



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 data-reporting period for Quarter 4, 2010. 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 October 4, 2010, 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 eleven laboratories in other countries. This panel was prepared from serum samples positive for Toxoplasma IgG and IgM purchased from Sera-Care (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 eleven 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.

Four 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 two false-negative interpretations and two false-positive interpretations. Laboratory results were evaluated on the basis of the final answers provided (screening only or confirmatory results). The mean and mode cutoffs for AutoDelfia participants were 11.0 and 11.5 IU/mL blood, respectively. The mean cutoff for the enzyme immunoassay methods was 0.225, with a range from 0.100 to 0.303 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 January 10, 2011. ❖

CDC/APHL

Direct inquiries to:
Centers for Disease Control and Prevention (CDC)
4770 Buford Highway, NE, MS/F43
Atlanta, GA 30341-3724

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

Phone: 770-488-7945
FAX: 770-488-4255
E-mail: JMei@cdc.gov

Editor: Joanne Mei
Production: Connie Singleton



NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA ANTIBODIES

QUARTER 4 – NOVEMBER 2010

LAB XXX

SPECIMEN CERTIFICATION – IgM

CDC ASSAYED LEVELS

Analyte	Specimen 40T1	Specimen 40T2	Specimen 40T3	Specimen 40T4	Specimen 40T5
Anti- <i>Toxoplasma</i> Immunoglobulin M CDC Mean Assayed Value (IU/mL blood)	335.5 ± 14.6	0.0 ± 0.0	45.5 ± 7.4	3.8 ± 7.6	195.0 ± 16.1

EXPECTED INTERPRETATIONS

Interpretation	Specimen 40T1	Specimen 40T2	Specimen 40T3	Specimen 40T4	Specimen 40T5
<i>Toxoplasma</i> Antibodies	2	1	2	1	2

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

SCREENING RESULTS – IgM

DATA VERIFICATION

Analyte	Specimen 40T1		Specimen 40T2		Specimen 40T3		Specimen 40T4		Specimen 40T5	
	Result	Code								
Anti- <i>Toxoplasma</i> antibodies (IU/mL blood)										

Reviewer's Comments

EVALUATION:.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

QUARTER 4 – NOVEMBER 2010

OVERALL STATISTICS – IgM

Table 1. Screening Results – Delfia Methods

Specimen	N	Outliers**	Mean (IU/mL blood)	UL (95%)	LL (95%)
40T1	5	0	346.7	451.2	242.3
40T2	5	0	0.0	0.0	0.0
40T3	5	0	58.6	77.1	40.1
40T4	5	0	1.1	4.4	0.0
40T5	5	0	218.9	282.8	155.1

** 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%)
40T1	3	0	0.758	1.632	0.000
40T2	3	0	0.038	0.084	0.000
40T3	3	0	0.177	0.328	0.025
40T4	3	0	0.077	0.253	0.000
40T5	3	0	0.488	1.306	0.000

** 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
40T1	0	11
40T2	11	0
40T3	2	9
40T4	11	0
40T5	1	10

*All Methods

Table 4. Frequency Distribution of Participants' Interpretations
CONFIRMATORY RESULTS

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
40T1	0	2
40T2	1	1
40T3	0	2
40T4	1	1
40T5	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**.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GA 30341

Director

Thomas R. Frieden, M.D., M.P.H.

Acting Director

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Theodore J. Meinhardt, Ph.D.

Chief

Newborn Screening and Molecular Biology Branch

Carla Cuthbert, Ph.D.

Chief Emeritus

Newborn Screening and Molecular Biology Branch

W. Harry Hannon, Ph.D.



Contributors: Barbara W. Adam
Carol Bell
Dana Chafin
Victor R. De Jesus, Ph.D.
Paul Dantonio
Marie C. Earley, Ph.D.
Elizabeth M. Hall
Christopher Haynes, Ph.D.
L. Omar Henderson, Ph.D.
Kristin Jones
Sharon Kerr
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Joanne Mei, Ph.D.
Nancy Meredith
Shannon O'Brien
David Simms
Robert Vogt, Ph.D.
Golriz Yazdanpanah
Sherri Zobel
Hui Zhou, Ph.D.

Production: Sarah Brown
Felicia Manning
Teresa Moore
Connie Singleton

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
SILVER SPRING, MD 20910



President

Patrick F. Luedtke, M.D., M.P.H.

Co-Chairpersons, Newborn Screening and Genetics in Public Health Committee

Cheryl Hermerath, M.B.A., DLM(ASCP), RM(NRCM)

Susan M. Tanksley, Ph.D.

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee

Gary Hoffman, B.S.

INQUIRIES TO:

Joanne Mei, Editor • Centers for Disease Control and Prevention (CDC)
Newborn Screening Quality Assurance Program • Mailstop F-43
4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • FAX (770) 488-4255 • E-mail: JMei@cdc.gov