TOXOPLASMA IgG EIA

Intended Use: For the qualitative, semi-quantitative or quantitative detection of human IgG antibodies to Toxoplasma gondii in human serum by enzyme immunoassay, as an aid in the determination of infection with Toxoplasma. When used as a qualitative test, Toxoplasma IgG EIA aids in the assessment of the patient's immunological response to toxoplasma. These reagents have not received FDA clearance for use in testing blood or plasma donors.

Summary of Test
1. Prepare 1:51 dilutions of Calibrator(s), Controls and samples in the test set Diluent. Mix well.
2. Place 100 µl of the dilutions in the Coated Wells; reserve one well for the reagent blank.
3. Incubate at room temperature for 30 ± 5 minutes.
4. Drain wells thoroughly. Wash wells 4 times with Wash Solution and drain.
5. Place 2 drops (or 100 µl) of Conjugate in wells.
6. Incubate at room temperature for 30 ± 5 minutes.
7. Drain wells thoroughly. Wash wells 4 times with Wash Solution and drain.
8. Place 2 drops (or 100 µl) of Substrate in wells.
9. Incubate at room temperature for 30 ± 5 minutes.
10. Stop the enzyme reaction with 2 drops (or 100 µl) of Stop Reagent.
11. Read absorbance at 405 nm against reagent blank.

Summary and Explanation of Test
Serologic studies indicate that infection with Toxoplasma gondii, an intracellular parasite and the causative agent of toxoplasmosis, is fairly widespread in the population worldwide. For example, it has been estimated that 30 % of the population in the United States exhibits serological evidence of exposure to Toxoplasma gondii (1). The organism can be transmitted during organ transplantation (2), by blood or leukocyte transfusion (3), contact with contaminated cat feces (4), or by ingestion of raw or undercooked meat from infected animals (5).

In adults the infection is usually asymptomatic, although symptomatic as well as fatal cases do occur. Symptoms range from swollen lymph nodes to those resembling infectious mononucleosis (1). In children, the disease may affect the central nervous system and the viscera. Congenital infection also occurs, and toxoplasmosis is a significant cause of mortality and congenital malformation (6-9).

Specific IgG antibody titers directed against Toxoplasma gondii prior to pregnancy, are correlated with immunity to infection (3). Inasmuch as infection may occur in utero if serologically negative women become infected during pregnancy, it is advisable for pregnant women to be tested for Toxoplasma specific antibodies early during their pregnancy, and serologically negative women should be monitored for toxoplasma IgG antibody during their pregnancy, and at delivery. Serologically positive results should be followed-up by testing for Toxoplasma specific IgM in the newborn. Because less than one percent of newborns are born with maternally transferred IgM, the presence of Toxoplasma specific IgM antibodies is an indication of toxoplasmosis (10).

The results of serologic tests are of value as presumptive evidence of toxoplasmosis. The Toxoplasma IgG EIA test is intended for the detection of IgG antibodies to toxoplasma. Test results are obtained after one and one-half hours incubation time. They are objective and normalized as Index values, or as International Units (IU/mL), which are traceable to the WHO Anti-Toxoplasma Serum, 3rd International Standard Preparation, 1994.

Principle of the Test
Diluted samples are incubated in antigen-coated wells. Toxoplasma antibodies (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme labeled antibodies to human IgG) is added and incubated. If IgG antibodies to toxoplasma are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end product which is read photometrically.

Reagents
Coated Wells Coated with sonicated Toxoplasma gondii antigen, Strain: RH. 12 eight-well strips.
Well Support One.
Diluent* 25 mL (pink color). Phosphate-buffered saline with a protein stabilizer.
Calibrator 1* 0.5 mL. Human serum. Strongly reactive for toxoplasma antibodies. Index and IU/mL values shown on vial label.
Calibrator 2* 0.5 mL. Human serum. Moderately reactive for toxoplasma antibodies. Index and IU/mL values shown on vial label.
Positive Control* 0.5 mL. Human serum. Reactive for toxoplasma antibodies. Index and IU/mL values shown on vial label.
Negative Control* 0.5 mL. Human serum. Non-reactive for toxoplasma antibodies.
Conjugate* 2 x 12 mL (green color). Goat anti-human IgG labeled with alkaline phosphatase (calf).
Substrate 12 mL. p-nitrophenyl phosphate.

Note: The substrate may develop a slight yellow color during storage. One hundred microliters of substrate should yield an absorbance value less than 0.35, when read in a microwell against air or water.

Wash Concentrate* 30 mL. Tris-buffered saline with Tween 20, pH 8.0. Prepare Wash Solution by adding the contents of the Wash Concentrate bottle to 1 liter of distilled or deionized water.
Stop Reagent 12 mL. Trisodium Phosphate 0.5 M.
* Contains 0.1% sodium azide.

Store these reagents according to the instructions on the bottle labels. Do not allow them to contact the skin or eyes. If contact occurs, wash with copious amounts of water.

Other Materials Required
1. Microplate washer
2. Pipettors for dispensing 4, 100 and 200 µl
3. Timer
4. 1 or 2 liter container for Wash Solution
5. Distilled or deionized water
6. Dilution tubes or microwells
7. Microwell reader capable of reading absorbance at 405 nm.
Precautions
1. For in vitro diagnostic use.
2. Test samples, Calibrator(s), Controls and the materials that contact them, should be handled as potential biohazards. The calibrators and controls have been found to be negative for HIV, hepatitis B surface antigen and HCV antibodies by licensed tests. However, because no method can offer complete assurance that HIV, hepatitis B virus, HCV or other infectious agents are absent, these materials should be handled at the Biosafety Level 2 as recommended for any potentially infectious serum or blood specimen in the Centers for Disease Control/National Institutes of Health Manual "Biosafety in Microbiological and Biomedical Laboratories", 1993, or latest edition.
3. The concentrations of anti-toxoplasma in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.
4. Avoid contact with open skin.
5. Never pipet by mouth.
6. Certain of the test reagents contain sodium azide. Azides are reported to react with lead and copper in plumbing to form compounds that may detonate on percussion. When disposing of solutions containing sodium azide, flush drains with large volumes of water to minimize the build-up of metal-azide compounds.
7. Do not interchange reagents from different reagent lots, except for Wash Concentrate, Substrate and Stop Reagent.
8. Incubation times recommended in the Test Procedure section should be adhered to.
9. Unused Coated Wells should be kept in their resealable bag with desiccant, and stored in the refrigerator.

Specimen Collection
Sera should be separated from clotted blood. If specimens are not tested within 8 hours, they should be stored at 2 to 8°C. for up to 48 hours. Beyond 48 hours specimens should be stored at -20°C. or below. Multiple freeze-thaw cycles should be avoided. Samples containing visible particulate matter should be clarified by centrifugation; and hemolyzed, icteric or grossly contaminated samples should not be used. Samples should not be heat-inactivated before testing.

Test Procedure
Allow all reagents and patient samples to reach room temperature before use. Return them promptly to refrigerator after use. The test procedure follows:
1. Prepare 1:51 dilutions of test samples, Calibrator(s), Positive and Negative Controls, in the test set Diluent. For example: add 4 µl of sample to 200 µl of Diluent in a dilution well or tube, and mix well.
2. Place an appropriate number of Coated Wells in the Well Support.
3. The concentrations of anti-toxoplasma in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.
4. Calibrate absorbance and index or IU/mL. For semi-quantitative results, use a calibration curve consisting of two or more calibrators.
5. Place 2 drops (or 100 µl) of Substrate into each well.
6. Place 2 drops (or 100 µl) of Stop Reagent into each well.
7. Place 2 drops (or 100 µl) of Control into each well.
8. Place 2 drops (or 100 µl) of Coated Wells into each well.
9. Place 2 drops (or 100 µl) of Positive Control into each well.
10. Place 2 drops (or 100 µl) of Negative Control into each well.
11. Place 2 drops (or 100 µl) of Diluent into each well.
12. Read and record the absorbance of the contents of each well at 405 nm against the reagent blank. Readings should be made within 2 hours after the reactions have been stopped.

Calculation of Results
Qualitative results may be calculated using a single calibrator. For semi-quantitative results, use a calibration curve consisting of two or more calibrators.

Single Calibrator (Calibrator 2)
Determine the Index value for each test sample (or Control) using the following formula:

\[
\text{Calibrator Index or IU/mL} \times \text{Test Sample Absorbance} = \text{Index or IU/mL}
\]

If the Calibrator is run in duplicate, use the average absorbance value to calculate results.

Calibration Curve
Alternatively, test results may be calculated from a three-point curve comprised of: Calibrator 1 (high-point), Calibrator 2 (mid-point) and the reagent blank (zero / origin), using a point-to-point curve fit. The upper range of the curve may be expanded by adding additional points. For example: the concentration of Calibrator 1 may be increased 1.5-fold, and 2-fold, by adding 6 µl and 8 µl of Calibrator 1 to 200 µl of the test set Diluent, and transferring 100 µl of each dilution to coated wells. The Index, or IU/mL values, assigned to these points, should be 1.5 and 2 times respectively, the value shown on the Calibrator 1 label. The extent to which the upper range of the standard curve may be expanded, will be limited by the calibrator(s) being used.
The Toxoplasma IgG EIA cut-off values were based on statistical analyses, i.e. mean + 3 standard deviations, of 101 serum specimens shown to be negative by another legally marketed device. They were validated in tests of known positive and negative specimens (see Performance Characteristics).

When equivocal results are obtained, another specimen should be obtained two to three weeks later, and tested in parallel with the initial specimen. If the second result is also equivocal, the patient can be considered to have a primary infection. The conversion of an individual patient's serum from negative to positive for toxoplasma IgG antibodies to the infectious agent in question, is defined as seroconversion, and indicates active or recent infection.

To determine a significant difference between acute/convalescent serum pairs, both specimens should be assayed concurrently. Dose response experiments performed at Laboratory C (Miami, FL), have shown that a 90 to 110 percent increase in the Toxoplasma IgG EIA Index value, corresponds to a two-fold increase in the toxoplasma IgG antibody level; and a 180 to 220 percent increase in Toxoplasma IgG EIA Index value, corresponds to a four-fold increase in the toxoplasma IgG antibody level.

Specimens which yield absorbance values above the range of the test set calibrator(s), may be pre-diluted in the test set Diluent and reassayed. The resulting Index value must be multiplied by the dilution factor. Example: If the specimen has been pre-diluted 1:5 before testing, the resulting Index value should be multiplied by 5.

The suggested method for reporting results is: The following results were obtained with the Bio-Rad Toxoplasma IgG EIA test. Values obtained with different manufacturer's assay methods may not be used interchangeably. The magnitude of the reported IgG level cannot be correlated to an endpoint titer. When the assay is used qualitatively, the magnitude of results above the cut-off is not an indicator of total antibody present.

Limitations
The results obtained with the Toxoplasma IgG EIA test serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves. Paired specimens should be collected during the acute and convalescent stages of infection, and tested concurrently to detect significant antibody increases. The semi-quantitative procedure should be used when testing paired sera only. Serum specimens obtained during the acute phase of infection may be negative by serological tests. If the assay is used with cord blood as the specimen source, positive results should be interpreted with caution. The presence of IgG antibodies to toxoplasma in cord blood may be the result of passive transfer of maternal antibody to the fetus. A negative result however, may be helpful in ruling out infection. Performance characteristics have not been determined with neo-natal or cord blood.

The performance characteristics of the Toxoplasma IgG EIA test for any matrix other than serum have not been established.

The results obtained with the Toxoplasma IgG EIA test serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves. Paired specimens should be collected during the acute and convalescent stages of infection, and tested concurrently to detect significant antibody increases. The semi-quantitative procedure should be used when testing paired sera only. Serum specimens obtained during the acute phase of infection may be negative by serological tests. If the assay is used with cord blood as the specimen source, positive results should be interpreted with caution. The presence of IgG antibodies to toxoplasma in cord blood may be the result of passive transfer of maternal antibody to the fetus. A negative result however, may be helpful in ruling out infection. Performance characteristics have not been determined with neo-natal or cord blood.

The performance characteristics of the Toxoplasma IgG EIA test for any matrix other than serum have not been established.

Expected Values
The incidence of toxoplasma IgG antibodies is related to age, socioeconomic condition and geographic location of the test population. In some areas 50 % or more of the population at age 20 years show a positive serological test (12). Serum samples obtained randomly from 143 normal South Florida blood donors were assayed by the Toxoplasma IgG EIA test. Forty-four samples (31 %) were positive for IgG antibodies to toxoplasma, ninety-six (67 %) were negative, and three (2 %) were equivocal. Of the positive samples, fifteen gave Index and IU/mL values greater than 7.5 and 226 respectively. The remaining twenty-nine positive samples yielded Index values between 1.2 and 7.5; and IU/mL values between 37 and 226. The mean Index and IU/mL values were 4 and 119 respectively. The ranges of these values are shown in Table 1.

<table>
<thead>
<tr>
<th>IU/mL Value Ranges</th>
<th>Index Value Ranges</th>
<th>Specimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 30</td>
<td>&lt; 1</td>
<td>97(13)</td>
</tr>
<tr>
<td>≥ 30 to &lt; 50</td>
<td>1 to &lt; 1.67</td>
<td>5(1)</td>
</tr>
<tr>
<td>≥ 50</td>
<td>≥ 1.67</td>
<td>41(3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IU/mL Value Ranges</th>
<th>Index Value Ranges</th>
<th>Specimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 30</td>
<td>&lt; 1</td>
<td>38(1)</td>
</tr>
<tr>
<td>≥ 30 to &lt; 50</td>
<td>1 to &lt; 1.67</td>
<td>3</td>
</tr>
<tr>
<td>≥ 50</td>
<td>≥ 1.67</td>
<td>50</td>
</tr>
</tbody>
</table>

Table 1. Results of tests of 143 Specimens (100% frozen), from Normal South Florida Donors, Performed at Laboratory C (Miami, FL), Using the Toxoplasma IgG EIA Test.

The incidence of toxoplasma IgG antibodies is related to age, socioeconomic condition and geographic location of the test population. In some areas 50 % or more of the population at age 20 years show a positive serological test (12). Serum samples obtained randomly from 143 normal South Florida blood donors were assayed by the Toxoplasma IgG EIA test. Forty-four samples (31 %) were positive for IgG antibodies to toxoplasma, ninety-six (67 %) were negative, and three (2 %) were equivocal. Of the positive samples, fifteen gave Index and IU/mL values greater than 7.5 and 226 respectively. The remaining twenty-nine positive samples yielded Index values between 1.2 and 7.5; and IU/mL values between 37 and 226. The mean Index and IU/mL values were 4 and 119 respectively. The ranges of these values are shown in Table 1.

Table 2. Results of tests of 91 Specimens, from Women of Childbearing Age (18-45), Performed at Laboratory A (Atlanta, GA), Laboratory B (Miami, FL) and at Laboratory C (Miami, FL), Using the Toxoplasma IgG EIA Test.
Performance Characteristics

Comparative Testing
Toxoplasma IgG EIA test results correlated very well with results of other serological tests. Sera from normal blood donors were assayed for the presence of toxoplasma IgG antibodies, using the Toxoplasma IgG EIA test and three other commercial tests, at two independent laboratories (Lab A, Atlanta, GA, and Lab B, Miami, FL) and at Laboratory C (Miami, FL). These results are shown below in Tables 3, 4 and 5, respectively.

Table 3. Results of Tests of 150 Specimens (54% frozen and 46% fresh), from North and South Carolina, Alabama, Georgia and Florida, Performed at Laboratory A (Atlanta, GA), Using the Toxoplasma IgG EIA Test and Another Commercial Test.

<table>
<thead>
<tr>
<th>Comparative</th>
<th>Toxoplasma IgG EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test #1</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>111 (29)</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
</tr>
<tr>
<td>**</td>
<td></td>
</tr>
</tbody>
</table>

- Relative sensitivity = 97.4 to 100
- Relative specificity = 86.2 to 100
- Overall Agreement = 95.6 to 100
- ** Calculated by the Normal Method (13).

( ) Number of female donors of childbearing age.

Table 4. Results of tests of 153 Specimens (77% frozen and 33% fresh), from South Florida, Performed at Laboratory B (Miami, FL), Using the Toxoplasma IgG EIA Test and Another Commercial Test.

<table>
<thead>
<tr>
<th>Comparative</th>
<th>Toxoplasma IgG EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test #2</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>83 (20)</td>
</tr>
<tr>
<td>Equivocal</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
</tr>
<tr>
<td>**</td>
<td></td>
</tr>
</tbody>
</table>

- Relative sensitivity = 94.4 to 100
- Relative specificity = 95.5 to 100
- Overall Agreement = 96.8 to 100
- ** Calculated by the Normal Method (13).

{ } Number of female donors of childbearing age.

Table 5. Results of tests of 143 Specimens (100% frozen), from South Florida, Performed at Laboratory C (Miami, FL), Using the Toxoplasma IgG EIA Test and Another Commercial Test.

<table>
<thead>
<tr>
<th>Comparative</th>
<th>Toxoplasma IgG EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test #1</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>41 (3)</td>
</tr>
<tr>
<td>Equivocal</td>
<td>1</td>
</tr>
<tr>
<td>Negative</td>
<td>3 (1)</td>
</tr>
<tr>
<td>**</td>
<td></td>
</tr>
</tbody>
</table>

- Relative sensitivity = 93.0 to 100
- Relative specificity = 93.6 to 100
- Overall Agreement = 95.5 to 100
- ** Calculated by the Normal Method (13).

( ) Number of female donors of childbearing age.

The recovery of the WHO Anti-Toxoplasma Serum, using the Toxoplasma IgG EIA test, with the Toxoplasma IgG EIA secondary standard, is plotted below in Figure 1.

Figure 1. Recovery of the WHO Anti-Toxoplasma Serum, 3rd International Standard Preparation, Using the Toxoplasma IgG EIA Test.

\[
y = 0.920x + 3.264 \quad r = 1.000
\]

95% CI: Slope = 0.791 to 1.013
y Intercept = -4.098 to 10.626

FOR REFERENCE USE ONLY: DO NOT USE in place of package inserts provided with each test kit.
Several strongly positive serum specimens were serially diluted (two-fold) in triplicate, and assayed by the Toxoplasma IgG EIA test. Typical results are shown in Figure 2.

Figure 2. Titration Curve for a Strongly Positive Specimen.

The triplicate data for each dilution are shown as points, the 95% confidence limits for each set of triplicate data are indicated by (x’s), and the 95% confidence limits for the slopes and y-intercepts are represented by straight lines. The formula for the linear regression for the triplicate data is shown in Figure 2.

Specificity
The Toxoplasma IgG EIA does not cross-react with IgG antibodies directed against the herpes viruses, which have been reported to cause heterotypic antibody responses. Of forty-five specimens which were unreactive in the Toxoplasma IgG EIA test, 19 were shown to contain moderate to high levels of antibody directed against cytomegalovirus, 24 against varicella zoster virus, 7 against Epstein-Barr virus, and 23 against herpes simplex virus types 1 & 2.

Precision
Eight serum specimens (2 negative and 6 positive) and the Toxoplasma IgG EIA positive and negative controls, were assayed in triplicate, on three separate occasions. The precision experiments were performed manually at two independent laboratories (Lab A and Lab B), and at Laboratory C. These results are shown below in Tables 6, 7 and 8 respectively.

Table 6. Results Intra-assay and Interassay Precision Tests Performed at Lab A. Values were calculated from Toxoplasma IgG EIA Index & IU/mL values.

<table>
<thead>
<tr>
<th>SAMPLE</th>
<th>INTRA-ASSAY</th>
<th></th>
<th></th>
<th>INTERASSAY</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN S.D C.V. %</td>
<td>MEAN S.D C.V. %</td>
<td>MEAN S.D C.V. %</td>
<td>MEAN S.D C.V. %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>INDEX IU/mL</td>
<td></td>
<td>INDEX IU/mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pos. Control</td>
<td>2.4 0.100 4.2</td>
<td>11.6</td>
<td>56.2</td>
<td>6.6</td>
<td>11.7</td>
<td>1.9</td>
<td>0.140</td>
<td>7.3</td>
<td>57.4</td>
</tr>
<tr>
<td>Neg. Control</td>
<td>0.6 0.000 NA</td>
<td>18.2</td>
<td>0.2</td>
<td>0.6</td>
<td>0.050 NA</td>
<td>17.2</td>
<td>1.2</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.7 0.058 NA</td>
<td>20.0</td>
<td>1.1</td>
<td>0.6</td>
<td>0.071 NA</td>
<td>19.0</td>
<td>1.6</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.8 0.000 NA</td>
<td>23.3</td>
<td>1.2</td>
<td>0.7</td>
<td>0.078 NA</td>
<td>21.3</td>
<td>1.8</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>2.8 0.289 10.2</td>
<td>85.0</td>
<td>7.4</td>
<td>8.7</td>
<td>2.6</td>
<td>0.397 15.0</td>
<td>79.4</td>
<td>11.3</td>
<td>14.3</td>
</tr>
<tr>
<td>4</td>
<td>2.4 0.153 6.5</td>
<td>70.5</td>
<td>5.3</td>
<td>7.5</td>
<td>2.2</td>
<td>0.224 10.3</td>
<td>65.0</td>
<td>6.4</td>
<td>9.8</td>
</tr>
<tr>
<td>5</td>
<td>5.0 0.600 12.0</td>
<td>151.0</td>
<td>18.0</td>
<td>11.9</td>
<td>5.0</td>
<td>0.546 11.0</td>
<td>149.8</td>
<td>16.3</td>
<td>10.9</td>
</tr>
<tr>
<td>6</td>
<td>3.4 0.586 17.1</td>
<td>102.6</td>
<td>17.8</td>
<td>17.4</td>
<td>3.2</td>
<td>0.557 17.2</td>
<td>96.7</td>
<td>17.2</td>
<td>17.8</td>
</tr>
<tr>
<td>7</td>
<td>2.0 0.058 2.8</td>
<td>61.2</td>
<td>3.0</td>
<td>4.9</td>
<td>2.2</td>
<td>0.219 10.1</td>
<td>65.1</td>
<td>7.0</td>
<td>10.7</td>
</tr>
<tr>
<td>8</td>
<td>2.1 0.100 4.8</td>
<td>62.6</td>
<td>2.6</td>
<td>4.1</td>
<td>2.5</td>
<td>0.450 17.8</td>
<td>75.9</td>
<td>13.4</td>
<td>17.6</td>
</tr>
</tbody>
</table>

Table 7. Results Intra-assay and Interassay Precision Tests Performed at Lab B. Values were calculated from Toxoplasma IgG EIA Index & IU/mL values.

<table>
<thead>
<tr>
<th>SAMPLE</th>
<th>INTRA-ASSAY</th>
<th></th>
<th></th>
<th>INTERASSAY</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN S.D C.V. %</td>
<td>MEAN S.D C.V. %</td>
<td>MEAN S.D C.V. %</td>
<td>MEAN S.D C.V. %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>INDEX IU/mL</td>
<td></td>
<td>INDEX IU/mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pos. Control</td>
<td>1.9 0.217 11.6</td>
<td>56.2</td>
<td>6.6</td>
<td>11.7</td>
<td>1.9</td>
<td>0.140 7.3</td>
<td>57.4</td>
<td>4.2</td>
<td>7.3</td>
</tr>
<tr>
<td>Neg. Control</td>
<td>0.2 0.017 NA</td>
<td>4.8</td>
<td>0.4</td>
<td>0.2</td>
<td>0.023 NA</td>
<td>5.1</td>
<td>0.7</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.3 0.042 NA</td>
<td>8.0</td>
<td>1.2</td>
<td>0.3</td>
<td>0.048 NA</td>
<td>8.7</td>
<td>1.3</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.3 0.036 NA</td>
<td>9.3</td>
<td>1.1</td>
<td>0.3</td>
<td>0.042 NA</td>
<td>10.0</td>
<td>1.4</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>2.4 0.089 3.7</td>
<td>71.5</td>
<td>2.5</td>
<td>3.6</td>
<td>2.5</td>
<td>0.123 5.0</td>
<td>73.7</td>
<td>3.6</td>
<td>4.9</td>
</tr>
<tr>
<td>4</td>
<td>1.8 0.046 2.6</td>
<td>53.4</td>
<td>1.3</td>
<td>2.5</td>
<td>2.0</td>
<td>0.220 11.1</td>
<td>59.4</td>
<td>6.6</td>
<td>11.1</td>
</tr>
<tr>
<td>5</td>
<td>5.2 0.268 5.2</td>
<td>154.9</td>
<td>7.9</td>
<td>5.1</td>
<td>5.4</td>
<td>0.356 6.7</td>
<td>160.6</td>
<td>10.7</td>
<td>6.6</td>
</tr>
<tr>
<td>6</td>
<td>3.1 0.087 2.8</td>
<td>93.1</td>
<td>2.6</td>
<td>2.8</td>
<td>3.2</td>
<td>0.128 4.0</td>
<td>97.5</td>
<td>3.8</td>
<td>3.9</td>
</tr>
<tr>
<td>7</td>
<td>2.2 0.120 5.5</td>
<td>65.1</td>
<td>3.6</td>
<td>5.5</td>
<td>2.3</td>
<td>0.191 6.5</td>
<td>68.0</td>
<td>5.7</td>
<td>8.4</td>
</tr>
<tr>
<td>8</td>
<td>2.5 0.171 6.8</td>
<td>75.4</td>
<td>5.2</td>
<td>6.9</td>
<td>2.4</td>
<td>0.211 8.8</td>
<td>72.0</td>
<td>6.3</td>
<td>8.8</td>
</tr>
</tbody>
</table>
Table 8. Results Intra-assay and Interassay Precision Tests Performed at Lab C. Values were calculated from Toxoplasma IgG EIA Index & IU/mL values.

<table>
<thead>
<tr>
<th>SAMPLE</th>
<th>INTRA-ASSAY</th>
<th></th>
<th></th>
<th>INTERASSAY</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN INDEX</td>
<td>S.D</td>
<td>C.V. %</td>
<td>MEAN INDEX</td>
<td>S.D</td>
<td>C.V. %</td>
</tr>
<tr>
<td>Pos. Control</td>
<td></td>
<td>2.0</td>
<td>0.058</td>
<td>60.0</td>
<td>1.4</td>
<td>2.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.6</td>
<td>0.158</td>
<td>8.0</td>
<td>2.4</td>
<td>2.9</td>
</tr>
<tr>
<td>Neg. Control</td>
<td></td>
<td>0.2</td>
<td>0.115</td>
<td>5.7</td>
<td>2.4</td>
<td>2.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.2</td>
<td>0.078</td>
<td>3.4</td>
<td>2.8</td>
<td>2.5</td>
</tr>
</tbody>
</table>

References

Distributed by:
Bio-Rad Laboratories
6565 185th Avenue NE
Redmond, WA 98052
For Customer Orders Call : 1-800-2-BIORAD 503925B
For Technical Service Call : 1-800-2-BIORAD (1-800 224-6723) November 2004