510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K101946

B. Purpose for Submission:

To obtain a substantial equivalence determination for a new device

C. Measurand:

Antibodies to *Toxoplasma gondii* (*T. gondii*) IgG

D. Type of Test:

A two-step enzyme immunoassay sandwich method with an enzyme linked fluorescent assay (ELFA)

E. Applicant:

bioMerieux Inc.

F. Proprietary and Established Names:

VIDAS® Toxo IgG Avidity Assay

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.3780; *Toxoplasma gondii* Serological Reagents

2. Classification:

   Class II

3. Product code:

   LGD; Enzyme Linked Immunosorbent Assay, *Toxoplasma gondii*

4. Panel:

   Microbiology (83)

H. Intended Use:

1. Intended use:

   The VIDAS® TOXO IgG Avidity assay is an automated qualitative test for the determination of anti-toxoplasma IgG avidity in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® TOXO IgG Avidity assay is intended for use in conjunction with results from the VIDAS TOXO IgG II and must have a positive titer, (≥ 8 IU/mL); other laboratory findings and clinical information to aid in the presumptive exclusion of a recently acquired (≤ 4 months) *Toxoplasma gondii* infection in pregnant women and patients with lymphadenopathy.

   VIDAS TOXO IgG Avidity assay performance has not been established for prenatal screening, for newborn testing, for use in immunocompromised patients and in cases of endogenous or exogenous reinfection by *Toxoplasma gondii*. This assay has not been cleared or approved by the FDA for blood/plasma donor screening.

2. Indications for use:

   The VIDAS® TOXO IgG Avidity assay is an automated qualitative test for the determination of anti-toxoplasma IgG avidity in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® TOXO IgG Avidity assay is intended for use in conjunction with results from the VIDAS TOXO IgG II and must have a positive titer, (≥ 8 IU/mL); other laboratory findings and clinical information to aid in the presumptive exclusion of a recently acquired (≤ 4 months) *Toxoplasma gondii* infection in pregnant women and patients with lymphadenopathy.

   VIDAS TOXO IgG Avidity assay performance has not been established for prenatal screening, for newborn testing, for use in immunocompromised patients and in cases of endogenous or exogenous reinfection by *Toxoplasma gondii*. This assay has not been cleared or approved by the FDA for blood/plasma donor screening.

3. Special condition for use statement:

   For prescription use only

4. Special instrument requirements:

   VIDAS and miniVIDAS

I. Device Description:

The VIDAS® Toxo IgG Avidity assay is a two-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA) performed on an automated VIDAS 30 or miniVIDAS instrument. The VIDAS instrument is attached to a computer and printer. Each instrument has five independent sections allowing multiple different assays to be run simultaneously. Each section can process up to six samples. Therefore, a fully loaded VIDAS can process thirty samples. The Solid Phase Receptacle serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips. The instrument performs all of the assay steps automatically.

Materials Provided:

30 dual TXGA strips	STR	Ready-to-use.
60 TXGA SPRs 2 x 30	SPR®	Ready-to-use. SPRs coated with toxoplasma antigen, RH Sabin strain grown in mice (5).
TXGA High avidity control 1 x 2 mL (liquid)	C1	Human serum* containing anti-toxoplasma IgG + protein stabilizer + 1 g/L sodium azide. The confidence interval in index is reported on the MLE card after the name: "Control C1 (+) Test Value Range". The confidence interval in "Relative Fluorescence Value (RFV)" is reported on the MLE card after the name: "C1 Ref RFV Range".
TXGA Low avidity control 1 x 1.2 mL (liquid)	C2	Human serum* containing anti-toxoplasma IgG + protein stabilizer + 1 g/L sodium azide. The confidence interval in index is reported on the MLE card after the name: "Control C2 (-) Test Value Range".
Sample diluent 2 x 6.5 mL (liquid)	R1	Human serum* containing protein stabilizer + 1 g/L sodium azide
1 MLE card (Master Lot Entry)		Specifications for the factory master data: to read the MLE data, please refer to the Operator's Manual.
1 Package insert		

J. Substantial Equivalence Information:

1. Predicate device name:

   VIDAS TOXO IgM Test System

2. Predicate 510(k) number:

   K923166

1. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The VIDAS® TOXO IgG Avidity assay is an automated qualitative test for the determination of anti-toxoplasma IgG avidity in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® TOXO IgG Avidity assay is intended for use in conjunction with results from the VIDAS TOXO IgG II and must have a positive titer, (≥ 8 IU/mL); other laboratory findings and clinical information to aid in the presumptive exclusion of a recently acquired (≤ 4 months) *Toxoplasma gondii* infection in pregnant women and patients with lymphadenopathy. VIDAS TOXO IgG Avidity assay performance has not been established for prenatal screening, for newborn testing, for use in immunocompromised patients and in cases of endogenous or exogenous reinfection by *Toxoplasma gondii*. This assay has not been cleared or approved by the FDA for blood/plasma donor screening.	The VIDAS® TOXO IgM (TXM) assay is intended for use with a VIDAS® (Vitek ImmunoDiagnostic Assay System) instrument as an automated enzyme-linked fluorescent immunoassay (ELFA) for the presumptive qualitative detection of anti-Toxoplasma gondii IgM antibodies in human serum, as an aid in the diagnosis of acute, recent, or reactivated Toxoplasma gondii infection. This assay must be performed in conjunction with an anti- Toxoplasma gondii lgG antibody assay. VIDAS TXM assay performance has not been established for prenatal screening or newborn testing. This assay has not been cleared by the FDA for blood/plasma donor screening.

Similarities		
Item	Device	Predicate
Control levels	Two	Two
Specimen Tested	Human serum	Human serum
Detection Method	Enzyme linked fluorescent immunoassay (ELFA)	Enzyme linked fluorescent immunoassay (ELFA)
Instrument	VIDAS Instruments	VIDAS Instruments

Differences		
Item	Device	Predicate
Analyte Measured	Anti-toxoplasma IgG	Anti-toxoplasma IgM
Cut-Offs	Low IgG avidity is < 0.200, Equivocal IgG avidity is 0.200 ≤ index < 0.300 and High IgG avidity is ≥ 0.300	Negative is <0.55, Positive is ≥0.65 and Equivocal is ≥0.55-<0.65

K. Standard/Guidance Document Referenced:

- CLSI EP05-A2: Evaluation of Precision Performance of Clinical Chemistry Devices- Second Edition
- CLSI EP07-A2: Interference Testing in Clinical Chemistry- Second Edition
- CLSI EP09-A2: Method Comparison and Bias Estimation Using Patient Samples- Second Edition

L. Test Principle:

The VIDAS® Toxo IgG Avidity assay is a two-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR) serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips. The instrument performs all of the assay steps automatically. The reaction medium is cycled in and out of the SPR several times. The VIDAS Toxo IgG Avidity uses a dual strip comprised of one reference strip and one test strip. The sample to be tested, after dilution, is dispensed into both sample wells of the dual strip: reference and test. Any anti-toxoplasma IgG present in the sample form complexes with the antigen coated to the solid phase. In the reference strip, non-specific antibodies are eliminated by washing, whereas specific antibodies remain coated to the solid phase. In the test strip, washing with the dissociating agent changes antigen-antibody links.

Only antibodies with high avidity remain bound to the solid phase, whereas antibodies with low avidity are eliminated.

Alkaline phosphatase labeled human anti-IgG antibody (conjugate) is then cycled in and out of the SPR, and binds with any human IgG coated on the interior of the SPR. Unbound conjugate is removed by washing. During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of antibodies present in the sample. At the end of the assay, results are automatically calculated by the instrument and then printed out. The ratio between the quantity of high avidity antibodies (test strip) and the quantity of total antibodies (reference strip) provides an index, which indicates antibody avidity in the tested sample.

M. Performance Characteristics:

1. Analytical performance:

a. Precision/Reproducibility:

Precision testing was performed using five serum samples (low avidity, equivocal avidity, and high avidity samples), positive and negative controls, twice daily for a total of ten days on the VIDAS instruments.

Reproducibility testing was performed using five serum samples (low avidity, equivocal avidity, and high avidity samples), positive and negative controls, and two reagent lots using the VIDAS instruments at three testing sites for ten days. Repeatability (within-run precision), between-run, between-day, between-lot, between-system and total precision were calculated based on the recommendations of CLSI EP05-A2. The overall CV for the specimens range was less than 10% for both analyzers, which is acceptable. The following results were obtained for the precision and reproducibility studies:

Sample		1	2	3	4	5
Mean index		(0.1196)	(0.2620)	(0.3209)	(0.5352)	(0.6843)
Source of Variation	N	CV (%)	CV (%)	CV (%)	CV (%)	CV (%)
Repeatability	240	7.9	7.8	5.7	6.1	7.1
Between-run	240	<0.1*	<0.1*	4.3	3.1	2.1
Between-day	240	2.0	2.9	<0.1*	<0.1*	<0.1*

Between-lot	240	<0.1*	5.0	1.8	1.5	0.6
Between-System	240	2.0	<0.1*	<0.1*	<0.1*	0.1
Total	240	8.4	9.7	7.4	7.0	7.4

* For the precision study, the components in which the %CVs were determined to be negligible are reported as <0.1.

The results obtained from precision and reproducibility studies appear to be acceptable.

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The instrument automatically calculates the avidity index as follows:

$$\text{Index} = \frac{\text{test RFV (washing with dissociating agent)}}{\text{reference RFV (washing without dissociating agent)}}$$

d. Detection limit:

Not applicable

e. Analytical specificity:

Cross-reactivity

The cross reactive study for the VIDAS Toxo IgG Avidity assay was evaluated by testing a total of ten different analytes: ANA, CMV, EBV, HAMA, HAV, HBV, HSV-2, RF, Rubella, and VZV based on the recommendations of CLSI EP07-A2. Testing included at least 5 samples with a low (or borderline) avidity index containing high titers of antibodies to a potentially interfering disease state, and five samples with a high avidity index containing high titers of antibodies to a potentially interfering disease state. Clinically significant interference was defined as either a > 20% change in index values or a result that altered assay interpretation, i.e., a low or equivocal avidity result changing to a high avidity result or a high avidity result changing to a borderline or low avidity result.

Samples	Samples with clinically significant interference
ANA (Anti-nuclear antibodies)	0/12
CMV (Cytomegalovirus)	0/10
EBV (Epstein Barr Virus)	0/10
HAMA (Human anti-mouse antibodies)	0/10
HAV (Hepatitis A Virus)	0/10
HBV (Hepatitis B Virus)	0/10
HSV-1 (Herpes Simplex Virus type 1)	1/12
HSV-2 (Herpes Simplex Virus type 2)	0/10
RF (Rheumatoid factor)	0/12
Rubella Virus	0/12
VZV (Varicella-Zoster Virus)	0/10

Results from low and borderline avidity index were not considered clinically relevant however interference was observed with one of the twelve HSV-1 samples tested. The results obtained from the cross reactive study appear to be acceptable.

Interference

An interference study was conducted that included low, equivocal and high samples for Toxo IgG avidity based on the recommendations of CLSI EP07-A2. The results obtained from the interference study are provided below.

Substance	**Tested Concentration**
Clindamycin	89.1 µmol/L (45 µg/mL)
Pyrimethamine	60 µg/mL
Spiramycin	15.0 µg/mL
Sulfamethoxazole	1.58 mmol/L (400 µg/mL)
Sulfapyridine	1.20 mmol/L (300 µg/mL)
Sulfasalazine	754 umol/L (300 µg/mL)
Trimethoprim	138 µmol/L (40 µg/mL)
Trimethoprim/Sulfamethoxazole	1.58 mmol/L (400 µg/mL) and 138 µmol/L (40 µg/mL), respectively
Bilirubin	0 to 510 µmol/L
Hemoglobin	0 to 300 µmol/L (monomer)

Human serum albumin	0 to 5 g/dL
Lipids	0 to 30 mg/mL equivalent in triglycerides

The results obtained from the interference study appear to be acceptable.

f. Assay cut-off:

The cut-off for the VIDAS Toxo IgG Avidity assay was established by using a ROC curve to assess the clinical accuracy of the assay. Additionally, an equivocal range was established to identify low avidity samples, which have avidity indices approaching the cut-off. A total of 357 (331 fresh and 26 frozen) samples were tested and were representative of the intended study population. Results obtained with the VIDAS Toxo IgG Avidity assay can be interpreted as follows:

Low IgG avidity is < 0.200
Equivocal IgG avidity is 0.200 ≤ index < 0.300
High IgG avidity is ≥ 0.300

Avidity	Results	Interpretation
index < 0.200	Low IgG avidity (Acute infection not excluded)	Unable to differentiate between past or recent infection. Infection ≤ 4 months not excluded, re-test with other method(s)
0.200 ≤ index < 0.300	Equivocal IgG avidity (Borderline)	
index ≥ 0.300	High IgG avidity (Chronic)	Strong indication of a primary infection excluded, i.e., primary infection occurred > 4 months previously.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical Studies:

a. Clinical Sensitivity:

The clinical performance of the VIDAS TOXO IgG Avidity assay was studied in a single study of samples from 386 subjects, enrolled prospectively or from samples previously collected for toxoplasmosis testing ('retrospective').

Study Design Population

A total of 386 subjects provided samples; all patients were required to have a VIDAS TOXO IgG II assay positive result (i.e. result ≥ 8 IU/mL), and either be pregnant or have acute lymphadenopathy due to suspected or confirmed toxoplasmosis infection. Samples were obtained from four clinical sites: Palo Alto, CA, Grenoble and Marseille, France and Cali, Colombia. Testing was performed at 3 US sites: Palo Alto, CA, Hackensack, NJ and Albuquerque, NM.

Of the 386 subjects, 104 subjects had initially equivocal results on composite reference testing. Thirty-one subjects had an additional sample available for repeat composite reference testing and are included in the primary analysis; results for the remaining 73 subjects without an evaluable response on the composite reference standard were excluded. Of the 313 total subjects analyzed (283 frozen samples and 30 fresh samples), 271 samples were from pregnant women, 42 from patients with lymphadenopathy (both males and females); 14 of the 271 pregnant women also had acute lymphadenopathy. Among the 313 subjects included in the final analysis, 31 had an initial equivocal result but a follow-up sample was available.

Of the 271 samples from pregnant women, 142 were from subjects enrolled prospectively and 129 subject samples were retrospectively tested samples; of the 56 patients with lymphadenopathy (including 14 pregnant women), 7 were from prospectively enrolled subjects and 49 were from retrospective samples.

All specimens were tested by both the VIDAS TOXO IgG Avidity assay and a composite reference method; the composite reference method was used for determining whether infection occurred recently or was more distant, and included the Sabin-Feldman Dye Test (DT), the VIDAS TOXO IgM ELISA assay, and the Differential Agglutination (AC/HS) test. Toxoplasmosis IgA and IgE ELISA assays were also performed and used as supportive information. All reference testing was performed at a Palo Alto, CA laboratory. 'Diagnostic truth' was assigned by results from the composite reference method and assigned as whether infection occurred ≤ 4 months or > 4 months previous to sample collection.

VIDAS TOXO IgG Avidity assay and composite referencing testing were performed on an initial specimen from each subject; if the initial specimen was equivocal by the composite reference method, a second follow up sample was tested in parallel with the initial specimen by the composite reference method to assist in determining a final diagnostic classification. Patients for whom a follow up sample was required but was unavailable were not included in the results below.

Study Results

The comparison between the VIDAS TOXO IgG Avidity assay and the Composite Reference Method was analyzed as follows: all samples (tables 1 and 2), frozen samples (tables 3 and 4), pregnant women (tables 5 and 6) and lymphadenopathy patients excluding pregnant women (tables 7 and 8). The results and interpretation are shown below.

Table 1: All samples – Results

		Composite Reference Method			
		≤ 4 months [Acute]	Equivocal	> 4 months [Chronic]	Total
VIDAS TXGA	Low	129	2	11	142
	Equivocal	6	1	10	17
	High	3	2	149	154
	Total	138	5*	170	313

* Results for five (1.6%) patients remained equivocal by the Composite Reference Method after follow-up sampling testing.

Table 2. All samples – Interpretation and Performance

		Composite Reference Method Interpretation		
		≤ 4 months not excluded [Acute & Equivocal] *	> 4 months [Chronic]	Total
VIDAS TXGA Interpretation	≤ 4 months not excluded [Low & Equivocal] *	138	21	159
	> 4 months [High]	5	149	154
	Total	143	170	313

Performance	%	95% Confidence Interval
Sensitivity	96.5	92.0 – 98.9
Specificity	87.6	81.7 – 92.2

* Samples equivocal by either the VIDAS TOXO IgG Avidity assay or the Composite Reference Method were analyzed as ≤ 4 months not excluded for their respective category.

Additional analyses: Of the 31 subjects included in the analysis with initial results that were equivocal on composite reference testing, results for testing additional samples available for these patients by the composite reference

method were as follows: 13 (41.9%) were interpreted as consistent with acute disease, 5 patients (16.1%) again had equivocal results, and 13 (41.9%) were interpreted as consistent with chronic disease. All of the 13 samples by composite reference testing (100%) had low avidity on the VIDAS TOXO IgG Avidity assay; however, of the 13 samples consistent with chronic infection, on composite reference testing, 7 (53.8%) had low avidity, 1 (7.7%) had equivocal results, and 5 (38.5%) had high avidity on the VIDAS TOXO IgG Avidity assay. An exploratory analysis where the results from these 31 samples were extrapolated to the 73 samples with equivocal composite reference testing (and not included in the analyses above) and combined with the 313 analyzed samples to approximate results for the original 386 subjects yielded a similar overall sensitivity of 94.6% (95% CI 90.3 – 97.4) but a noticeable drop in specificity to 80.5% (95% CI 74.3 – 85.8). These latter estimates may more closely approximate the results that would have been observed had repeat testing been possible on all initially equivocal composite reference samples.

Table 3: Frozen samples – Results

		Composite Reference Method			
		≤ 4 months [Acute]	Equivocal	> 4 months [Chronic]	Total
VIDAS TXGA	Low	129	2	10	141
	Equivocal	6	1	9	16
	High	3	2	121	126
	Total	138	5	140	283

Table 4: Frozen samples – Interpretation and Performance

		Composite Reference Method Interpretation		
		≤ 4 months not excluded [Acute & Equivocal]	> 4 months [Chronic]	Total
VIDAS TXGA Interpretation	≤ 4 months not excluded [Low & Equivocal]	138	19	157
	> 4 months [High]	5	121	126
	Total	143	140	283

Performance	%	95% Confidence Interval
Sensitivity	96.5	92.0 – 98.9
Specificity	86.4	79.6 – 91.6

For frozen samples from a combined pregnant women and lymphadenopathy population, the composite reference method results established that an infection occurring ≤ 4 months could not be excluded in 143 patients. In 138 (96.5%) of these 143 patients, VIDAS TXGA test results were Low or Equivocal at < 0.300. Thus the sensitivity of the VIDAS TXGA for the diagnosis that an acute infection (≤ 4 months) cannot be ruled out was 96.5%.

Table 5: Pregnant women – Results

		Composite Reference Method			
		≤ 4 months [Acute]	Equivocal	> 4 months [Chronic]	Total
VIDAS TXGA	Low	97 (89)*	2 (0)	9 (6)	108 (95)
	Equivocal	6 (5)	1 (1)	10 (3)	17 (9)
	High	3 (3)	1 (0)	142 (22)	146 (25)
	Total	106 (97)	4 (1)	161 (31)	271 (129)

* In each cell, the number not in parentheses represents the results from both prospective and retrospective samples. The number in parentheses represents the results from only the retrospective samples.

Table 6: Pregnant women – Interpretation and Performance

		Composite Reference Method Interpretation		
		≤ 4 months not excluded [Acute & Equivocal]	> 4 months [Chronic]	Total
VIDAS TXGA Interpretation	≤ 4 months not excluded [Low & Equivocal]	106 (95)*	19 (9)	125 (104)
	> 4 months [High]	4 (3)	142 (22)	146 (25)
	Total	110 (98)	161 (31)	271 (129)

* In each cell, the number not in parentheses represents the results from both prospective and retrospective samples. The number in parentheses represents the results from only the retrospective samples.

Performance	%	95% Confidence Interval
Overall Sensitivity	96.4	91.0 – 99.0
Overall Specificity	88.2	82.2 – 92.7
Retrospective Sensitivity	96.9	91.3 – 99.4
Retrospective Specificity	71.0	52.0 – 85.8
Prospective Sensitivity	91.7	61.5 – 99.8
Prospective Specificity	92.3	86.3 – 96.2

In the overall pregnant women population, the composite reference method results established that an infection occurring ≤ 4 months could not be excluded in 110 patients. In 106 (96.4%) of these 110 patients, VIDAS TXGA test results were Low or Equivocal at < 0.300. Thus the sensitivity of VIDAS TXGA for the diagnosis that an acute infection (≤ 4 months) cannot be ruled out was 96.4%.

Table 7: Lymphadenopathy patients (excluding pregnant women) – Results

		Composite Reference Method			
		≤ 4 months [Acute]	Equivocal	> 4 months [Chronic]	Total
VIDAS TXGA	Low	32 (30)*	0 (0)	2 (2)	34 (32)
	Equivocal	0 (0)	0 (0)	0 (0)	0 (0)
	High	0 (0)	1 (1)	7 (3)	8 (4)
	Total	32 (30)	1 (1)	9 (5)	42 (36)

* In each cell, the number not in parentheses represents the results from both prospective and retrospective samples. The number in parentheses represents the results from only the retrospective samples.

Table 8: Lymphadenopathy patients (excluding pregnant women) – Interpretation and Performance

		Composite Reference Method Interpretation		
		≤ 4 months not excluded [Acute & Equivocal]	> 4 months [Chronic]	Total
VIDAS TXGA Interpretation	≤ 4 months not excluded [Low & Equivocal]	32 (30)*	2 (2)	34 (32)
	> 4 months [High]	1 (1)	7 (3)	8 (4)
	Total	33 (31)	9 (5)	42 (36)

* In each cell, the number not in parentheses represents the results from both prospective and retrospective samples. The number in parentheses represents the results from only the retrospective samples.

Performance	%	95% Confidence Interval
Overall Sensitivity	97.0	84.2 – 99.9
Overall Specificity	77.8	40.0 – 97.2
Retrospective Sensitivity	96.8	83.3 – 99.9
Retrospective Specificity	60.0	14.7 – 94.7
Prospective Sensitivity	100.0	15.8 – 100.0
Prospective Specificity	100.0	39.8 – 100.0

In the overall lymphadenopathy population, the composite reference method results established that an infection occurring ≤ 4 months could not be

excluded in 33 patients. In 32 (97.0%) of these 33 patients, VIDAS TXGA test results were Low or Equivocal at < 0.300. Thus the sensitivity of the VIDAS TXGA for the diagnosis that an acute infection (≤ 4 months) cannot be ruled out was 97.0%.

These results met the acceptance criteria and are acceptable.

b. Clinical specificity:

See *Clinical sensitivity* section M.3.a

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected Values/Reference Range:

The TOXO IgG Avidity assay was tested with 148 prospectively collected specimens (fresh and frozen) representing subjects for whom the VIDAS TOXO IgG II result was ≥ 8 IU/mL. Of the 148 serum samples, 142 corresponded to pregnant women, and 6 to patients with lymphadenopathy. The percentage of high avidity results in these populations as determined by the VIDAS TOXO IgG Avidity assay was 85.2% for the pregnant women population and 66.7% for the lymphadenopathy population.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.