BIO-RAD

SEP 3 0 2002

ATTACHMENT I **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: K013839

DATE: September 10, 2002

APPLICANT: Bio-Rad
3, Boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France

OFFICIAL CORRESPONDENT: Sylvie Confida

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PRODUCT TRADE NAME: Bio-Rad Laboratories Platelia® Toxo IgG TMB

COMMON NAME: Toxoplasma IgG Enzyme Immunoassay (EIA)

CLASSIFICATION NAME: 21 CFR 866.3780, Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii

PREDICATE DEVICE: Bio-Rad Laboratories Platelia® Toxo IgG (K89497)

DEVICE DESCRIPTION

The Platelia® Toxo IgG TMB assay utilizes a solid-phase enzyme immunoassay technique referred to as an indirect ELISA. Diluted test samples are placed into the *T. gondii* antigen coated wells of the microplate. During incubation, *T. gondii* antibodies present in the test sample bind to the *T. gondii* antigen. After incubation, unbound antibodies and other serum proteins are removed by washing. The conjugate (peroxidase-labeled monoclonal antibody specific for human gamma chains) is added to the micropalte wells. During a second incubation, the labeled monoclonal antibody binds to the IgG antibody – *T. gondii* antigen complexes attached to the microplate wells. The unbound conjugate is removed by washing. The addition of peroxidase substrate and chromogen solutions initiates a color development reaction. The enzymatic reaction is stopped by addition of an acid. The optical density reading, obtained with a spectrophotometer set at 450nm, is proportional to the amount of *T. gondii* IgG antibody present in the test sample and is converted into IU/ml using a standard curve. Standard control sera are calibrated against the WHO standard (TOXM185).

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INTENDED USE

The Platelia® Toxo IgG TMB kit is an *in-vitro* diagnostic test kit for the qualitative and quantitative detection of anti-*Toxoplasma gondii* IgG in human serum or plasma (EDTA, Heparin, Citrate).

Note: The Platelia® Toxo IgG TMB assay has not been cleared/approved by the FDA for blood/plasma donor screening.

TECHNOLOGICAL CHARACTERISTICS

The Platelia® Toxo IgG TMB kit is a modified version of the Platelia® Toxo IgG kit and remains similar in form and function. The following comparison table indicates significant similarities and differences between the kits:

Comparison Table

Characteristics	**Platelia® Toxo IgG (Predicate)**	**Platelia® Toxo IgG TMB**
Format and Test Method	96-well microplate EIA, non-breakaway wells	96-well microplate EIA, breakaway wells
Intended Use	Assay for the qualitative and quantitative detection of anti-*Toxoplasma gondii* IgG in human serum	Assay for the qualitative and quantitative detection of anti-*Toxoplasma gondii* IgG in human serum or plasma
Positive Calibrators	Pooled human serum, negative for *T. gondii,* is used to dilute the positive calibrators	A synthetic matrix consisting of Tris-NaCl buffer, BSA, glycerol, and colorant is used to manufacture the negative control and to dilute the positive control.
Chromogen	*o.* phenylenediamine-2 HCL (OPD) tablets	Tetramethylbenzidine (TMB) solution
Wavelength	Dual wavelength reading at 492 nm and 620 nm.	Dual wavelength reading at 450 nm and 620 nm.

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PERFORMANCE SUMMARY

A. Precision Studies

Inter-assay and intra-assay reproducibility were determined by assaying two *T. gondii* IgG negative samples and four *T. gondii* IgG positive samples in triplicate, on three different days at three laboratory sites.

Site 1

	Neg 1		Neg 2		Pos 1		Pos 2		Pos 3		Pos 4	
	OD	IU/ml	OD	IU/ml	OD	IU/ml	OD	IU/ml	OD	IU/ml	OD	IU/ml
N=	9	9	9	9	9	9	9	9	9	9	9	9
Mean=	0.116		0.073		1.016	37.544	0.829	27.144	1.472	72.500	2.152	220.222
Within Run (intra-assay) sd=	0.011		0.005		0.069	3.871	0.026	1.375	0.061	12.670	0.061	12.936
%CV=	9.2%	N/A	6.6%	N/A	6.8%	10.3%	3.1%	5.1%	4.1%	17.5%	2.8%	5.9%
Total (inter-assay) sd=	0.009		0.004		0.060	3.216	0.021	1.229	0.053	10.454	0.060	13.070
%CV=	7.6%		5.6%		5.9%	8.6%	2.6%	4.5%	3.6%	14.4%	2.8%	5.9%

Site 2

	Neg 1		Neg 2		Pos 1		Pos 2		Pos 3		Pos 4	
	OD	IU/ml	OD	IU/ml	OD	IU/ml	OD	IU/ml	OD	IU/ml	OD	IU/ml
N=	9	9	9	9	9	9	9	9	9	9	9	9
Mean=	0.134		0.083		0.955	30.522	0.728	17.733	1.438	74.489	2.059	229.378
Within Run (intra-assay) sd=	0.007		0.007		0.010	0.631	0.024	1.107	0.020	2.835	0.031	9.941
%CV=	4.9%	N/A	9.0%	N/A	1.1%	2.1%	3.3%	6.2%	1.4%	3.8%	1.5%	4.3%
Total (inter-assay) sd=	0.016		0.012		0.073	2.492	0.062	2.124	0.097	9.374	0.060	20.109
%CV=	11.7%		14.8%		7.7%	8.2%	8.5%	12.0%	6.8%	12.6%	2.9%	8.8%

Site 3

	Neg 1		Neg 2		Pos 1		Pos 2		Pos 3		Pos 4	
	OD	IU/ml	OD	IU/ml	OD	IU/ml	OD	IU/ml	OD	IU/ml	OD	IU/ml
N=	9	9	9	9	9	8	9	9	9	9	9	9
Mean=	0.231		0.135		1.324	49.875	0.968	32.000	1.614	99.889	2.560	240.000
Within Run (intra-assay) sd=	0.011		0.022		0.065	3.682	0.040	2.000	0.068	15.899	0.171	0.000
%CV=	4.7%	N/A	16.1%	N/A	4.9%	7.4%	4.1%	6.3%	4.2%	15.9%	6.7%	0.0%
Total (inter-assay) sd=	0.012		0.028		0.104	6.935	0.114	8.775	0.256	40.746	0.161	0.000
%CV=	5.3%		21.1%		7.8%	13.9%	11.8%	27.4%	15.9%	40.8%	6.3%	0.0%

N/A = Not applicable

In addition, inter-assay and intra-assay reproducibility with plasma samples were determined by assaying three additional samples (one *T. gondii* IgG negative sample and two *T. gondii* IgG positive samples) in triplicate, on three different days, at one laboratory site.

Serum	Neg 1		Pos 1		Pos 2	
	OD	IU/ml	OD	IU/ml	OD	IU/ml
N =	9	9	9	9	9	9
Mean =	0.061		0.918	29.37	0.735	19.98
Within-Run (intra-assay) sd =	0.003		0.043	2.242	0.018	0.930
%CV =	4.9%	N/A	4.7%	7.6%	2.4%	4.7%
Total (inter-assay) sd =	0.002		0.098	2.936	0.052	1.131
%CV =	4.1%		10.7%	10.0%	7.0%	5.7%

EDTA	Neg 1		Pos 1		Pos 2	
	OD	IU/ml	OD	IU/ml	OD	IU/ml
N =	9	9	9	9	9	9
Mean =	0.047		0.909	28.83	0.672	16.73
Within-Run (intra-assay) sd =	0.003		0.050	2.555	0.041	2.197
%CV =	6.7%	N/A	5.5%	8.9%	6.1%	13.1%
Total (inter-assay) sd =	0.004		0.099	3.017	0.049	1.839
%CV =	8.1%		10.9%	10.5%	7.3%	11.0%

Citrate	Neg 1		Pos 1		Pos 2	
	OD	IU/ml	OD	IU/ml	OD	IU/ml
N =	9	9	9	9	9	9
Mean =	0.067		0.918	29.30	0.735	19.93
Within-Run (intra-assay) sd =	0.003		0.019	0.981	0.015	0.739
%CV =	4.3%	N/A	2.1%	3.3%	2.0%	3.7%
Total (inter-assay) sd =	0.004		0.072	1.373	0.063	1.602
%CV =	6.3%		7.8%	4.7%	8.6%	8.0%

Heparin	Neg 1		Pos 1		Pos 2	
	OD	IU/ml	OD	IU/ml	OD	IU/ml
N =	9	9	9	9	9	9
Mean =	0.060		0.910	28.89	0.714	18.91
Within-Run (intra-assay) sd =	0.010		0.015	0.805	0.037	1.877
%CV =	16.7%	N/A	1.7%	2.8%	5.1%	9.9%
Total (inter-assay) sd =	0.008		0.095	2.651	0.050	1.596
%CV =	13.9%		10.4%	9.2%	6.9%	8.4%

N/A = Not applicable

B. Comparison Studies

Performance of the Platelia® Toxo IgG TMB assay was evaluated against another commercially available enzyme immunoassay (EIA) by testing 468 prospective samples and 35 retrospective specimens from 11 seroconversion panels.

Platelia® Toxo IgG TMB vs OPD Correlation Table (combined results)

N = 503		TMB		
		Neg	Equivocal	Pos
O	Neg	339	5	1
P	Equivocal	0	3	3
D	Pos	0	3	149

Excluding equivocal samples, the combined results of comparative prospective and retrospective testing demonstrated the following :

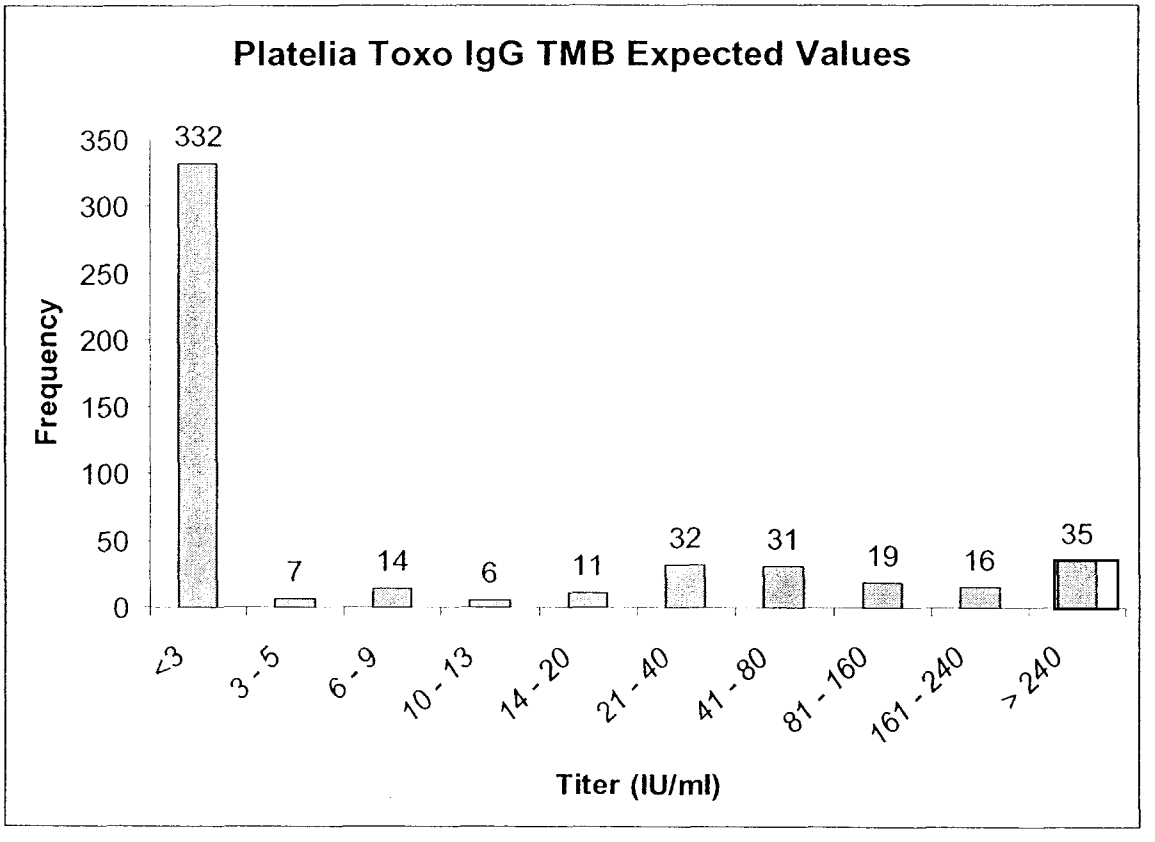
Negative agreement : 99.71% (339/340). The 95% confidence interval[26] is 98.98% - 100.00%.

Positive agreement : 100.00% (149/149). The 95% confidence interval[26] is 99.66% - 100.00%.

Overall agreement : 99.80% (488/489). The 95% confidence interval[26] is 99.29% - 100.00%.

C. Expected Values

A total of 503 fresh and frozen serum samples obtained from pregnant women during routine laboratory activities in the area of Paris, France were tested with the Platelia® Toxo IgG TMB assay. The distribution of IU/ml values is shown in the following chart.



D. CDC Test Panel

The following information is from a serum panel obtained from the CDC and tested by Bio-Rad Laboratories. 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 70 positive and 30 negative samples. The Platelia® Toxo IgG TMB assay demonstrated 100% agreement with the positive specimens and 100% agreement with the negative specimens.

Please Note: There should be no other statistical calculation or inferences drawn from the panel results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 3 0 2002

Mr. David Bhend
Regulatory Affairs Associate
Bio-Rad Laboratories
Diagnostics Group
6565 185th Avenue NE
Redmond, WA 98052

Re: k013839
Trade/Device Name: Platelia® Toxo IgG TMB
Regulation Number: 21 CFR 866.3780
Regulation Name: Toxoplasma gondii serological reagents
Regulatory Class: Class II
Product Code: LGD
Dated: July 19, 2002
Received: July 23, 2002

Dear Mr. Bhend:

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

ATTACHMENT G **INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K013839

Device Name: Platelia® Toxo IgG TMB

Indications for Use:

The Platelia® Toxo IgG TMB kit is an *in-vitro* diagnostic test kit for the qualitative and quantitative detection of anti-*Toxoplasma gondii* IgG in human serum or plasma (EDTA, Heparin, Citrate).

Note: The Platelia® Toxo IgG TMB assay 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)

Professional Use: _____

OR

Prescription Use: X
(Per 21 CFR 801.109)

Over-The-Counter Use: _____
(Optional Format 1-2-96)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013839