

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

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INTRODUCTION

This report is the quarterly summary of all data reported within the specified reporting period for Quarter 1, 2015. 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 January 12, 2015, a panel of five unknown dried blood spot (DBS) specimens prepared from human serum positive for exposure to *Toxoplasma gondii* was distributed to one laboratory in the United States and nine laboratories in other countries. This 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%.

PARTICIPANTS' RESULTS

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

Five laboratories reported using an enzyme immunoassay method and two used a fluorometric enzyme immunoassay. Two laboratories reported only IgG results from

a multiplexed platform for screening. The expected anti-*Toxoplasma* IgM values were based on CDC assayed values. Overall statistics from the various immunoassay methods are summarized in Tables 1a – 1c. The frequency distribution of participants' interpretations for screening results is shown in Table 2 and the frequency distribution of participants' interpretations for confirmatory results is shown in Table 3.

Expected interpretations (qualitative assessments) may differ by participant because of specific assessment practices. Overall, participants reported four false negative, and no false positive interpretations. Laboratory results were evaluated on the basis of the final answers provided (screening only or confirmatory results). The mean cutoff for the enzyme immunoassay methods was 0.229 OD, with a range from 0.1 to 0.400 OD and the mean cutoff for the multiplexed methods was 120 UA/mL serum. The mean cutoff for the fluorescence methods was 5.5 EIU/mL serum. 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 an EIA for IgG or a multiplexed platform for IgG.

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-*Toxoplasma* antibodies PT specimens on April 6, 2015. ❖

CDC/APHL

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

Quarter 1 – February 2015

OVERALL STATISTICS

Table 1a. Screening Results – Enzyme Immunoassay Methods (IgM)

| Specimen | N | Outliers* | Mean (OD)** | UL (95%) | LL (95%) |
|----------|---|-----------|-------------|----------|----------|
| 115T1 | 5 | 0 | 0.252 | 0.440 | 0.064 |
| 115T2 | 5 | 0 | 0.382 | 0.494 | 0.269 |
| 115T3 | 5 | 0 | 0.301 | 0.469 | 0.132 |
| 115T4 | 5 | 0 | 0.113 | 0.318 | 0.000 |
| 115T5 | 5 | 0 | 0.053 | 0.121 | 0.000 |

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

Table 1b. Screening Results – Multiplexed Immunoassay Methods (IgG only)

| Specimen | N | Outliers* | Mean (UA/mL)*** | UL (95%) | LL (95%) |
|----------|---|-----------|-----------------|----------|----------|
| 115T1 | 2 | 0 | 876.50 | 999.85 | 753.15 |
| 115T2 | 2 | 0 | 841.50 | 981.48 | 701.52 |
| 115T3 | 2 | 0 | 184.50 | 199.75 | 169.25 |
| 115T4 | 2 | 0 | 26.00 | 42.63 | 9.37 |
| 115T5 | 2 | 0 | 39.50 | 54.75 | 24.25 |

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

Table 1c. Screening Results – Fluorescence Immunoassay Methods (IgM)

| Specimen | N | Outliers* | Mean (EIU/ml)**** | UL (95%) | LL (95%) |
|----------|---|-----------|-------------------|----------|----------|
| 115T1 | 2 | 0 | 55.6 | 89.1 | 22.1 |
| 115T2 | 2 | 0 | 92.5 | 165.4 | 19.6 |
| 115T3 | 2 | 0 | 30.6 | 58.1 | 3.0 |
| 115T4 | 2 | 0 | 2.0 | 7.5 | 0.0 |
| 115T5 | 2 | 0 | 2.7 | 4.2 | 1.1 |

UL = upper limit LL = lower limit

** OD = Absorbance units

*** UA/mL = Arbitrary units/mL serum

**** EIU/mL = Enzyme immunoassay units/mL serum

Table 2. Frequency Distribution of Participants' Interpretations*
SCREENING RESULTS

| Specimen | Toxoplasma Antibody Non-Reactive | Toxoplasma Antibody Indeterminate | Toxoplasma Antibody Reactive |
|----------|-------------------------------------|--------------------------------------|---------------------------------|
| 115T1 | 2 | 1 | 6 |
| 115T2 | 1 | 0 | 8 |
| 115T3 | 1 | 1 | 7 |
| 115T4 | 9 | 0 | 0 |
| 115T5 | 9 | 0 | 0 |

*All Methods

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

| Specimen | Toxoplasma antibody Non-Reactive | Toxoplasma antibody Reactive |
|----------|-------------------------------------|---------------------------------|
| 115T1 | 0 | 2 |
| 115T2 | 0 | 2 |
| 115T3 | 0 | 2 |
| 115T4 | 2 | 0 |
| 115T5 | 2 | 0 |

*All methods

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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