

# Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

Volume 10, No. 2

May 2014

## INTRODUCTION

This report is the quarterly summary of all data reported within the specified data reporting period for Quarter 2, 2014. 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 April 7, 2014, 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 eight 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 ten 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.

Six 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 various 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 four false negative interpretations 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 0.244 OD, with a range from 0.1 to 0.318 OD; the mean cutoff for the multiplexed methods was 120 UA/mL serum, and the mean cutoff for the fluorescence methods was 5.0 EIU/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.

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-Toxoplasma antibodies PT specimens on July 14, 2014. ❖

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

Editors: Joanne Mei  
Irene Williams



NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

Quarter 2 – MAY 2014

OVERALL STATISTICS – IgM

Table 1a. Screening Results – Enzyme Immunoassay Methods

Specimen	N	Outliers*	Mean (OD)**	UL (95%)	LL (95%)
214T1	6	0	0.311	0.439	0.183
214T2	6	0	0.309	0.520	0.098
214T3	6	0	0.561	0.816	0.306
214T4	6	0	1.040	1.409	0.670
214T5	6	0	0.066	0.120	0.012

\* 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%)
214T1	2	0	153.5	166.0	141.0
214T2	2	0	208.3	236.7	179.8
214T3	2	0	299.5	300.9	298.1
214T4	2	0	468.8	487.5	450.0
214T5	2	0	208.3	210.3	206.2

\* 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%)
214T1	2	0	102.6	187.5	17.6
214T2	2	0	90.3	149.7	30.8
214T3	2	0	193.5	300.9	86.0
214T4	2	0	373.3	566.8	179.8
214T5	2	0	10.9	30.3	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
214T1	2	8
214T2	2	8
214T3	0	10
214T4	0	10
214T5	7	3

\*All Methods

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

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
214T1	0	3
214T2	0	3
214T3	0	3
214T4	0	3
214T5	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**.

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

**Director**

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

**Acting Director**

**National Center for Environmental Health**

Robin Ikeda, M.D., M.P.H.

**Director**

**Division of Laboratory Sciences**

James L. Pirkle, M.D., Ph.D.

**Chief**

**Newborn Screening and Molecular Biology Branch**

Carla Cuthbert, Ph.D.



**Contributors:** Barbara W. Adam  
Paul Dantonio  
Victor R. De Jesus, Ph.D.  
Marie C. Earley, Ph.D.  
Sharon Flores  
David Foreman  
Stephanie Foster  
Elizabeth M. Hall  
Christopher Haynes, Ph.D.  
Sarah Klass  
Francis Lee, Ph.D.  
Lixia Li, Ph.D.  
Timothy Lim, Ph.D.  
Daniel Mandel, Ph.D.  
Joanne Mei, Ph.D.  
Nancy Meredith  
Patrick Pickens  
Kelsey Sheard  
Jennifer Taylor, Ph.D.  
Robert Vogt, Ph.D.  
Irene Williams  
Golriz Yazdanpanah  
Hui Zhou, Ph.D.  
Sherri Zobel

**Production:** Sarah Brown  
Felicia Manning  
Connie Singleton

**ASSOCIATION OF PUBLIC HEALTH LABORATORIES**  
SILVER SPRING, MD 20910



**President**

Christine Bean, Ph.D., M.B.A., MT(ASCP)

**Chairman, Newborn Screening and Genetics in Public Health Committee**

Susan M. Tanksley, Ph.D.

**Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee**

Patrick Hopkin, B.S.

**INQUIRIES TO:**

*Irene Williams, 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: IWilliams1@cdc.gov*