510(k) SUMMARY

Date of Summary April 10, 2008

Product Name Platelia™ Lyme IgG

Sponsor

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

Correspondent

MDC Associates, LLC
Fran White, Regulatory Consultant
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Device The Platelia™ Lyme IgG is substantially equivalent to the Mardx *B. burgdorferi* IgG Assay

Manufacturer: Mardx Diagnostics, Inc.
Product: Mardx Lyme Disease EIA (IgG) Test – K894224

Product Attribute	Bio-Rad Platelia™ Lyme IgG	Mardx Lyme Disease Tests	Substantial Equivalent
Intended use	The Platelia™ Lyme IgG assay is a qualitative test intended for use in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum or plasma. The EIA system should be used to test serum or plasma from patients with a history and symptoms of infection with *B. burgdorferi*. All positive and equivocal specimens should be re-tested with a highly specific, second-tier test such as Western blot. Positive second-tier results are supportive evidence of infection with *B. burgdorferi*.	The MarDx *B. burgdorferi* Disease Enzyme Immunoassay (EIA) IgG Test is a qualitative test intended for use in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum. This EIA system should be used to test serum from patients with a history and symptoms of infection with *B. burgdorferi*. All positive and equivocal specimens should be re-tested with a highly specific, second-tier test such as Western blot. Positive second-tier results	√

	The diagnosis of Lyme disease should be made based on history and symptoms (such as erythema migrans), and other laboratory data, in addition to the presence of antibodies to *B. burgdorferi*. Negative results (either first or second-tier) should not be used to exclude Lyme disease.	are supportive evidence of infection with *B. burgdorferi*. The diagnosis of Lyme disease should be made based on history and symptoms (such as erythema migrans), and other laboratory data, in addition to the presence of antibodies to *B. burgdorferi*. Negative results (either first or second-tier) should not be used to exclude Lyme disease.	
Sample	Plasma or serum	Serum	√
Test methodology	ELISA	ELISA	√

PRODUCT DESCRIPTION

The Platelia™ Lyme IgG Assay is a qualitative assay for the detection of human IgG antibodies to *Borrelia burgdorferi* in human serum or plasma.

INTENDED USE

The Platelia™ Lyme IgG Test is a qualitative test intended for use in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum or plasma (K_3 EDTA, sodium heparin or sodium citrate). The EIA system should be used to test serum or plasma from patients with a history and symptoms of infection with *B. burgdorferi*. All positive and equivocal specimens should be re-tested with a specific, second-tier test such as Western blot. Positive second-tier results are supportive evidence of infection with *B. burgdorferi*. The diagnosis of Lyme disease should be made based on history and symptoms (such as *erythema migrans*), and other laboratory data, in addition to the presence of antibodies to *B. burgdorferi*. Negative results (either first or second-tier) should not be used to exclude Lyme disease.

SUMMARY OF TECHNOLOGY

The Platelia™ Lyme IgG Assay uses an indirect ELISA immuno-enzymatic method. Inactivated antigens of *Borrelia burgdorferi* B31 are used for coating the microplate. A monoclonal antibody labeled with peroxidase which is specific for human gamma chains (anti-IgG) is used as the conjugate.

PERFORMANCE DATA

Bio-Rad confirms that any/all data provided in this submission may be released upon request.

Sensitivity

a. Retrospective study

One hundred sixty-six patient samples confirmed positive for *Borrelia burgdorferi* infection by culture were run on the Platelia™ Lyme IgG assay. Disease stage was available for each sample tested. Data below summarizes the overall sensitivity of the assay, and the sensitivity considering the different stages of Lyme disease.

Performance of the Platelia™ Lyme IgG Assay on retrospective samples

		Positive	Equivocal	Negative	Total	% Sensitivity (1)
Platelia™ Lyme IgG	Early Stage	55	16	49	120	**59.2%** (71/120) CI(2) [50.2, 67.6]
	Disseminated Stage	18	2	13	33	**60.6%** (20/33) CI [43.7, 75.3]
	Late Stage	13	0	0	13	**100.0%** (13/13) CI [77.2, 100]
	All Stages	86	18	62	166	**62.7%** (104/166) CI [54.5, 69.0]

(1) *Equivocal results were considered as positive for calculation of sensitivity.*
(2) *CI = 95% Confidence Interval*

b. CDC Panel

The following information is from a serum panel obtained from the CDC and tested by the Platelia™ Lyme IgG Kit. 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 following data summarizes results obtained on Platelia™ Lyme IgG and a marketed device.

Performance of the Platelia™ Lyme IgG Assay on Lyme CDC panel

Time from onset	Platelia™ Lyme IgG				Predicate Lyme IgG EIA Assay			
	Positive or equivocal	Negative	Total	% agreement with clinical diagnosis (1)	Positive or equivocal	Negative	Total	% agreement with clinical diagnosis (1)
Normals	0	5	5	**100.0%** (5/5)	0	5	5	**100.0%** (5/5)
0-1 Month	2	3	5	**40.0%** (2/5)	3	2	5	**60.0%** (3/5)
1-2 Months	5	3	8	**62.5%** (5/8)	3	5	8	**37.5%** (3/8)
3-12 Months	10	7	17 (2)	**58.8%** (10/17)	10	8	18	**55.6%** (10/18)
> 1 Year	8	0	8	**100.0%** (8/8)	7	1	8	**87.5%** (7/8)
Total	25	18	43 (2)	**69.8%** (30/43)	23	21	44	**63.6%** (28/44)

(1) *Equivocal samples considered as positive*
(2) *One sample not tested due to insufficient sample volume*

Prospective study

A prospective study was conducted on 439 samples collected at two different sites from endemic region in United States and routinely tested for Lyme disease. The Platelia™ Lyme IgG assay was evaluated in comparison with the two-tier protocol recommended by the CDC (samples found positive or equivocal on ELISA are retested by Western Blot). Data are summarized below.

Performance of the Platelia™ Lyme IgG Assay on prospective samples

	Platelia™ Lyme IgG		
	Positive	Equivocal	Negative
Site 1 (n=339)	45	18	276
Site 2 (n=100)	10	7	83
Total (n=439)	**55**	**25**	**359**

Results of Western-Blot on prospective samples found positive or equivocal with the Platelia™ Lyme IgG Assay

	Lyme IgG		
	Platelia™ Lyme IgG Positive or Equivocal	**Western Blot IgG Positive**	**Positive Agreement samples (%)**
Site 1 (n=339)	61 [1]	6 [1]	9.8%
Site 2 (n=100)	17	3	17.6%
Total (n=439)	**78**	**9**	**11.5%**

[1] *Two samples were not interpretable on Western Blot IgG and were not considered for calculation.*

Analytical Specificity

Analytical specificity of the assay was determined by testing a panel of 183 samples obtained from blood donors. 100 samples were collected in states considered as non-endemic for Lyme disease (Nevada, Oregon and Louisiana). 83 samples were collected in northeastern US considered as endemic region for Lyme disease. Data provided summarizes the percent of positive/equivocal results obtained in each category.

Analytical specificity of Platelia™ Lyme IgG Assay in blood donors

	Endemic	**Non-Endemic**	**Total**
Number of samples tested	83	100	183
Positive or Equivocal	**1.2%** (1/83)	**0.0%** (0/100)	**0.5%** (1/183)

Precision

a. Intra-assay precision

In order to evaluate intra-assay precision, three samples close to equivocal zone and four samples spanning the assay range were respectively tested 20 and 30 times during the same run. The ratio (Sample OD/CO) was determined for each sample. The data were then analyzed for intra-assay and inter-assay precision according to the Clinical and Laboratory Standards Institute guidance (formerly NCCLS) EP-5A2 revised November 2004. Mean Ratio, Standard Deviation (SD) and Coefficient of Variation (%CV) for each of the seven specimens are provided.

Intra-assay precision of Platelia™ Lyme IgG

		N	Mean Ratio	SD	CV %
Near the Cut-Off samples	Sample 1	20	0.85	0.045	5.3%
	Sample 2	20	1.00	0.050	5.4%
	Sample 3	20	1.19	0.111	9.4%
Samples spanning the Platelia™ Lyme IgG assay range	Sample 4	30	0.20	0.010	6.4%
	Sample 5	30	0.95	0.082	8.6%
	Sample 6	30	1.38	0.116	8.4%
	Sample 7	30	6.31	0.134	2.1%

Inter-assay precision

In order to evaluate inter-assay precision, two negative, two equivocal, one medium and one high positive samples were tested twice a day in different runs for 20 days. The ratio (Sample OD/CO) was determined for each sample. Mean Ratio, Standard Deviation (SD) and Coefficient of Variation (%CV) for each of the seven specimens are provided.

Inter-assay precision of Platelia™ Lyme IgG

	N	Mean Ratio	SD	CV %
Negative 1	40	0.19	0.032	16.7%
Negative 2	40	0.23	0.025	10.9%
Low equivocal	40	0.85	0.115	13.5%
High equivocal	40	1.16	0.208	18.0%
Medium Positive	40	3.92	0.335	8.5%
High Positive	40	6.67	0.650	9.7%

Inter-site precision

In order to evaluate total assay precision, six samples (two negative, two weakly positive and two medium-to high positive samples) were tested at three different sites. Each sample was measured in singleton in three runs per day during five days, each run being performed by a different technician. The ratio (Sample OD/CO) was determined for each sample. Mean Ratio, Standard Deviation (SD) and Coefficient of Variation (%CV) for each of the six specimens are provided.
Total assay precision of Platelia™ Lyme IgG

		Between-Day Precision			Total Precision		
		Mean	SD	CV %	Mean	SD	CV %
Negative 1	Site 1	0.32	0.033	10.4%	0.40	0.075	18.6%
	Site 2	0.44	0.045	9.5%			
	Site 3	0.45	0.050	11.0%			
Negative 2	Site 1	0.31	0.031	9.8%	0.38	0.068	17.6%
	Site 2	0.43	0.028	6.6%			
	Site 3	0.41	0.060	14.6%			
Low Positive 1	Site 1	1.53	0.122	8.0%	1.59	0.202	12.7%
	Site 2	1.62	0.224	13.8%			
	Site 3	1.62	0.243	15.0%			
Low Positive 2	Site 1	1.41	0.115	8.1%	1.45	0.128	8.9%
	Site 2	1.45	0.155	10.7%			
	Site 3	1.48	0.108	7.3%			
High Positive 1	Site 1	3.06	0.256	8.4%	3.11	0.296	9.5%
	Site 2	3.19	0.357	11.2%			
	Site 3	3.08	0.267	8.7%			
High Positive 2	Site 1	3.37	0.498	14.8%	3.37	0.391	11.6%
	Site 2	3.40	0.335	9.9%			
	Site 3	3.36	0.344	10.2%			

Cross Reactivity

Sera from 161 individuals from United States with disease conditions other than Lyme disease were tested for potential cross-reactivity with the Platelia™ Lyme IgG assay. Results for sixteen conditions are presented.

Cross-reactivity conditions with Platelia™ Lyme IgG

Disease Condition	N	Positive / Equivocal
Syphilis	34	1
H. pylori	5	0
CMV IgG	10	0
EBV IgG	5	0
HSV IgG	10	0
Toxoplasmosis IgG	10	0
Rubella IgG	10	0
Measles IgG	10	0
Mumps IgG	10	0
VZV IgG	10	0
HIV	10	0
Antinuclear Antibodies (ANA)	10	0
Human anti-mouse antibodies (HAMA)	10	0

CRP	5	0
SLE	2	0
Rheumatoid Factor	9	0

MATRIX COMPARISON STUDY

Plasma *versus* serum comparisons were performed with a panel of 25 samples (12 negative and 13 positive or equivocal samples). See table 10 below.
istribution of percent difference *versus* serum

		<10%	≥10% to ≤20%	>20%	Mean of differences
Negative samples (n=12)	K3 EDTA	16.7%	8.3%	75.0%	-16.7%
	Na Heparin	33.3%	0.0%	66.7%	-12.4%
	Na Citrate	8.3%	8.3%	83.4%	-20.9%
Equivocal or Positive samples (n = 13)	K3 EDTA	46.1%	15.4%	38.5%	2.9%
	Na Heparin	61.5%	15.4%	23.1%	0.6%
	Na Citrate	38.5%	46.1%	15.4%	0.0%

A large variation has been observed on negative plasma compared to negative sera but without a change in results interpretation. However, the variation within the positive or equivocal samples is small and did not change the results interpretation.

INTERFERING SUBSTANCES
Samples containing 90 g/L of albumin or 100 mg/L of unconjugated bilirubin, lipemic samples containing the equivalent of 36 g/L of triolein (triglyceride), and hemolyzed samples containing up to 10 g/L of hemoglobin do not affect the results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MDC Associates, LLC
c/o Ms. Fran White
Regulatory Consultant
163 Cabot Street
Beverly, MA 01915

MAY - 8 2008

Re: k080012
Trade/Device Name: Platelia™ Lyme IgG Assay
Regulation Number: 21 CFR§ 866.3830
Regulation Name: Treponema pallidum treponemal test reagents.
Regulatory Class: Class II
Product Code: LSR
Dated: April 10, 2008
Received: April 14, 2008

Dear Ms. White:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 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): K080012

Device Name: Platelia™ Lyme IgG

Indications for Use:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080012