

K 955760

Enclosure 2

AUG - 2 1996

SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE TECHNICON TOXOPLASMA IgG METHOD FOR THE IMMUNO 1[®] SYSTEM

Listed below are comparisons of the performance between the IMMUNO 1[®] Toxoplasma IgG method (Attachment 1) and a similar device that was granted FDA determination of substantial equivalence: the Abbott IMx Toxoplasma IgG assay (Attachment 2). The comparative data with the Abbott IMx assay was collected at two outside clinical trial sites: University of Texas Medical Branch, Laboratory Medical Clinical Chemistry, Galveston, Texas and San Francisco General Hospital Clinical Laboratories, San Francisco, California. Two lots of IMMUNO 1[®] Toxoplasma IgG reagents were evaluated at each clinical site. IFA discrepant sample testing was done by BBI - North American Clinical Laboratories in New Britain, CT using Gull Laboratories Toxo IgG Indirect Fluorescent Antibody Test (Attachment 3). Discrepant samples for IFA testing were shipped directly to BBI from the clinical site.

INTENDED USE

This *in vitro* diagnostic method is intended to quantitatively and qualitatively measure Toxoplasma IgG in human serum on the *Technicon Immuno 1[®]* System. Measurements of Toxoplasma IgG are designed to aid in the determination of serological status by detecting IgG class antibodies to *Toxoplasma gondii* in human sera. The Technicon Immuno 1 Toxoplasma IgG method is not intended for use in screening blood or plasma donors. The method is intended for *in vitro* diagnostic use only on the Technicon IMMUNO 1[®] system.

CHARACTERISTICS

The Technicon IMMUNO 1[®] Toxoplasma IgG is calibrated with six calibrators having values of 0, 10, 20, 50, 100, 300 IU/mL and traceable to the WHO anti-Toxoplasma Serum International Standard (TOXS-60) described in Attachment 5. Agreement between Toxoplasma IgG SETpoint Calibrators and the WHO TOXS-60 Standard is shown in Figure 1.

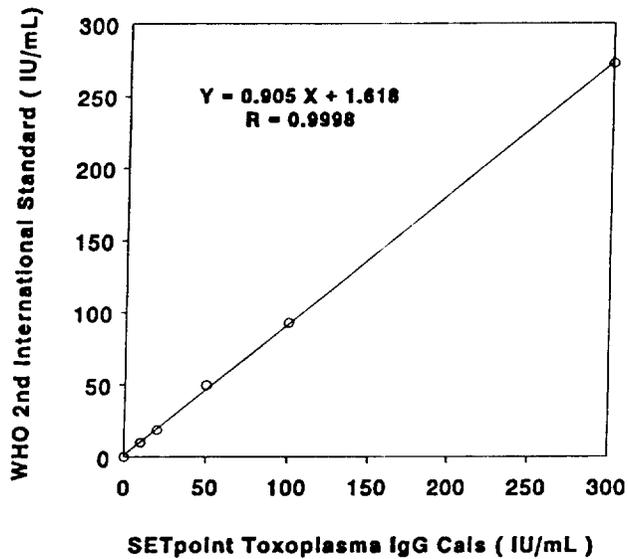


Figure 1. Correlation between WHO Second International Toxoplasma Standard Preparation and Immuno 1 Toxoplasma IgG method calibrated with the Technicon SETpoint Toxoplasma IgG Calibrators.

Linear regression analysis yielded the following results:

$Y = 0.905 X + 1.618$ $R^2 = 0.9998$ $95\% \text{ CL intercept} = \pm 2.44$ $95\% \text{ CL slope} = \pm 0.019$

METHOD COMPARISONS

Comparative results to the Abbott IMx were collected from two clinical trial sites each using two lots of Immuno 1 Toxoplasma IgG reagents. The clinical trial protocol and report are available in attachments contained in the 510(k). Resolution of discrepant results was done by IFA analysis using exclusion.

Samples with Immuno 1 values <12 IU/mL are considered negative for the presence of toxoplasma IgG antibodies. Samples with Immuno 1 values ≥ 12 IU/mL are considered positive for the presence IgG antibodies to toxoplasma gondii. The IMx Toxoplasma IgG method uses 6 IU/mL as the cut-off.

Clinical Sample Characterization

The distribution of Immuno 1 Toxoplasma IgG results within two populations consisting of 223 prenatal specimens submitted for routine Toxoplasma IgG testing at clinical site 1 and 225 specimens selected at random from routine laboratory specimens at clinical site 2 is shown in Table 1. A seronegative rate of 78% and 79.1 is observed at site 1 and site 2, respectively. These results are consistent with a seronegativity rate of 30% to 80% in the US population, Anderson SE and Remington JS: The diagnosis of toxoplasmosis. *Southern Med Jour* 68:1433-1443 (1975).

TABLE 1: DISTRIBUTION OF SERUM TECHNICON IMMUNO 1 TOXOPLASMA IgG VALUES IN PRENATAL AND HOSPITAL SPECIMENS

TECHNICON IMMUNO 1 TOXOPLASMA IgG (IU/mL)	PRENATAL SPECIMENS CLINICAL SITE 1		HOSPITAL SPECIMENS CLINICAL SITE 2	
	NO. OF SPECIMENS	% OF TOTAL	NO. OF SPECIMENS	% OF TOTAL
< 3	129	57.8	69	30.7
3 - 6	25	11.2	74	32.9
6 - 9	12	5.4	25	11.1
9 - 12	8	3.6	10	4.4
12 - 20	3	1.3	7	3.1
20 - 50	10	4.5	10	4.4
50 - 100	20	9.0	8	3.6
100 - 200	8	3.6	12	5.3
200 - 300	5	2.2	4	1.8
> 300	3	1.3	6	2.7
TOTAL	223	100	225	100

In addition to the site supplied specimens, each site augmented their study with an additional 75 supplemental serum specimens unique to each site. The supplemental specimens were masked having both negative and positive samples and were supplied frozen. The additional samples were necessary in order to raise the number of positive specimens analyzed at each site.

Of the 298 sera analyzed at clinical site 1, 110 had been frozen prior to analysis. Similarly, 117 out of the 300 sera analyzed at clinical site 2 had been frozen prior to analysis. The unfrozen specimens were fresh or had been stored at 2°C to 8°C for less than 1 week after collection.

Sensitivity, Specificity and Overall Agreement

Sensitivity and specificity results are presented in Table 2 relative to the Abbott IMx Toxoplasma IgG method. Single replicate results for both the Immuno 1 and Abbott IMx assay were collected for comparison at the clinical sites. Discrepant samples at clinical site 2 were subsequently tested twice on both instruments and classified as either positive or negative based on two out of three results. Additional masked samples from Boston Biomedica Inc. were supplied to both clinical trial sites (see Clinical Trial Protocol and Report for additional information) in order to increase the number of Toxoplasma IgG positives.

Table 2. Immuno 1 Toxoplasma IgG Sensitivity and Specificity relative to the Abbott IMx Toxoplasma IgG assay. Site 1 is the University of Texas Medical Branch in Galveston and Site 2 is San Francisco General Hospital. The cut-off for the Immuno 1 and IMx Toxoplasma IgG assays is 12 IU/mL and 6 IU/mL, respectively. Resolution by IFA excludes a discrepant result if agreement between IFA and Immuno 1 is found. The 95% confidence limits for sensitivity, specificity and overall agreement are calculated using exact binomial percentiles according to Blyth, C.R. , Approximate Binomial Confidence Limits, *J Amer. Stat. Assoc.*, **81**:843-855 (1986).

Site 1 University of Texas Medical Branch

Immuno 1 Rgts & Sample Description	Number of Results by IMx Classification	No. of Immuno 1 Results in Agreement with IMx Classification	Sensitivity, Specificity or Overall Agreement (%)	95% Confidence Limits (%)
Immuno 1 Lot 1 Rgts				
<u>Site 1 Supplied</u>				
<i>Sensitivity</i>	49	45	91.8	80.4 - 97.7
<i>Specificity</i>	174	170	97.7	94.2 - 99.4
<i>Overall Agreement</i>	223	215	96.4	93.1 - 98.4
<u>Supplemental Samples</u>				
<i>Sensitivity</i>	55	54	98.2	90.3 - 100
<i>Specificity</i>	20	18	90.0	68.3 - 98.8
<i>Overall Agreement</i>	75	72	96.0	88.8 - 99.2
<u>Combined</u>				
<i>Sensitivity</i>	104	99	95.2	89.1 - 98.4
<i>Specificity</i>	194	188	96.9	93.4 - 98.9
<i>Overall Agreement</i>	298	287	96.3	93.5 - 98.1
Immuno 1 Lot 2 Rgts				
<u>Site 1 Supplied</u>				
<i>Sensitivity</i>	49	46	93.9	83.1 - 98.7
<i>Specificity</i>	174	169	97.1	93.4 - 99.1
<i>Overall Agreement</i>	223	215	96.4	93.1 - 98.4
<u>Supplemental Samples</u>				
<i>Sensitivity</i>	55	53	96.4	87.5 - 99.6
<i>Specificity</i>	20	18	90.0	68.3 - 98.8
<i>Overall Agreement</i>	75	71	94.7	86.9 - 98.5
<u>Combined</u>				
<i>Sensitivity</i>	104	99	95.2	89.1 - 98.4
<i>Specificity</i>	194	187	96.4	92.7 - 98.5
<i>Overall Agreement</i>	298	286	96.0	93.1 - 97.9

Site 1 University of Texas Medical Branch - IFA Resolved

Immuno 1 Rgts & Sample Description	Number of Resolved Results	No. of Immuno 1 Results in Agreement with Resolved Results	Sensitivity, Specificity or Overall Agreement (%)	95% Confidence Limits (%)
Immuno 1 Lot 1 Rgts				
<u>Site 1 Supplied</u>				
Sensitivity	49	45	91.8	80.4 - 97.7
Specificity	172	170	98.8	95.9 - 99.9
Overall Agreement	221	215	97.3	94.2 - 99.0
<u>Supplemental Samples</u>				
Sensitivity	54	54	100	93.4 - 100
Specificity	19	18	94.7	74.0 - 99.9
Overall Agreement	73	72	98.6	92.6 - 100
<u>Combined</u>				
Sensitivity	103	99	96.1	90.4 - 98.9
Specificity	191	188	98.4	95.5 - 99.7
Overall Agreement	294	287	97.6	95.2 - 99.0
Immuno 1 Lot 2 Rgts				
<u>Site 1 Supplied</u>				
Sensitivity	49	46	93.9	83.1 - 98.7
Specificity	172	169	98.3	95.0 - 99.6
Overall Agreement	221	215	97.3	94.2 - 99.0
<u>Supplemental Samples</u>				
Sensitivity	54	53	98.2	90.1 - 100
Specificity	19	18	94.7	74.0 - 99.9
Overall Agreement	73	71	97.3	90.5 - 99.7
<u>Combined</u>				
Sensitivity	103	99	96.1	90.4 - 98.9
Specificity	191	187	97.9	94.7 - 99.4
Overall Agreement	294	286	97.3	94.7 - 98.8

Site 2 San Francisco General Hospital

Immuno 1 Rgts & Sample Description	Number of Results by IMx Classification	No. of Immuno 1 Results in Agreement with IMx Classification	Sensitivity, Specificity or Overall Agreement (%)	95% Confidence Limits (%)
Immuno 1 Lot 1 Rgts				
<u>Site 2 Supplied</u>				
<i>Sensitivity</i>	43	35	81.4	66.6 - 91.6
<i>Specificity</i>	182	170	93.4	88.8 - 96.5
<i>Overall Agreement</i>	225	205	91.1	86.6 - 94.5
<u>Supplemental Samples</u>				
<i>Sensitivity</i>	48	48	100	92.6 - 100
<i>Specificity</i>	27	26	96.3	81.0 - 99.9
<i>Overall Agreement</i>	75	74	98.7	92.8 - 100
<u>Combined</u>				
<i>Sensitivity</i>	91	83	91.2	83.4 - 96.1
<i>Specificity</i>	209	196	93.8	89.6 - 96.6
<i>Overall Agreement</i>	300	279	93.0	89.5 - 95.6
Immuno 1 Lot 2 Rgts				
<u>Site 2 Supplied</u>				
<i>Sensitivity</i>	44	33	75.0	59.7 - 86.8
<i>Specificity</i>	181	170	93.9	89.4 - 96.9
<i>Overall Agreement</i>	225	203	90.2	85.6 - 93.8
<u>Supplemental Samples</u>				
<i>Sensitivity</i>	48	47	97.9	88.9 - 99.9
<i>Specificity</i>	27	26	96.3	81.0 - 99.9
<i>Overall Agreement</i>	75	73	97.3	90.7 - 99.7
<u>Combined</u>				
<i>Sensitivity</i>	92	80	87.0	78.3 - 93.1
<i>Specificity</i>	208	196	94.2	90.1 - 97.0
<i>Overall Agreement</i>	300	276	92.0	88.3 - 94.8

Site 2 San Francisco General Hospital - IFA Resolved

Immuno 1 Rgts & Sample Description	Number of Resolved Results	No. of Immuno 1 Results in Agreement with Resolved Results	Sensitivity, Specificity or Overall Agreement (%)	95% Confidence Limits (%)
Immuno 1 Lot 1 Rgts				
<u>Site 2 Supplied</u>				
<i>Sensitivity</i>	43	35	81.4	66.6 - 91.6
<i>Specificity</i>	182	170	93.4	88.8 - 96.5
<i>Overall Agreement</i>	225	205	91.1	86.6 - 94.5
<u>Supplemental Samples</u>				
<i>Sensitivity</i>	48	48	100	92.6 - 100
<i>Specificity</i>	27	26	96.3	81.0 - 99.9
<i>Overall Agreement</i>	75	74	98.7	92.8 - 100
<u>Combined</u>				
<i>Sensitivity</i>	85	83	97.6	91.8 - 99.7
<i>Specificity</i>	206	196	95.1	91.3 - 97.6
<i>Overall Agreement</i>	291	279	95.9	92.9 - 97.9
Immuno 1 Lot 2 Rgts				
<u>Site 2 Supplied</u>				
<i>Sensitivity</i>	44	33	75.0	59.7 - 86.8
<i>Specificity</i>	181	170	93.9	89.4 - 96.9
<i>Overall Agreement</i>	225	203	90.2	85.6 - 93.8
<u>Supplemental Samples</u>				
<i>Sensitivity</i>	48	47	97.9	88.9 - 99.9
<i>Specificity</i>	27	26	96.3	81.0 - 99.9
<i>Overall Agreement</i>	75	74	98.7	92.8 - 100
<u>Combined</u>				
<i>Sensitivity</i>	85	80	94.1	86.8 - 98.1
<i>Specificity</i>	206	196	95.1	91.3 - 97.6
<i>Overall Agreement</i>	291	276	94.8	91.6 - 97.1

Combined Clinical Site 1 & 2 Results: Unresolved Results

Immuno 1 Rgts & Sample Description	Number of Results by IMx Classification	No. of Immuno 1 Results in Agreement with IMx Classification	Sensitivity, Specificity or Overall Agreement (%)	95% Confidence Limits (%)
Immuno 1 Lot 1 Rgts				
All Specimens				
<i>Sensitivity</i>	195	182	93.3	88.9 - 96.4
<i>Specificity</i>	403	384	95.3	92.7 - 97.1
<i>Overall Agreement</i>	598	566	94.6	92.5 - 96.3
Immuno 1 Lot 2 Rgts				
All Specimens				
<i>Sensitivity</i>	196	179	91.3	86.5 - 94.9
<i>Specificity</i>	402	383	95.3	92.7 - 97.1
<i>Overall Agreement</i>	598	562	94.0	91.8 - 95.7

Combined Clinical Site 1 & 2 Results: IFA Resolved

Immuno 1 Rgts & Sample Description	Number of Resolved Results	No. of Immuno 1 Results in Agreement with Resolved Results	Sensitivity, Specificity or Overall Agreement (%)	95% Confidence Limits (%)
Immuno 1 Lot 1 Rgts				
All Specimens				
<i>Sensitivity</i>	188	182	96.8	93.2 - 98.8
<i>Specificity</i>	397	384	96.7	94.5 - 98.2
<i>Overall Agreement</i>	585	566	96.8	95.0 - 98.0
Immuno 1 Lot 2 Rgts				
All Specimens				
<i>Sensitivity</i>	188	179	95.2	91.1 - 97.8
<i>Specificity</i>	397	383	96.5	94.2 - 98.1
<i>Overall Agreement</i>	585	562	96.1	94.2 - 97.5

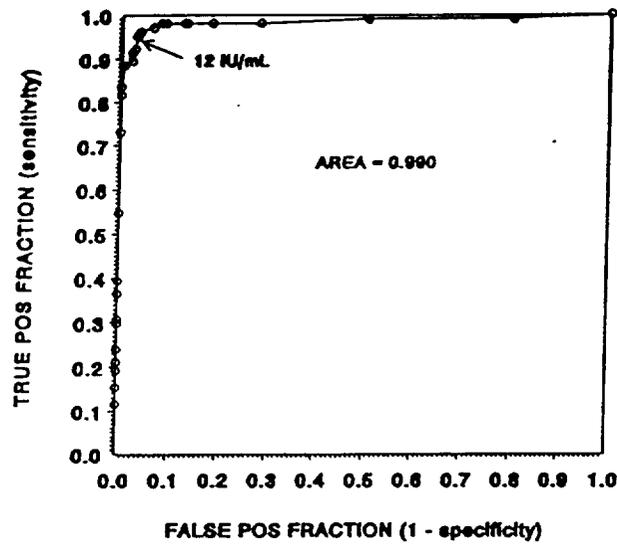
Table 3: IFA RESULTS ON DISCREPANT SAMPLES

STUDY LOCATION	COMPARATIVE METHOD	IMMUNO 1 DISCREPANCIES	DISCREPANT RESULTS	IFA POSITIVE	IFA NEGATIVE
Clinical Site 1 Lot 1 Rgts	Abbott IMx	False Negative	5	4	1
		False Positive	6	3	3
Lot 2 Rgts	Abbott IMx	False Negative	5	4	1
		False Positive	7	3	4
Clinical Site 2 Lot 1 Rgts	Abbott IMx	False Negative	8	2	6
		False Positive	13	3	10
Lot 2 Rgts	Abbott IMx	False Negative	12	5	7
		False Positive	12	2	10

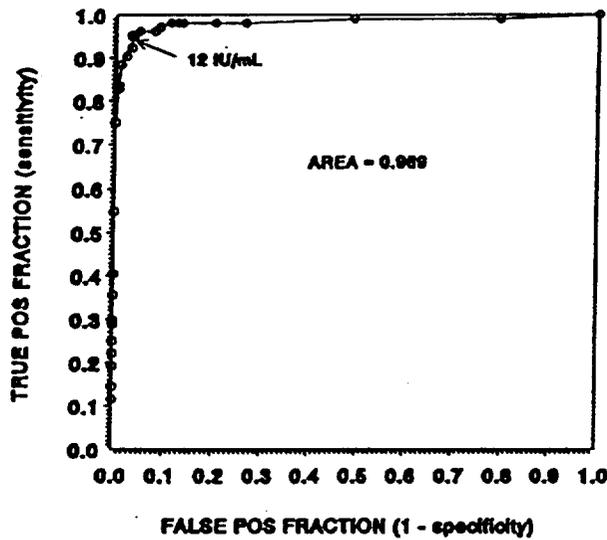
Receiver-Operating Characteristic (ROC) Analysis

The area under the ROC plots is used as an estimate of the diagnostic accuracy of the Immuno 1 Toxoplasma IgG assay relative to the IMx Toxoplasma IgG assay. ROC plots are shown in Figure 2 a-d for both TXG and TYG Immuno 1 Toxoplasma IgG reagent lots at Univ of Texas Medical Branch and San Francisco General Hospital.

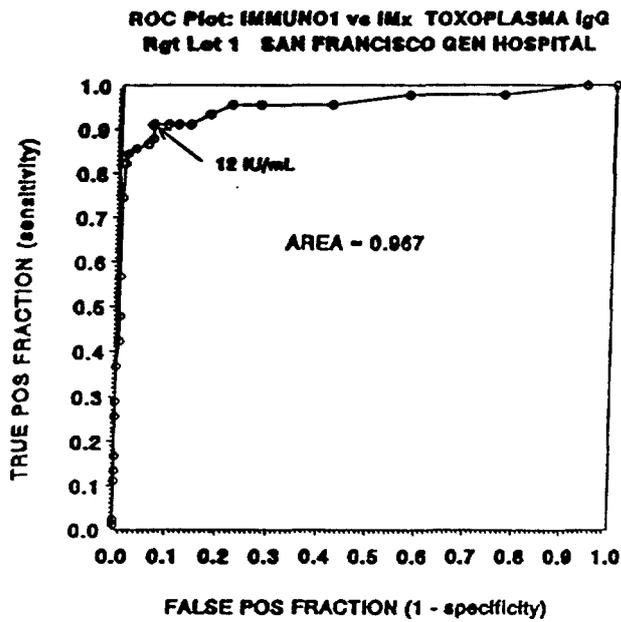
Figure 2. ROC Plot analysis of comparative Immuno 1 and IMx Toxoplasma IgG methods.



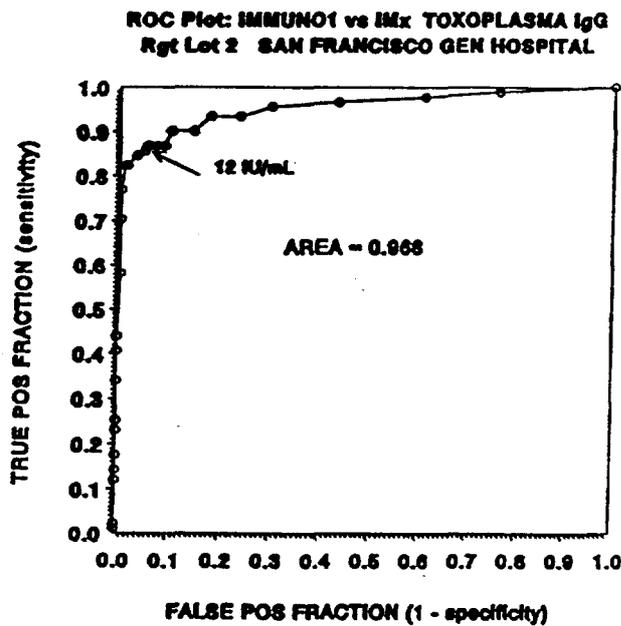
(a) ROC Plot. Immuno 1 vs IMx. University of Texas Medical Branch employing TXG Lot 1 Immuno 1 Toxoplasma IgG Reagents. (Area = 0.990)



(b) ROC Plot. Immuno 1 vs IMx. University of Texas Medical Branch employing Lot 2 Immuno 1 Toxoplasma IgG Reagents. (Area = 0.989)



(c). ROC Plot. Immuno 1 vs IMx. San Francisco General Hospital employing Lot 1 Immuno 1 Toxoplasma IgG Reagents. (Area = 0.967)



(d) ROC Plot. Immuno 1 vs IMx. San Francisco General Hospital employing Lot 2 Immuno 1 Toxoplasma IgG Reagents. (Area = 0.968)

Table 4. ROC Plot Areas for Immuno1 relative to the IMx Toxoplasma IgG Method

CLINICAL SITE	Immuno 1 Reagent Lot	Comparative Method	ROC Area
Univ of Texas MB	Lot 1	IMx	0.990
	Lot 2	IMx	0.989
San Francisco GH	Lot 1	IMx	0.967
	Lot 2	IMx	0.968
Combined Clinical Sites	Lot 1	IMx	0.980
	Lot 2	IMx	0.980

Comparison of Immuno 1 Toxoplasma IgG Reagent Lots

The clinical results obtained with both Lots of Immuno 1 Toxoplasma IgG Reagents evaluated at the University of Texas MB and San Francisco General Hospital were compared both with respect to classification and correlation of clinical values.

Table 5. Reproducibility of results between Immuno 1 Toxoplasma IgG Reagent Lots at Univ. of Texas and San Francisco General Hospital

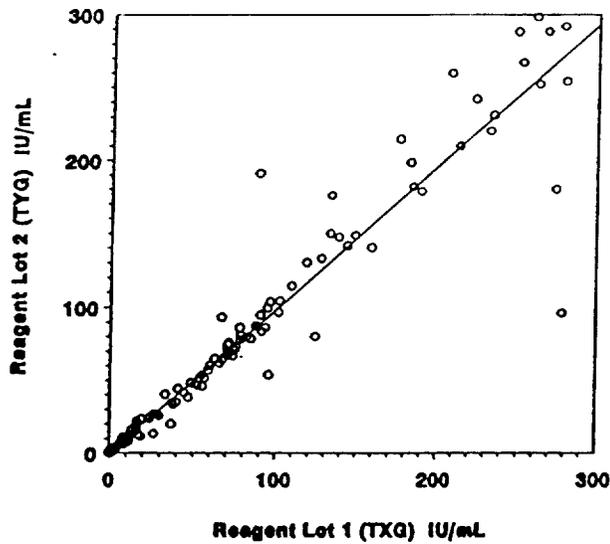
CLINICAL TRIAL SITE		LOT 2 REAGENTS		OVERALL AGREEMENT (%)
Univ. of Texas MB LOT 1 REAGENTS	Pos	104	1	99.0
	Neg	2	191	
San Francisco GH LOT 1 REAGENTS	Pos	91	4	98.7
	Neg	0	205	

Regression analysis of the results between reagent lots is given in Table 6. Correlation plots are presented in Figure 3 a&b.

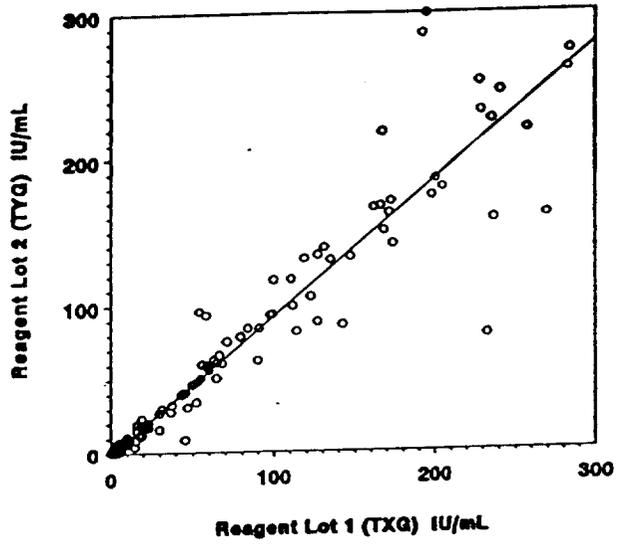
Table 6. Regression analysis of Immuno 1 results between reagent lots. Results above 300 IU/mL omitted.

Site	Immuno 1 Rubella IgG Reagent Lot	Y (intercept) \pm 95% C.I.	Slope \pm 95% C.I.	R value
Univ. of Texas MB	Lot 1 vs Lot 2	0.59 \pm 2.08	0.973 \pm 0.029	0.969
San Francisco GH	Lot 1 vs Lot 2	2.70 \pm 2.20	0.993 \pm 0.034	0.960

Figure 3. Correlation plots between Immuno 1 Toxoplasma IgG reagent lots 1 & 2. Results > 300 IU/mL are not shown.



(a) Immuno 1 IgG reagent Lot 1 versus Lot 2. Data was collected at the University of Texas Medical Branch at Galveston.



(b) Toxoplasma IgG reagent Lot 1 versus Lot 2. Data was collected at the San Francisco General Hospital.

Comparison of Immuno1 Toxoplasma IgG to IFA

The histogram in Figure 4 show the comparison between IFA and Immuno 1 Toxoplasma IgG results on 35 human sera 22 of which are negative. An IFA titre less than 16 is considered negative. IFA testing was performed by Boston Biomedica using Gull Laboratories IFA method. As expected the magnitude of the reported IgG level cannot be correlated to an endpoint titer.

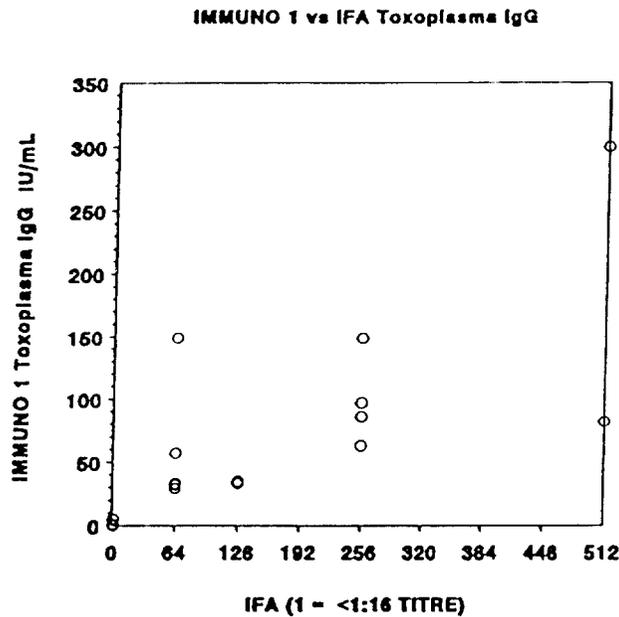


Figure 4. Comparison of Immuno 1 Toxoplasma IgG and IFA results. Twenty-two of the 35 specimens shown are have IFA negative having titers less than 1:16. These twenty-one of the IFA negative samples have Immuno 1 values less than or equal to 1.0 IU/mL with one result having an Immuno 1 value of 5 IU/mL.

Linearity

The linearity of the assay over the claimed range between 12 and 300 IU/mL is demonstrated in the following experiment. Eight patient samples and the were assayed in triplicate, diluted independently in Immuno 1 Sample Diluent B and measured in 2 separate runs. Fresh dilutions of 1:5 and 1:10 were made before each run. Linear regression analysis of the results are presented in Table 7 along with the 95% confidence intervals for the y-intercept and the slope.

Table 7. Linearity study.

Sample	Dil Factor	Run 1 Rep 1	Run 1 Rep 2	Run 2 Rep 1	Run 2 Rep 2	Total CV	Y - INTER ±95% C. L.	SLOPE ±95% C. L.	R value
Pat 1	1	222	215	198	207	4.9	-12.0 ± 5.5	222.4 ± 9.3	0.998
"	5	31	32	30	32	3.1			
"	10	12	12	10	11	8.5			
Pat 2	1	208	208	192	208	3.9	-8.8 ± 4.3	212.8 ± 7.3	0.999
"	5	35	35	32	33	4.4			
"	10	13	15	10	12	16.7			
Pat 3	1	154	152	145	122	10.2	-7.7 ± 7.7	150.9 ± 13.0	0.993
"	5	23	23	20	21	6.9			
"	10	8	8.6	7.5	8.1	5.6			
Pat 4	1	195	178	179	167	6.4	-7.0 ± 6.0	186.7 ± 10.2	0.997
"	5	31	29	31	31	3.3			
"	10	12	12	10.3	12	7.3			
Pat 5	1	232	229	208	212	5.5	-12.5 ± 6.5	232.6 ± 11.0	0.998
"	5	31	31	32	34	4.4			
"	10	13	14	11	12	10.3			
Pat 6	1	171	166	160	160	3.2	-9.0 ± 3.0	173.1 ± 5.0	0.999
"	5	24	25	24	25	2.4			
"	10	11	8.6	8.6	9	12.4			
Pat 7	1	316	302	295	307	2.9	-5.1 ± 5.1	310.1 ± 8.7	0.999
"	5	56	58	58	59	2.2			
"	10	26	20	25	30	16.3			
Pat 8	1	167	158	176	180	5.8	-10.9 ± 5.4	181.0 ± 9.1	0.997
"	5	24	22	22	25	6.5			
"	10	8.7	9.5	8.5	9.1	5.0			

INTERFERENCES

The use of hemolyzed (up to 1000 mg/dL of hemoglobin), lipemic (up to 900 mg/dL of triglycerides) or icteric (up to 25 mg/dL of total bilirubin) samples have no clinically significant effect on method performance, Table 8. Patient samples containing rheumatoid factor, antibodies to Epstein-Barr virus, cytomegalovirus, varicella zoster virus, Herpes Type I virus, Herpes Type II virus and rubeola (measles) virus produced no false positive results in comparison to the Sanofi Platelia method.

TABLE 8 POTENTIAL CHEMICAL INTERFERENCES

CHOLESTEROL

mg/dL	IU/mL TOXO IgG	% CV	% BIAS
50	13.2	3.9	6.5
0	12.4	9.0	
100	10.4	5.7	-9.6
0	11.4	2.1	
300	7.9	2.6	-2.5
0	8.1	6.5	
400	6.5	2.6	-9.7
0	7.2	.9	

TRIGLYCERIDE

mg/dL	IU/mL TOXO IgG	% BIAS
226	11.2	4.7
0	10.7	
470	9.1	2.2
0	8.9	
1180	5.9	0
0	5.9	

HEMOGLOBIN

mg/dL	IU/mL TOXO IgG	% CV	% BIAS
250	13.1	3.5	-10.9
0	14.7	1.4	
500	13.1	4	-3.7
0	13.6	6.3	
750	12.5	7.2	5.9
0	11.8	7.8	
1000	10.3	0.9	-11.2
0	7.8	11.6	

BILIRUBIN

mg/dL	IU/mL TOXO IgG	% CV	% BIAS
6.2	13.2	7.2	7.3
0	12.3	1.8	
12.5	10.5	1.9	7.1
0	9.8	2.1	
18.8	9.8	4.6	0
0	9.8	3.8	
25	10	2.4	3.1
0	9.7	2.7	

Potential Immunological Interferences

A panel of 60 human clinical samples positive for a variety of disease states and potentially interfering IgG antibodies was obtained from Boston Biomedica, Inc. Boston Biomedica COA (Attachment 12) for the specimens identifies the commercial assay kits used to identify the samples along with the test and control results. The samples were analyzed for discrepancies between Immuno 1 and Platelia Toxoplasma IgG results. As shown in Table 9 correlation between the two method classifications is good. Two samples results are discrepant between the Immuno 1 and Platelia. These samples are weakly positive by the Immuno 1 at 15.7 and 19.4 IU/mL with corresponding Platelia values of 4.7 and 4.9 IU/mL. The cut-off for Platelia is 6 IU/mL and 12 IU/mL for the Immuno 1 method. These are not considered significantly different results.

Table 9 Interference study results.

Antibody	Sample ID	Platelia Toxoplasma IgG		Immuno1 Toxoplasma IgG	
		IU/mL	Result	IU/mL	Result
anti-EBV Pos	AT4-2707-0139	4.7	NEG	15.7	POS
"	AT4-2707-0144	107.6	POS	150	POS
"	AT4-2707-0146	0.0	NEG	3	NEG
"	AT4-2707-0156	0.0	NEG	0	NEG
"	AT4-2707-0179	0.3	NEG	4	NEG
"	AT4-2707-0184	2.1	NEG	2	NEG
"	AT4-2707-0209	0.0	NEG	1	NEG
"	AT4-2707-0216	0.8	NEG	1	NEG
"	DL4-3508-0138	23.7	POS	26	POS
"	DL4-3508-0149	0.9	NEG	1	NEG
anti-CMV IgG	DL2-3501-0010	0.0	NEG	4	NEG
"	DL2-3501-0023	0.0	NEG	2	NEG
"	DL2-3501-0026	0.0	NEG	7	NEG
"	DL2-3501-0034	0.8	NEG	5	NEG
"	DL2-3501-0049	0.0	NEG	3	NEG
"	DL2-3501-0064	0.0	NEG	1	NEG
"	DL2-3501-0067	0.0	NEG	2	NEG
"	DL2-3501-0077	359.6	POS	453	POS
"	DL2-3501-0095	1.1	NEG	3	NEG
"	DL2-3501-0114	1.9	NEG	4	NEG
anti-VZV	E0-2606-0011	4.2	NEG	11	NEG
"	E0-2606-0037	1.9	NEG	1	NEG
"	E0-2606-0142	0.0	NEG	2	NEG
"	E0-2606-0218	57.4	POS	64	POS
"	E1-3402-0503	1.7	NEG	11	NEG
"	E1-3402-0518	1.0	NEG	2	NEG
"	E1-3402-0548	1.4	NEG	2	NEG
"	E1-3402-0567	0.4	NEG	2	NEG
"	DL3-3512-0054	0.8	NEG	2	NEG
"	DL3-3512-0065	0.7	NEG	2	NEG

RF Positive	DL4-3501-0082	0.0	NEG	1	NEG
"	DL4-3501-0085	1.1	NEG	5	NEG
"	DL4-3501-0095	159.6	POS	221	POS
"	DL4-3501-0105	4.9	NEG	19.4	POS
"	DL4-3501-0108	0.0	NEG	2	NEG
"	DL4-3501-0115	1	NEG	6	NEG
"	DL4-3501-0120	1.2	NEG	3	NEG
"	DL4-3501-0125	0.5	NEG	5	NEG
"	DL4-3501-0148	0.6	NEG	2	NEG
"	DL4-3501-0154	0.8	NEG	2	NEG
anti-HSV 1 or 2	AB3-2402-0001	27.7	POS	31	POS
"	AB3-2402-0002	3.4	NEG	2	NEG
"	AB3-2402-0003	2	NEG	1	NEG
"	AB3-2402-0004	0.7	NEG	1	NEG
"	AB3-2402-0007	1.7	NEG	2	NEG
"	AB3-2402-0008	0.0	NEG	1	NEG
"	AB3-2402-0009	0.0	NEG	1	NEG
"	AB3-2402-0010	0.0	NEG	1	NEG
"	AB3-2402-0011	0.6	NEG	2	NEG
"	AB3-2402-0012	0.9	NEG	0	NEG
Measles IgG	EB4-1205-0004	0.1	NEG	2	NEG
"	EB4-2707-0006	29.7	POS	59	POS
"	EB4-2707-0010	150.8	POS	222	POS
"	EB4-2707-0014	0.9	NEG	2	NEG
"	EB4-2707-0015	0.0	NEG	3	NEG
"	EB4-2707-0016	0.0	NEG	10	NEG
"	EB4-2707-0020	14.1	POS	32	POS
"	EB4-2707-0022	4.5	NEG	1	NEG
"	EB4-2707-0023	0.0	NEG	8.9	NEG
"	EB4-2707-0030	147.0	POS	211	POS

Quality control data for the Diagnostics Pasteur and Immuno 1 Toxoplasma IgG determinations are presented in Table 10 for the results in Table 9 and show compliance with specifications.

Table 10. Quality Control Data for Diagnostic Pasteur and Immuno 1 Toxoplasma Testing of Interference Samples

METHOD/CONTROL	OBTAINED	SPECIFICATION	RESULT
Platelia			
Pos Contrl 1/Neg Contrl	3.4	> 2	Valid
Pos Contrl 3	0.972 OD	> 0.8 OD	Valid
Immuno 1			
Medical Pool 1	0.3 IU/mL	< 4 IU/mL	Valid
Medical Pool 2	15.3 IU/mL	9.8 to 18.2 IU/mL	Valid
Medical Pool 4	106.8 IU/mL	65 to 121 IU/mL	Valid