Beckman Coulter Inc.
Stefanie K Berg
Senior Staff Quality Assurance
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K242095
Trade/Device Name: Access Toxo IgM II
Regulation Number: 21 CFR 866.3780
Regulation Name: Toxoplasma Gondii Serological Reagents
Regulatory Class: Class II
Product Code: LGD
Dated: July 17, 2024
Received: July 17, 2024

Dear Stefanie K Berg:

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).

JORGE L. MUNOZ -S

Digitally signed by JORGE L. MUNOZ -S
Date: 2024.10.11 12:38:31 -04'00'

Sincerely,
Jorge Munoz, Ph.D.
Branch Chief
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242095

Device Name
Access Toxo IgM II

Indications for Use *(Describe)*
The Access Toxo IgM II assay is a paramagnetic-particle chemiluminescent immunoassay for the qualitative detection of Toxoplasma gondii-specific IgM antibody in adult human serum and plasma using the Access Immunoassay Systems.

The Access Toxo IgM II assay is presumptive for the diagnosis of acute, recent, or reactivated Toxoplasma gondii infection in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with a Toxoplasma gondii-specific IgG antibody assay.

Note: This assay has not been cleared/approved by the FDA for the screening of blood or plasma donors in the United States.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

510(k) Number K242095

Date Prepared: October 9, 2024

Submitted By:
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Device Name
Common Name: enzyme linked immunoabsorbent assay, toxoplasma gondii
Trade Name: Access Toxo IgM II
Classification Name: Toxoplasma gondii serological reagents.
Classification Code: LGD
Classification Regulation: 21 CFR 866.3780

Predicate Device
Device Name: Access Toxo IgM II
510(k) Numbers: K003259

Device Description
The Access Toxo IgM II assay is a paramagnetic-particle chemiluminescent immunoassay for the qualitative detection of *Toxoplasma gondii*-specific IgM antibody in human serum and plasma using the Access Immunoassay Systems. The Access Toxo IgM II Calibrators are intended for use with the Access Toxo IgM II assay for the qualitative detection of *Toxoplasma gondii*-specific IgM antibody in adult human serum and plasma using the Access Immunoassay Systems. The Access Toxo IgM II QC is intended for monitoring system performance of the Access Toxo IgM II assay. The Access assay consists of the reagent pack, calibrators and QCs. Other items needed to run the assay include substrate and wash buffer. The Access assay reagent pack, Access assay calibrators, Access QCs, along with the UniCel DxI Wash Buffer II are designed for use with the DxI 9000 Access Immunoassay Analyzer in a clinical laboratory setting.

Intended Use

The Access Toxo IgM II assay is a paramagnetic-particle chemiluminescent immunoassay for the qualitative detection of *Toxoplasma gondii*-specific IgM antibody in adult human serum and plasma using the Access Immunoassay Systems.

The Access Toxo IgM II assay is presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infection in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with a *Toxoplasma gondii*-specific IgG antibody assay.

Note: This assay has not been cleared/approved by the FDA for the screening of blood or plasma donors in the United States.

Comparison of Technological Characteristics to the Predicate

Device & Predicate Device(s):	K242095 Candidate Device	K003259 Predicate
Device Trade Name	Same	Access Toxo IgM II Assay
General Device Characteristic Similarities		
Intended Use/Indications for Use	Same	The Access Toxo IgM II assay is a paramagnetic-particle chemiluminescent immunoassay for the qualitative detection of *Toxoplasma gondii*-specific IgM antibody in adult human serum and plasma using the Access Immunoassay Systems. The Access Toxo IgM II assay is presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infection in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with a *Toxoplasma gondii*-specific IgG antibody assay. Note: This assay has not been cleared/approved by the FDA for the screening of blood or plasma donors in the United States.
Analyte	Same	IgM antibody to *T. gondii*
Technology	Same	2-step (sandwich) chemiluminescence immunoassay
Format	Same	Chemiluminescent
Method	Same	Automated
Calibration	Same	Utilizes a stored calibration curve
Calibration frequency	Same	28 days

Device & Predicate Device(s):	K242095 Candidate Device	K003259 Predicate
Sample Type	Same	Serum and plasma
Results Interpretation	S/CO < 0.8 Non-Reactive 0.8 ≤ S.CO < 1.0 Equivocal S/CO ≥ 1.0 Reactive	S/CO < 1.0 Non-Reactive 0.8 ≤ S.CO < 1.0 Grey Zone S/CO ≥ 1.0 Reactive
Capture Antibody	Same	Anti-human IgM antibody (sheep)
Detection Antibody	Same	Inactivated *T. gondii* Ag - *T. gondii* (P30)-specific mouse monoclonal antibody conjugated to alkaline phosphatase (bovine) complex
Stability	Same	28 days after opening, 2-10°C
General Device Characteristic Differences		
Substrate	Lumi-Phos PRO substrate	Access Substrate
Instrument	DxI 9000 Access Immunoassay Analyzer	Access Immunoassay System

Standard/Guidance Document Referenced (if applicable):

CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition

CLSI EP12-3rd Edition-: Evaluation of Qualitative, Binary Output Examination Performance; Approved Guideline

Summary of Studies

Method Comparison:

A method comparison study was conducted to evaluate the performance of the Access Toxo IgM II assay by testing 152 samples, collected from the intended use population, to establish positive and negative percent agreement between the Access Toxo IgM II assay on the candidate DxI 9000 Immunoassay Analyzer and FDA-cleared Access 2 Immunoassay System. This study was performed at an internal site and agreement analysis is shown in table below.

Table 1 Performance Agreement of Access Toxo IgM II Assay on the Access 2 Immunoassay Analyzer to the DxI 9000 System (n=152)

Access Toxo IgM II			Access 2 Immunoassay Analyzer		
			Reactive	Grey Zone	Non-Reactive
DxI 9000 System	Reactive		41	0	0
	Equivocal		0	4	0
	Non-Reactive		0	0	107
	Total		41	4	107
		Positive Percent Agreement (PPA)		41 / 41 = 100%	95% CI[a] = 91.43% to 100.00%
		Negative Percent Agreement (NPA)		107 / 107 = 100%	95% CI[a] = 96.53% to 100.00%

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

Imprecision:

The assay was designed to have within-laboratory imprecision of ≤ 20.0% CV.

Within-Laboratory Precision: A study based on CLSI EP05-A3[19] performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for a minimum of 20 days. Three lots of reagent and calibrator were tested on three analyzers for the study (one lot per instrument). Analysis was performed combining the imprecision studies for the three lots to estimate the contribution of instrument, reagent lot and calibrator lot factors. While the contribution of instrument, reagent lot, and calibrator lot variability is confounded across the three studies, a single between-lot & instrument variance component was estimated to represent the contribution of all three sources of variability. The combined results for all three lots are presented below.

Sample	N	Mean (S/CO)	Repeatability (Within-Run)		Between-Run		Between-Day		Between Lot & Instrument[a]		Overall Precision[b]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	240	0.14	0.004	2.8%	0.005	3.6%	0.003	1.9%	0.006	4.7%	0.009	6.8%
Sample 2	240	1.03	0.040	3.9%	0.024	2.3%	0.010	0.9%	0.038	3.7%	0.061	5.9%
Sample 3	240	5.59	0.151	2.7%	0.083	1.5%	0.160	2.9%	0.230	4.1%	0.329	5.9%
Sample 4	240	8.77	0.207	2.4%	0.169	1.9%	0.213	2.4%	0.368	4.2%	0.502	5.7%

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

[b] Overall within-laboratory variability includes within-run, between-run, between-day, and between-lot variance components.

A reproducibility study based on CLSI EP05-A3[19] performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in replicates of 5 in 1 run per day for a minimum of 5 days. Three reagent lots and one calibrator lot were tested on three analyzers for the study. The combined results for all three lots are presented below.

Sample	N	Mean (S/CO)	Repeatability (Within-Run)		Between-Day[a]		Between-Instrument		Between- Reagent Lot		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	225	0.14	0.004	3.2%	0.005	4.0%	0.004	2.8%	0.005	3.5%	0.009	6.8%
Sample 2	225	1.10	0.034	3.1%	0.044	4.0%	0.008	0.7%	0.015	1.4%	0.058	5.3%
Sample 3	225	4.83	0.117	2.4%	0.154	3.2%	0.000	0.0%	0.047	1.0%	0.199	4.1%
Sample 4	225	9.26	0.210	2.3%	0.316	3.4%	0.081	0.9%	0.170	1.8%	0.424	4.6%

[a] Days and runs are confounded

[b] Reproducibility includes within-run, between-day, between-instrument, and between-lot variance components.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access Toxo IgM II assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access Toxo IgM II assay on the Access 2 Immunoassay System as demonstrated through the information and data provided in this submission.