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 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

Specimen	Expected Value (EIU/mL)	SD	Clinical Assessment
418T1	0.0	3.1	1
418T2	33.8	5.8	2
418T3	0.0	5.7	1
418T4	0.0	5.6	1
418T5	108.9	24.5	2

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

Specimen	N	Mean	SD
418T1	5	0.023	0.011
418T2	5	0.344	0.219
418T3	5	0.092	0.063
418T4	5	0.039	0.029
418T5	5	0.366	0.174

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

Specimen	N	Mean	SD
418T1	2	22.4	4.0
418T2	2	216.9	32.2
418T3	2	50.4	17.3
418T4	2	12.8	3.4
418T5	2	201.1	29.1

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

Specimen	Toxoplasma antibody Non-reactive	Toxoplasma antibody Reactive
418T1	9	0
418T2	1	8
418T3	9	0
418T4	9	0
418T5	1	8

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

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