

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 2, 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 April 4, 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

In order to receive an evaluation, you must use the current data report form and report all relevant information. This form can be downloaded from our website at http://www.cdc.gov/labstandards/nsqap_resources.html#QCReportForms

We processed data from twelve participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Seven laboratories reported using an enzyme immunoassay method (OD), one reported using an ELISA (EIU/mL) and one used a fluorometric enzyme immunoassay (EIU/mL). 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 were based on CDC assayed values. Specimen 216T3 did not reach the required 80% consensus among participants and was therefore not evaluated. Overall statistics from two immunoassay methods are summarized in Tables 1a and 1b. 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. 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 interpretations.

The mean cutoff for the IgM enzyme immunoassay methods was 0.230 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 only reported cutoff for the fluorescence method 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.

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

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

Quarter 2 – May 2016

OVERALL STATISTICS

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

Specimen	N	Mean (OD)*	SD	%CV
216T1	7	0.021	0.014	66.2
216T2	7	0.032	0.026	80.4
216T3	7	0.108	0.083	76.8
216T4	7	0.419	0.202	48.2
216T5	7	0.043	0.062	144.3

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

Specimen	N	Mean (UA/mL)**
216T1	2	49.5
216T2	2	251.5
216T3	2	606.5
216T4	2	420.5
216T5	2	69.5

* OD = Absorbance Units

** UA/mL = Arbitrary Units/mL serum

Table 2. Frequency Distribution of Participants' Interpretations*
 SCREENING RESULTS (Both IgM and IgG Screening)

Specimen	Toxoplasma antibody Non-Reactive	Toxoplasma antibody Reactive
216T1	12	0
216T2	10	2
216T3	7	5
216T4	2	10
216T5	12	0

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

Specimen	Toxoplasma antibody Non-Reactive	Toxoplasma antibody Reactive
216T1	3	0
216T2	3	0
216T3	0	3
216T4	0	3
216T5	3	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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