

510(k) SUMMARY

K081362

Date of Summary

May 13, 2008

JUN 26 2008

Product Name

Platelia™ Platelia™ Lyme IgM

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 IgM Assay is substantially equivalent to the Mardx *B. burgdorferi* EIA.

Manufacturer: Mardx Diagnostics, Inc.
Product: Mardx Lyme Disease EIA (IgM) Test – K894293

Product Attribute	Bio-Rad Platelia™ Lyme IgM Assay	Mardx Lyme Disease Test	Substantial Equivalent
Intended use	The Platelia™ Lyme IgM Assay is a qualitative test intended for use in the presumptive detection of human IgM antibodies to <i>Borrelia burgdorferi</i> 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 <i>B. burgdorferi</i> . All positive and equivocal specimens should be re-	The MarDx <i>B. burgdorferi</i> Disease Enzyme Immunoassay (EIA) IgM Test Systems is a qualitative test intended for use in the presumptive detection of human IgM antibodies to <i>Borrelia burgdorferi</i> in human serum. This EIA system should be used to test serum from patients with a history and symptoms of infection with <i>B.</i>	√

	<p>tested with a specific, second-tier test such as Western blot. Positive second-tier results are supportive evidence of infection with <i>B. burgdorferi</i>. 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 <i>B. burgdorferi</i>. Negative results (either first or second-tier) should not be used to exclude Lyme disease.</p>	<p><i>burgdorferi</i>. 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 <i>B. burgdorferi</i>. 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 <i>B. burgdorferi</i>. Negative results (either first or second-tier) should not be used to exclude Lyme disease.</p>	
Sample	Plasma or serum	Serum	√
Test methodology	ELISA	ELISA	√

PRODUCT DESCRIPTION

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

INTENDED USE

The Platelia™ Lyme IgM Assay is a qualitative test intended for use in the presumptive detection of human IgM 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 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 IgM Assay is an enzyme immunoassay with capture of the IgM on the solid phase. Anti-human μ -chains antibodies are coated on the solid phase (wells of the microplate). A mixture of the *Borrelia* B31 antigen and the monoclonal anti-*Borrelia* antigen antibody labeled with peroxidase is used as the conjugate.

PERFORMANCE DATA

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

Intra-Assay Precision

To confirm the intra assay precision of the Platelia™ Lyme assay two studies were run.

- Three samples close to the cut off value were tested 20 times during the same run, according to the assessed kit's protocol.
- Various samples spanning the assay range were tested 30 times during the same run, according to the assessed kit's protocol.

Samples close to the grey zone (20x)

Sample	OD			RATIO		
	Mean	SD	CV	Mean	SD	CV
Cut-Off	0.30	0.005	1.7%	0.99	0.02	1.8%
Grey Zone min	0.27	0.009	3.3%	0.87	0.029	3.3%
Grey Zone max	0.36	0.009	2.4%	1.19	0.029	2.4%

Various samples (30x)

Sample	OD			RATIO		
	Mean	SD	CV	Mean	SD	CV
Negative	0.08	0.013	15%	0.24	0.04	15.2%
Low positive	0.42	0.019	4.4%	1.17	0.052	4.4%
Medium	0.67	0.025	3.7%	1.88	0.070	3.7%
High	1.57	0.038	2.4%	4.23	0.104	2.5%

Conclusion:

The coefficient of variation was less than 5% for positive samples.

Cross Reactivity

The following potentially cross-reactive sera were run on the Platelia Lyme IgM assay.

Platelia™ Lyme IgM

Disease Condition	N	Positive / Equivocal
Syphilis	34	1
CMV IgM	5	1
EBV IgM	5	5
HSV IgM	10	0

Disease Condition	N	Positive / Equivocal
Toxoplasmosis IgM	10	0
Rubella IgM	10	0
Measles IgM	10	0
Mumps IgM	10	2
VZV IgM	6	0
HIV	10	0
Antinuclear Antibodies (ANA)	10	1
Heterophile Antibodies (HAMA)	10	0
CRP	5	2
SLE	2	0
Rheumatoid Factor	9	0

Interfering Substances

The following potentially interfering substances were tested on the Platelia Lyme IgM.

Platelia™ Lyme IgM

	Acceptance Criteria	Hemoglobin	Bilirubin	Triglycerin	Albumin
Slope (a)	$0.85 < a < 1.15$	0.907	0.916	0.889	0.893
Y axis intercept (b)	< 0.10	0.071	0.050	0.061	0.073
Correlation coeff	> 0.975	0.999	0.999	0.997	0.999
a+b	$0.85 < a+b < 1.15$	0.978	0.966	0.950	0.966

CDC Lyme Disease Serum Panel

Performance of Platelia™ Lyme IgM Assay on Lyme CDC panel

Time from onset	Platelia™ Lyme IgM				Western Blot IgM			
	Positive or equivocal	Negative	Total	% agreement with clinical diagnosis ⁽¹⁾	Positive	Negative	Total	% agreement with clinical diagnosis ⁽¹⁾
Normals	1	4	5	80.0% (4/5)	0	5	5	100.0% (5/5)
0-1 Month	4	1	8	80.0% (4/5)	3	2	5	60.0% (3/5)
1-2 Months	6	2	8	75.0% (6/8)	7	1	8	87.5% (7/8)
3-12 Months	14	3	17 ⁽²⁾	82.4% (14/17)	6	12	18	33.3% (6/18)
> 1 Year	4	4	8	50.0% (4/8)	3	5	8	37.5% (3/8)
Total	29	14	43 ⁽²⁾	74.4% (32/43)	19	25	44	54.5% (24/44)

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



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Fran White
Regulatory Consultant
Bio-Rad
163 Cabot Street
Beverly, MA 01915

JUN 26 2008

Re: K081362
Trade/Device Name: Platelia™ Lyme IgM
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagent
Regulatory Class: Class II
Product Code: LSR
Dated: May 14, 2008
Received: May 15, 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.

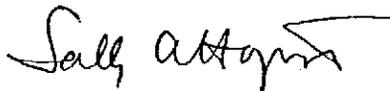
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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" (21 CFR 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): K081362

Device Name: Platelia™ Lyme IgM

Indications for Use:

The Platelia™ Lyme IgM Assay is a qualitative test intended for use in the presumptive detection of human IgM antibodies to *Borrelia burgdorferi* in human serum or plasma (K₃ EDTA, sodium heparin, or sodium citrate). The EIA test 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.

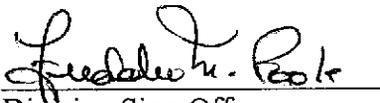
Prescription Use X
(Part 21 CFR 801 Subpart D)

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

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