Newborn Screening Quality Assurance Program

Quarterly Report
Volume 13, No.2

anti-*Toxoplasma* Antibodies in Dried Blood Spots Proficiency Testing Program (TOXOPT)

2017 Quarter 2 May

Introduction

This report summarizes the data reported within the specified period for the Quarter 2, 2017, anti-*Toxoplasma* Antibody in dried blood spots (DBS) PT Program. It is distributed to all participants, state laboratory directors, and program colleagues by request. The tables within this report provide certification profiles for the distributed specimens, statistical analysis of the quantitative data, and frequency distribution summaries for expected interpretations. An evaluation of your laboratory's data is attached to this summary.

Certification of PT Specimens

This DBS 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%. Table 1 provides the anti-Toxoplasma IgM expected values based on the NSQAP assayed values determined for each specimen by fluoroimmunoassay. Expected Clinical Assessments were based on a cutoff of 10 EIU/mL.

Table 1. NSQAP anti -*Toxoplasma* IgM Expected Values

Specimen	Expected Value (EIU/mL)	SD	Clinical Assessment
217T1	212.5	20.8	2
217T2	0.0	3.2	1
217T3	0.0	3.0	1
217T4	0.0	3.3	1
217T5	0.0	3.1	1

1 = *Toxoplasma* antibody non-reactive 2 = *Toxoplasma* antibody reactive

Distribution of PT Specimens

On April 3, 2017 a panel of five unknown DBS specimens was distributed to three laboratories in the United States and 14 laboratories in other countries.

Participant Results

- Quantitative Screening Results

We processed data from 9 participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Three laboratories reported using an enzyme immunoassay method (OD), two reported using an ELISA (EIU/mL) and one used a fluorometric enzyme immunoassay (EIU/mL) to detect IgM. Two laboratories reported IgG results from a multiplexed platform (Arbitrary Units UA/mL), and one lab did not report quantitative data. Overall statistics and cutoff information for the various immunoassay methods are summarized in Table 2.

Table 2. Overall Statistics—Screening Results for Immunoassay Methods

Method/ Antibody	Specimen	N	Mean	SD	Mean Reported Cutoffs	Range Reported Cutoffs
Enzyme Immunoassay IgM (OD*)	217T1	3	0.435	0.123	0.189	0.100—0.400
	217T2	3	0.027	0.033		
	217T3	3	0.031	0.038		
	217T4	3	0.022	0.025		
	217T5	3	0.025	0.022		
Enzyme Immunoassay IgM (EIU/mL**)	217T1	2	308.0	88.0	100	80-120
	217T2	2	98.0	5.7		
	217T3	2	50.7	14.8		
	217T4	2	46.7	1.6		
	217T5	2	28.1	3.2		
Fluorescence Immunoassay IgM (EIU/mL**)	217T1	NA	NA	NA	NA	NA
	217T2	NA	NA			
	217T3	NA	NA			
	217T4	NA	NA			
	217T5	NA	NA			
Multiplexed Immunoassay IgG (UA/mL***)	217T1	2	508.0	52.3	>120	>120
	217T2	2	29.5	3.5		
	217T3	2	22.5	2.1		
	217T4	2	41.0	2.8		
	217T5	2	21.5	3.5		

OD = Absorbance Units **EIU/mL = Enzyme International Units/mL serum ***UA/mL =Arbitrary Units/mL serum

- Quantitative Confirmatory Results

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. One laboratory provided confirmatory results using an EIA for IgG.

- Qualitative Clinical Assessments

Qualitative assessments may differ by participant because of specific assessment practices. Laboratory results were evaluated on the basis of the final assessments provided (screening only or confirmatory results). The frequency distribution of participant screening and confirmatory Clinical Assessments for both IgM and IgG are shown in Table 3.

Table 3. Frequency Distribution of Reported Clinical Assessments—All Methods

Type of Testing	Specimen	Toxoplasma antibody Non-reactive	Toxoplasma antibody Reactive
Screening	217T1	0	9
	217T2	8	1
	217T3	9	0
	217T4	9	0
	217T5	9	0
Confirmatory	217T1	0	1
	217T2	1	0
	217T3	1	0
	217T4	1	0
	217T5	1	0

Evaluations

Overall, participants reported no False-negative and one False-positive final Clinical Assessments.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter's TOXOPT specimens on July 10, 2017.

The content of this report may also be located on our website at:
http://www.cdc.gov/labstandards/nsqap_reports.html

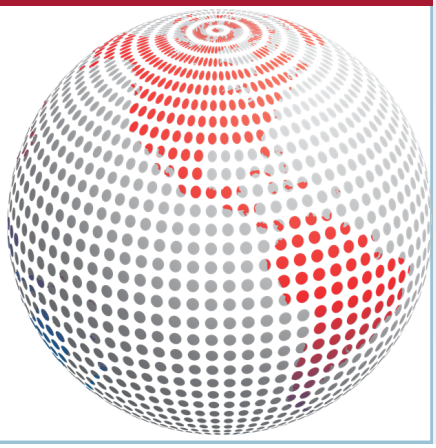
This program is co-sponsored by the Centers for Disease Control and Prevention (CDC) and The Association of Public Health Laboratories (APHL)

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Direct inquiries to:

Centers for Disease Control and Prevention
4770 Buford Highway NE, MS/F19
Atlanta, GA 30341-3724
Phone: 404-488-7945 Email: jvm0@cdc.gov

Editors
Joanne Mei
Irene Williams



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

Acting Director
Anne Schuchat, M.D. (RADM, USPHS)

Director
National Center for Environmental Health
Patrick Breysse, 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:

Carter Asef
Quan Bui
John Bernstein
Paul Dantonio
Sharon Flores
Elizabeth M. Hall
Christopher Haynes, Ph.D.
Brandon Kenwood
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Daniel Mandel, Ph.D.
Joanne Mei, Ph.D.
Kristina Mercer
Gyliann Peña
Sean Scott
Robert Vogt, Ph.D.
Irene Williams
Sophia Winchester
Golriz Yazdanpanah
Sherri Zobel

Production:

Sarah Brown
Kimberly Coulter
LoNeka Shockley
Kizzy Stewart

ASSOCIATION OF PUBLIC HEALTH LABORATORIES SILVER SPRING, MD 20910

President
A. Christian Whelen, PhD, D(ABMM)

Chairman, Newborn Screening and Genetics in Public Health Committee
Susan Tanksley, Ph.D. and Michele Caggana, Sc.D., FACMG

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee
Patricia R. Hunt, B.A. and Joseph Orsini, Ph.D.

Chairman, Newborn Screening Molecular Subcommittee
Rachel Lee, Ph.D.

INQUIRIES TO:

Irene Williams, Editor • Centers for Disease Control and Prevention (CDC) • Newborn Screening Quality Assurance Program
Mailstop F-24 • 4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • NSQAPDMT@cdc.gov
E-mail: IWilliams1@cdc.gov