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 3, 2019, 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>319T1</td>
<td>0.0</td>
<td>5.7</td>
<td>1</td>
</tr>
<tr>
<td>319T2</td>
<td>0.0</td>
<td>5.6</td>
<td>1</td>
</tr>
<tr>
<td>319T3</td>
<td>0.0</td>
<td>7.9</td>
<td>1</td>
</tr>
<tr>
<td>319T4</td>
<td>201.2</td>
<td>22.8</td>
<td>2</td>
</tr>
<tr>
<td>319T5</td>
<td>94.6</td>
<td>14.4</td>
<td>2</td>
</tr>
</tbody>
</table>

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

Distribution of PT Specimens

On June 25, 2019, 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 12 participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Eight 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 (greater than 4 SD) data was removed from these statistics.

Table 2a. Overall Statistics – Screening Results for Immunoassay Methods
Method/Antibody: Enzyme Immunoassay IgM (OD)
Mean Reported Cutoff: 0.227
Cutoff Range: 0.100 – 0.298

<table>
<thead>
<tr>
<th>Specimen</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>319T1</td>
<td>8</td>
<td>0.078</td>
<td>0.075</td>
</tr>
<tr>
<td>319T2</td>
<td>8</td>
<td>0.036</td>
<td>0.039</td>
</tr>
<tr>
<td>319T3</td>
<td>8</td>
<td>0.064</td>
<td>0.042</td>
</tr>
<tr>
<td>319T4</td>
<td>8</td>
<td>0.558</td>
<td>0.426</td>
</tr>
<tr>
<td>319T5</td>
<td>8</td>
<td>0.193</td>
<td>0.183</td>
</tr>
</tbody>
</table>
Quantitative Confirmatory Results
Participants were asked to confirm specimens that screened above their screening cutoff for Toxoplasma-antibodies. Three laboratories provided confirmatory results using an enzyme immunoassay for IgG.

Qualitative 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 and confirmatory testing for IgG are shown in Tables 3a and 3b.

Table 2b. Overall Statistics – Screening Results for Immunoassay Methods
Method/Antibody: Enzyme Immunoassay IgM (EIU/mL)
Mean Reported Cutoff: 83
Cutoff Range: 10 - 120

<table>
<thead>
<tr>
<th>Specimen</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>319T1</td>
<td>3</td>
<td>78.9</td>
<td>35.4</td>
</tr>
<tr>
<td>319T2</td>
<td>3</td>
<td>18.3</td>
<td>14.4</td>
</tr>
<tr>
<td>319T3</td>
<td>3</td>
<td>59.2</td>
<td>31.5</td>
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<td>319T4</td>
<td>3</td>
<td>282.2</td>
<td>59.9</td>
</tr>
<tr>
<td>319T5</td>
<td>3</td>
<td>171.3</td>
<td>44.9</td>
</tr>
</tbody>
</table>

Table 3a. Frequency Distribution of Reported Clinical Assessments — All Methods
Screening Testing (IgM)

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Toxoplasma antibody Non-reactive</th>
<th>Toxoplasma antibody Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>319T1</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>319T2</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>319T3</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>319T4</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>319T5*</td>
<td>5</td>
<td>7</td>
</tr>
</tbody>
</table>

*Specimen 319T5 was not evaluated due to lack of 80% participant consensus.

Table 3b. Frequency Distribution of Reported Clinical Assessments—All Methods
Confirmatory Testing (IgG)

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Toxoplasma antibody Non-reactive</th>
<th>Toxoplasma antibody Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>319T1</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>319T2</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>319T3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>319T4</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>319T5</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>
Evaluations

Overall, participants reported three misclassifications. Specimen 319T5 was not evaluated due to lack of 80% consensus among participants.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter’s TOXOPT specimens on September 24, 2019.

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