



# Newborn Screening Quality Assurance Program

## PROFICIENCY TESTING

## Toxoplasma Quarterly Report

Volume 6, No. 3

August 2010

### INTRODUCTION

This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 3, 2010. 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 July 12, 2010, 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 eleven laboratories in other countries. This panel was prepared from serum samples positive for *Toxoplasma* IgG and IgM purchased from SeraCare (Medford, Massachusetts). These serum samples were mixed with washed red blood cells and the final hematocrit was adjusted to 50%.

### 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 (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 ten 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 median and mode cutoffs for AutoDelfia participants were 11.3 and 11.5 IU/mL blood, respectively. The mean cutoff for the enzyme immunoassay methods was 0.245, with a range from 0.100 to 0.354 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.

Results from this survey indicate that Toxo-IgM methods vary in the ability to detect antibody from DBS prepared with commercially certified, Toxo-positive sera. NSQAP strives to prepare DBS materials that challenge all methods and laboratories. ❖

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-*Toxoplasma* antibodies PT specimens on October 4, 2010. ❖

**CDC/APHL**

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA ANTIBODIES

QUARTER 3 – AUGUST 2010

LAB XXX

SPECIMEN CERTIFICATION - IgM

CDC ASSAYED LEVELS

| Analyte                                                                             | Specimen 30T1 | Specimen 30T2 | Specimen 30T3 | Specimen 30T4 | Specimen 30T5 |
|-------------------------------------------------------------------------------------|---------------|---------------|---------------|---------------|---------------|
| Anti- <i>Toxoplasma</i> Immunoglobulin M<br>CDC Mean Assayed Value<br>(IU/mL blood) | 116.1 ± 13.9  | 0.0 ± 0.0     | 45.5 ± 7.4    | 23.1 ± 5.3    | 195.0 ± 16.1  |

EXPECTED INTERPRETATIONS

| Interpretation               | Specimen 30T1 | Specimen 30T2 | Specimen 30T3 | Specimen 30T4 | Specimen 30T5 |
|------------------------------|---------------|---------------|---------------|---------------|---------------|
| <i>Toxoplasma</i> Antibodies | 2             | 1             | 2             | 2             | 2             |

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

NE = clinical assessment not evaluated

SCREENING RESULTS - IgM

DATA VERIFICATION

| Analyte                                             | Specimen 30T1 |      | Specimen 30T2 |      | Specimen 30T3 |      | Specimen 30T4 |      | Specimen 30T5 |      |
|-----------------------------------------------------|---------------|------|---------------|------|---------------|------|---------------|------|---------------|------|
|                                                     | Result        | Code |
| Anti- <i>Toxoplasma</i> antibodies<br>(IU/mL blood) |               |      |               |      |               |      |               |      |               |      |

*Reviewer's Comments*

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

*ANTI-TOXOPLASMA Antibodies*

QUARTER 3 – AUGUST 2010

OVERALL STATISTICS – IgM

Table 1. Screening Results – Delfia Methods

| Specimen | N | Outliers** | Mean (IU/mL blood) | UL (95%) | LL (95%) |
|----------|---|------------|--------------------|----------|----------|
| 30T1     | 5 | 0          | 123.0              | 143.5    | 102.4    |
| 30T2     | 5 | 0          | 0.0                | 0.0      | 0.0      |
| 30T3     | 5 | 0          | 54.8               | 67.9     | 41.7     |
| 30T4     | 5 | 0          | 22.3               | 27.6     | 17.0     |
| 30T5     | 5 | 0          | 210.3              | 222.6    | 198.0    |

\*\* 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%) |
|----------|---|------------|-----------|----------|----------|
| 30T1     | 3 | 0          | 0.266     | 0.566    | 0.000    |
| 30T2     | 3 | 0          | 0.040     | 0.062    | 0.018    |
| 30T3     | 3 | 0          | 0.222     | 0.311    | 0.133    |
| 30T4     | 3 | 0          | 0.204     | 0.347    | 0.060    |
| 30T5     | 3 | 0          | 0.528     | 0.955    | 0.102    |

\*\* 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 |
|----------|-----------------------------------------|-------------------------------------|
| 30T1     | 4                                       | 7                                   |
| 30T2     | 11                                      | 0                                   |
| 30T3     | 2                                       | 9                                   |
| 30T4     | 1                                       | 10                                  |
| 30T5     | 3                                       | 8                                   |

\*All Methods

Table 4. Frequency Distribution of Participants' Interpretations  
CONFIRMATORY RESULTS

| Specimen | <i>Toxoplasma</i> antibody non-reactive | <i>Toxoplasma</i> antibody reactive |
|----------|-----------------------------------------|-------------------------------------|
| 30T1     | 0                                       | 2                                   |
| 30T2     | 2                                       | 0                                   |
| 30T3     | 0                                       | 2                                   |
| 30T4     | 0                                       | 2                                   |
| 30T5     | 0                                       | 2                                   |

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**.

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