



Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

Volume 8, No. 1

February 2012

INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 1, 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 January 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 laboratory 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 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.

Eight laboratories reported using "other". Four used 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 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. 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 one false-negative interpretation and no false-positive interpretations. 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 0.231, with a range from 0.100 to 0.325 OD; the mean cutoff for the multiplexed methods was 120 UA/mL blood.

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. One laboratory 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 April 2, 2012. ❖

CDC/APHL

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-*TOXOPLASMA* ANTIBODIES

QUARTER 1 – FEBRUARY 2012

LAB XXX

SPECIMEN CERTIFICATION - IgM

CDC ASSAYED LEVELS

Analyte	Specimen 112T1	Specimen 112T2	Specimen 112T3	Specimen 112T4	Specimen 112T5
Anti- <i>Toxoplasma</i> Immunoglobulin M CDC Mean Assayed Value (IU/mL blood)	232.7 ± 16.3	8.6 ± 17.1	0.1 ± 0.3	65.3 ± 8.6	149.9 ± 12.6

EXPECTED INTERPRETATIONS

Interpretation	Specimen 112T1	Specimen 112T2	Specimen 112T3	Specimen 112T4	Specimen 112T5
<i>Toxoplasma</i> Antibodies	2	1	1	2	2

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

SCREENING RESULTS - IgM

DATA VERIFICATION

Analyte	Specimen 112T1		Specimen 112T2		Specimen 112T3		Specimen 112T4		Specimen 112T5	
	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 2012

OVERALL STATISTICS – IgM

Table 1a. Screening Results – Enzyme Immunoassay Methods

Specimen	N	Outliers**	Mean (OD)	UL (95%)	LL (95%)
112T1	4	0	0.796	1.217	0.375
112T2	4	0	0.087	0.226	0.000
112T3	4	0	0.081	0.190	0.000
112T4	4	0	0.308	0.444	0.172
112T5	4	0	0.469	0.741	0.196

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

Table 1b. Screening Results – Multiplexed Immunoassay Methods

Specimen	N	Outliers**	Mean (UA)	UL (95%)	LL (95%)
112T1	2	0	236.0	247.1	224.9
112T2	2	0	94.0	96.8	91.2
112T3	2	0	38.5	45.4	31.6
112T4	2	0	132.8	127.2	133.6
112T5	2	0	176.5	180.7	172.3

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

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

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
112T1	0	8
112T2	8	0
112T3	8	0
112T4	1	7
112T5	0	8

*All Methods

Table 3. Frequency Distribution of Participants' Interpretations
CONFIRMATORY RESULTS

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
112T1	0	1
112T2	1	0
112T3	1	0
112T4	0	1
112T5	0	1

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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