

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

2017 Quarter 3 August

Introduction

This report summarizes the data reported within the specified period for the Quarter 3, 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 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
317T1	0.0	3.1	1
317T2	0.0	3.3	1
317T3	33.8	5.8	2
317T4	212.5	20.8	2
317T5	0.0	3.2	1

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

Distribution of PT Specimens

On July 10, 2017 a panel of five unknown DBS specimens was distributed to three laboratories in the United States and 14 laboratories in other countries.

Participant Results

◆ Quantitative Screening Results

We processed data from eight participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Four laboratories reported using an enzyme immunoassay method (OD), two reported using an ELISA (EIU/mL), one used a fluorometric enzyme immunoassay (EIU/mL) to detect IgM, 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.

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*)	317T1	4	0.007	0.004	0.197	0.100—0.400
	317T2	4	0.013	0.008		
	317T3	4	0.013	0.123		
	317T4	4	0.402	0.148		
	317T5	4	0.017	0.020		
Enzyme Immunoassay IgM (EIU/mL**)	317T1	2	29.7	2.8	120	80-120
	317T2	2	48.6	10.0		
	317T3	2	337.9	1.4		
	317T4	2	310.6	32.3		
	317T5	2	88.7	1.5		

OD = Absorbance Units **EIU/mL = Enzyme International 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.

◆ 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	317T1	8	0
	317T2	8	0
	317T3*	3	5
	317T4	1	7
	317T5	8	0
Confirmatory	317T1	2	0
	317T2	2	0
	317T3*	1	1
	317T4	1	1
	317T5	2	0

* Specimen 317T3 was not evaluated due to lack of 80% participant consensus.

Evaluations

Overall, participants reported one 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 October 2, 2017.

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

**This program is co-sponsored by the Centers for Disease Control and Prevention (CDC) and
The Association of Public Health Laboratories (APHL)**

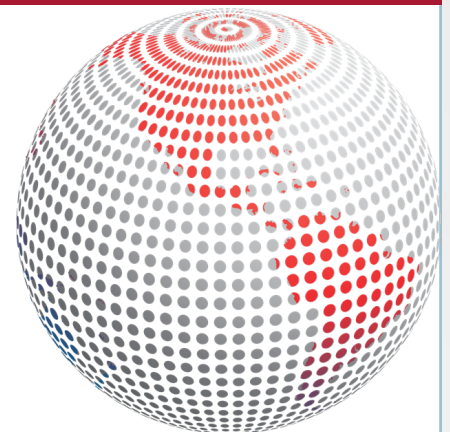
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This *NEWBORN SCREENING QUALITY ASSURANCE PROGRAM* report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories.

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