Newborn Screening Quality Assurance Program

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

In co-sponsorship with Association of Public Health Laboratories (APHL)
Provided by the Newborn Screening and Molecular Biology Branch
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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 1, 2020, 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

Specimen	Expected Value (EIU/mL)	SD	Clinical Assessment
2011401	123.9	20.3	2
2011402	0.0	7.9	1
2011403	0.0	6.7	1
2011404	0.0	5.6	1
2011405	31.2	12.3	2

Distribution of PT Specimens

On January 14, 2020, 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 seven participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Six laboratories reported using an enzyme immunoassay (EIA) method to detect IgM, with units reported in OD. One used a fluorometric enzyme immunoassay (EIU/mL). Overall statistics and cutoff information for the EIA methods are summarized in Tables 2. Extreme outlier (greater than 4 SD) data was removed from these statistics.

Table 2. Overall Statistics – Screening Results for Immunoassay Methods
Method/Antibody: Enzyme Immunoassay IgM (OD)
Mean Reported Cutoff: 0.345
Cutoff Range: 0.100 – 0.910

Specimen	N	Mean	SD
2011401	6	0.511	0.290
2011402	6	0.104	0.085
2011403	6	0.081	0.074
2011404	6	0.053	0.055
2011405	6	0.338	0.272

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

Specimen	Toxoplasma antibody Non-reactive	Toxoplasma antibody Reactive
2011401	3	4
2011402	6	1
2011403	6	1
2011404	6	1
2011405*	4	3

*Specimen 2011405 was Not Evaluated.

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

Specimen	Toxoplasma antibody Non-reactive	Toxoplasma antibody Reactive
2011401	0	3
2011402	3	0
2011403	3	0
2011404	3	0
2011405	0	3

Evaluations

For Specimen 2011401, participants reported one misclassification for IgM. Specimen 2011405 was considered “Not Evaluated.” Laboratories that reported both screening and confirmatory results correctly identified the reactive specimens.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter’s TOXOPT specimens on June 23, 2020.

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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