Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

Volume 5, No. 3

August 2009

INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 3, 2009. 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 13, 2009, 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 ten laboratories in other countries.

PARTICIPANTS' RESULTS

We processed data from twelve 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.

Five laboratories reported using AutoDelfia to measure anti-*Toxoplasma* IgM: one used Delfia and six reported using "other". Three of those in the "other" category used an enzyme immunoassay method; one used a fluorescent enzyme immunoassay method; and two 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 four false-positive interpretations and no false-negative interpretations. Laboratory results were evaluated on the basis of the final answers provided (screening only or confirmatory results). The median and mode cutoffs for AutoDelfia participants were 11.5 and 11.5 IU/mL blood, respectively. The median cutoff for the enzyme immunoassay methods was 0.393, with a range from 0.100 to 0.414 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.

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-*Toxoplasma* antibodies PT specimens on October 5, 2009.

CDC/APHL

This program is cosponsored by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL).

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-*TOXOPLASMA* ANTIBODIES

QUARTER 3 – AUGUST 2009

LAB XXX

SPECIMEN CERTIFICATION - IgM

CDC ASSAYED LEVELS

Analyte	Specimen 39T1	Specimen 39T2	Specimen 39T3	Specimen 39T4	Specimen 39T5
Anti-*Toxoplasma* Immunoglobulin M CDC Mean Assayed Value (IU/mL blood)	399.7 ± 48.5	232.7 ± 16.3	3.8 ± 7.6	8.6 ± 17.1	1.4 ± 1.9

EXPECTED INTERPRETATIONS

Interpretation	Specimen 39T1	Specimen 39T2	Specimen 39T3	Specimen 39T4	Specimen 39T5
Toxoplasma Antibodies	2	2	1	1	1

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

SCREENING RESULTS - IgM DATA VERIFICATION

Analyte	Specimen 39T1		Specimen 39T2		Specimen 39T3		Specimen 39T4		Specimen 39T5	
	Result	Code	Result	Code	Result	Code	Result	Code	Result	Code
Anti-*Toxoplasma* antibodies (IU/mL blood)										

Reviewer's Comments

EVALUATION: No misclassifications were reported – Anti-*Toxoplasma* Antibodies 100% Satisfactory.
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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

QUARTER 3 – AUGUST 2009

OVERALL STATISTICS – IgM

Table 1. Screening Results – Delfia Methods

Specimen	N	Outliers**	Mean (IU/mL blood)	UL (95%)	LL (95%)
39T1	6	0	336.2	388.3	284.0
39T2	6	0	226.9	249.4	204.4
39T3	6	0	8.8	28.1	0.0
39T4	6	0	4.5	17.1	0.0
39T5	6	0	1.3	5.1	0.0

** 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%)
39T1	3	0	1.223	1.644	0.801
39T2	3	0	0.711	0.894	0.527
39T3	3	0	0.091	0.184	0.0
39T4	3	0	0.107	0.227	0.0
39T5	3	0	0.090	0.202	0.0

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

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

Specimen	*Toxoplasma* antibody non-reactive	*Toxoplasma* antibody reactive
39T1	0	12
39T2	0	12
39T3	11	1
39T4	12	0
39T5	12	0

*All Methods

Table 4. Frequency Distribution of Participants' Interpretations
CONFIRMATORY RESULTS

Specimen	*Toxoplasma* antibody non-reactive	*Toxoplasma* antibody reactive
39T1	0	2
39T2	0	2
39T3	1	1
39T4	1	1
39T5	1	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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