



Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

Volume 7, No. 1

February 2011

INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 1, 2011. 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 January 10, 2011, 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 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 eight participants. Laboratories were asked to report IgM screening results in IU/mL blood or Absorbance (OD). In the statistical summary analysis, we did not include data that were outside the 99% confidence interval.

One laboratory reported using AutoDelfia to measure anti-*Toxoplasma* IgM: no laboratories used Delfia and seven reported using "other". Three of those in the "other" category used an enzyme immunoassay method; one used a fluorescent enzyme immunoassay method; and three used a multiplexed platform. The expected anti-*Toxoplasma* IgM values were based on CDC assayed values. Overall statistics from

the AutoDelfia and Delfia methods were combined (Table 1). Results from the enzyme immunoassay methods are summarized in Table 2. 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. When the reported clinical assessment differs from our expected clinical assessment, the grading algorithm is used to evaluate test performance. An explanation of the grading algorithm can be found on the NSQAP data-reporting Web site or in the annual summary report. Overall, participants reported three false-negative interpretations and no false-positive interpretations. Laboratory results were evaluated on the basis of the final answers provided (screening only or confirmatory results). Since only one lab was able to report data for the AutoDelfia method, there was no mean cutoff. The mean cutoff for the enzyme immunoassay methods was 0.435, with a range from 0.100 to 0.900 OD.

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 EIAs for IgG or IgM. Results from this survey indicate that Toxo-IgM methods vary in the ability to detect antibody from DBS prepared with commercially certified, Toxo-positive sera and also with patient sera from a specimen bank. NSQAP strives to prepare DBS materials that challenge all methods and laboratories.

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-*Toxoplasma* antibodies PT specimens on April 4, 2011.

CDC/APHL

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-*TOXOPLASMA* ANTIBODIES

QUARTER 1 – FEBRUARY 2011

LAB XXX

SPECIMEN CERTIFICATION - IgM

CDC ASSAYED LEVELS

Analyte	Specimen 11T1	Specimen 11T2	Specimen 11T3	Specimen 11T4	Specimen 11T5
Anti- <i>Toxoplasma</i> Immunoglobulin M CDC Mean Assayed Value (IU/mL blood)	88.0 ± 7.2	37.7 ± 6.2	0.1 ± 0.3	335.5 ± 14.6	73.8 ± 5.5

EXPECTED INTERPRETATIONS

Interpretation	Specimen 11T1	Specimen 11T2	Specimen 11T3	Specimen 11T4	Specimen 11T5
<i>Toxoplasma</i> Antibodies	2	2	1	2	2

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

SCREENING RESULTS - IgM

DATA VERIFICATION

Analyte	Specimen 11T1		Specimen 11T2		Specimen 11T3		Specimen 11T4		Specimen 11T5	
	Result	Code								
Anti- <i>Toxoplasma</i> antibodies (IU/mL blood)										

Reviewer's Comments

EVALUATION:

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

QUARTER 1 – FEBRUARY 2011

OVERALL STATISTICS – IgM

Table 1. Screening Results – Delfia Methods

Specimen	N	Outliers**	Mean (IU/mL blood)	UL (95%)	LL (95%)
11T1	1	0	Statistics for this method are not applicable		
11T2	1	0			
11T3	1	0			
11T4	1	0			
11T5	1	0			

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

Table 2. Screening Results – Enzyme Immunoassay Methods

Specimen	N	Outliers**	Mean (OD)	UL (95%)	LL (95%)
11T1	3	1	0.218	0.538	0.097
11T2	3	1	0.161	0.176	0.145
11T3	3	1	0.031	0.046	0.015
11T4	3	1	0.863	1.219	0.506
11T5	3	1	0.342	0.404	0.279

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

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

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
11T1	2	6
11T2	3	5
11T3	8	0
11T4	0	8
11T5	1	7

*All Methods

Table 4. Frequency Distribution of Participants' Interpretations
CONFIRMATORY RESULTS

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
11T1	0	2
11T2	0	2
11T3	2	0
11T4	0	2
11T5	0	2

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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