Newborn Screening Quality Assurance Program

Quarterly Report
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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

Specimen	Expected Value (EIU/mL)	SD	Clinical Assessment
417T1	0.0	3.1	1
417T2	0.0	3.0	1
417T3	33.8	5.8	2
417T4	212.5	20.8	2
417T5	0.0	3.2	1

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)

Method/ Antibody	Specimen	N	Mean	SD	Mean Reported Cutoffs	Range Reported Cutoffs
Enzyme Immunoassay IgM (OD[a])	417T1	6	0.021	0.019	0.196	0.100—0.287
	417T2	6	0.024	0.020		
	417T3	6	0.128	0.068		
	417T4	6	0.454	0.283		
	417T5	6	0.024	0.016		
Enzyme Immunoassay IgM (EIU/mL[b])	417T1	2	30.5	1.8	120	NA
	417T2	2	58.7	25.0		
	417T3	2	235.5	7.1		
	417T4	2	366.7	37.4		
	417T5	2	93.5	9.2		
Multiplex Immunoassay IgG (UA/mL[c])	417T1	2	40.0	4.2	120	NA
	417T2	2	39.5	10.6		
	417T3	2	615.0	50.9		
	417T4	2	662.0	31.1		
	417T5	2	30.5	7.8		

[a]OD = Absorbance Units [b]EIU/mL = Enzyme International Units/mL serum [c]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

Type of Testing	Specimen	Toxoplasma antibody Non-reactive	Toxoplasma antibody Reactive
Screening	417T1	13	0
	417T2	13	0
	417T3*	5	8
	417T4	2	11
	417T5	13	0
Confirmatory	417T1	4	0
	417T2	4	0
	417T3*	1	3
	417T4	1	3
	417T5	4	0

*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

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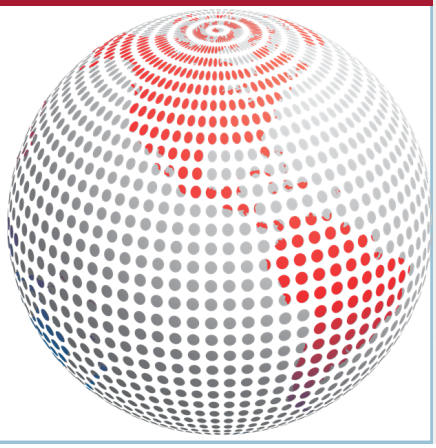

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