August 30, 2024

Abbott Laboratories
Laura Fraczek
Regulatory Affairs Senior Specialist
100 Abbott Park Rd.
Abbott Park, Illinois 60064

Re: K233932
Trade/Device Name: Alinity i Toxo IgM
Regulation Number: 21 CFR 866.3780
Regulation Name: Toxoplasma Gondii Serological Reagents
Regulatory Class: Class II
Product Code: LGD
Dated: December 13, 2023
Received: December 14, 2023

Dear Laura Fraczek:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JORGE L. MUNOZ -S
Digitally signed by JORGE L. MUNOZ -S
Date: 2024.08.30 10:42:40 -04'00'

Jorge Munoz, Ph.D.
Branch Chief
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233932

Device Name
Alinity i Toxo IgM

Indications for Use *(Describe)*

The Alinity i Toxo IgM assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgM antibodies to Toxoplasma gondii in human serum, serum separator, and plasma tubes (lithium heparin, lithium heparin separator, and tripotassium EDTA) on the Alinity i system.
The Alinity i Toxo IgM assay is to be used as an aid in the diagnosis of acute or recent Toxoplasma gondii infection in suspected individuals including women of child-bearing age. It is recommended that the assay be performed in conjunction with a Toxoplasma gondii IgG assay.
The Alinity i Toxo IgM assay has not been cleared 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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510(k) Summary

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. 510(k) Number

K233932

II. Applicant Name

Abbott Laboratories
Department 09AA
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Primary contact person for all communications:

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Date summary prepared: August 28, 2024

III. Device Name

Alinity i Toxo IgM

Reagents

Trade Name: Alinity i Toxo IgM Reagent Kit
Device Classification: Class II
Classification Name: *Toxoplasma gondii* serological reagents
Governing Regulation: 21 CFR 866.3780
Code: LGD

Calibrator

Trade Name: Alinity i Toxo IgM Calibrator
Device Classification: Class II
Classification Name: *Toxoplasma gondii* serological reagents
Governing Regulation: 21 CFR 866.3780
Code: LGD

Controls

Trade Name: Alinity i Toxo IgM Controls
Device Classification: Class II
Classification Name: *Toxoplasma gondii* serological reagents
Governing Regulation: 21 CFR 866. 3780
Code: LGD

IV. Predicate Device

bioMérieux VIDAS TOXO IgM assay (k923166)

V. Description of Device

Reagents

The kit configurations of the Alinity i Toxo IgM Reagent Kit are described below.

List Number (LN)	**07P4740**	**07P4745**
Tests per cartridge	100	500
Number of cartridges per kit	2	2
Tests per kit	200	1000
Microparticles	6.6 mL	27.0 mL
Conjugate	6.1 mL	26.5 mL

- **Microparticles:** Anti-human IgM (murine, monoclonal) antibody coated microparticles in TRIS buffer with protein (bovine and goat) stabilizers, and detergent. Minimum concentration: 0.08 % solids. Preservatives: antimicrobial agents.

- **Conjugate:** Conjugate complex consisting of acridinium-labeled anti-Toxoplasma p30 antigen antibody (murine, monoclonal) and native *Toxoplasma gondii* lysate in phosphate buffer with protein (bovine) stabilizer, and detergent. Minimum concentration: 25 µg/mL. Preservative: sodium azide.

Calibrator

The Alinity i Toxo IgM Calibrator is described below.

- **Calibrator 1:** Contains anti-Toxoplasma p30 antigen IgM antibody (human, monoclonal) prepared in recalcified human plasma. The calibrator is reactive for IgM antibodies to *Toxoplasma gondii* (anti-Toxo IgM). Preservatives: ProClin 950 and sodium azide.

Calibrator	Quantity
Calibrator 1	1 x 3.0 mL

The Alinity i Toxo IgM Calibrator is manufactured and referenced to an internal reference standard.

Controls

The Alinity i Toxo IgM Controls are described below.

- **Negative Control:** Contains recalcified human plasma.
- **Positive Control:** Contains anti-Toxoplasma p30 antigen IgM antibody (human, monoclonal) prepared in recalcified human plasma. The positive control is reactive for IgM antibodies to *Toxoplasma gondii* (anti-Toxo IgM).
- Preservatives: ProClin 950 and sodium azide.

The targets and ranges for the controls are provided in the table below.

Control	Quantity	Anti-Toxo IgM	
		Target (S/CO)	**Range (S/CO)**
Negative Control	1 x 4.0 mL	-	< 0.67
Positive Control	1 x 4.0 mL	2.50	1.25 - 3.75

The Alinity i Toxo IgM Positive Control is referenced to an internal reference standard.

Biological Principles of the Procedure

The Alinity i Toxo IgM assay is an automated, two-step immunoassay for the qualitative detection of IgM antibodies to *Toxoplasma gondii* in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Pre-diluted sample and anti-human IgM murine monoclonal antibody coated paramagnetic microparticles are combined and incubated. Together with IgM antibodies of other specificities, anti-Toxo specific IgM present in the sample binds to the anti-human IgM murine monoclonal antibody coated microparticles, forming an antibody-antibody complex. The mixture is washed. A conjugate complex consisting of an acridinium-labeled anti-Toxo p30 antigen murine monoclonal F(ab')2 fragment and native *Toxoplasma gondii* lysate, containing the p30 antigen, is added to create a reaction mixture and incubated. This conjugate complex is bound by anti-Toxo specific IgM that has been captured by the anti-human IgM murine monoclonal antibody coated microparticles, forming an antibody-antibody-conjugate complex. 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 IgM in the sample and the RLU detected by the system optics.

The presence or absence of anti-Toxo IgM in the sample is determined by comparing the chemiluminescent RLU in the reaction to the cutoff RLU determined from an active calibration.

VI. Intended Use of the Device

The Alinity i Toxo IgM assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgM antibodies to *Toxoplasma gondii* in human serum, serum separator, and plasma tubes (lithium heparin, lithium heparin separator, and tripotassium EDTA) on the Alinity i system.

The Alinity i Toxo IgM assay is to be used as an aid in the diagnosis of acute or recent *Toxoplasma gondii* infection in suspected individuals including women of child-bearing age. It is recommended that the assay be performed in conjunction with a *Toxoplasma gondii* IgG assay.

The Alinity i Toxo IgM assay has not been cleared for use in screening blood, plasma, or tissue donors.

VII. Comparison of Technological Characteristics

The Alinity i Toxo IgM assay (subject device) utilizes a CMIA methodology for the qualitative *in vitro* detection of IgM antibodies to *Toxoplasma gondii* and is intended for use on the Alinity i system.

The similarities and differences between the subject device and the predicate device are presented in the following tables.

Assay Similarities

Characteristics	**Subject Device** **Alinity i Toxo IgM** **K233932**	**Predicate Device** **VIDAS TOXO IgM Assay** **k923166**
Intended Use and Indications for Use	The Alinity i Toxo IgM assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgM antibodies to *Toxoplasma gondii* in human serum, serum separator, and plasma tubes (lithium heparin, lithium heparin separator, and tripotassium EDTA) on the Alinity i system. The Alinity i Toxo IgM assay is to be used as an aid in the diagnosis of acute or recent *Toxoplasma gondii* infection in suspected individuals including women of child-bearing age. It is recommended that the assay be performed in conjunction with a *Toxoplasma gondii* IgG assay. The Alinity i Toxo IgM assay has not been cleared for use in screening blood, plasma, or tissue donors.	The VIDAS® TOXO IgM (TXM) assay is intended for use on the instruments of the VIDAS® family (VITEK® ImmunoDiagnostic Assay System) 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® TOXO IgM (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.
Calibrator(s)	1 Calibrator	1 Calibrator
Control(s)	2 (Negative and Positive)	2 (Negative and Positive)

Assay Differences

Characteristics	Subject Device Alinity i Toxo IgM K233932	Predicate Device VIDAS TOXO IgM Assay k923166
Antigen and Antibody Used	• Anti-Toxoplasma p30 antigen antibody (murine, monoclonal) and native *Toxoplasma gondii* lysate • Anti-human IgM murine monoclonal antibody	• Immunocomplex of *T. gondii* antigen (RH Sabin strain) • Mouse monoclonal anti-P30 antibodies
Type of Specimen	Serum and Plasma	Serum
Methodology	Chemiluminescent microparticle immunoassay	Enzyme-linked fluorescent immunoassay
Interpretation of Results	Nonreactive: < 0.83 S/CO Grayzone/Equivocal: 0.83 to < 1.00 S/CO Reactive: ≥ 1.00 S/CO	Negative: < 0.55 Test Value Equivocal: ≥ 0.55 to < 0.65 Test Value Positive: ≥ 0.65 Test Value
Components	Microparticles – Anti-human IgM (murine, monoclonal) antibody coated microparticles in TRIS buffer with protein (bovine and goat) stabilizers, and detergent. Minimum concentration: 0.08 % solids. Preservatives: antimicrobial agents. Conjugate – Conjugate complex consisting of acridinium-labeled anti-Toxoplasma p30 antigen antibody (murine, monoclonal) and native *Toxoplasma gondii* lysate in phosphate buffer with protein (bovine) stabilizer, and detergent. Minimum concentration: 25 µg/mL. Preservative: sodium azide.	Solid Phase Receptacle (SPR) – SPR coated goat anti-µ chain antibodies Reagent Strip – Strip consists of 10 wells covered with labeled, foil seal. The wells contain the various reagents required for the assay including: • Sample diluent: 300 µL of TRIS buffered saline (0.05 mol/L, pH 7.4) with protein and chemical stabilizers and 1 g/L sodium azide. • Pre-wash: 600 µL of TRIS buffered saline (0.05 mol/L, pH 7.4) with protein and chemical stabilizers and 1 g/L sodium azide. • Wash buffer: 600 µL of TRIS buffered saline (0.05 mol/L, pH 7.4) with protein and chemical stabilizers and 1 g/L sodium azide. • Conjugate: 400 µL of immunocomplex of *T. gondii* antigen (RH Sabin strain) grown in mice (9) and mouse monoclonal anti-P30 antibodies

Characteristics	Subject Device Alinity i Toxo IgM K233932	Predicate Device VIDAS TOXO IgM Assay k923166
		conjugated to alkaline phosphatase with gentamycin 0.02% and 0.9 g/L sodium azide. • Reading cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/L) + diethanolamine (DEA) (0.62 mol/L or 6.6%, pH 9.2) + 1 g/L sodium azide (300 µL).
Calibration Storage	Maximum of 30 days	14 days

VIII. Summary of Nonclinical Performance

A. Assay Cutoff

The cutoff for the Alinity i Toxo IgM assay was established using samples characterized with a commercially available anti-Toxo IgM assay. A total of 1219 samples (1053 anti-Toxo IgM nonreactive samples and 166 anti-Toxo IgM reactive samples) were included. A receiver-operating characteristic analysis showed a clear separation of the nonreactive and reactive results using a cutoff of 1.00 S/CO (with a grayzone from 0.83 to < 1.00 S/CO).

B. Within- Laboratory Precision (20-Day)

A 20-day within-laboratory precision study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 3 lots of the Alinity i Toxo IgM reagents, 3 lots of the Alinity i Toxo IgM Calibrator, 3 lots of the Alinity i Toxo IgM Controls, and 1 instrument. Two controls and 4 recalcified human plasma panels (representing serum matrix) were tested in 3 replicates at 2 separate times per day on 20 days using 3 reagent lot/calibrator lot combinations, where a unique reagent lot and a unique calibrator lot are paired. The performance is shown in the following table.

Sample ID	N	Mean (S/CO)	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Lot [a]		Overall Within Laboratory [b]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control	360	0.14	0.012	NA[c]	0.000	NA[c]	0.004	NA[c]	0.008	NA[c]	0.014	NA[c]
Positive Control	360	2.72	0.077	2.8	0.034	1.3	0.031	1.2	0.051	1.9	0.104	3.8
True Nonreactive Panel	358 [d]	0.14	0.013	NA[c]	0.000	NA[c]	0.005	NA[c]	0.006	NA[c]	0.015	NA[c]
High Nonreactive Panel	360	0.81	0.028	NA[c]	0.006	NA[c]	0.009	NA[c]	0.027	NA[c]	0.040	NA[c]
Low Reactive Panel	359 [d]	1.34	0.047	3.5	0.000	0.0	0.007	0.5	0.042	3.2	0.064	4.7
Reactive Panel	359 [d]	2.54	0.078	3.1	0.000	0.0	0.023	0.9	0.073	2.9	0.109	4.3

[a] Alinity i Toxo IgM reagent lot and Alinity i Toxo IgM calibrator lot are confounded, and the confounding effect is represented by between-lot.

[b] Overall within-laboratory variability contains repeatability (within-run), between-run, between-day, and between-lot variance components.

[c] Not applicable

[d] In cases where n < 360, replicate(s) were excluded due to an instrument error and no results were reported.

* 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. Analytical Specificity

Potentially Interfering Endogenous Substances

The Alinity i Toxo IgM assay was evaluated for potential interference caused by endogenous substances based on guidance from CLSI EP07, 3rd ed.* and CLSI EP37, 1st ed.† Each substance was evaluated using samples containing anti-Toxo IgM at the target ranges of 0.60 to 0.99 S/CO and 1.00 to 2.00 S/CO.

No significant interference (interference ≤ +0.10 S/CO for samples < 1.00 S/CO and ≥ -10% for samples ≥ 1.00 S/CO) was observed at the following concentrations.

No Significant Interference	
Potentially Interfering Substance	**Interferent Level**
Unconjugated Bilirubin	40 mg/dL
Conjugated Bilirubin	40 mg/dL
Hemoglobin	1000 mg/dL
Total Protein	15 g/dL
Triglycerides	3000 mg/dL

Potentially Interfering Other Conditions

The Alinity i Toxo IgM assay was evaluated for potential interference caused by HAMA and RF based on guidance from CLSI EP07, 3rd ed.*16*. Each condition was evaluated using samples containing anti-Toxo IgM at the following target range: 1.00 to 1.40 S/CO.

No significant interference (interference ≤ ± 10%) was observed at the following concentrations.

* 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.

No Significant Interference	
Potentially Interfering Other Condition	**Interferent Level**
HAMA	800 ng/mL
RF	200 IU/mL

Potentially Interfering Drugs and Other Substances

The Alinity i Toxo IgM assay was evaluated for potential interference caused by exogenous substances based on guidance from CLSI EP07, 3rd ed. and CLSI EP37, 1st ed. Each substance was evaluated using samples containing anti-Toxo IgM at the target ranges of 0.60 to 0.99 S/CO and 1.00 to 2.00 S/CO.

No significant interference (interference ≤ +0.10 S/CO for samples < 1.00 S/CO and ≥ -10% for samples ≥ 1.00 S/CO) was observed at the following concentrations.

No Significant Interference	
Potentially Interfering 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

Potential Cross-Reactivity

Potential cross-reactivity for the Alinity i Toxo IgM assay was determined by testing a total of 177 serum specimens from individuals with other medical conditions unrelated to Toxoplasmosis infection, in addition to individuals with high titer Toxoplasmosis IgG. Out of 10 RF specimens, one resulted in a false reactive result with the Alinity i Toxo IgM assay.

Category	**n**	**Number of Alinity i Toxo IgM False Reactive Results**
Anti-dsDNA Antibodies	10	0
Anti-nuclear Antibody (ANA)	10	0
Cytomegalovirus (IgM)	10	0
Epstein-Barr Virus (EBV) IgM	9	0
Herpes Simplex Virus Types 1/2 (IgG/IgM)	18	0
Human anti-mouse antibody	10	0
Hyper IgG	10	0
Hyper IgM	10	0
Influenza vaccine recipients	10	0
Measles (IgM)	10	0
Parvovirus B19 (IgG)	6	0
Parvovirus B19 (IgM)	4	0
Rheumatoid Factor	10	1[a]
Rubella (IgM)	10	0
Samples from immunocompromised patients	10	0
Syphilis	10	0
Toxoplasmosis High Titer (IgG)	10	0
Varicella Zoster Virus	10	0
Total	177	1

[a] One out of 10 RF specimens was falsely reactive with the Alinity i Toxo IgM assay.

D. Matrix Equivalency

A study was performed to evaluate whether specific blood collection tube types are suitable for use with the Alinity i Toxo IgM assay. The matrix collection tube type equivalency study was conducted including 43 donors of reactive (20 donors) and nonreactive (23 donors) samples in 5 types of blood collection tubes (serum, serum separator, lithium heparin plasma, lithium heparin plasma separator, and tripotassium EDTA plasma) for use with the Alinity i Toxo IgM assay. Data was analyzed using regression analysis comparing numerical S/CO results of all matrices to serum to evaluate any potential bias. All of the blood collection tube types tested are acceptable for use with the Alinity i Toxo IgM assay.

E. Class Specificity

Class specificity testing of the Alinity i Toxo IgM assay demonstrated reactivity only to human anti-Toxoplamsa IgM. No reactivity to human anti-Toxoplasma IgG was observed.

F. CDC Panel Agreement

The Centers for Disease Control and Prevention (CDC) *Toxoplasma* 1998 Human Serum Panel was tested using the Alinity i Toxo IgM assay. The Alinity i Toxo IgM assay results were submitted to the CDC for data analysis and for the result interpretation for each sample. The panel consisted of 32 true positive Toxoplasma specimens and 65 true negative Toxoplasma specimens. The Alinity i Toxo IgM assay detected the 32 positive specimens as reactive and the 65 negative specimens as nonreactive. The CDC performed kit sensitivity (positive percent agreement [PPA]) and kit specificity (negative percent agreement [NPA]) analyses and sent the results to Abbott.

The percent agreement of the Alinity i Toxo IgM assay relative to the CDC results was calculated. The PPA was 100% with a 95% confidence interval (CI) of 89.28% to 100.00%. The NPA was 100% with a 95% CI of 94.42% to 100.00%.

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.

Alinity i Toxo IgM Interpretation	CDC Interpretation		Positive % Agreement (95% CI)[a]	Negative % Agreement (95% CI)[a]
	Positive	Negative		
Reactive	32	0	100.00 (32/32) (89.28, 100.00)	100.00 (65/65) (94.42, 100.00)
Grayzone/Equivocal	0	0		
Nonreactive	0	65		

[a] The 95% CI for negative percent agreement and positive percent agreement were estimated using the Wilson score method.

IX. Summary of Clinical Performance

A. Expected Values

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity i Toxo IgM results from the clinical method comparison study for each category in the US intended use population are summarized in the following table.

Category	Alinity i Toxo IgM Result			
	Number of Reactive (%)	Number of Grayzone/ Equivocal (%)	Number of Nonreactive (%)	Total
Population 1	1 (0.6)	0 (0.0)	168 (99.4)	169
Population 2	1 (0.5)	0 (0.0)	206 (99.5)	207
Total	2 (0.5)	0 (0.0)	374 (99.5)	376

Note: Population 1 are consecutively collected remnant specimens sent to a laboratory for anti-Toxo IgM testing. Population 2 are consecutively collected remnant specimens from pregnant women sent to a laboratory for anti-Toxo IgM testing.

The Alinity i Toxo IgM assay was reactive in 2 (0.5%) of the collected specimens in the US intended use population (n = 376).

B. Reproducibility Study (5-Day)

A 5-day reproducibility study was conducted at 3 US sites, using the same sample panels used in the within-laboratory precision study, in addition to one positive and one negative control based on the guidance from CLSI EP05-A3. Four replicates per sample were evaluated in 2 runs per day over 5 days. Testing was conducted using 3 lots of the Alinity i Toxo IgM reagents, 2 lots of the Alinity i Toxo IgM Calibrator, and 1 lot of the Alinity i Toxo IgM Controls at each of the 3 testing sites.

Sample	N	Mean S/CO	Repeatability		Between-Run		Between-Day		Between-Site		Between-Lot[a]		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control	360	0.13	0.013	NA[c]	0.002	NA[c]	0.001	NA[c]	0.009	NA[c]	0.008	NA[c]	0.018	NA[c]
Positive Control	360	2.62	0.074	2.8	0.031	1.2	0.022	0.8	0.056	2.1	0.075	2.9	0.132	5.1
True Nonreactive Panel	360	0.11	0.013	NA[c]	0.000	NA[c]	0.004	NA[c]	0.006	NA[c]	0.008	NA[c]	0.017	NA[c]
High Nonreactive Panel	360	0.76	0.030	NA[c]	0.009	NA[c]	0.006	NA[c]	0.000	NA[c]	0.023	NA[c]	0.041	NA[c]
Low Reactive Panel	360	1.3	0.042	3.2	0.017	1.3	0.000	0.0	0.016	1.3	0.040	3.1	0.067	5.1
Reactive Panel	360	2.49	0.077	3.1	0.032	1.3	0.019	0.8	0.059	2.4	0.080	3.2	0.136	5.5

[a] Alinity i Toxo IgM reagent lot and Alinity i Toxo IgM calibrator lot are confounded, and the confounding effect is represented by between-lot.

[b] Reproducibility contains repeatability, between-run, between-day, between-lot, between-site, and site-lot interaction variance components.

[c] Not applicable

C. Clinical Agreement

A clinical method comparison study was conducted to evaluate the clinical performance of the Alinity i Toxo IgM assay based on guidance from CLSI EP12-A2, 2nd ed.[*], to evaluate the percent agreement between the Alinity i Toxo IgM investigational assay and a current FDA-cleared, commercially available anti-Toxo IgM assay with specimens collected from 2 populations. Population 1 was comprised of 897 consecutively collected remnant specimens sent to a laboratory for anti-Toxo IgM testing including specimens collected in the US (n = 169) and outside of the US (n = 710), and Population 2 was comprised of 207 consecutively collected remnant specimens from pregnant women sent to a laboratory for anti-Toxo IgM testing in the US.

Demographic information for specimens collected in the US from Population 1 and 2 is shown in the table below (n=376).

Specimen	Age	Female (n)	Male (n)	Unknown (n)	Total (n)
Population 1 (n=**169**)	≤ 5 years	2	2	0	**4**
	6 to 21 years	5	7	0	**12**
	22 to 59 years	75	36	1	**112**
	≥ 60 years	20	19	0	**39**
	Unknown	0	2	0	**2**
	Total	**102**	**66**	**1**	**169**
Population 2 (n=**207**)	≤ 5 years	0	0	0	**0**
	6 to 21 years	8	0	0	**8**
	22 to 59 years	196	0	0	**196**
	≥ 60 years	0	0	0	**0**
	Unknown	3	0	0	**3**
	Total	**207**	**0**	**0**	**207**
Total	≤ 5 years	**2**	**2**	**0**	**4**
	6 to 21 years	**13**	**7**	**0**	**20**
	22 to 59 years	**271**	**36**	**1**	**308**
	≥ 60 years	**20**	**19**	**0**	**39**
	Unknown	**3**	**2**	**0**	**5**
	Total	**309**	**66**	**1**	**376**

[*] 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.

PPA and NPA between the Alinity i Toxo IgM assay and an FDA-cleared assay was calculated for each population separately and are shown in the tables below.

Specimen Category	Alinity i Toxo IgM Result	Comparator Result			Positive % Agreement (95% CI)[a]	Negative % Agreement (95% CI)[a]
		Positive	Equivocal	Negative		
Population 1 (n=897)	Reactive	150	16	11	94.94 (150/158) (90.33, 97.41)	94.44 (697/738) (92.55, 95.88)
	Grayzone/Equivocal	1	1	14		
	Nonreactive	6	1	697		
	Total	157	18	722		
Specimen Category	**Alinity i Toxo IgM Result**	**Comparator Result**			**Positive % Agreement (95% CI)[a]**	**Negative % Agreement (95% CI)[a]**
		Positive	**Equivocal**	**Negative**		
Population 2[b] (n=234)	Reactive	18	0	0	94.74 (18/19) (75.36, 99.06)	100.00 (215/215) (98.24, 100.00)
	Grayzone/Equivocal	0	0	0		
	Nonreactive	1	0	215		
	Total	19	0	215		

[a] The 95% CI for PPA and NPA were estimated using the Wilson score method.

[b] Twenty-seven specimens from Population 1 were from pregnant females and therefore, were also included in Population 2.

X. Conclusion Drawn from Nonclinical and Clinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the subject device (Alinity i Toxo IgM) performance is substantially equivalent to the predicate assay (bioMérieux VIDAS TOXO IgM assay, k923166).