[3/28/2025]

Beckman Coulter Inc.
Audree Demmers
Director Quality Assurance
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K242022
Trade/Device Name: Access Toxo IgG
Regulation Number: 21 CFR 866.3780
Regulation Name: Toxoplasma Gondii Serological Reagents
Regulatory Class: Class II
Product Code: LGD
Dated: July 10, 2024
Received: July 11, 2024

Dear Audree Demmers:

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: 2025.03.28 11:34:01 -04'00'

Jorge Munoz, Ph.D.
Deputy Branch Chief
Division of Microbiology Devices
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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)*
K242022

Device Name
Access Toxo IgG

Indications for Use *(Describe)*
The Access Toxo IgG assay is a paramagnetic-particle, chemiluminescent immunoassay for the qualitative and quantitative determination of IgG antibodies to Toxoplasma gondii in human serum using the Access Immunoassay Systems. The Access Toxo IgG assay aids in the diagnosis of Toxoplasma gondii infection and may be used to assess the immune status of pregnant women.

This product is not FDA cleared/approved for the screening of blood or plasma donors. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens or infants.

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.

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 **K242022**

Date Prepared: 03/25/2025

Submitted By:
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Regulatory Information

Regulation Number: 21 CFR 866.3780
Regulation Description: Toxoplasma gondii serological reagents
Trade Name: Access Toxo IgG
Classification Name: Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii
Product Code: LGD
Device Class: II

Predicate Device

Device Name: Access Toxo IgG
510(k) Numbers: K080869

Device Description

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

The Access Toxo IgG assay consists of the reagent pack, calibrators, and quality controls (QCs), packaged separately. Other items needed to run the assay include substrate and wash buffer.

Intended Use

The Access Toxo IgG assay is a paramagnetic-particle, chemiluminescent immunoassay for the qualitative and quantitative determination of IgG antibodies to *Toxoplasma gondii* in human serum, using the Access Immunoassay Systems. The Access Toxo IgG assay aids in the diagnosis of *Toxoplasma gondii* infection and may be used to assess the immune status of pregnant women.

This product is not FDA cleared/approved for the screening of blood or plasma donors. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens or infants.

Comparison with Predicate(s)

Device & Predicate Device(s):	Candidate Test K242022	Predicate K080869
Device Trade Name	Access Toxo IgG	Access Toxo IgG
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	The Access Toxo IgG assay is a paramagnetic-particle, chemiluminescent immunoassay for the qualitative and quantitative determination of IgG antibodies to *Toxoplasma gondii* in human serum using the Access Immunoassay Systems. The Access Toxo IgG assay aids in the diagnosis of *Toxoplasma gondii* infection and may be used to assess the immune status of pregnant women. This product is not FDA cleared/approved for the screening of blood or plasma donors. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens or infants.
Analyte	Same	IgG antibody to *T. gondii*
Technology	Same	Two-step immunoenzymatic assay
Format	Same	Chemiluminescent
Method	Same	Automated

Device & Predicate Device(s):	Candidate Test K242022	Predicate K080869
Calibration	Same	Utilizes a stored calibration curve
Calibration Frequency	Same	28 days
Sample Type	Same	Serum
Analytical Measuring Interval	3.2 – 450 IU/mL	0 – 450 IU/mL
Results Interpretation	Same	<7.5 IU/mL: Non-Reactive ≥7.5 - <10.5 IU/mL: Equivocal ≥10.5 IU/mL: Reactive
Capture Reagent	Same	Paramagnetic particles coated with *T. gondii* (strain RH) solubilized membrane antigen
Detection Antibody	Same	Mouse monoclonal anti-human IgG antibody- alkaline phosphatase (bovine) conjugate
Open Kit 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 2 Immunoassay System

Standard/Guidance Document Referenced (if applicable):

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

CLSI EP06-2nd Edition-: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition

CLSI EP12-Ed3, Evaluation of Qualitative, Binary Output Examination Performance, Third Edition.

Summary of Studies

Method Comparison:

A method comparison of 140 native serum samples using the Access Toxo IgG assay on the DxI 9000 Access Immunoassay Analyzer and the Access 2 Immunoassay System was conducted to compare the performance on both systems. Positive percent agreement (PPA) and negative percent agreement (NPA) between the Access Toxo IgG assay run on the DxI 9000 Immunoassay Analyzer and the Access 2 Immunoassay System was calculated for the Access Toxo IgG assay and are shown in Table 1.

Table 1: Performance Agreement of Access Toxo IgG assay on the Access 2 Immunoassay Analyzer and the DxI 9000 Immunoassay Analyzer (n=140)

Access Toxo IgG		**Access 2 Immunoassay Analyzer**			
		Reactive	**Equivocal**	**Non-reactive**	**Total**
DxI 9000 Immunoassay Analyzer	Reactive	40	0	0	40
	Equivocal	0	1	0	1
	Non-Reactive	0	0	99	99
	Total	40	1	99	140
	PPA[a]	100.00% (40/40)	95% CI = 91.24% to 100%		
	NPA[b]	100.00% (99/99)	95% CI = 96.26% to 100.00		

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

Imprecision:

Precision studies were designed to have within-laboratory imprecision as listed below:

- ≤ 0.64 IU/mL SD at concentrations < 3.2 IU/mL
- ≤ 20.0% CV at concentrations ≥ 3.2 IU/mL

a) *Within-Laboratory Precision:* A study based on CLSI EP05-A3 performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for 20 days. Six serum samples were tested using 3 reagent lot/calibrator lot combinations, where a unique reagent lot and calibrator lot were paired. The data were analyzed for repeatability

(within-run), between-run, between-day, between lot and instrument and overall precision. Within-laboratory precision data summary is shown in **Table 2**.

Table 2: Access Toxo IgG assay 20-day Within-Laboratory Precision on the DxI 9000 Access Immunoassay Analyzer

Sample	N	Mean (IU/mL)	Repeatability (Within-Run)		Between-Run		Between-Day		Between Lot and Instrument[a]		Overall Precision[b]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	240	2.7	0.15	5.3	0.16	5.8	0.10	3.6	0.29	10.8	0.38	13.9
Sample 2	240	8.3	0.36	4.3	0.24	2.9	0.43	5.2	0.61	7.3	0.86	10.4
Sample 3	240	13.1	0.56	4.3	0.54	4.2	0.35	2.7	1.34	10.2	1.59	12.1
Sample 4	240	69.3	3.03	4.4	3.17	4.6	2.17	3.1	6.56	9.5	8.18	11.8
Sample 5	240	174.2	7.29	4.2	6.80	3.9	6.28	3.6	14.01	8.0	18.30	10.5
Sample 6	240	361.0	20.45	5.7	12.55	3.5	20.38	5.6	14.07	3.9	34.48	9.6

[a] Access Toxo IgG reagent lot, Access Toxo IgG calibrator lot and DxI 9000 instruments are confounded, and the confounding effect is represented by between-lot and instrument.

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

b) *Reproducibility (between-Instrument Precision):* A reproducibility study based on CLSI EP05-A3 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. The study tested 6 serum samples with the Access Toxo IgG on 3 DxI 9000 Access Immunoassay Analyzers in an internal site. The samples were tested with 3 lots of Access Toxo IgG reagents, and 1 lot of Access Toxo IgG calibrator on each instrument. Summary of the data is shown in **Table 3**.

Table 3: Access Toxo IgG assay Reproducibility on the DxI 9000 Access Immunoassay Analyzer

Sample	N	Mean (IU/mL)	Repeatability (Within-run)		Between-Day/Run[a]		Between Reagent Lot		Between-Instrument		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	225	2.5	0.16	6.4	0.17	7.0	0.11	4.5	0.14	5.6	0.29	11.9
Sample 2	225	7.9	0.40	5.0	0.42	5.3	0.25	3.1	0.35	4.5	0.72	9.1
Sample 3	225	12.4	0.57	4.6	0.51	4.1	0.58	4.7	0.55	4.4	1.11	8.9
Sample 4	225	67.4	3.17	4.7	2.96	4.4	3.66	5.4	2.90	4.3	6.37	9.4
Sample 5	225	169.7	7.83	4.6	9.04	5.3	9.64	5.7	6.24	3.7	16.58	9.8
Sample 6	225	377.5	25.58	6.8	30.77	8.2	22.70	6.0	21.45	5.7	50.76	13.4

[a] Days and runs are confounded.

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

Linearity: A study based on CLSI EP06-ED2 performed with the Access Toxo IgG assay on the DxI 9000 Access Immunoassay Analyzer determined the assay demonstrated linearity across the measuring interval of 3.2 – 450 IU/mL.

Limit of Blank (LoB): The claimed LoB for Access Toxo IgG assay on the DxI 9000 Access Immunoassay Analyzer is 0.8 IU/mL.

Limit of Detection (LoD): The claimed LoD for Access Toxo IgG assay on the DxI 9000 Access Immunoassay Analyzer is 1.5 IU/mL.

Limit of Quantitation (LoQ): The claimed LoQ for Access Toxo IgG assay on the DxI 9000 Access Immunoassay Analyzer is 3.2 IU/mL.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access Toxo IgG assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access Toxo IgG assay on the Access 2 Immunoassay System as demonstrated through the information and data provided in this submission. The performance testing presented in this submission provides evidence that the device is safe and effective in its intended use.