MAY 2 3 2008

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.

The assigned 510(k) number is: **K080869**

Submitter's Name and Address

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Date Prepared: May 22, 2008

Device Names

Proprietary Name:	Access Toxo IgG Assay, Access Toxo IgG Calibrators, Access Toxo IgG QC
Common Name:	*Toxoplasma gondii* serological reagents
Classification Name:	Enzyme Linked Immunoabsorbent Assay, *Toxoplasma Gondii*

Predicate Devices

Access Toxo IgG Assay, Calibrators, QC (Part Numbers: 34450, 34455, 34459)
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
510(k) Numbers: K951495, K032162

AxSYM Toxo IgG Antibody Assay
Abbott Laboratories, Inc.
100 Abbott Park Road
Abbott Park, IL 60064
510(k) Number: K954575

Device Description

The Access Toxo IgG Assay, Toxo IgG Calibrators, Toxo IgG QC, and the Access Immunoassay Analyzers (Access, Access 2, Synchron LXi 725, UniCel DxC 600i, UniCel Dxl 600 and UniCel Dxl 800) comprise the Access Immunoassay Systems for the quantitative and qualitative determination of anti-*Toxoplasma gondii* IgG in human serum.

Intended Use

The Access Toxo IgG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative and qualitative determination of IgG antibodies to *Toxoplasma gondii* in human serum using the Access Immunoassay Systems.

Summary of Analytical Studies

Analytical Sensitivity

The analytical sensitivity of the Access Toxo IgG Assay was estimated by repeat testing of a low does sample following CLSI document, EP17-A. The mean limit of quantitation (LoQ) was 3.2 IU/mL.

Dilution Recovery (Linearity)

Recovery with WHO Standard

Five dilutions of the Third International Standard for Anti-Toxoplasma Serum (TOXM) were tested in duplicate in a single run. The recovery performance is presented in the following table.

WHO Standard Recovery

Expected Dose (IU/mL)	Observed Dose (IU/mL	Mean Observed Dose (IU/mL)	Recovery
6.0	5.8 6.0	5.9	98.3%
30.0	26.6 25.2	25.9	86.3%
60.0	65.4 64.8	65.1	108.5%
120.0	117.0 114.4	115.7	96.4%
240.0	183.6 191.1	187.4	78.1%

Linearity with High Patient Samples

Four highly reactive sera were diluted from 1/1.5 to 1/32 in Access Toxo IgG Calibrator, S0. These dilutions were tested in quadruplicate and the results were compared to expected values based on the neat sample determination (eight replicates). The mean recovery for the four sera was 100% and ranged from 93.8% to 109.1%.

Analytical Specificity/Interference

A study was conducted to investigate potential cross-reactivity with immunoglobulins resulting from exposure to other infectious agents that can produce symptoms similar to *Toxoplasma* infection (CMV, Epstein-Barr virus, HIV, HSV-1, HSV-2, malaria, measles, rubella VZV, mumps and *Treponema*). In addition, interference due to heterophilic antibodies (HAMA), abnormal immune system conditions (myeloma, rheumatoid factor, ANA) and influenza vaccine was evaluated. A total of 311 samples were tested. Nine samples (2.9%) that were non-reactive by another commercially available assay were equivocal or reactive in the Access Toxo IgG Assay. The observed performance with each condition is presented in the following table:

Condition	Number tested	Equivocal or Reactive in Access Toxo IgG
ANA	14	0
CMV IgG	8	0
EBV IgG	13	0
HAV Ab	10	0
HBV (HBsAg)	11	0
HCV Ab	14	0
HIV	43	2
HSV-1 IgG	3	0
HSV-2 IgG	8	2
Malaria	7	0
Measles IgG	13	0
Myeloma IgG	12	0
Rheumatoid Factor	15	0
Rubella IgG	12	0
VZV IgG	11	0
HAMA/Heterophilic Antibody	20	2
Mumps IgG	65	2
Influenza (vaccine recipients)	23	0
Syphilis	43	1

The Access Toxo IgG Assay was not significantly affected by the presence of 300 mg/L bilirubin (100 mg/L free + 200 mg/L conjugated), 30 g/L triolein (triglycerides), 90 g/L albumin or 20 g/L hemoglobin.

Reproducibility

Reproducibility/repeatability of the Access Toxo IgG Assay was estimated at one internal (Site 3) and two external sites (Sites 1 and 2). Each site performed one run per day over seven test days. Nine serum samples were run in replicates of five in each run.

Site 1

		Daily Calibration				Stored Calibration			
Sample	N	Mean Dose (IU/mL)	Intra-assay %CV	Inter-assay %CV	Total %CV	Mean Dose (IU/mL)	Intra-assay %CV	Inter-assay %CV	Total %CV
A001	35	3.18	14.2	6.3	15.5	3.44	12.2	5.5	13.4
A002	35	9.51	5.9	6.3	8.7	9.71	5.8	6.3	8.5
A010	35	12.6	5.1	8.2	9.6	12.9	5.1	2.3	5.6
A003	35	14.9	5.4	9.6	11.0	15.3	5.6	5.6	8.0
A004	35	19.4	8.9	6.9	11.2	19.9	8.9	6.9	11.3
A009	35	44.1	4.4	6.3	7.7	46.0	4.6	2.7	5.3
A005	35	92.7	4.9	3.5	6.1	95.6	4.7	7.1	8.5
A006	35	235.2	7.0	6.4	9.5	261.0	8.0	6.6	10.4
A007	35	271.7	7.7	5.0	9.2	304.2	8.1	8.2	11.5

Site 2

		Daily Calibration				Stored Calibration			
Sample	N	Mean Dose (IU/mL)	Intra-assay %CV	Inter-assay %CV	Total %CV	Mean Dose (IU/mL)	Intra-assay %CV	Inter-assay %CV	Total %CV
A001	35	4.15	6.0	7.8	9.8	3.78	5.8	10.5	12.0
A002	35	7.92	3.5	7.6	8.4	7.17	3.5	6.3	7.2
A010	35	11.4	5.6	5.9	8.1	10.3	5.5	2.7	6.1
A003	35	12.2	3.4	7.3	8.0	11.1	3.4	4.7	5.9
A004	35	17.3	4.6	6.8	8.2	15.8	4.7	4.9	6.8
A009	35	39.8	4.5	2.7	5.3	36.7	4.5	4.6	6.5
A005	35	84.0	7.5	9.0	11.7	76.2	8.0	7.4	10.9
A006	35	235.5	5.0	6.3	8.0	219.6	5.1	9.9	11.1
A007	35	266.7	4.7	4.7	6.7	250.5	5.0	8.4	9.8

Site 3

		Daily Calibration				Stored Calibration			
Sample	N	Mean Dose (IU/mL)	Intra-assay %CV	Inter-assay %CV	Total %CV	Mean Dose (IU/mL)	Intra-assay %CV	Inter-assay %CV	Total %CV
A001	35	3.78	8.0	18.6	20.3	3.98	7.3	13.5	15.4
A002	35	9.22	6.6	4.5	7.9	9.30	4.3	4.9	6.5
A010	35	14.1	4.5	7.0	8.4	14.0	4.4	5.7	7.2
A003	35	13.7	4.7	4.9	6.8	13.7	4.5	3.4	5.7
A004	35	19.4	3.7	0.8	3.8	19.1	3.6	1.6	3.9
A009	35	47.4	3.2	5.3	6.2	46.2	3.3	4.3	5.4
A005	35	91.6	2.9	5.5	6.2	95.0	3.4	4.2	5.4
A006	35	268.7	4.9	4.5	6.6	269.4	4.5	0.0	4.3
A007	35	321.8	5.3	2.7	5.9	322.7	6.2	2.4	6.7

Combined Results

		Daily Calibration					Stored Calibration				
Sample	N	Mean Dose (IU/mL)	Intra-assay %CV	Inter-assay %CV	Inter-site %CV*	Total %CV*	Mean Dose (IU/mL)	Intra-assay %CV	Inter-assay %CV	Inter-site %CV*	Total %CV*
A001	105	3.70	13.5	6.9	13.0	20.0	3.73	12.1	5.7	6.9	15.1
A002	105	8.88	7.7	2.5	9.4	12.5	8.73	6.9	2.7	15.6	17.3
A010	105	12.7	8.1	2.4	10.5	13.5	12.4	6.3	0.3	15.2	16.4
A003	105	13.6	8.1	3.1	9.8	13.1	13.4	6.6	0.7	15.6	17.0
A004	105	18.7	7.6	3.1	6.3	10.3	18.3	7.8	1.8	11.8	14.3
A009	105	43.8	6.1	1.6	8.6	10.7	43.0	5.4	1.1	12.6	13.7
A005	105	89.4	7.2	3.4	5.1	9.5	88.9	7.1	3.9	12.3	14.8
A006	105	246.4	7.2	3.2	7.7	11.0	250.0	7.9	3.5	10.6	13.7
A007	105	286.7	7.0	1.3	10.6	12.7	292.5	8.8	2.9	12.8	15.8

*The inter-site and total estimates also include contributions from inter-lot variation.

The observed average total %CV was 12.6% with daily calibration and 15.3% using a stored calibration curve.

Summary of Clinical Studies

Method Comparison

Studies comparing the performance of the Access Toxo IgG assay with the Abbott AxSYM Toxo IgG method were conducted at one external site in south-central France (Site 1), one external site in the northeastern United States (Site 2) and at the manufacturer's site (Site 3). The external sites tested samples collected from their own routine prenatal screening population as well as specimens from males and non-pregnant females that had Toxo IgG testing ordered. Two clinical sample suppliers provided the routine Toxo IgG test specimens for the U.S. site. The manufacturer tested prenatal specimens collected at three hospitals in north-central France.

Method agreement results for the prospective (fresh) and retrospective (frozen) collections by test site are presented in the following two tables.

Retrospective/Prospective Patient Population

		Comparison EIA	+	+	+	EQV	EQV	EQV	-	-	-
	n	Access	+	EQV	-	+	EQV	-	+	EQV	-
Site 1	406	Frozen	154	3	2	3	3	4	0	2	235
Site 2	28	Fresh	4	0	1	0	0	0	0	0	23
Site 2	433	Frozen	190	2	0	4	6	0	1	0	230
Site 3	558	Frozen	356	2	0	2	0	0	1	1	196

Agreement Table for Retrospective/Prospective Patient Population

n			Positive Agreement (%)	95% Conf. Int.	Negative Agreement (%)	95% Conf. Int.
Site 1	406	Frozen	94.5	89.8 - 97.4	97.9	95.2 – 99.3
Site 2	28	Fresh	80.0	28.5 – 99.5	100	85.3 - 100
Site 2	433	Frozen	99.0	96.3 – 99.9	97.9	95.1 – 99.3
Site 3	558	Frozen	99.4	98.0 – 99.9	98.0	94.9 – 99.4

These results are presented for the prenatal and diagnostic populations (male and female) by test site in the next two tables.

Pregnant/Non-Pregnant Population

		Comparison EIA	+	+	+	EQV	EQV	EQV	-	-	-
	n	Access	+	EQV	-	+	EQV	-	+	EQV	-
Site 1	229	Pregnant	37	3	0	2	2	2	0	1	182
Site 2	173	Pregnant	13	0	1	0	0	0	1	0	158
Site 3	558	Pregnant	356	2	0	2	0	0	1	1	196
Site 1	76	Female	47	0	2	1	0	2	0	0	24
Site 1	101	Male	70	0	0	0	1	0	0	1	29
Site 2	180	Female	97	2	0	4	6	0	0	0	71
Site 2	108	Male	84	0	0	0	0	0	0	0	24

Table 4: Agreement Table for Pregnant/Non-Pregnant Population

	n		Positive Agreement (%)	95% Conf. Int.	Negative Agreement (%)	95% Conf. Int.
Site 1	229	Pregnant	88.1	74.4 – 96.0	98.4	95.3 – 99.7
Site 2	173	Pregnant	92.9	66.3 – 99.8	99.4	96.5 – 100
Site 3	558	Pregnant	99.4	98.0 – 99.9	98.0	94.9 – 99.4
Site 1	76	Female	92.2	81.1 – 97.8	96.0	79.7 – 99.9
Site 1	101	Male	100	94.9 – 100	96.7	82.8 – 99.9
Site 2	180	Female	98.0	92.9 – 99.8	94.7	86.9 – 98.5
Site 2	108	Male	100	95.7 - 100	100	85.8 - 100

CDC *Toxoplasma* 1998 Human Serum Panel

The Access Toxo IgG Assay exhibited 100% sensitivity and specificity with the 100-member CDC *Toxoplasma* 1998 Human Serum Panel. 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 an endorsement of the assay by the CDC.

Conclusion

The Access Toxo IgG Assay, Calibrators and QC (Part numbers: A31588, A31589, A31590) on the Access Immunoassay Systems are substantially equivalent to the AxSYM Toxo IgG Assay and the Access Toxo IgG Assay, Calibrators and QC (Part numbers: 34450, 34455, 34459) for the quantitative and qualitative determination of IgG antibodies to *Toxoplasma gondii* in human serum.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. David M. Ikeda
Staff Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

MAY 2 3 2008

Re: K080869
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: March 31, 2008
Received: March 31, 2008

Dear Mr. Ikeda:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080869

Device Name: Access Toxo IgG
Access Toxo IgG Calibrators
Access Toxo IgG QC

Indications For 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.

Note: In the United States, 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.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K080869