Subject/Title: **ASI TOXOPLASMA IgG EIA TEST**		Doc#: 810096AG
Effective Date: 01/26/18	Supersedes Revision/Date: 02/18/16 **(1)**	Revision: 01/26/18 **(2)**
Prepared by: ASI	QA Approval by:	Copy/Dept.:

FOR IN VITRO DIAGNOSTIC USE

1.0 INTENDED USE:

1.1 For the qualitative, semiquantitative 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

2.0 SUMMARY AND EXPLANATION

2.1 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].

2.2 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].

2.3 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].

2.4 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.

3.0 PRINCIPLE OF PROCEDURE:

3.1 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.

4.0 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*	0.3 ml. Human serum. Strongly reactive for toxoplasma antibodies. Index and IU/ml values shown on vial label.
Calibrator 2*	0.3 ml. Human serum. Moderately reactive for toxoplasma antibodies. Index and IU/ml values shown on vial label.
Positive Control*	0.3 ml. Human serum. Reactive for toxoplasma antibodies. Index and IU/ml values shown on vial label.
Negative Control*	0.3 ml. Human serum. Nonreactive for toxoplasma antibodies.
Conjugate	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.

5.0 WARNINGS AND PRECAUTIONS

5.1 For *in vitro* diagnostic use.

5.2 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,

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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.

5.3 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.
5.4 Avoid contact with open skin.
5.5 Never pipet by mouth.
5.6 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.
5.7 R 21/22: Harmful in contact with skin and if swallowed.
5.8 S24/25 - 36/37/39: Avoid contact with skin and eyes. Wear suitable protective clothing, gloves and eye/face protection. For further information, refer to product SDS.
5.9 Do not interchange reagents from different reagent lots, except for Diluent, Wash Concentrate, Substrate and Stop Reagent.
5.10 Do not use reagents beyond their stated expiration date.
5.11 Incubation times recommended in the Test Procedure section should be adhered to.
5.12 Unused Coated Wells should be kept in their resealable bag with desiccant, and stored in the refrigerator.
5.13 Do not smoke, eat, drink, or apply cosmetics in areas where plasma/serum samples are handled.

6.0 HANDLING AND PROCEDURAL NOTES

6.1 In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples.
6.2 Do not use past the expiration date indicated on the kit.

7.0 STORAGE INSTRUCTIONS

7.1 Store all reagents at 2 to 8° C in an upright position when not in use. Do not freeze reagents.

8.0 INDICATIONS OF DETERIORATION

8.1 Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.
8.2 Bacterial contamination of reagents or specimens may cause false positive results.

9.0 SPECIMEN COLLECTION AND STORAGE

9.1 Sera should be separated from clotted blood.
9.2 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.
9.3 Multiple freeze-thaw cycles should be avoided.
9.4 Samples containing visible particulate matter should be clarified by centrifugation; and hemolyzed, icteric, and grossly contaminated samples should not be used.
9.5 Samples should not be heat-inactivated before testing.

10.0 PERFORMANCE OF TEST

10.1 Materials Provided:

	96 Tests		
Coated Wells	12 eight-well strips	Positive Control	0.3 ml
Well Support	1	Negative Control	0.3 ml
Diluent	25 ml	Conjugate	12 ml
Calibrator 1	0.3 ml	Substrate	12 ml
Calibrator 2	0.3 ml	Stop Reagent	12 ml
Wash Concentrate	30 ml		

10.2 Additional Materials Required:

10.2.1 Microplate washer
10.2.2 Pipettors for dispensing 4, 100 and 200 µl
10.2.3 Timer
10.2.4 1 or 2 liter container for Wash Solution
10.2.5 Distilled or deionized water
10.2.6 Dilution tubes or microwells
10.2.7 Microwell reader capable of reading absorbance at 405 nm.

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11.0 TEST PROCEDURE

11.1 Preparation for the Assay

11.1.1 Allow all reagents and patient samples to reach room temperature before use. Return them promptly to refrigerator after use. The test procedure follows:

11.1.2 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 200µl of Diluent in a dilution well or tube, and mix well.
***Note**: For qualitative assays, Calibrator 2 may be used; for semi-quantitative and quantitative assays, use Calibrator 1 and Calibrator 2.*

12.0 ASSAY PROTOCOL

12.1 Place an appropriate number of Coated Wells in the Well Support.
***Note:** For combination testing (multiple assays per plate), the strips should be assembled on a white background with good lighting. Be sure to note the placement of each strip.*

12.2 Transfer 100 µl of each diluted Calibrator, Control and patient sample to the wells.
***Note:** Include one well which contains 100 µl of Diluent only. This will serve as the reagent blank and will be ultimately used to zero the photometer before reading the test results.*

12.3 Incubate the wells at room temperature (20 to 25^{o} C.) for 30 ± 5 minutes.

12.4 Wash wells four times with at least 250 µL/well/wash. Do not allow the wells to soak between washes. Drain thoroughly after the last wash.

12.5 Place 2 drops (or 100 µl) of Conjugate into each well.

12.6 Incubate the wells at room temperature for 30 ± 5 minutes.

12.7 Wash wells four times with at least 250 µL/well/wash. Do not allow the wells to soak between washes. Drain thoroughly after the last wash.

12.8 Place 2 drops (or 100 µl) of Substrate into each well.

12.9 Incubate at room temperature for 30 ± 5 minutes.

12.10 Place 2 drops (or 100 µl) of Stop Reagent into each well.

12.11 Read and record the absorbance of the contents of each well at 405 nm against the reagent blank.
***Note:** Adjust the photometer to zero absorbance at 405 nm against the reagent blank. Readings should be made within 2 hours after the reactions have been stopped.*

13.0 QUALITY CONTROL

13.1 Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls and calibrator(s) must be included. If they do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the kit and contact ASI Technical Support at 800-654-0146.

14.0 INTERPRETATION OF RESULTS

14.1 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:

$$\frac{\text{Calibrator Index or IU/ml}}{\text{Calibrator Absorbance}} \times \text{Test Sample Absorbance} = \text{Test Sample Index or IU/ml}$$

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

14.2 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.

14.3 Test Validation Criteria

14.3.1 The Calibrator(s), Positive and Negative Controls must be included in each test run.

14.3.2 The absorbance values of Calibrator 1 and Calibrator 2, must be at least 0.7 and 0.3 respectively, when read against the reagent blank.

14.3.3 The absorbance value of the reagent blank should be less than 0.35.

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14.3.4 The Negative Control must have an Index value less than 0.9, or an IU/ml value less than 27.

14.3.5 The Positive Control must have an Index value, or an IU/ml value, within the range printed on the label. When performing qualitative tests, users may supply an alternative Positive Control if they wish.

14.3.6 To validate the upper range of the assay when performing the semi-quantitative and quantitative procedures, the Positive Control should be run at higher concentrations. For example, the Positive Control should be assayed at 1.5-fold and 2-fold concentrations by adding 6 µl and 8 µl of the Positive Control, to 200 µl aliquots of the test set Diluent, and transferring 100 µl of each of these dilutions to coated wells. The expected value ranges for these concentrated controls would be 1.5 times and 2 times respectively, the expected value ranges printed on the Positive Control label. If the control values do not fall within the specified ranges, the assay is invalid and should be repeated. Optionally, users may supply alternative positive controls if they wish. If any of these criteria are not met, the test is invalid and should be repeated.

14.4 Interpretation of Results

Index Value	IU / ml	Interpretation
< 0.9	< 27	Negative
≥ 0.9 < 1.1	≥ 27 < 33	Equivocal
≥ 1.1	≥ 33	Positive

14.4.1 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 specimen is also equivocal, the patient is negative for primary or recent infection, and equivocal for antibody status. If the second sample is positive, the patient can be considered to have a primary infection. The conversion of an individual patient's serum from negative to positive for antibodies to the infectious agent in question, is defined as seroconversion, and indicates active or recent infection.

14.4.2 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.

14.4.3 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.

15.0 LIMITATIONS OF THE PROCEDURE

15.1 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.

15.2 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 neonatal or cord blood.

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

15.4 Titration experiments (please see Figure 2) have shown that the upper limit of linearity for Toxoplasma IgG EIA IU/ml values is approximately 250.

16.0 EXPECTED VALUES

16.1 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].

16.2 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 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.

IU/ml Value Ranges	Index Value Ranges	Specimens	
< 30	< 1	97 {13}	67.8%
≥ 30 to< 50	≥ 1 to < 1.67	5 {1}	3.5%
≥ 50	≥ 1.67	41 {3}	28.7%

{ } Number of female donors of childbearing age.

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16.3 Ninety-one women of childbearing age (18 to 45 years) were identified in the clinical studies. They ranged in age from 19 to 45, with a mean age of 32. Of these, 53 (58.2 %) were positive, 2 (2.2 %) were equivocal, and 36 (39.6 %) were negative, when tested by the Toxoplasma IgG EIA test. The ranges of values obtained for these women are shown in Table 2.

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.

IU/ml Value Ranges	Index Value Ranges	Specimens	
< 30	< 1	38	41.8 %
≥ 30 to < 50	≥ 1 to < 1.67	3	3.3 %
≥ 50	≥ 1.67	50	54.9 %

17.0 PERFORMANCE CHARACTERISTICS

17.1 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.

Comparative	Toxoplasma IgG EIA				
Test #1	Positive	Equivocal	Negative		95%CI**
Positive	111 {29}	0	1	Relative sensitivity*	97.4 to 100
Negative	2	4 {2}	32 {7}	Relative specificity*	86.2 to 100
				Overall Agreement*	95.6 to 100

* Excluding equivocal results

** 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.

Comparative	Toxoplasma IgG EIA				
Test #2	Positive	Equivocal	Negative		95%CI**
Positive	83 {20}	1	2	Relative sensitivity*	94.4 to 100
Equivocal	0	0	2		
Negative	0	0	65 {16}	Relative specificity*	95.5 to 100
				Overall Agreement*	96.8 to 100

* Excluding equivocal results

** 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.

Comparative	Toxoplasma IgG EIA				
Test #1	Positive	Equivocal	Negative		95%CI**
Positive	41 {3}	0	0	Relative sensitivity	93.0 to 100
Equivocal	1	0	0		
Negative	3 {1}	2	96 {13}	Relative specificity*	93.6 to 100
				Overall Agreement*	95.5 to 100

* Excluding equivocal results

** Calculated by the Normal Method[13].

{ } Number of female donors of childbearing age..

17.2 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.

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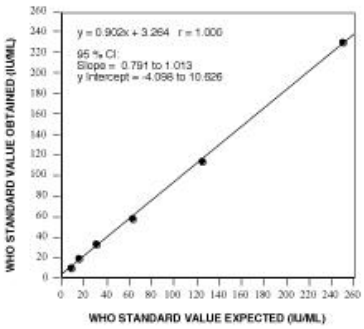
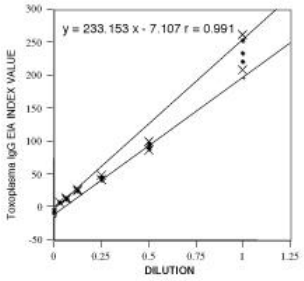
Figure 1. Recovery of the WHO Anti-Toxoplasma Serum, 3rd International Standard Preparation, Using the Toxoplasma IgG EIA Test.



17.3 Titration curve

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.

17.4 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.

17.5 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.

SAMPLE	INTRA-ASSAY						INTERASSAY					
	INDEX			IU/ml			INDEX			IU/ml		
	MEAN	S.D.	C.V. %	MEAN	S.D.	C.V. %	MEAN	S.D.	C.V. %	MEAN	S.D.	C.V. %
Pos. Control	2.4	0.100	4.2	71.5	2.6	3.6	2.3	0.190	8.2	68.8	5.6	8.2
Neg. Control	0.6	0.000	NA	18.2	0.2	NA	0.6	0.050	NA	17.2	1.2	NA
1	0.7	0.058	NA	20.0	1.1	NA	0.6	0.071	NA	19.0	1.6	NA
2	0.8	0.000	NA	23.3	1.2	NA	0.7	0.078	NA	21.3	1.8	NA
3	2.8	0.289	10.2	85.0	7.4	8.7	2.6	0.397	15.0	79.4	11.3	14.3
4	2.4	0.153	6.5	70.5	5.3	7.5	2.2	0.224	10.3	65.0	6.4	9.8
5	5.0	0.600	12.0	151.0	18.0	11.9	5.0	0.546	11.0	149.8	16.3	10.9
6	3.4	0.586	17.1	102.6	17.8	17.4	3.2	0.557	17.2	96.7	17.2	17.8
7	2.0	0.058	2.8	61.2	3.0	4.9	2.2	0.219	10.1	65.1	7.0	10.7
8	2.1	0.100	4.8	62.8	2.6	4.1	2.5	0.450	17.8	75.9	13.4	17.6

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

	INTRA-ASSAY						INTERASSAY					
SAMPLE	INDEX			IU/ml			INDEX			IU/ml		
	MEAN	S.D.	C.V. %	MEAN	S.D.	C.V. %	MEAN	S.D.	C.V.%	MEAN	S.D.	C.V. %
Pos. Control	1.9	0.217	11.6	56.2	6.6	11.7	1.9	0.140	7.3	57.4	4.2	7.3
Neg. Control	0.2	0.017	NA	4.8	0.4	NA	0.2	0.023	NA	5.1	0.7	NA
1	0.3	0.042	NA	8.0	1.2	NA	0.3	0.048	NA	8.7	1.3	NA
2	0.3	0.036	NA	9.3	1.1	NA	0.3	0.042	NA	10.0	1.4	NA
3	2.4	0.089	3.7	71.5	2.5	3.6	2.5	0.123	5.0	73.7	3.6	4.9
4	1.8	0.046	2.6	53.4	1.3	2.5	2.0	0.220	11.1	59.4	6.6	11.1
5	5.2	0.268	5.2	154.9	7.9	5.1	5.4	0.356	6.7	160.6	10.7	6.6
6	3.1	0.087	2.8	93.1	2.6	2.8	3.2	0.128	4.0	97.5	3.8	3.9
7	2.2	0.120	5.5	65.1	3.6	5.5	2.3	0.191	8.5	68.0	5.7	8.4
8	2.5	0.171	6.8	75.4	5.2	6.9	2.4	0.211	8.8	72.0	6.3	8.8

Table 8. Results Intra-assay and Interassay Precision Tests Performed at Lab C. Values were calculated from Toxoplasma IgG EIA Index & IU/ml values.

	INTRA-ASSAY						INTERASSAY					
SAMPLE	INDEX			IU/ml			INDEX			IU/ml		
	MEAN	S.D.	C.V. %	MEAN	S.D.	C.V.%	MEAN	S.D.	C.V.%	MEAN	S.D.	C.V.%
Pos. Control	2.0	0.058	2.8	60.0	0.9	1.4	2.2	0.058	2.6	58.6	2.7	4.6
Neg. Control	0.2	0.000	NA	6.1	0.4	NA	0.2	0.000	NA	5.7	0.0	NA
1	0.3	0.000	NA	9.7	0.0	NA	0.3	0.033	NA	9.1	0.6	NA
2	0.4	0.058	NA	10.3	0.5	NA	0.3	0.044	NA	9.6	0.7	NA
3	2.4	0.115	4.7	72.1	3.6	5.0	2.3	0.183	8.0	67.8	5.2	7.6
4	1.9	0.200	10.5	56.3	5.9	10.5	1.8	0.206	11.5	53.9	5.7	10.5
5	5.1	0.586	11.6	150.8	18.2	12.1	4.8	0.412	8.6	143.1	12.6	8.8
6	3.0	0.058	1.9	88.3	2.4	2.7	2.8	0.158	5.6	84.0	5.1	6.1
7	2.1	0.100	4.8	62.9	2.9	4.5	2.0	0.176	8.8	59.9	4.6	7.8
8	2.2	0.058	2.6	67.2	0.8	1.1	2.3	0.078	3.4	68.7	2.4	3.5

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