June 12, 2025

ID-FISH Technology, Inc.
Jyotsna Shah
Vice President of Research and Development
556 Gibraltar Drive
Milpitas, California 95035

Re: K242872
Trade/Device Name: iDart Lyme IgM ImmunoBlot Kit
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema Pallidum Treponemal Test Reagents
Regulatory Class: Class II
Product Code: LSR
Dated: May 19, 2025
Received: May 20, 2025

Dear Jyotsna Shah:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Deputy Division Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242872

Device Name
iDart Lyme IgM ImmunoBlot Kit

Indications for Use *(Describe)*
The iDart™ Lyme IgM ImmunoBlot Kit is an immunoblot assay intended for the in vitro qualitative detection of IgM antibodies to Borrelia burgdorferi in human serum. The iDart Lyme IgM ImmunoBlot Kit is intended to detect antibodies to Lyme Screen Antigen (LSA) and multiple other B. burgdorferi antigens following a modified two-tier test methodology. Positive results from the iDart Lyme IgM ImmunoBlot Kit are supportive evidence for the presence of antibodies and exposure to B. burgdorferi. Negative results do not preclude infection with B. burgdorferi. iDart™ Lyme IgM ImmunoBlot Kit is intended to aid in the diagnosis of Lyme disease and the test kit should only be used on samples from patients with clinical history, signs and symptoms consistent with Lyme disease. The iDart Lyme IgM Immunoblot Kit is not intended as a screen for asymptomatic patients.

Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION SUMMARY

I. BACKGROUND INFORMATION:

A. 510(k) Number

K242872

B. Applicant

ID-FISH Technology, Inc.
556 Gibraltar Drive
Milpitas CA 95035 USA

C. Contact Person

Dr. Jyotsna Shah
VP of Research and Development
regulatory@idfishtechnology.com
1-650-269-8610

D. Date Prepared

May 20, 2025

E. Proprietary and Established Names

iDart™ Lyme IgM ImmunoBlot Kit

F. Regulatory Information

Product Code(s):	LSR – Reagents, Borrelia Serological Reagent
Classification:	Class II
Regulation Section:	21 CFR 866.3830 - Treponema Pallidum Treponemal Test Reagents
Panel:	MI - Microbiology

II. SUBMISSION/DEVICE OVERVIEW:

A. Purpose for Submission:

To obtain a substantial equivalence determination for a new device.

B. Measurand:

IgM antibodies to *Borrelia burgdorferi (B. burgdorferi)*

C. Type of Test:

ImmunoBlot Assay

III. INTENDED USE/INDICATIONS FOR USE:

A. Intended Use(s):

The iDart™ Lyme IgM ImmunoBlot Kit is an immunoblot assay intended for the in vitro qualitative detection of IgM antibodies to *Borrelia burgdorferi* in human serum. The iDart™ Lyme IgM ImmunoBlot Kit is intended to detect antibodies to Lyme Screen Antigen (LSA) and multiple other *B. burgdorferi* antigens following a modified two-tier test methodology. Positive results from the iDart™ Lyme IgM ImmunoBlot Kit are supportive evidence for the presence of antibodies and exposure to *B. burgdorferi*. Negative results do not preclude infection with *B. burgdorferi*. iDart™ Lyme IgM ImmunoBlot Kit is intended to aid in the diagnosis of Lyme disease and the test kit should only be used on samples from patients with clinical history, signs and symptoms consistent with Lyme disease. The iDart™ Lyme IgM Immunoblot Kit is not intended as a screen for asymptomatic patients.

Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures.

B. Indication(s) for Use:

iDart™ Lyme IgM ImmunoBlot Kit should be used for diagnosing Lyme Disease in patients with a clinical history, and signs and symptoms consistent with Lyme Disease. It is not intended for use in asymptomatic patients.

C. Special Conditions for Use Statement(s):

For in vitro diagnostic use only
For professional use only
For prescription use only

IV. DEVICE CHARACTERISTICS:

A. Device Description:

The iDart™ Lyme IgM ImmunoBlot tests are line immunoblot assays. Antigenic proteins specific for Borrelia species that cause Lyme Disease are produced by recombinant DNA technology in Escherichia coli. The purified proteins are then applied as discrete lines on a nitrocellulose membrane along with two control proteins.

The iDart™ Lyme IgM ImmunoBlot Kit contains IgM ImmunoBlot strips and the proteins are applied in the following order: C1 (IgG/IgM – conjugate control), C2 (Protein L – calibrator/serum control), P93, P41 (2 antigen bands), P39 (2 antigen bands), P23 (9 antigen bands), P31 (9 antigen bands), P34, C10 and LSA (a chimeric VlsE peptide termed the Lyme Screen Antigen).

B. Principle of procedures:

The iDart™ Lyme IgM ImmunoBlot test is a line blot assay. The recombinant Borrelial proteins, along with 2 controls proteins are dispensed onto a nitrocellulose membrane by spraying.
During the test procedure, if antibodies to *Borrelia burgdorferi* infection are present in the human serum sample, they will bind to the antigens sprayed onto the nitrocellulose strips. After removing serum and unbound antibodies by washing, the nitrocellulose strip is incubated with an anti-human IgM antibody conjugated with Alkaline Phosphatase.
After removing the unbound conjugated antibody by a washing step, visualization of the antigen-antibody complex is accomplished by the addition of a substrate 5-bromo, 4-chloro, 3-indolylphosphate (BCIP) and nitroblue tetrazolium (NBT) which forms a strong bluish purple reaction product by the action of alkaline phosphatase. The reaction is stopped by washing the nitrocellulose strip with distilled or deionized water. Depending on the observed band pattern one can interpret the presence or absence of specific IgM antibodies to *B. burgdorferi* antigens.

V. SUBSTANTIAL EQUIVALENCE INFORMATION:

A. Predicate Device Name(s):

Viramed Borrelia All-In-One ViraChip Test Kit

B. Predicate 510(k) Number(s):

K220016

C. Comparison with Predicate(s):

Item	Device:	Predicate:
	iDart™ Lyme IgM ImmunoBlot Kit	**Viramed Borrelia All-In-One ViraChip Test Kit (K220016)**
Similarities		
Intended Use	The iDart™ Lyme IgM ImmunoBlot Kit is an immunoblot assay intended for the in vitro qualitative detection of IgM antibodies to *Borrelia burgdorferi* in human serum. The iDart™ Lyme IgM ImmunoBlot Kit is intended to detect antibodies to Lyme Screen Antigen (LSA) and multiple other *B. burgdorferi* antigens following a modified two-tier test methodology. Positive results from the iDart™ Lyme IgM ImmunoBlot Kit are supportive evidence for the presence of antibodies and exposure to *B. burgdorferi*. Negative results do not preclude infection with *B. burgdorferi*. iDart™ Lyme IgM ImmunoBlot Kit is intended to aid in the diagnosis of Lyme disease and the test kit should only be used on samples from patients with clinical history, signs and symptoms consistent with Lyme disease. The iDart™ Lyme IgM Immunoblot Kit is not intended as a screen for asymptomatic patients. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures. For in vitro diagnostic use only For professional use only For prescription use only	The Viramed Biotech AG Borrelia All-In-One ViraChip is an in vitro qualitative microarray assay for the detection of IgM and IgG antibodies to Borrelia burgdorferi in human serum. The assay is intended for testing serum samples from symptomatic patients or those suspected of Lyme Disease. It is intended to detect antibodies to VlsE and multiple other B. burgdorferi antigens following a modified two-tier test methodology. Positive results from the Viramed Biotech AG Borrelia All-In-One ViraChip are supportive evidence for the presence of antibodies and exposure to B. burgdorferi, the causative agent for Lyme disease. Negative results do not preclude infection with B. burgdorferi. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures as an aid in diagnosis of Lyme disease. The Viramed Biotech AG Borrelia All-In-One ViraChip Test must be used with a ViraChip Reader and the ViraChip Software.
Specimen Type	Serum	Serum
Antibodies Detected	IgM	IgM and IgG
Controls	Positive Control serum, Negative Control Serum	Positive Control serum, Negative Control Serum
Method	Qualitative	Qualitative
Differences		
Item	**Device**	**Predicate**
Assay Technology	ImmunoAssay	Antigen Coated wells (Microarrays)

Antigens	Recombinant antigenic proteins - LSA antigen (chimeric VlsE peptide termed the Lyme Screen Antigen), C10, 93 kD, 41 kD, 39 kD, 34 kD, 31 kD and 23 kD	VlsE, 93 kD, 58 kD, 45 kD, 39 kD, 30 kD, 23 kD, 21 kD, 19 kD, 18 kD, and 17 kD antigens of *B.burgdorferi*
Procedure	Line Blot Assay Borrelia IgM antibodies to specific antigen bands. Wash between sample and conjugate incubation steps, incubate with substrate	Wash after Sample and Conjugate Step
Sample Volume	20ul neat serum in 1000ml sample diluent	Samples diluted 1:76 and 100 µL added per well
Reagents	Sample diluent, Wash Buffer, Milk powder, Conjugate Buffer, Substrate solution	10X Wash Buffer, Sample Buffer, Chromogen/Substrate Solution
Result Generation	Manual reading	Automated with ViraChip Reader

VI. STANDARDS/GUIDANCE DOCUMENTS REFERENCED:

Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia burgdorferi - Guidance for Industry and FDA Staff - MARCH 2013

VII. PERFORMANCE CHARACTERISTICS (IF/WHEN APPLICABLE):

A. Analytical Performance:

1. Reproducibility:

The iDart™ Lyme IgM ImmunoBlot Kit was tested in a blind study to evaluate reproducibility across 3 separate sites each with 2 operators over 5 days, 2 runs a day, using a panel of coded samples containing different levels of anti-B. burgdorferi IgM: negative, high negative, low positive, moderate positives, and high positive samples . This study generated 90 replicates per sample. There was 100% agreement on all test results across runs, days and sites (See Table 1).

Table 1. Reproducibility Study Summary - Overall – All Sites – 6 operators/5 days/ 3 replicates

Sample #	Sample Type	IgM	# of Samples (+)	Expected Result	% samples matched to expected result
MA	High Positive	P	90/90	P	100%
MB	Moderate Positive	P	90/90	P	100%
MC	Moderate Positive	P	90/90	P	100%
MD	Low Positive	P	90/90	P	100%
ME	High Negative	N	0/90	N	100%
MF	Negative	N	0/90	N	100%

2. Analytical Specificity/Interference:

Analytical Specificity

Table 2 and 3 below show the results of testing iDart™ Lyme IgM ImmunoBlot Kit on samples collected from a population in the US of 177 apparently healthy individuals from endemic areas resulted with 99.44% specificity and 127 samples collected from healthy individuals in non-endemic areas with 99.21% specificity.

Table 2: iDart™ IgM ImmunoBlot Kit - Analytical Specificity (Endemic) (N=177)

Sample Source	N	IgM	% Positive
CDC	50	1	2.00%
BAY AREA FOUNDATION (NY, MA, WI)	127	0	0.00%
TOTAL	177	1	0.56%
Agreement		99.44%	

Table 3: iDart™ IgM ImmunoBlot Kit - Analytical Specificity (Non- Endemic) (N=127)

Sample Source	N	IgM	% Positive
CDC	45	1	2.22%
IGeneX, Inc.	82	0	0.00%
TOTAL	127	1	0.79%
Agreement		99.21%	

Cross-Reactivity Study

A cross-reactivity study was performed on specimens known to contain potentially cross-reactive antibodies to Lyme infection. A total of 243 serum samples from patients with bacterial or viral infections, as well as sera from patients with diagnoses that could be confused with Lyme disease, were tested. Based on the data presented in Table 4, the iDart™ Lyme IgM ImmunoBlot Kit demonstrated 97.94% specificity to samples containing antibodies to non-*Borrelia* pathogens or autoimmune diseases.

Table 4: iDart™ Lyme Borrelia IgM ImmunoBlot Kit - Analytical Specificity

Source	**Disease State**	**N**	**IgM Positive**	**% Cross-reactivity**
CDC	Fibromyalgia	15	0	0%
	Mononucleosis	15	1	6.67%
	Multiple sclerosis	15	0	0%
	Rheumatoid arthritis	11	0	0%
	Severe periodontitis	14	0	0%
	Syphilis	14	0	0%
	Leptospira	10	2*	20.00%*
IGeneX, Inc.	Rheumatoid Factor	5	0	0%
	ANA	5	0	0%
	Bartonella	11	0	0%
	Bartonella & Anaplasma	1	0	0%
	Bartonella &TBRF Borrelia	1	0	0%
	Babesiosis	8	0	0%

	Babesiosis & Tick-Borne Relapsing Fever	2	0	0%
	Babesiosis & Rickettsiosis	1	0	0%
	Tick Borne Relapsing Fever	10	0	0%
	Tick-Borne Relapsing Fever & Anaplasma	1	0	0%
	Tick-Borne Relapsing Fever & Ehrlichiosis	1	0	0%
	Tick-Borne Relapsing Fever & Rickettsia	1	0	0%
	Anaplasmosis	8	0	0%
	Anaplasmosis & Ehrlichiosis	1	0	0%
	Ehrlichiosis	4	0	0%
	Rickettsiosis	11	0	0%
New York Biologics (NY)	HIV	6	0	0%
	HCV	5	0	0%
	HSV1	7	0	0%
	CMV	11	0	0%
	EBV	9	0	0%
Kamineni Life Sciences Pvt. Ltd, Hydrabad (India)	Pregnant women	11	0	0%
	H. pylori	9	1	11.11%
Warde Medical Laboratory (MI)	Parvovirus-19	10	1	10.00%
	Varicella-zoster virus	10	0	0%
False Positive			5	
Agreement		243	97.94%	

* Two Leptospira samples positive by iDart Lyme IgM testing were also positive for IgM with STTT.

Interference from Endogenous Analytes

The potential interfering effect of endogenous substances in patient samples when using the iDart Lyme IgM ImmunoBlot was evaluated using one positive, one low positive and one negative Borrelia IgM samples. Samples were spiked with the endogenous substances at the final concentrations listed in the table below. All samples were tested in singlicate. No interference was observed in the tested samples.

Table 5. Effect of Interference Substances on iDart™ Lyme IgM ImmunoBlot Kit

Agent	Concentration in serum	iDart™ Lyme IgM ImmunoBlot Kit result			Effect on iDart™ Lyme IgM ImmunoBlot Kit
		High Pos (mA)	Low Pos (mB)	Negative (mC)	
Bilirubin	1mg/dL (low)	Positive	Positive	Negative	No effect
Bilirubin	15mg/dL (high)	Positive	Positive	Negative	No effect
Albumin	3.5g/dL (low)	Positive	Positive	Negative	No effect
Albumin	5g/dL (high)	Positive	Positive	Negative	No effect
Cholesterol	150mg/dL (low)	Positive	Positive	Negative	No effect
Cholesterol	250mg/dL (high)	Positive	Positive	Negative	No effect
Triglycerides	150mg/dL (low)	Positive	Positive	Negative	No effect
Triglycerides	500mg/dL (high)	Positive	Positive	Negative	No effect
Hemoglobin	10g/dL (low)	Positive	Positive	Negative	No effect
Hemoglobin	20g/dL (high)	Positive	Positive	Negative	No effect

3. Assay Reportable Range:
   Not applicable.

4. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   Not applicable.

5. Detection Limit:
   Not applicable.

6. Assay Cut-Off:
   Not applicable.

B. Clinical Studies:

1. Method Comparison with comparators (STTT):
   The performance of the iDart™ Lyme IgM ImmunoBlot Kit for detection of Borrelial-specific antibodies was compared to FDA-cleared EIA and immunoblot as part of the standard two-tier test methodology (STTT). Results are summarized below. A total of 997 serum samples were procured from IGeneX, Inc. and tested at three clinical sites. Table 6 bellow summarizes the distribution of samples per testing site.

Table 6. Sample distribution by clinical site and cohort.

	Number of Samples	Sample Type	Vendor Providing Samples
Site 1	304	Prospectively collected serum samples	IGeneX Inc.
Site 2	357	Prospectively collected serum samples	IGeneX Inc.
Site 3	336	Prospectively collected serum samples	IGeneX Inc.

All samples were blinded, re-coded, and tested at the respective clinical sites as per the instructions for use for the iDart™ Lyme IgM ImmunoBlot Kit. Overall performance is summarized in Table 7.

Table 7. Performance Summary. iDart™ Lyme IgM ImmunoBlot Kit vs STTT

N=997		STTT	
		Positive (+)	Negative (-)
iDart™ Lyme IgM ImmunoBlot Kit	Positive (+)	60	18
	Negative (-)	6	913
	Total	66	931
	PPA (95% CI)	90.91% (81.55%– 95.77%)	
	NPA (95% CI)	98.07% (96.96%– 98.77%)	

2. Clinical Sensitivity/Specificity:
   CDC Serum Panel:
   A reference Pre-Marketing Panel of 258 serum samples were received from CDC. These samples were from patients diagnosed with Lyme Disease at different stages (Stages 1, 2, and 3), Lyme disease look-like infections (infectious mononucleosis, multiple sclerosis, rheumatoid arthritis, fibromyalgia and severe periodontitis), and from healthy controls living in endemic and non-endemic regions of Lyme disease. Results are analyzed according to disease stages and compared to STTT (See Table 8).

Table 8. Performance on CDC Pre-Marketing Panel with respect to different Disease Stages. iDart Lyme IgM ImmunoBlot Kit vs STTT (N=258)

Disease Stage	Stage I		Stage II		Stage III		Overall		Healthy controls		Disease Controls	
N	50		9		20		79		95		84	
Test Kits	iDart	STTT	iDart	STTT	iDart	STTT	iDart	STTT	iDart	STTT	iDart	STTT
Positive	33	28	8	7	11	9	52	44	2	1	1	3
Negative	17	22	1	2	9	11	27	35	93	94	83	81
Sensitivity	66.0%	56.0%	88. 9%	77. 8%	55.0%	45.0%	65.8%	55.7%				
Agreement									97.9%	98.9%	98.8%	96.4%

3. Other

Clinical Supportive Data:

Fresh and Frozen Samples Comparison Study

The Clinical Performance of iDart™ Lyme IgM ImmunoBlot Kit is equivalent between fresh and frozen samples. This is supported by the evidence shown in this study by which samples were tested fresh and after frozen. This study demonstrates that freezing does not alter the performance of **iDart™ Lyme IgM ImmunoBlot Kit** in comparison to testing of fresh samples.

Table 9: Fresh and Frozen Samples Tested with iDart™ Lyme IgM ImmunoBlot Kit

Sample Type	**Tested**	**N**	*Interpretation Criteria* - POSITIVE: LSA positive or indeterminant and one or more bands from at least TWO of the following groups are present – LSA, P41, P39, P23, P31 and P34 are present. NEGATIVE: If the band pattern does not meet the positive criteria.	
			IgM	**Neg**
Fresh Samples	Within 2 weeks of collection. (stored refrigerated)	**63**	21	42
Frozen Samples	After being Frozen (2-22 (days)	**63**	21	42

Antibody Class Specificity

This study was conducted to demonstrate the antibody class specificity of the **goat anti-human IgM Conjugate** used in the **iDart™ Lyme IgM ImmunoBlot Kit**. 8 previously tested patient samples that includes 4 negatives and 4 positives were included in the study. These samples were tested in **iDart™ Lyme Diluent** provided with the test kit.

3 sets of anti-human IgM conjugate were prepared and tested.

- Control – no additives
- 1ug/ml of human IgG
- 1ug/ml of human IgM

The iDart™ Lyme IgM ImmunoBlot Kit is intended to detect IgM antibodies to *B. burgdorferi* antigens from patients with clinical history, signs and symptoms consistent with Lyme disease. This study demonstrates that iDart™ Lyme IgM ImmunoBlot Kit is specific in detecting IgM antibodies in Lyme patient samples.

Table 12: iDart™ Lyme IgM ImmunoBlot Kit - Antibody Specificity Study Summary

Sample #	Sample Type #	No treatment (a); goat antihuman IgM conjugate treated with human IgG (b) or with human IgM (c).	iDart™ Lyme IgM ImmunoBlot Kit								
			LSA Positive or Indeterminant AND one or more bands from at least TWO of the following groups are present – P41, P39, P23, P31 and P34 are present; and NEGATIVE if the Lyme ImmunoBlot IgM band pattern does not meet the positive criteria.						LSA	Band Groups	IgM
			P41	P39	P23	P31	P34	LSA			
A	High Positive	No treatment	P	P	P	P	3+	3+	P	P	P
		Human IgG	P	P	P	P	3+	3+	P	P	P
		Human IgM							N	N	N
B	Moderate Positive	No treatment	P	P	P	P	3+	3+	P	P	P
		Human IgG	P	P	P	P	3+	3+	P	P	P
		Human IgM							N	N	N
C	Moderate Positive	No treatment	P		P	P	3+	3+	P	P	P
		Human IgG	P		P	P	3+	3+	P	P	P
		Human IgM							N	N	N
D	High Negative	No treatment						1+	P	N	N
		Human IgG						1+	P	N	N
		Human IgM							N	N	N
E	Low Positive	No treatment	P		P		I	2+	P	P	P
		Human IgG	P		P		I	2+	P	P	P
		Human IgM							N	N	N
F	Negative	No treatment							N	N	N
		Human IgG							N	N	N
		Human IgM							N	N	N
G	Negative	No treatment							N	N	N
		Human IgG							N	N	N
		Human IgM							N	N	N
H	Negative	No treatment							N	N	N
		Human IgG							N	N	N
		Human IgM							N	N	N

C. Clinical Cut-Off:

Not applicable.

D. Expected Values/Reference Range:

Not applicable.

VIII. PROPOSED LABELING:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

IX. CONCLUSION:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.