



# Newborn Screening Quality Assurance Program

## PROFICIENCY TESTING

## Toxoplasma Quarterly Report

Volume 8, No. 3

August 2012

### INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 3, 2012. 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 9, 2012, a panel of five unknown dried-blood-spot (DBS) specimens prepared from human serum positive for exposure to *Toxoplasma gondii* was distributed to two laboratories in the United States and seven 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 seven participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. In the statistical summary analysis, we did not include data that were outside the 99% confidence interval.

Three laboratories reported using an enzyme immunoassay method; two used a fluorometric enzyme immunoassay; and two used a multiplexed platform. The expected

anti-*Toxoplasma* IgM values were based on CDC assayed values. Overall statistics from the enzyme 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 one false-negative interpretation and one false-positive interpretation. 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 0.207, with a range from 0.100 to 0.275 OD; the mean cutoff for the multiplexed methods was 120 UA/mL (arbitrary units/mL serum); and the mean cutoff for the fluorescence immunoassay methods was 5.5 EIU (enzyme immunoassay units/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. Based on final interpretations, these three laboratories reported no misclassifications. ❖

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-*Toxoplasma* antibodies PT specimens on October 1, 2012. ❖

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-*TOXOPLASMA* ANTIBODIES

QUARTER 3 – AUGUST 2012

LAB XXX

SPECIMEN CERTIFICATION - IgM

CDC ASSAYED LEVELS

Analyte	Specimen 312T1	Specimen 312T2	Specimen 312T3	Specimen 312T4	Specimen 312T5
Anti- <i>Toxoplasma</i> Immunoglobulin M CDC Mean Assayed Value (EIU/mL serum)	0.0 ± 1.4	44.9 ± 5.8	106.8 ± 11.6	0.0 ± 1.9	0.0 ± 2.7

EXPECTED INTERPRETATIONS

Interpretation	Specimen 312T1	Specimen 312T2	Specimen 312T3	Specimen 312T4	Specimen 312T5
<i>Toxoplasma</i> Antibodies	1	2	2	1	1

1 = *Toxoplasma* antibody non-reactive    2 = *Toxoplasma* antibody reactive    NE = clinical assessment not evaluated

SCREENING RESULTS - IgM

DATA VERIFICATION

Analyte	Specimen 312T1		Specimen 312T2		Specimen 312T3		Specimen 312T4		Specimen 312T5	
	Result	Code								
Anti- <i>Toxoplasma</i> antibodies (OD)										

*Reviewer's Comments*

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

*ANTI-TOXOPLASMA Antibodies*

QUARTER 3 – AUGUST 2012

OVERALL STATISTICS – IgM

Table 1a. Screening Results – Enzyme Immunoassay Methods

Specimen	N	Outliers*	Mean (OD)**	UL (95%)	LL (95%)
312T1	3	0	0.049	0.124	0.000
312T2	2	1	0.205	0.238	0.172
312T3	3	0	0.593	0.932	0.253
312T4	2	1	0.041	0.186	0.000
312T5	3	0	0.133	0.455	0.000

\* Outliers are not included in N                      UL = upper limit                      LL = lower limit

Table 1b. Screening Results – Multiplexed Immunoassay Methods

Specimen	N	Outliers*	Mean (UA/mL)***	UL (95%)	LL (95%)
312T1	2	0	34.7	35.8	33.6
312T2	2	0	71.4	73.2	69.5
312T3	2	0	198.6	202.8	194.3
312T4	2	0	51.1	53.3	48.9
312T5	2	0	110.1	110.7	109.4

\* Outliers are not included in N                      UL = upper limit                      LL = lower limit

Table 1c. Screening Results – Fluorescence Immunoassay Methods

Specimen	N	Outliers*	Mean (EIU)****	UL (95%)	LL (95%)
312T1	2	0	0.8	2.8	0.0
312T2	2	0	56.6	75.3	37.8
312T3	2	0	196.0	213.8	178.1
312T4	2	0	2.0	7.4	0.0
312T5	2	0	1.4	5.3	0.0

\* Outliers are not included in N                      UL = upper limit                      LL = lower limit

\*\* OD = Absorbance units

\*\*\* UA/mL = Arbitrary units/mL serum

\*\*\*\* EIU = Enzyme immunoassay units/mL serum

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

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
312T1	7	0
312T2	3	4
312T3	0	7
312T4	7	0
312T5	6	1

\*All Methods

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

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
312T1	3	0
312T2	0	3
312T3	0	3
312T4	3	0
312T5	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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