510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K210596

B Applicant

Abbott Laboratories

C Proprietary and Established Names

ARCHITECT Toxo IgG

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LGD	Class II	21 CFR 866.3780 - Toxoplasma Gondii Serological Reagents	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of the ARCHITECT Toxo IgG Reagent Kit

B Measurand:

IgG antibody to *Toxoplasma gondii*

C Type of Test:

chemiluminescent microparticle immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

The ARCHITECT Toxo IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of IgG antibodies to *Toxoplasma gondii* in human serum and plasma on the ARCHITECT i System.

The ARCHITECT Toxo IgG assay is to be used as an aid in the determination of immune status to *T gondii* in individuals, including women of child-bearing age, and as an aid in the diagnosis of *T gondii* infection. A positive result does not distinguish between recent and past infection.

Not intended for use in screening blood, plasma or tissue donors.

B Indication(s) for Use:
See Intended Use.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

ARCHITECT i System

IV Device/System Characteristics:

A Device Description:

The ARCHITECT i System is regulated under 21 CFR 862.2160 as Class I devices exempt from premarket notification. The ARCHITECT i System is a fully automated immunoassay system that allows random and continuous access as well as priority and automated retest processing. The ARCHITECT Toxo IgG Reagents, Calibrator, and Controls are designed to be used on the ARCHITECT i2000SR instrument.

Reagents
The ARCHITECT Toxo IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of IgG antibodies to *Toxoplasma gondii* in human serum and plasma on the ARCHITECT i System.

The ARCHITECT Toxo IgG assay is to be used as an aid in the determination of immune status to *Toxoplasma gondii* in individuals, including women of child-bearing age, and as an aid in the diagnosis of *Toxoplasma gondii* infection.

B Principle of Operation:

This assay is a two-step immunoassay for the quantitative determination of IgG antibodies to *Toxoplasma gondii* in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Pre-diluted sample, recombinant *Toxoplasma gondii* antigen (containing recombinant antigens P30[SAG1] and P35[GRA8]) coated paramagnetic microparticles, and assay diluent are combined and incubated. The *Toxoplasma gondii* specific antibodies present in the sample bind to the recombinant *Toxoplasma gondii* antigen (containing recombinant antigens P30[SAG1] and P35[GRA8]) coated microparticles. The mixture is washed. Murine anti-human IgG acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of anti-Toxo IgG in the sample and the RLU detected by the system optics.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Vidas Toxo Igg II (txg) Assay Model 30 210

B Predicate 510(k) Number(s):
K993319

C Comparison with Predicate(s):

Table 2. Similarities and *Differences* Between

Device & Predicate Device(s):	**Device: ARCHITECT Toxo IgG K21059**	**Predicate: VIDAS TOXO IgG II Assay (K993319, Package Insert 30 210-01 March 2019)**
General Device Characteristic Similarities		
Intended Use	The Toxo IgG assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of IgG antibodies to *Toxoplasma gondii* in human serum and plasma on the ARCHITECT i System. The Toxo IgG assay is to be used as an aid in the determination of immune status to *Toxoplasma gondii* in individuals including women of childbearing age and as an aid in the diagnosis of *Toxoplasma gondii* infection.	VIDAS TOXO IgG II is an automated quantitative test for use on a VIDAS analyzer for the measurement of anti-*Toxoplasma gondii* IgG in human serum. It is intended for use as an aid in determination of immune status. It is not intended for use in testing (screening) blood donors.
Controls	2 (Negative and Positive)	2 (Negative and Positive)
Standardization	The ARCHITECT Toxo IgG Calibrators are referenced to the World Health Organization (WHO) First International Standard (01/600) for anti-Toxoplasma IgG.	The VIDAS TXG calibrator consists of Human serum containing anti-Toxoplasma IgG and is calibrated against the WHO standard
Assay Protocol	2-step	2-step

General Device Characteristic Differences		
Antigen Used	P30 (SAG1) and P35 (GRA8)	Cytoplasmic Toxoplasma antigen (RH Sabin strain)
Type of Specimen	Serum and plasma	Serum
Methodology	Chemiluminescence Immunoassay	Enzyme-linked fluorescent immunoassay (ELFA)
Interpretation of Results	Nonreactive: < 1.6 IU/mL Grayzone/Equivocal: 1.6 to < 2.7 IU/mL Reactive: ≥ 2.7 IU/mL	Negative: < 4 IU/mL Equivocal: From ≥ 4 to < 8 IU/mL Positive: ≥ 8 IU/mL
Components	Microparticles – Recombinant *Toxoplasma gondii* antigen coated microparticles in MES buffer with protein (bovine). Minimum concentration: 0.03% solids. Preservative: ProClin 300. Conjugate – Murine acridinium-labeled anti-human IgG in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.05 µg/mL. Preservatives: antimicrobial agents. Assay Diluent – TRIS buffer with protein (murine) and protein (bovine). Preservative: ProClin 300.	Solid Phase Receptacle (SPR®) – PR coated with membrane and cytoplasmic Toxoplasma antigen (RH Sabin strain) grown in mice Reagent Strip – Strip consists of 10 wells covered with labeled foil seal. The wells contain the various reagents required for the assay including: Serum diluent: TRIS buffer (50 mmol/l) pH 7.4 + protein and chemical stabilizers + 1 g/L of sodium azide. Pre-washing buffer: TRIS (50 mmol/l) pH 7.4 + protein and chemical stabilizers + 1 g/L of sodium azide Washing buffer: TRIS (50 mmol/L) pH 7.4 + protein and chemical stabilizers + 1g/L of sodium azide Conjugate: Alkaline phosphatase labeled monoclonal anti-human IgG antibodies (mouse) + 1 g/L of sodium azide Serum diluent: TRIS buffer (50 mmol/L) pH 7.4 + protein and chemical stabilizers + 1 g/L of sodium azide Reading cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/L) + diethanolamine (DEA) (0.62 mol/L or 6.6%, pH9.2) + 1 g/L sodium azide
Calibrators	6 (Calibrators A to F)	1 Calibrator
Calibration Storage	Maximum of 30 days	14 days

VI Standards/Guidance Documents Referenced:

Standards

• CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline–Third Edition

• CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. (InVitro Diagnostics)

• CLSI EP07, 3rd ed., Interference Testing in Clinical Chemistry

• CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline— Second Edition

• CLSI M36-A, Clinical Use and Interpretation of Serologic Tests for *Toxoplasma gondii;* Approved Guideline – First Edition

Guidances

• Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005.

•Postmarket Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff; issued on December 28, 2016.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision was determined based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A3. Samples included a negative control, a positive control, and 5 panels numbered 1-5 respectively as follows: true negative, high negative, low positive, moderate positive, and high positive.

Testing was performed using 1 ARCHITECT i2000SR instrument, 3 reagent lots, 3 calibrator lots, and 3 control lots.

Each reagent lot was paired with a different lot of calibrator. A calibration per reagent lot was performed on each instrument by testing the calibrators in replicates of 2.

The samples were tested in a minimum of 2 replicates (from separate sample cups) 2 times per day (separated by a minimum of 2 hours) on at least 20 different days.

The within-laboratory imprecision results for the ARCHITECT Toxo IgG assay are shown in the following table:

Sample	n	Mean (IU/mL)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD (Range[a])	%CV (Range[a])
Negative Control	118	0.0	0.01	NA[c]	0.01 (0.01-0.02)	NA[c]
Positive Control 1	120	6.4	0.16	2.5	0.16 (0.15-0.19)	2.5 (2.4-3.1)
Panel 1	118	0.1	0.03	NA[c]	0.04 (0.04-0.05)	NA[c]
Panel 2	120	1.5	0.06	NA[c]	0.06 (0.06-0.06)	NA[c]
Panel 3	120	4.2	0.16	3.8	0.16 (0.11-0.18)	3.8 (2.9-4.5)
Panel 4	120	8.9	0.25	2.8	0.26 (0.23-0.26)	2.9 (2.7-2.9)
Panel 5	119	69.3	1.76	2.5	1.91 (1.78-1.93)	2.8 (2.6-2.8)

[a] The indicated samples were not evaluated against evaluation criteria because the observed mean values (Negative Control = 0.0 IU/mL; Panel 1 = 0.0 to 0.1 IU/mL; Panel 2 = 1.4 to 1.5 IU/mL) were not within the range specified in the evaluation criteria, where, only samples targeted between 3.0 IU/mL to the upper limit of the analytical measuring interval (75.0 IU/mL). were evaluated.

The ARCHITECT Toxo IgG assay demonstrated acceptable precision.

2. Linearity:

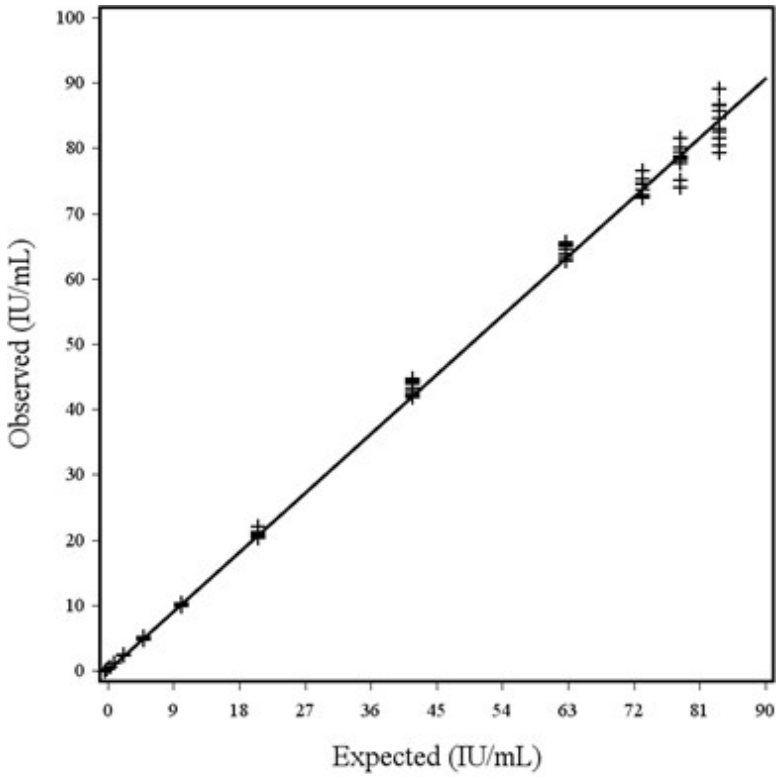
A study was performed based on guidance from CLSI EP06-A.
One unique sample set, consisting of at least 9 samples/pools spanning the analytical measuring range of the assay, was prepared as described in the table below, where sample/pool 1 was the high sample and sample/pool 13 was the low sample.

Sample/Pool Number	Samples/Pools Used for Dilution	Preparation Step
1	NA	NA
2	1, 3	4
3	1, 4	3

4	1, 5	2
5	1, 13	1
6	5, 13	5
7	6, 13	6
8	7, 13	7
9	8, 13	8
10	9, 13	9
11	10, 13	10
12	11, 13	11
13	NA	NA

Samples were tested in replicates of 10 along with calibrators and controls and the mean observed concentration of each sample/pool was calculated. The %CV for all samples used in the analysis were checked and found to be within the imprecision requirement of less than or equal to 10 %CV for representative specimens within the range of 3.0 IU/mL to the upper limit of the analytical measuring interval (75.0 IU/mL). The linearity of the ARCHITECT Toxo IgG assay was considered acceptable if the data set was determined to be linear or if the deviation from linearity was within or equal to ± 0.3 IU/mL for samples with concentrations < 3.0 IU/mL or within or equal to ± 10% for samples with concentrations ≥ 3.0 IU/mL. This assay is linear across the analytical measuring interval of 0.2 to 75.0 IU/mL

Dataset/Regression Type: Use All Samples



Linear: Y = 0 + 1.0073*X
Quadratic: Y = -0.3 + 1.0613*X + -0.0007*X^2
Cubic: Y = 0 + 0.9713*X + 0.0024*X^2 + 0*X^3

3. Analytical Specificity/Interference:

A study was performed based on guidance from CLSI EP07, 3rd ed. and EP37, 1st ed. Each substance was tested at 2 levels of the analyte (approximately 2.0 IU/mL and 4.0 IU/mL). No significant interference (interference within or equal 0.3 IU/mL for samples < 3.0 IU/mL and within or equal 10 % for samples ≥ 3.0 IU/mL) was observed at the following concentrations.

Potentially Interfering Endogenous Substance	**Interferent Level**
Bilirubin (Conjugated)	≤ 40 mg/dL
Bilirubin (Unconjugated)	≤ 40 mg/dL
Hemoglobin	≤ 1000 mg/dL
Total Protein	≤ 15 g/dL
Triglycerides	≤ 3000 mg/dL

Potentially Interfering Drug and Other Substance	**Interferent Level**
Ascorbic Acid	≤ 300 mg/L

Atovaquone	≤ 120 mg/L
Beta Carotene	≤ 6 mg/L
Biotin	≤ 4250 ng/mL
Clindamycin	≤ 5.1 mg/dL
Folic Acid	≤ 100 nmol/L
Pyrimethamine	≤ 15 mg/L
Spiramycine	≤ 4.2 mg/L
Sulfadiazine	≤ 25.5 mg/dL
Sulfamethoxazole	≤ 210 mg/dL
Trimethoprim	≤ 4.2 mg/dL

In addition to individuals with Toxoplasmosis (High titer IgM), the ARCHITECT Toxo IgG assay was also evaluated for potential cross-reactivity from serum specimens from individuals with medical conditions or other disease states unrelated to toxoplasmosis.

Clinical Category Potentially Interfering Condition	**N**	**Number of ARCHITECT Toxo IgG Reactive Results**
Anti-dsDNA Antibodies	10	0
Anti-nuclear Antibody	10	0
Cytomegalovirus (CMV) IgG	10	0
Epstein-Barr Virus (EBNA-1 IgG)	10	0
Epstein-Barr Virus (VCA IgG)	10	0
Influenza Vaccine Recipients (IgG or IgM)	10	0
Human Anti-Mouse Antibody	10	0
Herpes Simplex Virus Types 1 (IgG)	9	0
Herpes Simplex Virus Types 2 (IgG)	10	0
Hyper IgG (polyclonal)	10	0
Measles (IgG)	10	0
Hyper IgG (monoclonal)	4	0
Parvo-B19 virus (IgG)	10	0
Rheumatoid Factor	10	0
Rubella (IgG)	7	0
Syphilis (IgG)	10	0
Toxoplasmosis (High titer IgM)	5	0
Varicella Zoster Virus	9	0
Total	164	0

4. Assay Reportable Range:

   See linearity above.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The WHO First International Standard (01/600) for Anti-Toxoplasma IgG is used to assign a concentration value to a Toxo IgG positive plasma stock. Using this concentration value, traceable to the WHO standard, the Toxo IgG positive plasma stock is then diluted to the

target concentrations of the ARCHITECT Toxo IgG Calibrators B-F and Positive Control 1 in order to manufacture the Rare Primaries and Rare Positive Control 1. The Rare Primaries are used to manufacture the primary calibrators. The Rare Positive Control is used to manufacture the primary positive control stocks.

Verification of Traceability to WHO standard Summary

N	Mean (IU/mL)	SD	Difference[a] (IU/mL)	% Difference[b]
10	20.2	0.37	0.2	1.2

[a] Difference = mean IU/mL - 20 IU/mL
[b] % Difference = Difference IU/mL x 100 / 20 IU/mL

Calibrators cover the calibration range of the assay (0.0 - 200.0 IU/mL). The calibrators are at the following anti-Toxo IgG concentrations:

Calibrator	Target Anti-Toxo IgG Concentration (IU/mL)
A	0.0
B	5.0
C	25.0
D	50.0
E	100.0
F	200.0

The controls are at the following proposed target Toxo IgG concentrations and ranges:

Control	Control Range IU/mL
Negative Control (Control −)	≤ 0.5
Positive Control 1 (Control +1)	3.0 to 9.0

The ARCHITECT Toxo IgG assay demonstrated acceptable accuracy when reading the Anti-Toxo IgG WHO international standard using a regular/list ARCHITECT Toxo IgG calibration curve for evaluation.

6. Detection Limit:

The LoB, LoD, and LoQ study was performed based on guidance from the CLSI document EP17-A2. Testing occurred over a minimum of 3 days. In order to obtain at least 60 replicates of each sample level, the 4 zero-analyte samples were tested in a minimum of 5 replicates and the 8 low-analyte samples were tested in a minimum of 10 replicates on each day of testing.

The maximum LoB value was 0.1 IU/mL, and ranged from 0.0 to 0.1 IU/mL, the maximum LoD value was 0.2 IU/mL, and ranged from 0.1 to 0.2 IU/mL, and the LoQ was 0.2 IU/mL.

7. Assay Cut-Off:

As with all analyte determinations, the anti-Toxo IgG value should be used in conjunction with information available from clinical evaluation and other diagnostic procedures. The

following table provides the cut off values and the interpretations/recommendations for the assay.

Concentration Values	Instrument Interpretation	Interpretation of Results and Retest Procedure
< 1.6 IU/mL	Nonreactive	Individuals with such results are presumed not to be infected with *T gondii* and susceptible to acute infection. A negative result does not always exclude the possibility of *T gondii* infection. Patients with negative results in suspected early disease cases should be retested in 3 weeks.
1.6 to < 2.7 IU/mL	Grayzone/Equivocal	Specimens that are considered grayzone/equivocal may contain low levels of anti-Toxo IgG. It is recommended to obtain a second sample within a reasonable period of time (e.g., 2 weeks) and to repeat ARCHITECT Toxo IgG testing.
≥ 2.7 IU/mL	Reactive	Specimens that are considered reactive for anti-Toxo IgG indicate recent or past infection. A reactive result does not distinguish between recent and past infection.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A clinical study (method comparison) was performed in the US based on guidance from CLSI EP12-A2, 2nd ed. to evaluate the percent agreement between the ARCHITECT Toxo IgG investigational assay and a current FDA cleared commercially available anti-Toxo IgG assay with routine order and preselected positive specimens collected in the US (n=777 for routine order and n=84 for preselected positive) and outside of the US (n=482 for routine order and n=71 for preselected positive) and specimens collected from pregnant females in the US (n=200).

Routine Order

Specimen Category	ARCHITECT Toxo IgG Result	Comparator Result			Negative % Agreement (95% CI)[a]	Positive % Agreement (95% CI)[a]
		Positive	Equivocal	Negative		
Routine Order	Reactive	145	3	6	98.63 (1082/1097) (97.76, 99.17)	92.95 (145/156) (87.82, 96.02)
	Equivocal	8	6	6		
	Nonreactive	1	2	1082		

[a] The 95% confidence interval (CI) for negative percent agreement and positive percent agreement were estimated using the Wilson Score method.

Twenty-six discrepant samples from routine order were tested using the Dye Test resulting in either negative, low positive, or inconclusive interpretation. Two of the 3 ARCHITECT Toxo IgG nonreactive samples were negative by Dye Test, and 1 was inconclusive. One of the 9

ARCHITECT Toxo IgG reactive samples was low positive by Dye Test, 7 were negative, and 1 was inconclusive. Ten of the 14 ARCHITECT equivocal samples were negative by Dye Test, 3 were low positive, and 1 was inconclusive.

Preselected Positive

Specimen Category	ARCHITECT Toxo IgG Result	Comparator Result			Negative % Agreement (95% CI)[a]	Positive % Agreement (95% CI)[a]
		Positive	Equivocal	Negative		
Preselected Positive	Reactive	145	0	0	100.00 (1/1) (20.65, 100.00)	94.77 (145/153) (90.02, 97.33)
	Equivocal	6	1	0		
	Nonreactive	2	0	1		

[a] The 95% confidence interval (CI) for negative percent agreement and positive percent agreement were estimated using the Wilson Score method.

Eight discrepant samples from preselected positive were tested using the Dye Test resulting in either negative, low positive, or inconclusive interpretation. One of the 2 ARCHITECT Toxo IgG nonreactive samples was negative by Dye Test, and 1 was low positive. One of the 6 ARCHITECT equivocal samples were negative by Dye Test, 3 were low positive, and 2 were inconclusive.

Pregnant Females

Specimen Category	ARCHITECT Toxo IgG Result	Comparator Result			Negative % Agreement (95% CI)[a]	Positive % Agreement (95% CI)[a]
		Positive	Equivocal	Negative		
Pregnant Females	Reactive	14	0	0	100.00 (186/186) (97.98, 100.00)	93.33 (14/15) (70.18, 98.81)

[a] The 95% confidence interval (CI) for negative percent agreement and positive percent agreement were estimated using the Wilson Score method.

Note: One additional pregnant female specimen from routine order collection was included.

One discrepant sample with ARCHITECT Toxo IgG nonreactive interpretation from pregnant females was negative by Dye Test.

CDC Panel Agreement

The *CDC Toxoplasma 1998 Human Serum Panel* was obtained from the Centers for Disease Control and Prevention (CDC) and tested on the ARCHITECT Toxo IgG assay. The results were submitted to the CDC for data evaluation. The panel consisted of 70 true positive Toxoplasma specimens and 30 true negative Toxoplasma specimens as defined by the Dye Test.

The ARCHITECT Toxo IgG assay detected 68 out of the 70 positive specimens as reactive and 2 out of the 70 positive specimens as grayzone/equivocal (both grayzone/equivocal specimens were aliquots of the same sample). Of the 30 negative specimens, the ARCHITECT Toxo IgG assay detected all 30 specimens as nonreactive.

The ARCHITECT Toxo IgG assay demonstrated 97% agreement with the positive specimens (sensitivity) and 100% agreement with the negative specimens (specificity).

2. Matrix Comparison:

A study was performed to evaluate whether specific blood collection tube types are suitable for use with the ARCHITECT Toxo IgG assay.
Samples were obtained from a specimen vendor from a minimum of 40 donors in the control tube type (serum) and in the following evaluation tube types:

- serum separator
- tripotassium EDTA
- lithium heparin plasma separator
- lithium heparin

The blood collection tubes from one individual constituted one donor set. The samples were processed by the vendor and the samples, which were collected by the vendor in the tube types

above, were received frozen at Abbott Laboratories. None of the samples were spiked; all samples were tested neat.
Each sample was tested in a minimum of 2 replicates using 1 lot each of reagents, calibrator, and controls on 1 ARCHITECT i2000SR instrument.

All of the blood collection tube types tested are acceptable for use with the ARCHITECT Toxo IgG assay.

C Clinical Studies:

1. Clinical Sensitivity:
   NA

2. Clinical Specificity:

   NA

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   See Method Comparison study

D Clinical Cut-Off:

NA

E Expected Values/Reference Range:

Due to geographic locations or demographics, assay results obtained in individual laboratories may vary from data presented.

Of the 1614 specimens tested in the ARCHITECT Toxo IgG clinical study, 977 were from the intended use population in the US. Either age or sex was not reported for 14 specimens. Of the remaining 963 specimens, 763 (79.2%) were routine order (384 female and 379 male, 0 to 88 years old) and 200 (20.8%) were pregnant females (19 to 53 years old). The mean age of the 963 specimens was 40 years.

The ARCHITECT Toxo IgG assay was reactive in 110 (11.4%) of the collected specimens in the intended use population in the US (n = 963). Testing of the specimens was performed at 3 clinical testing sites located in New York City and Farmingdale, New York and Palo Alto, California.

The distribution of ARCHITECT Toxo IgG reactive, grayzone/equivocal, and nonreactive results of the 963 US intended use population specimens by age and sex is summarized in the following table.

Age Range (Years)	Sex	ARCHITECT Toxo IgG Result			
		Number of Reactive (%)_	Number of Grayzone/Equivocal (%)	Number of Nonreactive (%)	Total
0 to 12	Female	2 (11.1)	0 (0.0)	16 (88.9)	18
	Male	0 (0.0)	0 (0.0)	36 (100.0)	36
13 to 21	Female	2 (3.9)	0 (0.0)	49 (96.1)	51
	Male	3 (8.8)	0 (0.0)	31 (91.2)	34
22 to 29	Female	12 (9.2)	0 (0.0)	118 (90.8)	130
	Male	2 (5.6)	0 (0.0)	34 (94.4)	36
30 to 39	Female	12 (6.6)	2 (1.1)	167 (92.3)	181
	Male	5 (12.2)	0 (0.0)	36 (87.8)	41
40 to 49	Female	5 (9.1)	1 (1.8)	49 (89.1)	55
	Male	7 (12.7)	0 (0.0)	48 (87.3)	55
50 to 59	Female	5 (9.1)	0 (0.0)	50 (90.9)	55
	Male	12 (19.4)	1 (1.6)	49 (79.0)	62
60 to 64	Female	8 (25.0)	0 (0.0)	24 (75.0)	32
	Male	7 (15.9)	0 (0.0)	37 (84.1)	44
65 to 100	Female	23 (37.1)	1 (1.6)	38 (61.3)	62
	Male	10 (14.1)	4 (5.6)	57 (80.3)	71
Total		115 (11.9)	9(0.9)	839 (87.1)	963

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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