

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

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INTRODUCTION

This report is the quarterly summary of all data reported within the specified reporting period for Quarter 4, 2015. 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 October 5, 2015, a panel of five unknown dried blood spot (DBS) specimens prepared from human serum was distributed to two laboratories in the United States and eight 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 nine participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units.

Five laboratories reported using an enzyme immunoassay method and two used a fluorometric enzyme immunoassay. Two laboratories reported only IgG results from a multiplexed platform for screening. The expected anti-Toxoplasma IgM values were based on CDC assayed

values. Overall statistics from the various immunoassay methods are summarized in Tables 1a – 1c. The frequency distribution of participants' interpretations for screening results is shown in Table 2 and the frequency distribution of participants' interpretations for confirmatory results is shown in Table 3.

Expected interpretations (qualitative assessments) may differ by participant because of specific assessment practices. Overall, participants reported two false negative interpretations for specimen 415T3 and two false positive interpretations for specimen 415T2. Laboratory results were evaluated on the basis of the final answers provided (screening only or confirmatory results). The mean cutoff for the enzyme immunoassay methods was 0.249 OD, with a range from 0.1 to 0.421 OD and the mean cutoff for the multiplexed methods was 120 UA/mL serum. The mean cutoff for the fluorescence methods was 8.0 EIU/mL serum. 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 or a multiplexed platform for IgG.

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-Toxoplasma antibodies PT specimens on January 11, 2016. ❖

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

Quarter 4 – November 2015

OVERALL STATISTICS

Table 1a. Screening Results – Enzyme Immunoassay Methods (IgM)

Specimen	N	Mean (OD)*	SD	%CV
415T1	5	0.064	0.093	144.9
415T2	5	0.054	0.055	101.4
415T3	5	0.230	0.214	93.1
415T4	5	0.424	0.189	44.6
415T5	5	0.065	0.083	127.9

Table 1b. Screening Results – Multiplexed Immunoassay Methods (IgG only)

Specimen	N	Mean (UA/mL)**	SD	%CV
415T1	2	76.4	5.7	7.5
415T2	2	186.7	8.4	4.5
415T3	2	825.0	63.6	7.7
415T4	2	605.5	21.9	3.6
415T5	2	84.1	5.9	7.1

Table 1c. Screening Results – Fluorescence Immunoassay Methods (IgM)

Specimen	N	Mean (EIU/mL)***	SD	%CV
415T1	2	0.8	1.1	141.4
415T2	2	1.8	2.5	141.4
415T3	2	56.6	29.4	52.0
415T4	2	302.0	34.6	11.5
415T5	2	0.9	1.3	141.1

* OD = Absorbance Units

** UA/mL = Arbitrary Units/mL serum

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

Table 2. Frequency Distribution of Participants' Interpretations*
SCREENING RESULTS

Specimen	Toxoplasma Antibody Non-Reactive	Toxoplasma Antibody Reactive	Toxoplasma Antibody Indeterminate
415T1	9	0	0
415T2	7	2	0
415T3	3	6	0
415T4	0	8	1
415T5	9	0	0

*All Methods

Table 3. Frequency Distribution of Participants' Interpretations*
CONFIRMATORY RESULTS

Specimen	Toxoplasma antibody Non-Reactive	Toxoplasma antibody Reactive
415T1	3	0
415T2	3	0
415T3	0	3
415T4	0	3
415T5	3	0

*All methods

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