

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

Volume 11, No. 2

May 2015

INTRODUCTION

This report is the quarterly summary of all data reported within the specified reporting period for Quarter 2, 2015. 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 6, 2015, a panel of five unknown dried blood spot (DBS) specimens prepared from human serum positive for exposure to *Toxoplasma gondii* was distributed to one laboratory 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 eight 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.

Five laboratories reported using an enzyme immunoassay method and one used a fluorometric enzyme immunoassay. Two laboratories reported only IgG results from

a multiplexed platform for screening. 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 no false negative, and two 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 0.216 OD, with a range from 0.1 to 0.400 OD and the mean cutoff for the multiplexed methods was 120 UA/mL serum. The mean cutoff for the fluorescence methods was 5.5 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. Two 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 13, 2015. ❖

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
Irene Williams



NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

Quarter 2 – May 2015

OVERALL STATISTICS

Table 1a. Screening Results – Enzyme Immunoassay Methods (IgM)

Specimen	N	Outliers*	Mean (OD)**	UL (95%)	LL (95%)
215T1	5	0	0.105	0.218	0.000
215T2	5	0	0.261	0.526	0.000
215T3	5	0	0.258	0.333	0.184
215T4	5	0	0.461	0.780	0.142
215T5	5	0	0.064	0.116	0.012

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

Table 1b. Screening Results – Multiplexed Immunoassay Methods (IgG only)

Specimen	N	Outliers*	Mean (UA/mL)***	UL (95%)	LL (95%)
215T1	2	0	37.0	53.6	20.4
215T2	2	0	860.0	887.7	832.3
215T3	2	0	202.0	210.3	193.7
215T4	2	0	290.0	317.7	262.3
215T5	2	0	41.0	57.6	24.4

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

Table 1c. Screening Results – Fluorescence Immunoassay Methods (IgM)

Specimen	
215T1	Statistics not applicable, N=1
215T2	
215T3	
215T4	
215T5	

** OD = Absorbance units

*** UA/mL = Arbitrary units/mL serum

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

Specimen	Toxoplasma Antibody Non-Reactive	Toxoplasma Antibody Reactive
215T1	7	1
215T2	0	8
215T3	1	7
215T4	0	8
215T5	7	1

*All Methods

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

Specimen	Toxoplasma antibody Non-Reactive	Toxoplasma antibody Reactive
215T1	2	0
215T2	0	2
215T3	0	2
215T4	0	2
215T5	2	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.

Director

National Center for Environmental Health

Patrick Breyse, Ph.D.

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.
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
Iris Landers
Felicia Manning
LoNeka Shockley

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
SILVER SPRING, MD 20910



President

Dan Rice, DrPH, MS.

Chairman, Newborn Screening and Genetics in Public Health Committee

Susan M. Tanksley, Ph.D.

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee

Patrick Hopkins, 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