K012075 JAN 1 0 2002

510(k) Summary of Safety and Effectiveness
IMMULITE and IMMULITE 2000 Toxoplasma IgM

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	January 8, 2002
Device Name: **Trade:**	IMMULITE® Toxoplasma IgM IMMULITE® 2000 Toxoplasma IgM
Catalog Number:	LKTM1 (100 tests), LKTM2 (200 tests) L2KTM2 (200 tests), L2KTM6 (600 tests)
Common:	Reagent system for the detection of IgM antibodies to Toxoplasma gondii in human serum
Classification:	Class II device, 83-LGD (21CFR 866.3780)
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045 (The Quality System of Diagnostic Products Corporation is registered to ISO 9001:1994)
Establishment Registration Number	DPC's Registration Number 2017183
Substantially Equivalent Predicate Device:	Vidas (ELFA) Toxo IgM (K923166) Zeus Scientific Toxo IgM ELISA Test System (K913787)
Description of Devices:	IMMULITE and IMMULITE 2000 Toxoplasma IgM are clinical devices for use with their respective IMMULITE and IMMULITE 2000 Automated Immunoassay Analyzers.

Intended Use of the Device:

IMMULITE® Toxoplasma IgM is a solid-phase chemiluminescent enzyme immunoassay for *in vitro* diagnostic use with the IMMULITE® Analyzer – for the presumptive qualitative detection of IgM antibodies to Toxoplasma in human serum or plasma (EDTA or heparinized), particularly for women of childbearing age. When performed in conjunction with a Toxoplasma IgG assay, the IMMULITE® Toxoplasma IgM can be used as an aid in the presumptive diagnosis of acute, recent or reactivated Toxoplasma infection.

IMMULITE® 2000 Toxoplasma IgM is a solid-phase chemiluminescent enzyme immunoassay for *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer – for the presumptive qualitative detection of IgM antibodies to Toxoplasma in human serum or plasma (EDTA or heparinized), particularly for women of childbearing age. When performed in conjunction with a Toxoplasma IgG assay, the IMMULITE® 2000 Toxoplasma IgM can be used as an aid in the presumptive diagnosis of acute, recent or reactivated Toxoplasma infection.

Performance Equivalence:

Diagnostic Products Corporation (DPC) asserts that IMMULITE Toxoplasma IgM and IMMULITE 2000 Toxoplasma IgM produce substantially equivalent results to other commercially marketed assays, such Vidas (ELFA) Toxo IgM or Zeus Scientific Toxo IgM ELISA Test System.

Technology Comparison:

Provided below is a comparison of DPC's IMMULITE and IMMULITE 2000 Toxoplasma IgM technology vs. the Zeus Scientific Toxo IgM ELISA Test System and Vidas Toxo IgM technology.

IMMULITE Toxoplasma IgM is a solid-phase, two-step chemiluminescent enzyme immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with partially purified Toxoplasma gondii antigen.

Prediluted patient sample (1-in-21 dilution) and a protein-based buffer are simultaneously introduced into the Test Unit, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, Toxoplasma -specific IgM in the sample binds to the Toxoplasma antigen-coated bead. Unbound serum is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human IgM antibody is introduced, and the Test Unit is incubated for approximately another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Test Unit is incubated for a further 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving

precision by providing a window for multiple readings. The bound complex -- and thus also the photon output, as measured by the luminometer -- is related to the presence of Toxoplasma IgM in the sample. A result is then obtained by comparing the patient result to the response of the cutoff material (i.e., the adjustor).

IMMULITE 2000 Toxoplasma IgM is a solid-phase, two-step chemiluminescent enzyme immunoassay. The solid phase, a polystyrene bead added to an IMMULITE 2000 Reaction Tube, is coated with partially purified Toxoplasma gondii antigen.

Prediluted patient sample (1-in-20 dilution) and a protein-based buffer are simultaneously introduced into the Reaction Tube, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, Toxoplasma -specific IgM in the sample binds to the Toxoplasma antigen-coated bead. Unbound serum is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human IgM antibody is introduced, and the Reaction Tube is incubated for approximately another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Reaction Tube is incubated for a further 5 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex -- and thus also the photon output, as measured by the luminometer -- is related to the presence of Toxoplasma IgM in the sample. A result is then obtained by comparing the patient result to the response of the cutoff material (i.e., the adjustor)

Zeus Scientific Toxo IgM ELISA Test System is an enzyme-linked immunosorbent assay (ELISA) designed to detect IgM class antibodies to T. gondii antigen. Patient serum samples to be assayed for antibody are first diluted and incubated in microwells coated with T. gondii antigen. Any antigen specific IgM antibody in the sample will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components.

Peroxidase conjugated goat anti-human IgM is added to the wells and the plate is incubated. The conjugate will react with IgM antibody immobilized on the solid phase in step 2. The wells are washed to remove unreacted conjugate.

The microtiter wells containing immobilized peroxidase conjugate are incubated with peroxidase substrate solution. Hydrolysis of the substrate by peroxidase produces a color change. After a period of time, the reaction is stopped and the color intensity of the solution is measured photometrically. The color intensity of the solution is directly related to the antibody concentration in the test sample.

Vidas Toxo IgM is an enzyme-linked fluorescent immunoassay (ELFA) performed in an automated Vidas instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR) serves as the solid phase as well as the pipettor for the assay. The SPR is coated with goat anti-μ chain

antibodies. The Vidas TXM assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are in the sealed TXM Reagent Strips.

After a sample dilution step, the sample is cycled in and out of the SPR for a specific length of time. IgM antibodies present in the specimen will bind to the anti-μ chain antibodies coating the interior of the SPR. Unbound sample components are washed away. An Immunocomplex of T. gondii antigen and mouse monoclonal anti-P30 antibodies conjugated with alkaline phosphatase is cycled in and out of the SPR and will attach to the human anti-T. gondii IgM bound to the SPR wall. A final wash step removes unbound conjugate.

A fluorescent substrate is introduced into the SPR. Enzyme remaining on the wall of the SPR will catalyze the conversion of the substrate to the fluorescent product. The intensity of the fluorescence is measured by the optical scanner in the instrument.

Expected Values

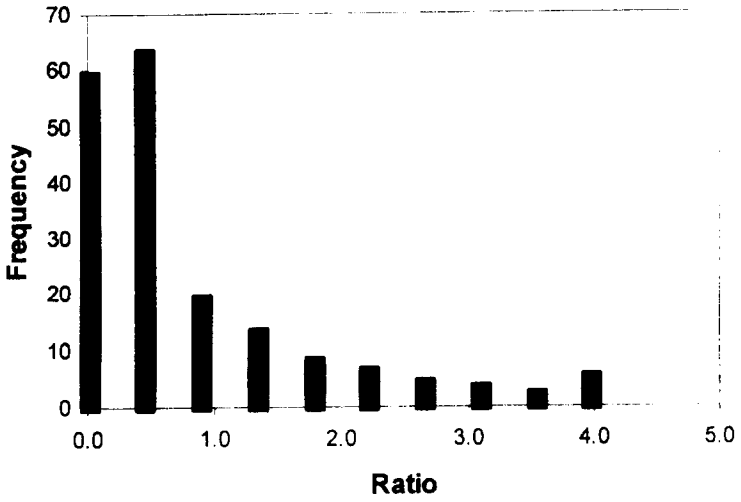
Individuals infected with the Toxoplasma organism will typically exhibit detectable levels of IgM antibody immediately before or soon after the onset of symptoms.2 IgM titers normally decline within four to six months, but may persist at low levels up to a year. 4 Patients with active toxoplasma chorioretinitis usually have undetectable levels of IgM.

The prevalence of Toxoplasma infection can vary depending on a number of factors such as age, gender, geographical location, socio-economic status, race, type of test used, specimen collection and handling procedures, and clinical and epidemiological history of individual patients. There are approximately 3000 cases of congenital toxoplasmosis reported per year, with an average of 0.6 cases per 1000 pregnancies in the United States.

IMMULITE Toxoplasma IgM
Studies with presumed healthy, asymptomatic subjects and individuals suspected of acute toxoplasma viral infection were conducted at two clinical sites in the southern and northeastern United States. The study in the southern United States consisted of 172 specimens from 93 pregnant women and 79 individuals with various conditions. IMMULITE Toxoplasma IgM tests on these samples yielded the following results:

	Total	Positive		Negative		Indeterminate	
Subjects	n	n	%	n	%	n	%
Pregnant	93	22	24%	64	69%	7	8%
Various	79	14	18%	62	78%	3	4%
All	172	36	21%	126	73%	10	6%

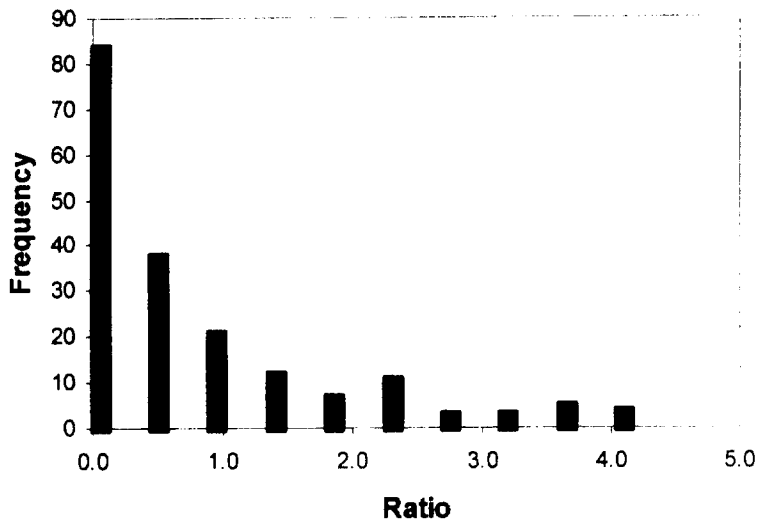
Observed signal/cutoff ratios for all samples



The study in the northeastern United States consisted of 168 specimens from 91 pregnant women and 77 individuals with various conditions. IMMULITE Toxoplasma IgM tests on these samples yielded the following results:

	Total	Positive		Negative		Indeterminate	
Subjects	n	n	%	n	%	n	%
Pregnant	91	20	22%	65	71%	6	7%
Various	77	14	18%	60	78%	3	4%
All	168	34	20%	125	74%	9	5%

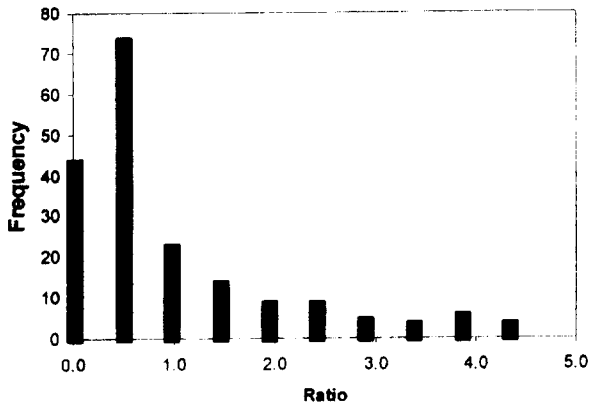
Observed signal/cutoff ratios for all samples



IMMULITE 2000 Toxoplasma IgM
Studies with presumed healthy, asymptomatic subjects and individuals suspected of acute toxoplasma viral infection were conducted at one clinical sites in the southern United States. The study consisted of 172 specimens from 93 pregnant women and 79 individuals with various conditions. IMMULITE 2000 Toxoplasma IgM tests on these samples yielded the following results:

	Total	Positive		Negative		Indeterminate	
Subjects	n	n	%	n	%	n	%
Pregnant	93	23	25%	61	66%	9	10%
Various	79	16	20%	59	75%	4	5%
All	172	39	23%	120	70%	13	8%

Observed signal/cutoff ratios for all samples



Performance Characteristics

Clinical Performance

In a clinical study in the southern United States, a total of 172 frozen samples from apparently healthy male and female subjects, pregnant women and patients suspected of being toxoplasma IgM positive were tested by IMMULITE Toxoplasma IgM and by a commercially available enzyme immunoassay (Kit A- Zeus Scientific Toxo IgM ELISA Test System). These samples were also tested for Toxoplasma IgG. The IMMULITE Toxoplasma IgM results were compared to the results of Kit A.

Comparison for all subjects

	IMMULITE Toxoplasma IgM		
Kit A	Positive	Indeterm	Negative
Positive	36	9	4
Indeterm	0	1	6
Negative	0	0	116

Positive Agreement: 90.0% (36/40, 95% CI: 76.3% - 97.2%)
Negative Agreement: 100% (116/116, 95% CI: 96.9% - 100%)
Agreement: 97.4% (152/156, 95% CI: 93.6% - 99.3%)

Comparison for pregnant subjects

	IMMULITE Toxoplasma IgM		
Kit A	Pos	Ind	Neg
Pos	22	7	2
Ind	0	0	4
Neg	0	0	58

Positive Agreement: 91.7% (22/24, 95% CI: 73.0% - 99.0%)
Negative Agreement: 100% (58/58, 95% CI: 93.8% - 100%)
Agreement: 97.6% (80/82, 95% CI: 91.5% - 99.7%)

In another clinical study in the northeastern United States, a total of 168 frozen samples from apparently healthy male and female subjects, pregnant women and patients suspected of being toxoplasma IgM positive were tested by IMMULITE Toxoplasma IgM and another commercially available enzyme immunoassay (Kit B - Vidas Toxo IgM). These samples were also tested for Toxoplasma IgG. The IMMULITE Toxoplasma IgM results were compared to the results of Kit B.

Comparison for all subjects

	IMMULITE Toxoplasma IgM		
Kit B	Positive	Indeterm	Negative
Positive	28	4	1
Indeterm	0	0	2
Negative	6	5	122

Positive Agreement: 96.6% (28/29, 95% CI: 82.2% - 99.9%)
Negative Agreement: 95.3% (122/128, 95% CI: 90.1% - 98.3%)
Agreement: 95.5% (150/157, 95% CI: 91.0% - 98.2%)

Comparison for pregnant subjects

	IMMULITE Toxoplasma IgM		
Kit B	Pos	Ind	Neg
Pos	16	4	0
Ind	0	0	1
Neg	4	2	64

Positive Agreement: 100% (16/16, 95% CI: 79.4% - 100%)
Negative Agreement: 94.1% (64/68, 95% CI: 85.6% - 98.4%)
Agreement: 95.2% (80/84, 95% CI: 88.3% - 98.7%)

In a clinical study in the southern United States, a total of 172 frozen samples from normal male and female subjects, pregnant women and patients suspected of being toxoplasma IgM positive were tested by IMMULITE 2000 toxoplasma IgM, and by a commercially available enzyme immunoassays (Kit A- Zeus Scientific Toxo IgM ELISA Test System). These samples were also tested for Toxoplasma IgG. The IMMULITE 2000 Toxoplasma IgM results were compared to the results of Kit A.

Comparison for all subjects

	IMMULITE 2000 Toxoplasma IgM		
Kit A	Positive	Indeterm	Negative
Positive	38	9	2
Indeterm	1	3	3
Negative	0	1	115
Positive Agreement:	95.0%	(38/40, 95% CI: 83.1% - 99.4%)	
Negative Agreement:	100%	(115/115, 95% CI: 96.8% - 100%)	
Agreement:	98.7%	(153/155, 95% CI: 95.4% - 99.8%)	

Comparison for pregnant subjects:

	IMMULITE 2000 Toxoplasma IgM		
Kit A	Pos	Ind	Neg
Pos	23	7	1
Ind	0	2	2
Neg	0	0	58
Positive Agreement:	95.8%	(23/24, 95% CI: 78.9% - 99.9%)	
Negative Agreement:	100%	(58/58, 95% CI: 93.8% - 100%)	
Agreement:	98.8%	(81/82, 95% CI: 93.4% - 100%)	

In a study at DPC, IMMULITE 2000 Toxoplasma IgM was compared to IMMULITE Toxoplasma IgM on 291 samples:

	IMMULITE 2000 Toxoplasma IgM		
IMMULITE	Positive	Indeterm	Negative
Positive	15	0	0
Indeterm	3	0	0
Negative	0	5	268
Positive Agreement:	100%	(15/15, 95% CI: 78.2% - 100%)	
Negative Agreement:	100%	(268/268, 95% CI: 98.6% - 100%)	
Agreement:	100%	(283/283, 95% CI: 98.7% - 100%)	

Indeterminate results were excluded from calculations.

Performance Data

Precision (Serum): Precision studies for IMMULITE Toxoplasma IgM assay were conducted at three different sites: in-house at DPC (Site 1) and at two sites in the southern and northeasten United States (Sites 2 and 3). At Site 1, samples were assayed in duplicate over the course of 20 days, two runs per day, for a total of 40 runs and 80 replicates. (See "Site 1" table). At Sites 2 and 3, samples were assayed in triplicate over the course of 5 days, one run per day, for a total of 5 runs and 15 replicates. (See "Site 2" and "Site 3" tables). The means, within-run and total CVs were calculated by the Analysis of Variance. Results are expressed as a signal-to-cutoff ratio. Precision statistics are summarized below.

IMMULITE Toxoplasma IgM Precision – Serum (ratio): Site 1

		Within-Run		Total	
	Mean	SD	CV	SD	CV
1	3.03	0.241	8.0%	0.337	11.1%
2	1.42	0.110	7.8%	0.155	10.9%
3	0.928	0.055	5.9%	0.089	9.5%
4	0.579	0.033	5.7%	0.055	9.4%
5	0.25*	—	—	—	—

* Consistently at a very low ratio

IMMULITE Toxoplasma IgM Precision – Serum (ratio): Site 2

		Within-Run		Total	
	Mean	SD	CV	SD	CV
1	3.30	0.184	5.6%	0.203	6.2%
2	1.56	0.113	7.2%	0.110	7.1%
3	0.980	0.068	6.9%	0.063	6.4%
4	0.650	0.032	4.9%	0.030	4.6%
5	0.284*	—	—	—	—

* Consistently at a very low ratio

IMMULITE Toxoplasma IgM Precision – Serum (ratio): Site 3

		Within-Run		Total	
	Mean	SD	CV	SD	CV
1	3.10	0.110	3.5%	0.152	4.9%
2	1.38	0.099	7.2%	0.097	7.0%
3	0.910	0.029	3.2%	0.056	6.2%
4	0.600	0.022	3.7%	0.030	5.0%
5	0.266*	—	—	—	—

* Consistently at a very low ratio

Precision (Serum): Precision studies for IMMULITE 2000 Toxoplasma IgM assay were conducted at two different sites: in-house at DPC (Site 1) and in the southern United States (Site 2). At both sites, samples were assayed in triplicate over the course of 5 days, one run per day, for a total of 5 runs and 15 replicates. (See "Site 1" and "Site 2" tables). The means, within-run and total CVs were calculated by the Analysis of Variance. Results are expressed as a signal-to-cutoff ratio.

IMMULITE 2000 Toxoplasma IgM Precision – Serum (ratio): Site 1

		Within-Run		Total	
	Mean	SD	CV	SD	CV
1	3.90	0.081	2.1%	0.094	2.4%
2	2.07	0.150	7.2%	0.149	7.2%
3	1.34	0.074	5.5%	0.071	5.3%
4	0.810	0.092	11.4%	0.082	10.1%
5	0.262*	—	—	—	—

*Consistently at a very low ratio

IMMULITE 2000 Toxoplasma IgM Precision – Serum (ratio): Site 2

		Within-Run		Total	
	Mean	SD	CV	SD	CV
1	3.20	0.130	4.1%	0.138	4.3%
2	1.72	0.109	6.3%	0.113	6.6%
3	1.18	0.044	3.7%	0.078	6.6%
4	0.720	0.031	4.3%	0.104	14.4%
5	0.300*	—	—	—	—

*Consistently at a very low ratio

Precision (Plasma): Precision studies for IMMULITE Toxoplasma IgM and IMMULITE 2000 Toxoplasma IgM assays on plasma samples (EDTA and heparin) were conducted at DPC by testing samples in triplicate over the course of 3 days, two runs per day, for a total of 6 runs and 18 replicates. The means, within-run and total CVs were calculated by the Analysis of Variance. Results are expressed as a signal-to-cutoff ratio. Precision statistics are summarized below.

IMMULITE Toxoplasma IgM Precision – EDTA (ratio):

		Within-Run		Total	
	Mean	SD	CV	SD	CV
1	0.262	0.023	8.8%	0.033	12.6%
2	1.11	0.052	4.7%	0.069	6.2%
3	1.33	0.075	5.6%	0.077	5.8%
4	1.66	0.087	5.2%	0.083	5.0%

IMMULITE 2000 Toxoplasma IgM Precision – EDTA (ratio):

		Within-Run		Total	
	Mean	SD	CV	SD	CV
1	0.259	0.0191	7.4%	0.0183	7.1%
2	1.00	0.06	6.0%	0.052	5.2%
3	1.21	0.097	8.0%	0.084	6.9%
4	1.51	0.084	5.6%	0.073	4.8%

IMMULITE Toxoplasma IgM Precision – Heparin (ratio):

		Within-Run		Total	
	Mean	SD	CV	SD	CV
1	0.67	0.077	11.5%	0.081	12.1%
2	1.18	0.089	7.5%	0.123	10.4%
3	1.42	0.112	7.9%	0.136	9.6%
4	1.71	0.137	8.0	0.161	9.4%

IMMULITE 2000 Toxoplasma IgM Precision – Heparin (ratio):

		Within-Run		Total	
	Mean	SD	CV	SD	CV
1	0.65	0.068	10.5%	0.07	10.8%
2	1.2	0.061	5.1%	0.057	4.8%
3	1.32	0.073	5.5%	0.071	5.4%
4	1.54	0.084	5.5%	0.078	5.1%

Crossreactivity: Crossreactivity: A study was conducted to evaluate whether the measurement of Toxoplasma IgM antibody is affected by closely related microorganisms. Ninety-three seronegative sera containing antibodies to Varicella Zoster Virus (n=3), Measles (n=10), Cytomegalovirus (CMV) (n=10), Herpes Simplex Virus (n=10), Toxoplasma (n=10), *mycloplasma pneumoniae* (n=10), Epstein-Barr Virus (n=10), Syphilis (n=10) and Parvovirus (n=10) and rheumatoid factor (n=10) were tested by IMMULITE and IMMULITE 2000 Toxoplasma IgM and all yielded negative results.

Interference: Conjugated or unconjugated bilirubin: no effect up to 20 mg/dL
Lipemia: no effect of triglycerides up to 3000 mg/dL
Hemoglobin: no effect up to 539 mg/dL

Anti-coagulants: Twenty-eight blood samples drawn into plain, heparinized and EDTA vacutainer tubes were assayed by the IMMULITE 2000 Toxoplasma IgM assay. Results (in S/CO ratio) from the anticoagulant tubes were compared with those from the serum tubes in regression analyses:

Regressions:	Heparin = 0.96 × (Serum) + 0.05	r = 0.991
	EDTA = 0.93 × (Serum) + 0.04	r = 0.992
Means (S/CO ratio):	Serum = 0.80	
	Heparin = 0.82	
	EDTA= 0.79	

Gel Barrier: Twenty-eight blood samples drawn into plain and SST vacutainer tubes were assayed by the IMMULITE 2000 Toxoplasma IgM assay. Results (in S/CO ratio) from the SST tubes were compared with those from the serum tubes in a regression analysis:

Regressions:	SST = 0.97 × (Serum) + 0.08	r = 0.994
Means (S/CO ratio):	Serum = 0.80	
	SST = 0.85	

CDC Toxoplasma 1998 Human Serum Panel

The following information is from a serum panel obtained from the CDC and tested by DPC. 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.

The panel consists of 32 positive and 65 negative samples. IMMULITE Toxoplasma IgM demonstrated 97.9% total agreement with the CDC results. There was 93.8% agreement with the positive specimens and 100% agreement with the negative specimens. IMMULITE 2000 Toxoplasma IgM demonstrated 99.0% total agreement with the CDC results. There was 96.9% agreement with the positive specimens and 100% agreement with the negative specimens.

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for the IMMULITE Toxoplasma IgM and IMMULITE 2000 Toxoplasma IgM assays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 0 2002

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045-5597

Re: k012075
Trade/Device Name: IMMULITE® and IMMULITE® 2000 Toxoplasma IgM
Regulation Number: 21 CFR 866.3780
Regulation Name: Toxoplasma gondii serological reagents
Regulatory Class: Class II
Product Code: LGD
Dated: November 30, 2001
Received: December 3, 2001

Dear Dr. Levine:

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 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012075

Device Name: **IMMULITE® Toxoplasma IgM and IMMULITE® 2000 Toxoplasma IgM**

Indications For Use:

IMMULITE® Toxoplasma IgM - For in vitro diagnostic use with the IMMULITE® Analyzers – for the presumptive qualitative detection of IgM antibodies to Toxoplasma gondii in human serum, particularly for women of childbearing age. When performed in conjunction with a Toxoplasma IgG assay, the IMMULITE® Toxoplasma IgM can be used as an aid in the presumptive diagnosis of acute, recent or reactive Toxoplasma gondii infection. This product has not been cleared/approved by the FDA for blood/plasma donor screening.

IMMULITE® 2000 Toxoplasma IgM - For in vitro diagnostic use with the IMMULITE® 2000 Analyzers – for the presumptive qualitative detection of IgM antibodies to Toxoplasma gondii in human serum, particularly for women of childbearing age. When performed in conjunction with a Toxoplasma IgG assay, the IMMULITE® 2000 Toxoplasma IgM can be used as an aid in the presumptive diagnosis of acute, recent or reactive Toxoplasma gondii infection. This product has not been cleared/approved by the FDA for blood/plasma donor screening.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012075

✓ Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)