

Newborn Screening Quality Assurance Program anti-*Toxoplasma* Antibodies 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, S110-3
Atlanta, GA 30341-3724
Email: NSQAPDMT@cdc.gov

Final Quarterly Report
Volume 21, No. 2a
Issued: November 19, 2025

AMENDED REPORT

This amended report replaces anti-*Toxoplasma* Antibodies Proficiency Testing Program (TOXOPT) report, Volume 21, No.2. This report corrects the Expected Value, SD and Clinical Assessments listed in Table 1. NSQAP anti-*Toxoplasma* IgM Expected Values (EIU, Enzyme International Units/mL serum).

REPORT AUTHORIZATION

Dr. Stanimila Nikolova, Laboratory Chief, Proficiency Testing and Reference Material reviewed and authorized this report.

CONFIDENTIALITY STATEMENT

NSQAP participant information and evaluations are strictly confidential and only available by accessing the NSQAP Participant Portal.

Introduction

This report summarizes the results collected within the specified period for Quarter 3, 2025, anti-*Toxoplasma* Antibodies in dried blood spots (DBS) Proficiency Testing (PT) Program. This report is posted to the Newborn Screening Quality Assurance Program (NSQAP) Participant Portal. The tables in this report provide certification profiles for the distributed specimens, statistical analysis of the quantitative data, and frequency distribution summaries for expected interpretations.

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 (EIU, Enzyme International Units/mL serum)

Specimen	Expected Value (EIU/mL)	SD	Clinical Assessment
20253014001	2385.00	290.3	Toxoplasmosis antibody reactive
20253014002	4.20	6.9	Toxoplasmosis antibody non-reactive
20253014003	0.00	6.9	Toxoplasmosis antibody non-reactive
20253014004	94.60	14.4	Toxoplasmosis antibody reactive
20253014005	0.00	5.7	Toxoplasmosis antibody non-reactive

Distribution of PT Specimens

On June 24, 2025, NSQAP distributed a panel of five unknown DBS specimens to 14 laboratories.

Participant Results

Quantitative Screening Results

Participants reported results in the NSQAP Participant Portal.

We processed data from 14 participants. NSQAP asked laboratories to report IgM screening results in absorbance optical density (OD) or other units. Eleven laboratories reported results using absorbance (OD) unit of measure, one reported U/mL and two reported median fluorescence intensity (MFI) units.

IgM detection methods with results in absorbance (OD) units were reported by eight laboratories who used TOXO Enzyme Immunoassay (EIA), one laboratory used Imunoscreen Toxoplasma IgM, one laboratory used Biolisa Toxoplasma IgM DBS – Bioclin, and one laboratory used Toxoplasma IgM DBS Imunoscreen MBIolog. Two laboratories who reported results for IgM in MFI units used the NeoMAP TOXO Interscientifica Multiplex method. One laboratory who reported results for IgM in U/mL units used the GSP Neonatal Anti-Toxoplasma IgM method.

Table 2 summarizes overall statistics and cutoff information for the EIA method absorbance (OD) which was the only method with ≥ 3 participants reporting data.

Qualitative Clinical Assessments

NSQAP evaluated laboratory results as acceptable or unacceptable when compared with the expected clinical assessment. Table 3 shows the frequency distribution of clinical assessments.

Table 2. Overall Statistics – Screening Results for Immunoassay Methods

Method/Antibody: TOXO Enzyme Immunoassay IgM (OD)

Mean Reported Cutoff: 0.229

Cutoff Range: 0.100 – 0.493

Specimen	N	Mean	SD
20253014001	8	3.567	2.670
20253014002	8	0.088	0.098
20253014003	8	0.080	0.107
20253014004	8	0.422	0.490
20253014005	8	0.106	0.115

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

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody Reactive
20253014001	0	14
20253014002	13	1
20253014003	13	1
20253014004	2	12
20253014005	10	4

Evaluations

Eight unacceptable clinical assessments were reported for anti-*Toxoplasma* antibodies PT.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter's TOXOPT specimens on September 23, 2025.

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

Acting Director

Jim O'Neill, MA

Director National Center for Environmental Health

Aaron Bernstein, MD, MPH

Director Division of Laboratory Sciences

Benjamin Blount, PhD

Chief Newborn Screening and Molecular Biology Branch

Carla Cuthbert, PhD

Contributors

Omar Aboul Houda, BS
Alexander Alvarado, BA
Ian Barham, BS
John Bernstein, MS
Christofer Brown, BS
Michelle Chaney, BS
David Cobb, PhD
Elya Courtney, MPH
Farzana Dola, BS
Katherine Duneman, MS
Christian Freeman, PhD
Marcus Gaffney, PhD
Ernesto Gonzales Reyes, PhD

Christopher Greene, PhD
Rebecca Giuntoli, MS
Rosemary Hage, PhD
Amanda Haney, BS
Miyono Hendrix, MS
Cynthia Hinton, PhD
Samantha Isenberg, PhD
Arieian Johnson, BS
Jihyun Kim, MS
Rachel Lee, PhD
Timothy Lim, PhD
Elizabeth McCown, BS
Joanne Mei, PhD

Auriel Moseley, MS
Stanimila Nikolova, PhD
Ivy Onyechi, MS
Gyliann Peña, MS
Daquille Peppers, MS,
Kostas Petritis, PhD
C. Austin Pickens, PhD
Eladia Smead, BS
Kizzy Stewart
Robert Vogt, PhD
Monique Wright, BS
Golriz Yazdanpanah, MS
Sherri Zobel, BS

President

Megan Crumpler, PhD

Chairman, Newborn Screening Committee

Joseph Orsini, Ph.D.

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee

Patrice Held, Ph.D, Adrienne Manning, BS, and Inderneel Sahai, MD

Chairman, Newborn Screening Molecular Subcommittee

Denise Kay, Ph.D and Richard Olney, MD, MPH

INQUIRIES TO:

Editors: Auriel Moseley

Centers for Disease Control and Prevention (CDC), Newborn Screening Quality Assurance Program

Mailstop S110-3, 4770 Buford Highway, N.E., Atlanta, GA 30341-3724 Email: NSQAPDMT@cdc.gov