention (CDC) and The Association of Public Health Laboratories (APHL)

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Direct inquiries to:
Centers for Disease Control and Prevention
4770 Buford Highway NE, MS/F19
Atlanta, GA 30341-3724
Phone: 404-488-7945 Email: jvm0@cdc.gov

Editors
Joanne Mei
Irene Williams
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

Acting Director
Brenda Fitzgerald, M.D.

Director
National Center for Environmental Health
Patrick Breysse, Ph.D.

Director
Division of Laboratory Sciences
James L. Pirkle, M.D., Ph.D.

Chief
Newborn Screening and Molecular Biology Branch
Carla Cuthbert, Ph.D.

Contributors:
Carter Asef
John Bernstein
Quan Bui
Paul Dantonio
Sharon Flores
Elizabeth M. Hall
Christopher Haynes, Ph.D.
Brandon Kenwood
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Daniel Mandel, Ph.D.
Joanne Mei, Ph.D.
Kristina Mercer
Gyliann Peña
Konstantinos Petritis, Ph.D.
Sean Scott
Robert Vogt, Ph.D.
Irene Williams
Sophia Winchester
Golriz Yazdapanah
Sherri Zobel

Production:
Sarah Brown
Kimberly Coulter

Kizzy Stewart

ASSOCIATION OF PUBLIC HEALTH LABORATORIES SILVER SPRING, MD 20910

President
Ewa King, PhD

Chairman, Newborn Screening and Genetics in Public Health Committee
Michele Caggana, Sc.D., FACMG

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee
Patricia R. Hunt, B.A. and Joseph Orsini, Ph.D.

Chairman, Newborn Screening Molecular Subcommittee
Rachel Lee, Ph.D.

INQUIRIES TO:
Irene Williams, Editor • Centers for Disease Control and Prevention (CDC) • Newborn Screening Quality Assurance Program
Mailstop F-24, 4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • NSQAPDMT@cdc.gov
E-mail: IWilliams1@cdc.gov