

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

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INTRODUCTION

This report is the quarterly summary of all anti-Toxoplasma Antibody Proficiency Testing (PT) data submitted within the specified reporting period for Quarter 3, 2016. The attached tables provide the certification profiles for the distributed specimens, the verification of your reported data, the statistical analysis of the quantitative data, and the frequency distribution summaries for expected interpretations. We distribute this PT report to all participants, state laboratory directors, and program colleagues by request.

On July 11, 2016 a panel of five unknown dried blood spot (DBS) specimens prepared from human serum was distributed to two laboratories in the United States and twelve laboratories in other countries. This 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%.

PARTICIPANTS' RESULTS

We processed data from twelve participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Six laboratories reported using an enzyme immunoassay method (OD), one reported using an ELISA (EIU/mL) and two 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. The expected anti-Toxoplasma IgM values shown in Table 1 were based

on CDC assayed values. Overall statistics from the various immunoassay methods are summarized in Tables 2a-c. The frequency distribution of participants' interpretations for screening results is shown in Table 3 and the frequency distribution of participants' interpretations for confirmatory results is shown in Table 4.

Expected interpretations (qualitative assessments) may differ by participant because of specific assessment practices. Laboratory results were evaluated on the basis of the final interpretations provided (screening only or confirmatory results). Overall, participants reported two False-negative and two False-positive final interpretations.

The mean cutoff for the IgM enzyme immunoassay methods was 0.211 OD, with a range from 0.1 to 0.420 OD and the mean cutoff for the multiplexed methods was 120 UA/mL serum. The mean cutoff for the methods that report EIU/mL units for IgM was 8.0 EIU/mL. 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 EIA for IgG and one laboratory reported a chemiluminescence confirmatory method for IgM.

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-Toxoplasma antibodies PT specimens on October 3, 2016. ❖

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Table 1. CDC anti-TOXOPLASMA EXPECTED VALUES (IgM)

Specimen Number	Expected Value (EIU/mL)	SD	Assessment
316T1	179.4	4.9	2
316T2	0.0	7.4	1
316T3	0.0	3.7	1
316T4	0.0	2.4	1
316T5	0.0	3.7	1

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OVERALL STATISTICS

Table 2a. Screening Results – Enzyme Immunoassay Methods (IgM)

Specimen	N	Mean (OD)*	SD	%CV
316T1	6	0.702	0.09	12.8
316T2	6	0.063	0.02	26.0
316T3	6	0.065	0.05	69.2
316T4	6	0.069	0.00	5.9
316T5	6	0.078	0.07	86.9

Table 2b. Screening Results – Fluorescence Immunoassay Methods (IgM)

Specimen	N	Mean (EIU/mL)***
316T1	2	190.3
316T2	2	0.7
316T3	2	1.2
316T4	2	1.3
316T5	2	2.3

Table 2c. Screening Results – Multiplexed Immunoassay Methods (IgG only)

Specimen	N	Mean (UA/mL)**
316T1	2	447.0
316T2	2	24.0
316T3	2	54.0
316T4	2	31.5
316T5	2	18.0

* OD = Absorbance Units

** UA/mL = Arbitrary Units/mL serum

***EIU/mL = Enzyme International Units/mL serum

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Table 3. Frequency Distribution of Participants' Interpretations*
SCREENING RESULTS (Both IgM and IgG Screening)

Specimen	Toxoplasma antibody Non-Reactive	Toxoplasma antibody Reactive
316T1	2	10
316T2	12	0
316T3	12	0
316T4	11	1
316T5	11	1

Table 4. Frequency Distribution of Participants' Interpretations*
CONFIRMATORY RESULTS (IgM and IgG)

Specimen	Toxoplasma antibody Non-Reactive	Toxoplasma antibody Reactive
316T1	1	3
316T2	4	0
316T3	4	0
316T4	4	1
316T5	4	0

*All methods

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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