Newborn Screening Quality Assurance Program

Quarterly Report
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anti-*Toxoplasma* Antibody in Dried Blood Spots Proficiency Testing Program (TOXOPT)

2017 Quarter 1 February

Introduction

This report summarizes the data reported within the specified data-reporting period for the Quarter 1, 2017, anti-*Toxoplasma* Antibody in dried blood spots (DBS) 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 by fluoroimmunoassay for each specimen.

Table 1. NSQAP anti -*Toxoplasma* IgM Expected Values

Specimen	Expected Value (EIU/mL)	SD	Clinical Assessment
117T1	0.0	3.1	1
117T2	0.0	3.3	1
117T3	0.0	3.0	1
117T4	0.0	3.2	1
117T5	212.5	20.8	2

1 = *Toxoplasma* antibody non-reactive 2 = *Toxoplasma* antibody reactive

Distribution of PT Specimens

On January 11, 2017 a panel of five unknown DBS specimens was distributed to two laboratories in the United States and fifteen laboratories in other countries.

Participant Results

- Quantitative Screening Results

We processed data from ten participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Five laboratories reported using an enzyme immunoassay method (OD), one reported using an ELISA (EIU/mL) and one used a fluorometric enzyme immunoassay (EIU/mL) to detect IgM. Two laboratories reported IgG results from a multiplexed platform (Arbitrary Units UA/mL) and one reported IgG (EIU/mL) results by chemiluminescence for screening. One laboratory did not report quantitative results. Overall statistics and cutoff information for the various immunoassay methods are summarized in Table 2.

Table 2. Overall Statistics—Screening Results for Immunoassay Methods

Method/ Antibody	Specimen	N	Mean	SD	Mean Reported Cutoff	Range
Enzyme Immunoassay IgM (OD*)	117T1	5	0.018	0.013	0.234	0.100—0.400
	117T2	5	0.010	0.007		
	117T3	5	0.024	0.023		
	117T4	5	0.024	0.032		
	117T5	5	0.588	0.114		
Enzyme Immunoassay IgM (EIU/mL**)	117T1	1	38.7	NA	NA	NA
	117T2	1	45.1			
	117T3	1	42.1			
	117T4	1	72.9			
	117T5	1	313.5			
Fluorescence Immunoassay IgM (EIU/mL**)	117T1	1	0.0	NA	NA	NA
	117T2	1	0.0			
	117T3	1	0.0			
	117T4	1	2.2			
	117T5	1	173.0			
Multiplexed Immunoassay IgG (UA/mL***)	117T1	2	25.0	NA	>120	>120
	117T2	2	44.0			
	117T3	2	28.5			
	117T4	2	20.5			
	117T5	2	524.5			

OD = Absorbance Units **EIU/mL = Enzyme International Units/mL serum ***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. Two laboratories provided confirmatory results using an EIA for IgG, and one laboratory reported a chemiluminescence confirmatory method for 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	117T1	10	0
	117T2	10	0
	117T3	10	0
	117T4	10	0
	117T5	2	8
Confirmatory	117T1	3	0
	117T2	3	0
	117T3	3	0
	117T4	3	0
	117T5	1	2

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 April 3, 2017.

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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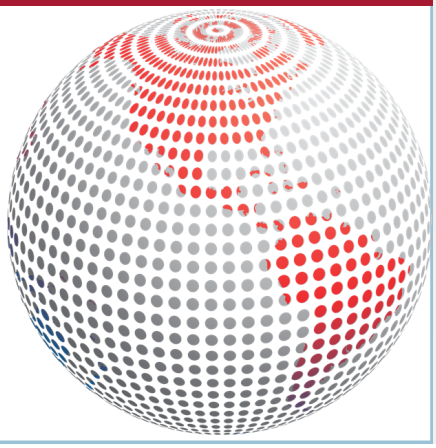

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