Newborn Screening Quality Assurance Program

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

Report Authorization

This report has been reviewed and authorized by Dr. Joanne Mei, Laboratory Chief, Newborn Screening Quality Assurance Program.

Confidentiality Statement

NSQAP participant information and evaluations are strictly confidential and shared only with individual participants, unless written authorization for release is received.

Introduction

This report summarizes the data reported within the specified period for Quarter 4, 2018, 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>418T1</td>
<td>0.0</td>
<td>3.1</td>
<td>1</td>
</tr>
<tr>
<td>418T2</td>
<td>33.8</td>
<td>5.8</td>
<td>2</td>
</tr>
<tr>
<td>418T3</td>
<td>0.0</td>
<td>5.7</td>
<td>1</td>
</tr>
<tr>
<td>418T4</td>
<td>0.0</td>
<td>5.6</td>
<td>1</td>
</tr>
<tr>
<td>418T5</td>
<td>108.9</td>
<td>24.5</td>
<td>2</td>
</tr>
</tbody>
</table>

1 = Toxoplasma antibody Non-reactive
2 = Toxoplasma antibody Reactive

Distribution of PT Specimens

On September 25, 2018, a panel of five unknown DBS specimens was distributed to two laboratories in the United States and 16 laboratories in other countries.

Participant Results

Quantitative Screening Results

We processed data from 9 participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Five laboratories reported using an enzyme immunoassay method with units reported in OD To detect IgM. Three reported using an enzyme immunoassay with units reported in EIU/mL and one used a fluorometric enzyme immunoassay (EIU/mL). Overall statistics and cutoff information for the various immunoassay methods are summarized in Tables 2a and 2b. Extreme outlier data was removed from these statistics.

Table 2a. Overall Statistics – Screening Results for Immunoassay Methods

Method/Antibody: Enzyme Immunoassay IgM (OD)
Mean Reported Cutoff: 0.302
Cutoff Range: 0.100 – 0.600

<table>
<thead>
<tr>
<th>Specimen</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>418T1</td>
<td>5</td>
<td>0.023</td>
<td>0.011</td>
</tr>
<tr>
<td>418T2</td>
<td>5</td>
<td>0.344</td>
<td>0.219</td>
</tr>
<tr>
<td>418T3</td>
<td>5</td>
<td>0.092</td>
<td>0.063</td>
</tr>
<tr>
<td>418T4</td>
<td>5</td>
<td>0.039</td>
<td>0.029</td>
</tr>
<tr>
<td>418T5</td>
<td>5</td>
<td>0.366</td>
<td>0.174</td>
</tr>
</tbody>
</table>
Table 2b. Overall Statistics – Screening Results for Immunoassay Methods
Method/Antibody: Enzyme Immunoassay IgM (EIU/mL)
Mean Reported Cutoff: 120
Cutoff Range: NA

<table>
<thead>
<tr>
<th>Specimen</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>418T1</td>
<td>2</td>
<td>22.4</td>
<td>4.0</td>
</tr>
<tr>
<td>418T2</td>
<td>2</td>
<td>216.9</td>
<td>32.2</td>
</tr>
<tr>
<td>418T3</td>
<td>2</td>
<td>50.4</td>
<td>17.3</td>
</tr>
<tr>
<td>418T4</td>
<td>2</td>
<td>12.8</td>
<td>3.4</td>
</tr>
<tr>
<td>418T5</td>
<td>2</td>
<td>201.1</td>
<td>29.1</td>
</tr>
</tbody>
</table>

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. Two laboratories provided confirmatory results using an enzyme immunoassay for IgG.

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

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

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Toxoplasma antibody Non-reactive</th>
<th>Toxoplasma antibody Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>418T1</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>418T2</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>418T3</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>418T4</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>418T5</td>
<td>1</td>
<td>8</td>
</tr>
</tbody>
</table>

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 on January 15, 2019.

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

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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