May 19, 2022

Abbott Laboratories
Linda Sohn
Regulatory Project Manager
Dept 09AA, Bldg. Ap8-1, 100 Abbott Park Rd.
Abbott Park, Illinois 60064

Re: K210596
Trade/Device Name: ARCHITECT Toxo IgG
Regulation Number: 21 CFR 866.3780
Regulation Name: Toxoplasma Gondii Serological Reagents
Regulatory Class: Class II
Product Code: LGD
Dated: February 26, 2021
Received: March 1, 2021

Dear Linda Sohn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief, General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number K210596

Device Name
ARCHITECT Toxo IgG

Indications for Use *(Describe)*

ARCHITECT Toxo IgG

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 detection 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.

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

I. Applicant Name

Abbott Diagnostics
Department 09AA, Building AP8A,
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Abbott Park, IL 60064

Primary contact person for all communications:

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Date Summary prepared: May 18, 2022

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Abbott Diagnostic Division
Telephone Number: (224) 668-9286
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II. Device Name

ARCHITECT Toxo IgG

Reagents

Trade Name: ARCHITECT Toxo IgG Reagent Kit
Device Classification: Class II
Classification Name: *Toxoplasma gondii* serological reagents
Governing Regulation: 21 CFR § 866.3780
Code: LGD

Calibrator

Trade Name: ARCHITECT Toxo IgG Calibrator
Device Classification: Class II
Classification Name: *Toxoplasma gondii* serological reagents
Governing Regulation: 21 CFR § 866.3780
Code: LGD

Controls

Trade Name: ARCHITECT Toxo IgG Controls
Device Classification: Class II
Classification Name: *Toxoplasma gondii* serological reagents
Governing Regulation: 21 CFR § 866.3780
Code: LGD

Predicate Device:

BioMérieux VIDAS TOXO IgG II (TXG) assay (k993319)

III. Description of Device

Reagents

The ARCHITECT Toxo IgG reagent kit contains:

- **Microparticles:** (1 bottle x 6.6 mL per 100-test / 1 bottle x 27.0 mL per 500-test) Recombinant *Toxoplasma gondii* antigen coated microparticles in MES buffer with protein (bovine). Minimum concentration: 0.03% solids. Preservative: ProClin 300.
- **Conjugate:** (1 bottle x 5.9 mL per 100-test / 1 bottle x 26.3 mL per 500-test). Murine acridinium-labeled anti-human IgG in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.05 µg/mL. Preservatives: antimicrobial agents.
- **Assay Diluent:** (1 bottle x 10.0 mL per 100-test / 1 bottle x 50.9 mL per 500-test). TRIS buffer with protein (murine) and protein (bovine). Preservative: ProClin 300.

Calibrators

The ARCHITECT Toxo IgG Calibrators:

- Calibrator A - 1 Bottle (4.0 mL); an aqueous solution with protein (bovine) stabilizer. Preservative: ProClin 300.
- Calibrators B through F - 5 bottles (4.0 mL each); contain anti-Toxo IgG in an aqueous solution with protein (bovine) stabilizer. Preservative: ProClin 300.

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 ARCHITECT Toxo IgG Calibrators are referenced to the World Health Organization (WHO) First International Standard (01/600) for anti-Toxoplasma IgG.

Controls

The ARCHITECT Toxo IgG Controls:

- Negative Control - 1 Bottle (8.0 mL); contains recalcified human plasma with protein (ovine) stabilizer. Preservatives: ProClin 950 and sodium azide.
- Positive Control 1 - 1 Bottle (8.0 mL); contains anti-Toxo IgG in aqueous solution with protein (bovine) stabilizer. Preservative: ProClin 300.

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

Principles of the Procedure

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.

IV. Intended Use of the Device

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 detection 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.

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

V. Comparison of Technological Characteristics

The ARCHITECT Toxo IgG assay (subject device) utilizes a chemiluminescent microparticle immunoassay (CMIA) methodology for the quantitative *in vitro* determination of IgG antibodies to *Toxoplasma gondii* and is intended for use on the ARCHITECT i System.

The similarities and differences between the subject device and the predicate assay are presented in the Assay Similarities table.

Assay Similarities

Characteristics	Subject Device ARCHITECT Toxo IgG	Predicate Device VIDAS TOXO IgG II Assay (K993319, Package Insert 30 210-01 [March 2019])
Intended Use and Indications for 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 detection 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. Not intended for use in screening blood, plasma, or tissue donors.	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

Assay Differences

Characteristics	Subject Device ARCHITECT Toxo IgG	Predicate Device VIDAS TOXO IgG II Assay (K993319, Package Insert 30 210-01 [March 2019])
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 Reactive: ≥ 8 IU/mL

Assay Differences

Characteristics	Subject Device ARCHITECT Toxo IgG	Predicate Device VIDAS TOXO IgG II Assay (K993319, Package Insert 30 210-01 [March 2019])
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). 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. Summary of Nonclinical Performance

A. Within- Laboratory Precision (20-Day)

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 3 lots of the ARCHITECT Toxo IgG reagents, 3 lots of the ARCHITECT Toxo IgG Calibrators, and 3 lots of the ARCHITECT Toxo IgG Controls and 1 instrument. Two controls and 5 human serum panels were assayed in a minimum of 2 replicates at 2 separate times per day on 20 days on 3 reagent lot/calibrator lot combinations, where a unique reagent lot and a unique calibrator lot are paired. The performance from a representative combination is shown in the following table.

Sample	N	Mean (IU/mL)	Within-Run (Repeatability)		Within-Laboratory[a] (Total)	
			SD	%CV	SD (Range[b])	%CV (Range[b])
Negative Control	118	0.0	0.01	N/A[c]	0.01 (0.01 – 0.02)	N/A[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	N/A[c]	0.04 (0.04 – 0.05)	N/A[c]
Panel 2	120	1.5	0.06	N/A[c]	0.06 (0.06 – 0.06)	N/A[c]
Panel 3	120	4.2	0.16	3.8	0.18 (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] Includes within-run, between-run, and between-day variability.
[b] Minimum and maximum SD or %CV across all reagent lot/calibrator lot combinations.
[c] Not applicable

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

B. Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.* Testing was conducted using 3 lots of the ARCHITECT Toxo IgG reagents on each of 2 instruments over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and lower limit of quantitation (LLoQ) values are summarized below.

	IU/mL
LoB[a]	0.1
LoD[b]	0.2
LLoQ[c]	0.2

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.
[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.
[c] The LLoQ is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met and was determined from n ≥ 60 replicates of low-analyte level samples.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

C. Linearity

A study was performed based on guidance from CLSI EP06-A.*

This assay is linear across the analytical measuring interval of 0.2 to 75.0 IU/mL.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. CLSI Document EP06-A. Wayne, PA: CLSI; 2003.

D. Analytical Specificity

Potentially Interfering Endogenous Substances, Drugs, and Other Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.* and CLSI 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 ± 0.3 IU/mL for samples < 2.7 IU/mL and within ± 10% for samples ≥ 2.7 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

* Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

† Clinical and Laboratory Standards Institute (CLSI). *Supplemental Tables for Interference Testing in Clinical Chemistry*. 1st ed. CLSI supplement EP37. Wayne, PA: CLSI; 2018.

Potentially Interfering Other Conditions

A total of 164 specimens from individuals with medical conditions unrelated to *T gondii* infection and specimens containing potentially interfering substances were evaluated. No tested specimens resulted in Reactive Results.

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

E. 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 results were aliquots of the same specimen). 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).

The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply endorsement of the assay by the CDC.

VII. Summary of Clinical Performance

A. Expected Values

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 the 963 specimens was 40 years.

The ARCHITECT Toxo IgG assay was reactive in 115 (11.9%) 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			Total
		Number of Reactive (%)	Number of Grayzone/Equivocal (%)	Number of Nonreactive (%)	
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

The ARCHITECT Toxo IgG results for each category in the intended use population are summarized in the following table.

Specimen Category	ARCHITECT Toxo IgG Result			Total
	Number of Reactive (%)	Number of Grayzone/Equivocal (%)	Number of Nonreactive (%)	
Routine Order	101 (13.2)	9 (1.2)	653 (85.6)	763
Pregnant Females	14 (7.0)	0 (0.0)	186 (93.0)	200
Total	115 (11.9)	9 (0.9)	839 (87.1)	963

B. System Reproducibility

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 3 lots of the ARCHITECT Toxo IgG reagents, 2 lots of the ARCHITECT Toxo IgG Calibrators, and 2 lots of the ARCHITECT Toxo IgG Controls and 1 instrument at each of the 3 clinical sites. Two controls and 5 human serum panels were assayed in 4 replicates at 2 separate times per day on 5 different days.

Sample	N	Mean (IU/mL)	Within-Run (Repeatability)		Within-Laboratory[a] (Total)		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV
Negative Control	360	0.0	0.02	N/A[c]	0.02	N/A[c]	0.02	N/A[c]
Positive Control 1	360	6.4	0.15	2.3	0.18	2.8	0.22	3.5
Panel 1	360	0.0	0.04	N/A[c]	0.04	N/A[c]	0.05	N/A[c]
Panel 2	360	1.4	0.06	N/A[c]	0.06	N/A[c]	0.08	N/A[c]
Panel 3	360	4.2	0.12	2.8	0.12	2.9	0.23	5.6
Panel 4	360	9.0	0.21	2.4	0.25	2.8	0.53	5.9
Panel 5	360	69.4	2.02	2.9	2.20	3.2	4.68	6.7

[a] Includes within-run, between-run, and between-day variability.
[b] Includes within-run, between-run, between-day, between-site, between-lot and the site-lot interaction variability.
[c] Not applicable

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

C. Percent Agreement

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% Confidence Interval)[a]	Positive % Agreement (95% Confidence Interval)[a]
		Positive	Equivocal	Negative		
Routine Order	Reactive	148	4	8	98.54 (1082/1098) (97.65, 99.10)	94.87 (148/156) (90.21, 97.38)
	Equivocal	5	5	4		
	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-three of the 24 discordant 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 11 ARCHITECT Toxo IgG reactive samples was low positive by Dye Test, 9 were negative, and 1 was inconclusive. Seven of the 9 ARCHITECT equivocal samples were negative by Dye Test, and 2 were low positive.

* Clinical and Laboratory Standards Institute (CLSI). *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*. CLSI Document EP12-A2. Wayne, PA: CLSI; 2008.

Preselected Positive

Specimen Category	ARCHITECT TOXO IgG Result	Comparator Result			Negative % Agreement (95% Confidence Interval)[a]	Positive % Agreement (95% Confidence Interval)[a]
		Positive	Equivocal	Negative		
Preselected Positive	Reactive	148	0	0	100.00 (1/1) (20.65, 100.00)	96.73 (148/153) (92.58, 98.60)
	Equivocal	3	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.

Five discordant 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 3 ARCHITECT equivocal samples was negative by Dye Test, 1 was low positive, and 1 was inconclusive.

Pregnant Females

Specimen Category	ARCHITECT TOXO IgG Result	Comparator Result			Negative % Agreement (95% Confidence Interval)[a]	Positive % Agreement (95% Confidence Interval)[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)
	Equivocal	0	0	0		
	Nonreactive	1	0	186		

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

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

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

Negative percent agreement and positive percent agreement from the specimen categories above were calculated according to the formulas below:

		Comparator Toxo IgG Result		
		Positive	**Equivocal**	**Negative**
ARCHITECT TOXO IgG Result	Reactive	A	B	C
	Equivocal	D	E	F
	Nonreactive	G	H	I

Positive Percent Agreement = A/(A+D+G+H) x 100%

Negative Percent Agreement = I/(C+F+I+B) x 100%

VIII. Conclusion Drawn from Nonclinical and Clinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the subject device (ARCHITECT Toxo IgG) performance is substantially equivalent to the predicate assay (VIDAS TOXO IgG II assay, k993319).

The similarities and differences between the subject device and the predicate assay are presented in the Assay Similarities table. The results presented in this 510(k) provide reasonable assurance that the subject ARCHITECT Toxo IgG assay is safe and effective for the stated intended use. Differences between the subject device and the predicate assay shown in the tables do not affect the safety and effectiveness of the subject device.

There is no known potential adverse effect to the operator when using this *in vitro* device according to the ARCHITECT Toxo IgG reagent package insert.