Newborn Screening Quality Assurance Program

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

In co-sponsorship with Association of Public Health Laboratories (APHL)
Provided by the Newborn Screening and Molecular Biology Branch
Centers for Disease Control and Prevention
4770 Buford Highway NE, MS/F19
Atlanta, GA 30341-3724
Email: NSQAPDMT@cdc.gov

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Report Authorization

This report has been reviewed and authorized by Dr. Joanne Mei, Laboratory Chief, Newborn Screening Quality Assurance Program.

Confidentiality Statement

NSQAP participant information and evaluations are strictly confidential and shared only with individual participants, unless written authorization for release is received.

Introduction

This report summarizes the data reported within the specified period for Quarter 3, 2019, anti-*Toxoplasma* Antibody in dried blood spots (DBS) Proficiency Testing (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
319T1	0.0	5.7	1
319T2	0.0	5.6	1
319T3	0.0	7.9	1
319T4	201.2	22.8	2
319T5	94.6	14.4	2

1 = *Toxoplasma* antibody Non-reactive
2 = *Toxoplasma* antibody Reactive

Distribution of PT Specimens

On June 25, 2019, a panel of five unknown DBS specimens was distributed to two laboratories in the United States and 16 laboratories in other countries.

Participant Results

Quantitative Screening Results

We processed data from 12 participants. Laboratories were asked to report IgM screening results in Absorbance (OD) or other units. Eight laboratories reported using an enzyme immunoassay method with units reported in OD to detect IgM. Three reported using an enzyme immunoassay with units reported in EIU/mL and one used a fluorometric enzyme immunoassay (EIU/mL). Overall statistics and cutoff information for the various immunoassay methods are summarized in Tables 2a and 2b. Extreme outlier (greater than 4 SD) data was removed from these statistics.

Table 2a. Overall Statistics – Screening Results for Immunoassay Methods
Method/Antibody: Enzyme Immunoassay IgM (OD)
Mean Reported Cutoff: 0.227
Cutoff Range: 0.100 – 0.298

Specimen	N	Mean	SD
319T1	8	0.078	0.075
319T2	8	0.036	0.039
319T3	8	0.064	0.042
319T4	8	0.558	0.426
319T5	8	0.193	0.183

Table 2b. Overall Statistics – Screening Results for Immunoassay Methods
Method/Antibody: Enzyme Immunoassay IgM (EIU/mL)
Mean Reported Cutoff: 83
Cutoff Range: 10 - 120

Specimen	N	Mean	SD
319T1	3	78.9	35.4
319T2	3	18.3	14.4
319T3	3	59.2	31.5
319T4	3	282.2	59.9
319T5	3	171.3	44.9

Quantitative Confirmatory Results

Participants were asked to confirm specimens that screened above their screening cutoff for *Toxoplasma*-antibodies. Three laboratories provided confirmatory results using an enzyme immunoassay 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 assessment provided (screening only or confirmatory results). The frequency distribution of participant screening for IgM and confirmatory testing for IgG are shown in Tables 3a and 3b.

Table 3a. Frequency Distribution of Reported Clinical Assessments —All Methods
Screening Testing (IgM)

Specimen	Toxoplasma antibody Non-reactive	Toxoplasma antibody Reactive
319T1	10	2
319T2	12	0
319T3	12	0
319T4	2	10
319T5*	5	7

*Specimen 319T5 was not evaluated due to lack of 80% participant consensus.

Table 3b. Frequency Distribution of Reported Clinical Assessments—All Methods
Confirmatory Testing (IgG)

Specimen	Toxoplasma antibody Non-reactive	Toxoplasma antibody Reactive
319T1	3	0
319T2	3	0
319T3	3	0
319T4	0	3
319T5	0	3

Evaluations

Overall, participants reported three misclassfifications. Specimen 319T5 was not evaluated due to lack of 80% consensus among participants.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter's TOXOPT specimens on September 24, 2019.

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

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
Robert R. Redfield, M.D.

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, BS
Nicole Baird, Ph.D
John Bernstein, MS
Quan Bui, MS
Suzanne Cordovado, Ph.D
Paul Dantonio, MS
Katherine Duneman, MS
Sharon Flores, MS
Christopher Greene, Ph.D
Elizabeth Hall, BS
Laura Hancock, MS
Christopher Haynes, Ph.D
Jessica Hendricks, MS
Miyono Hendrix, MS
Laura C. Hildreth, BS
Deborah Koontz, Ph.D
Francis Lee, Ph.D
LiXia Li, Ph.D
Tim Lim, Ph.D
Daniel Mandel, Ph.D
Joanne Mei, Ph.D
Kristina Mercer, Ph.D
Stanimila Nikolova, Ph.D
Gyliann Pena, MS
Kostas Petritis, Ph.D
C. Austin Pickens, Ph.D
Blanche Temate, Ph.D
E. Shannon Torres, Ph.D
Robert Vogt, Ph.D
Irene Williams, MS
Sophia Winchester, BS
Golriz Yazdanpanah, MS
Sherri Zobel, BS

Production
Vinay Anumula, MS
Kizzy Stewart
Joy Pressley

ASSOCIATION OF PUBLIC HEALTH LABORATORIES SILVER SPRING, MD 20910

President
Joanne Bartkus, PhD

Chairman, Newborn Screening and Genetics in Public Health Committee
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-19, 4770 Buford Highway, N.E., Atlanta, GA 30341-3724
E-mail: NSQAPDMT@cdc.gov