



Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

Volume 5, No. 2

May 2009

INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 2, 2009. 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, 2009, 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 ten laboratories in other countries.

PARTICIPANTS' RESULTS

We processed data from eleven participants. Laboratories were asked to report IgM screening results in IU/mL blood or Absorbance (OD). In the statistical summary analysis, we did not include data that were outside the 99% confidence interval.

Four laboratories reported using AutoDelfia to measure anti-*Toxoplasma* IgM: one used Delfia and six reported using "other". Three of those in the "other" category used an enzyme immunoassay method; one used a fluorescent enzyme immunoassay method; and two used a multiplexed platform. The expected anti-*Toxoplasma* IgM values were based on CDC assayed values. Overall statistics from the AutoDelfia and

Delfia methods were combined so as not to identify an individual laboratory (Table 1). Results from the enzyme immunoassay methods are summarized in Table 2. The frequency distribution of participants' interpretations for screening results is shown in Table 3 and the frequency distribution of participants' interpretations for confirmatory results is shown in Table 4.

Expected interpretations (qualitative assessments) may differ by participant because of specific assessment practices. When the reported clinical assessment differs from our expected clinical assessment, the grading algorithm is used to evaluate test performance. An explanation of the grading algorithm can be found on the NSQAP data-reporting Web site or in the annual summary report. Overall, participants reported three false-positive interpretations and no false-negative interpretations. Laboratory results were evaluated on the basis of the final answers provided (screening only or confirmatory results). The median and mode cutoffs for AutoDelfia participants were 11.4 and 11.5 IU/mL blood, respectively. The median cutoff for the enzyme immunoassay methods was 0.286, with a range from 0.100 to 0.412 OD.

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 EIAs for IgG or IgM.

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-*Toxoplasma* antibodies pilot PT specimens on July 13, 2009. ❖

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

Editor : Joanne Mei
Production: Connie Singleton



NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA ANTIBODIES

QUARTER 2 – MAY 2009

LAB XXX

SPECIMEN CERTIFICATION - IgM

CDC ASSAYED LEVELS

Analyte	Specimen 29T1	Specimen 29T2	Specimen 29T3	Specimen 29T4	Specimen 29T5
Anti- <i>Toxoplasma</i> Immunoglobulin M CDC Mean Assayed Value (IU/mL blood)	335.5 ± 14.6	197.4 ± 6.3	11.7 ± 11.0	1.5 ± 0.9	0.0 ± 0.0

EXPECTED INTERPRETATIONS

Interpretation	Specimen 29T1	Specimen 29T2	Specimen 29T3	Specimen 29T4	Specimen 29T5
<i>Toxoplasma</i> Antibodies	2	2	1	1	1

1 = *Toxoplasma* antibody non-reactive 2 = *Toxoplasma* antibody reactive NE = clinical assessment not evaluated

SCREENING RESULTS - IgM

DATA VERIFICATION

Analyte	Specimen 29T1		Specimen 29T2		Specimen 29T3		Specimen 29T4		Specimen 29T5	
	Result	Code								
Anti- <i>Toxoplasma</i> antibodies (IU/mL blood)										

Reviewer's Comments

EVALUATION:

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

QUARTER 2 – May 2009

OVERALL STATISTICS – IgM

Table 1. Screening Results – Delfia Methods

Specimen	N	Outliers**	Mean (IU/mL blood)	UL (95%)	LL (95%)
29T1	5	0	293.4	341.2	245.6
29T2	5	0	198.6	242.3	154.8
29T3	5	0	2.4	6.7	0.0
29T4	5	0	3.8	10.2	0.0
29T5	5	0	1.1	2.1	0.2

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

Table 2. Screening Results – Enzyme Immunoassay Methods

Specimen	N	Outliers**	Mean (OD)	UL (95%)	LL (95%)
29T1	3	0	1.113	1.521	0.705
29T2	3	0	0.666	0.770	0.561
29T3	3	0	0.106	0.199	0.014
29T4	3	0	0.117	0.216	0.018
29T5	3	0	0.099	0.178	0.020

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

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

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
29T1	0	10
29T2	0	10
29T3	10	0
29T4	10	0
29T5	10	0

*All Methods

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

QUARTER 2 – May 2009

Table 4. Frequency Distribution of Participants' Interpretations
CONFIRMATORY RESULTS

Specimen	<i>Toxoplasma</i> antibody non-reactive	<i>Toxoplasma</i> antibody reactive
29T1	0	2
29T2	0	2
29T3	1	1
29T4	1	1
29T5	1	1

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

Richard E. Besser, M.D.

Director

National Center for Environmental Health

Howard Frumkin, M.D., Dr.P.H., M.P.H.

Director

Division of Laboratory Sciences

Eric J. Sampson, Ph.D.

Acting Chief

Newborn Screening and Molecular Biology Branch

Eric J. Sampson, Ph.D.

W. Harry Hannon, Ph.D. (Management Consultant/CTR)



Contributors: Barbara W. Adam
Carol Bell
Paul Dantonio
Victor R. De Jesus, Ph.D.
Rena Driscoll-Dunn
Marie C. Earley, Ph.D.
L. Omar Henderson, Ph.D.
Sharon Kerr
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Zuzheng (Roy) Luo
Elizabeth McCown
Joanne Mei, Ph.D.
Nancy Meredith
Hien Nguyen
Shannon O'Brien
David Simms
Sherri Stevens
Robert Vogt, Ph.D.
Golriz Yazdanpanah
Hui Zhou, Ph.D.

Production: Sarah Brown
Felicia Manning
Teresa Moore
Connie Singleton



ASSOCIATION OF PUBLIC HEALTH LABORATORIES
WASHINGTON, DC 20036-3320

President

Frances Pouch-Downes, Dr.P.H.

Chairman, Newborn Screening and Genetics in Public Health Committee

Cheryl Hermerath, M.B.A., DLM(ASCP), RM(NRM)

Chairman, Newborn Screening Quality Assurance Subcommittee

Gary Hoffman, BS

INQUIRIES TO:

Carol Bell, 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: CBell@cdc.gov