Newborn Screening Quality Assurance Program

PROFICIENCY TESTING **Toxoplasma Quarterly Report**

Volume 9, No. 4 December 2013

INTRODUCTION

This report is the quarterly summary of all data reported within the specified data reporting period for Quarter 4, 2013. 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 23, 2013, 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 six 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.

Four 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 enzyme 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 interpretations 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 0.249 OD, with a range from 0.1 to 0.333 OD; the mean cutoff for the multiplexed methods was 120 UA/mL serum, and the mean cutoff for the fluorescence methods was 30.5 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. Four 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 January 13, 2014. ❖

CDC/APHL

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

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

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

Editors: Joanne Mei
Irene Williams

CENTERS FOR DISEASE CONTROL AND PREVENTION

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

Quarter 4 – DECEMBER 2013

OVERALL STATISTICS – IgM

Table 1a. Screening Results – Enzyme Immunoassay Methods

Specimen	N	Outliers*	Mean (OD)**	UL (95%)	LL (95%)
413T1	4	0	0.314	0.442	0.185
413T2	4	0	0.564	0.735	0.392
413T3	4	0	0.080	0.123	0.037
413T4	4	0	0.852	1.152	0.553
413T5	4	0	0.083	0.128	0.037

* 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%)
413T1	2	0	184.0	222.8	145.2
413T2	2	0	310.5	342.4	278.6
413T3	2	0	189.5	215.8	163.2
413T4	2	0	430.5	612.1	248.9
413T5	2	0	210.5	239.6	181.4

* 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%)
413T1	2	0	90.9	164.6	17.2
413T2	2	0	160.7	252.3	69.0
413T3	2	0	16.4	61.1	0.0
413T4	2	0	249.5	327.2	171.7
413T5	2	0	10.0	37.5	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	*Toxoplasma* antibody non-reactive	*Toxoplasma* antibody reactive
413T1	0	8
413T2	0	8
413T3	6	2
413T4	0	8
413T5	6	2

*All Methods

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

Specimen	*Toxoplasma* antibody non-reactive	*Toxoplasma* antibody reactive
413T1	0	4
413T2	0	4
413T3	4	0
413T4	0	4
413T5	4	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 M. Ikeda, M.D., M.P.H., RADM, USPHS
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
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