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: K013837

DATE:	September 10, 2002
APPLICANT:	Bio-Rad 3, Boulevard Raymond Poincaré 92430 Marnes-la-Coquette, France
PHONE: **FAX:**	33-1-47-95-6138 33-1-47-95-6242
OFFICIAL CORRESPONDENT:	Sylvie Confida
PRODUCT TRADE NAME:	Bio-Rad Platelia® Toxo IgM TMB
COMMON NAME:	Toxoplasma IgM Enzyme Immunoassay (EIA)
CLASSIFICATION NAME:	21 CFR 866.3780, Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii
PREDICATE DEVICE:	Kallestad Diagnostics Platelia® Toxo IgM (K89498)

DEVICE DESCRIPTION

The Platelia® Toxo IgM TMB assay is a qualitative assay which utilizes an immunoenzymatic double sandwich method. Diluted samples and controls are placed into microplate wells coated with antibodies to human IgM. The IgM antibodies present in the samples are captured by the solid phase. Remaining antibodies (including any of the IgG class) and other serum proteins are removed by washing. A solution containing *T. gondii* antigen and conjugate (monoclonal antibody to *T. gondii* labeled with horseradish peroxidase) is placed into each well. *T. gondii* IgM antibodies in the test sample that are captured on the solid phase bind the *T. gondii* antigen-conjugate complex. Excess *T. gondii* antigen and conjugate are removed by washing. A peroxidase substrate and chromogen solution is added which reacts with the conjugate to initiate a color development reaction. This reaction is stopped by the addition of an acid. The optical density readings for the test samples are obtained with a spectrophotometer set at a wavelength of 450 nm. The presence of *T. gondii* IgM antibodies in an individual sample is determined by comparing the optical density reading for the sample to the optical density reading of the cut-off control serum.

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INTENDED USE

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

Note:

- Patient testing with the Platelia® Toxo IgM assay must be performed in conjunction with an anti-*Toxoplasma gondii* IgG antibody assay.
- The Platelia® Toxo IgM assay is presumptive for the detection of anti-*Toxoplasma gondii* IgM antibodies and presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infection.
- The performance of the Platelia® Toxo IgM assay has not been cleared/approved by the FDA for blood/plasma donor screening.

TECHNOLOGICAL CHARACTERISTICS

The Platelia® Toxo IgM TMB kit is a modified version of the Platelia® Toxo IgM 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 IgM (Predicate)**	**Platelia® Toxo IgM TMB**
Format and Test Method	96-well microplate EIA, non-breakaway wells	96-well microplate EIA, breakaway wells
Intended Use	Assay for the qualitative detection of anti-*Toxoplasma gondii* IgM in human serum	Assay for the qualitative detection of anti-*Toxoplasma gondii* IgM in human serum or plasma
Positive and Negative Controls	Pooled human serum, negative for *T. gondii,* is used to manufacture the negative control and to dilute the positive control.	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* IgM negative samples and four *T. gondii* IgM 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	S/CO	OD	S/CO	OD	S/CO	OD	S/CO	OD	S/CO	OD	S/CO
N=	9	9	9	9	9	9	9	9	9	9	9	9
Mean=	0.027	0.052	0.022	0.042	0.742	1.438	0.660	1.278	0.825	1.599	1.477	2.862
Within Run (intra-assay) sd=	0.001	0.003	0.002	0.003	0.011	0.021	0.011	0.022	0.016	0.031	0.017	0.034
%CV=	5.2%	5.1%	7.5%	7.6%	1.5%	1.4%	1.7%	1.7%	1.9%	1.9%	1.2%	1.2%
Total (inter-assay) sd=	0.002	0.005	0.001	0.003	0.020	0.041	0.013	0.038	0.013	0.048	0.032	0.050
%CV=	8.1%	9.7%	6.7%	6.3%	2.6%	2.8%	2.0%	3.0%	1.6%	3.0%	2.1%	1.7%

Site 2

	Neg 1		Neg 2		Pos 1		Pos 2		Pos 3		Pos 4	
	OD	S/CO	OD	S/CO	OD	S/CO	OD	S/CO	OD	S/CO	OD	S/CO
N=	9	9	9	9	9	9	9	9	9	9	9	9
Mean=	0.031	0.050	0.029	0.048	0.746	1.206	0.669	1.083	0.776	1.255	1.511	2.444
Within Run (intra-assay) sd=	0.007	0.011	0.007	0.011	0.025	0.040	0.015	0.024	0.009	0.015	0.051	0.082
%CV=	22.5%	23.0%	22.6%	23.2%	3.3%	3.3%	2.3%	2.3%	1.2%	1.2%	3.4%	3.4%
Total (inter-assay) sd=	0.009	0.016	0.007	0.012	0.024	0.061	0.015	0.066	0.012	0.063	0.046	0.151
%CV=	29.9%	32.8%	22.3%	24.4%	3.2%	5.0%	2.2%	6.1%	1.5%	5.0%	3.0%	6.2%

Site 3

	Neg 1		Neg 2		Pos 1		Pos 2		Pos 3		Pos 4	
	OD	S/CO	OD	S/CO	OD	S/CO	OD	S/CO	OD	S/CO	OD	S/CO
N=	9	9	9	9	9	9	9	9	9	9	9	9
Mean=	0.032	0.057	0.024	0.042	0.769	1.393	0.705	1.278	0.684	1.227	1.346	2.426
Within Run (intra-assay) sd=	0.004	0.007	0.006	0.011	0.055	0.104	0.023	0.044	0.011	0.020	0.061	0.107
%CV=	11.6%	12.1%	24.0%	25.3%	7.1%	7.5%	3.3%	3.5%	1.6%	1.6%	4.5%	4.4%
Total (inter-assay) sd=	0.014	0.022	0.010	0.016	0.073	0.203	0.077	0.212	0.119	0.150	0.098	0.150
%CV=	43.7%	38.7%	41.2%	36.8%	9.5%	14.6%	11.0%	16.6%	17.4%	12.2%	7.3%	6.2%

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

Serum	Neg 1		Pos 1		Pos 2	
	OD	S/CO	OD	S/CO	OD	S/CO
N =	9	9	9	9	9	9
Mean =	0.022	0.04	0.710	1.26	1.083	1.92
Within-Run (intra-assay) sd =	0.002	0.003	0.019	0.034	0.029	0.052
%CV =	8.7%	8.8%	2.7%	2.7%	2.7%	2.7%
Total (inter-assay) sd =	0.003	0.006	0.035	0.077	0.051	0.074
%CV =	14.5%	14.9%	4.9%	6.1%	4.8%	3.9%

EDTA	Neg 1		Pos 1		Pos 2	
	OD	S/CO	OD	S/CO	OD	S/CO
N =	9	9	9	9	9	9
Mean =	0.024	0.04	0.761	1.35	1.063	1.88
Within-Run (intra-assay) sd =	0.002	0.004	0.019	0.034	0.019	0.033
%CV =	8.3%	8.3%	2.5%	2.6%	1.7%	1.8%
Total (inter-assay) sd =	0.002	0.004	0.036	0.030	0.056	0.076
%CV =	8.5%	9.4%	4.7%	2.2%	5.2%	4.0%

Citrate	Neg 1		Pos 1		Pos 2	
	OD	S/CO	OD	S/CO	OD	S/CO
N =	9	9	9	9	9	9
Mean =	0.022	0.04	0.674	1.19	1.075	1.91
Within-Run (intra-assay) sd =	0.001	0.002	0.017	0.029	0.020	0.036
%CV =	5.0%	5.0%	2.5%	2.5%	1.9%	1.9%
Total (inter-assay) sd =	0.002	0.004	0.031	0.038	0.043	0.091
%CV =	9.9%	10.6%	4.5%	3.2%	4.0%	4.8%

Heparin	Neg 1		Pos 1		Pos 2	
	OD	S/CO	OD	S/CO	OD	S/CO
N =	9	9	9	9	9	9
Mean =	0.022	0.04	0.719	1.27	1.034	1.83
Within-Run (intra-assay) sd =	0.001	0.002	0.012	0.020	0.022	0.039
%CV =	4.4%	4.4%	1.6%	1.6%	2.1%	2.1%
Total (inter-assay) sd =	0.002	0.003	0.024	0.031	0.059	0.115
%CV =	11.3%	8.7%	3.3%	2.4%	5.7%	6.3%

B. Comparison Studies

Performance of the Platelia Toxo IgM TMB assay was evaluated against another commercially available enzyme immunoassay (EIA) by testing 348 patient samples and 97 specimens from 40 seroconversion panels. The combined results of the patient and seroconversion panel testing demonstrate an agreement of 99.53%.

Platelia Toxo IgM TMB vs IgM EIA Correlation Table (combined results)

N = 445		TMB		
		Neg	Equivocal	Pos
IgM EIA	Neg	271	0	0
	Equivocal	4	3	0
	Pos	2	11	154

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

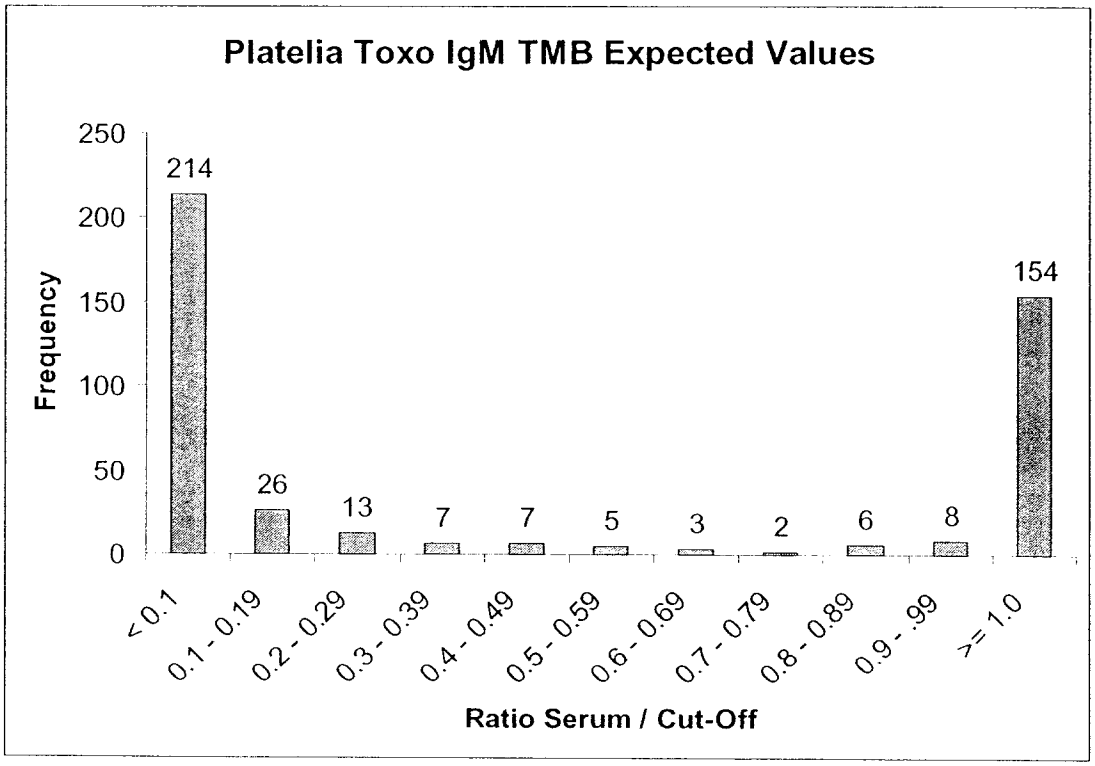
Negative agreement : 100.00% (271/271). The 95% confidence interval[26] is 99.82 – 100.00%.

Positive agreement : 98.72% (154/156). The 95% confidence interval[26] is 96.61 – 100.00%.

Overall agreement : 99.53% (425/427). The 95% confidence interval[26] is 98.76% - 100.00%.

C. Expected Values

A total of 445 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 IgM TMB assay. The distribution of serum / cut-off ratio 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 32 positive and 65 negative samples. The Platelia® Toxo IgM 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: k013837
Trade/Device Name: Platelia® Toxo IgM 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): K013837

Device Name: Platelia® Toxo IgM TMB

Indications for Use:

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

Note:

- Patient testing with the Platelia® Toxo IgM assay must be performed in conjunction with an anti-*Toxoplasma gondii* IgG antibody assay.
- The Platelia® Toxo IgM assay is presumptive for the detection of anti-*Toxoplasma gondii* IgM antibodies and presumptive for the diagnosis of acute, recent or reactivated *Toxoplasma gondii* infection.
- The performance of the Platelia® Toxo IgM assay has not been established for neonate testing.
- The Platelia® Toxo IgM assay has not been cleared/approved by the FDA for blood/plasma donor screening.

Woody Dubon
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013837

(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)