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

August 12, 2024

Re: K233367
Trade/Device Name: iDart Lyme IgG ImmunoBlot Kit
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema Pallidum Treponemal Test Reagents
Regulatory Class: Class II
Product Code: LSR
Dated: July 5, 2024
Received: July 8, 2024

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.

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.
Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
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)*
K233367

Device Name
iDart™ Lyme IgG ImmunoBlot Kit

Indications for Use *(Describe)*
The iDart™ Lyme IgG ImmunoBlot Kit is an immunoblot assay intended for the in vitro qualitative detection of IgG antibodies to Borrelia burgdorferi in human serum. The iDart Lyme IgG ImmunoBlot Kit is intended to detect antibodies to LSA and multiple other B. burgdorferi antigens following a modified two-tier test methodology. Positive results from the iDart Lyme IgG 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 IgG 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 IgG 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

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.

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION SUMMARY

I. BACKGROUND INFORMATION:

A. 510(k) Number

K233367

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

July 30, 2024

E. Proprietary and Established Names

iDart™ Lyme IgG 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:

IgG 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 IgG ImmunoBlot Kit is an immunoblot assay intended for the in vitro qualitative detection of IgG antibodies to Borrelia burgdorferi in human serum. The iDart Lyme IgG ImmunoBlot Kit is intended to detect antibodies to LSA and multiple other B. burgdorferi antigens following a modified two-tier test methodology. Positive results from the iDart Lyme IgG 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 IgG 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 IgG 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 IgG 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 IgG 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 IgG ImmunoBlot Kit contains IgG ImmunoBlot strips and the proteins are applied in the following order: C1 (IgG/IgM – conjugate control), C2 (Protein L – calibrator/serum control), P93, P41, P39, P23, P31, P66, P58, P45, P34, P30, P28, P18 and LSA (a chimeric VlsE peptide termed the Lyme Screen Antigen).

B. Principle of procedures:

During the test procedure, diluted human serum is added to the immunoblot strip. Antibodies to Borrelia infection, if present, will bind to antigen lines on the nitrocellulose strips. After removing serum and unbound antibodies by washing, the nitrocellulose strip is incubated with alkaline phosphatase conjugated anti-human IgG antibody for detecting IgG antibodies.
After removing the unbound alkaline phosphatase conjugated antibody by washing, the antigen-antibody complex is visualized as bands by adding the alkaline phosphatase substrate 5-bromo, 4-chloro, 3-indolylphosphate (BCIP) and nitro blue tetrazolium (NBT) to form a strong bluish-purple precipitate. The reaction is stopped by washing the nitrocellulose strip with distilled or deionized water. A strip reading guide included in each test kit shows the location of specific antigens in the test strip. Every immunoblot strip has two functional control bands. The test strip is only valid when both control bands are visible after completion of the test. Any band found having a visual intensity equal to or greater than the C2 control band intensity is considered as a significant (positive) band. Depending on the observed bands pattern, one can interpret the presence or absence of Lyme specific IgG antibodies in the patient serum.

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 IgG ImmunoBlot Kit	**Viramed Borrelia All-In-One ViraChip Test Kit (K220016)**
Similarities		
Intended Use	The iDart™ Lyme IgG ImmunoBlot Kit is an immunoblot assay intended for the in vitro qualitative detection of IgG antibodies to Borrelia burgdorferi in human serum. The iDart Lyme IgG ImmunoBlot Kit is intended to detect antibodies to LSA and multiple other B. burgdorferi antigens following a modified two-tier test methodology. Positive results from the iDart Lyme IgG 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 IgG 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 IgG 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. 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	IgG	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), 93 kD, 66 kD, 58 kD, 45 kD, 41 kD, 39 kD, 34 kD, 31 kD, 30 kD, 28 kD, 23 kD and 18 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 IgG antibodies to specific antigen bands. Wash between sample and conjugate incubation steps, incubate with substrate	Wash after Sample and Conjugate Step
Sample Volume	10 µl neat serum in 1000 ml 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 IgG 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 blinded and coded samples of negative, moderate negative, high negative, low positive, moderate positive and high positive samples for IgG. It is concluded that there was 100% agreement of all bands among all runs, all days and across 3 sites for the **iDart™ Lyme IgG ImmunoBlot Kit** (See Table 1).

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

Sample #	**Sample Type**	**Number of Bands Present/sample**	**IgG**	**# of Samples (+)**	**Expected Result**	**% samples matched to expected result**
GA	High Positive	13	P	90/90	P	100%
GB	Moderate Positive	10	P	90/90	P	100%
GC	Negative-1	5	N	0/90	N	100%
GD	Negative-2	0	N	0/90	N	100%
GE	Negative-3	1	N	0/90	N	100%
GF	Low Positive	5	P	90/90	p	100%

2. Analytical Specificity/Interference:

Analytical Specificity

Table 2 and 3 below shows the results of testing iDart™ Lyme IgG ImmunoBlot Kit on samples collected from a population of 313 apparently healthy individuals from endemic areas, and 112 samples collected from healthy individuals in non-endemic areas in the US.

Table 2: iDart Lyme IgG ImmunoBlot results for samples collected from healthy individuals in endemic areas.

Source	N (313)	IgG Positive
CDC	**62**	0
BAY AREA LYME FOUNDATION (NY, MA, WI)	**251**	2
TOTAL	**313**	2
Specificity		**99.36%**

Table 3: iDart Lyme IgG ImmunoBlot results for samples collected from healthy individuals in non-endemic areas.

Source	N (112)	IgG Positive
CDC	**62**	0
CA	**50**	0
TOTAL	**112**	0
Specificity		**100%**

Cross-Reactivity Study

A cross reactivity study was performed on specimens known to contain potentially cross-reactive antibodies to Lyme infection. Serum samples from patients with bacterial/viral infections and sera from patients with diagnoses that can be confused with the late manifestations of Lyme disease were tested. Based on the data presented in Table 4, there was no cross-reactivity with antibodies to all non- Borrelia pathogens or autoimmune diseases tested with the iDart™ Lyme IgG ImmunoBlot Kit.

Table 4: iDart™ Lyme IgG ImmunoBlot Kit - Cross Reactivity

Source	Disease State	N (376)	IgG			% Cross-reactivity
			LSA	2+ Bands	IgG Positive	
CDC	Fibromyalgia	15	0	0	0	0%
	Mononucleosis	15	0	1	0	0%
	Multiple sclerosis	15	0	0	0	0%
	Rheumatoid arthritis	15	0	0	0	0%
	Severe periodontitis	15	0	0	0	0%
	Syphilis	15	0	0	0	0%
IGeneX (CA)	Babesiosis	28	0	0	0	0%
	Bartonellosis	48	0	0	0	0%
	Ehrlichiosis	5	0	0	0	0%
	Anaplasmosis	7	0	0	0	0%
	Rickettsiosis	22	0	0	0	0%
	Tick Borne Relapsing Fever	14	0	0	0	0%
New York Biological (NY)	HIV*	12	0	0	0	0%
	RPR	23	0	2	0	0%
	HSV1	8	0	1	0	0%
	HSV2	2	0	0	0	0%
	CMV	13	0	0	0	0%
	EBV	27	0	0	0	0%
BEI	RSV	4	0	0	0	0%
	FLU	21	0	0	0	0%
Kamineni Life Sciences Pvt.	Pregnant women	12	0	0	0	0%

Ltd, Hydrabad (India)	*H. pylori*	10	0	0	0	0%
Warde Medical Laboratory (MI)	Parvovirus-19	10	0	0	0	0%
	Varicella-zoster virus	10	0	1	0	0%
CDC	Leptospira	10	0	0	0	0%
False Positive			0	5	0	0%
Specificity			**100%**	**98.67%**	**100%**	

Interference from Endogenous Analytes

The potential interfering effect of endogenous substances in patient samples when using the iDart Lyme IgG ImmunoBlot was evaluated using one positive, one low positive and one negative Borrelia IgG 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 he tested samples.

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

Agent	Concentration in serum	iDart™ Lyme IgG result			Effect on ImmunoBlot Kit
		High Positive	Low Positive	Negative	
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 (low)	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 IgG 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 768 serum samples were procured from two vendors and tested at three clinical sites. Table 6 bellow summarizes the distribution of samples per testing site and cohort.

Table 6: Sample distribution by clinical site and cohort.

	Number of Samples	Sample Type	Vendors Providing Samples
Site 1	290	Clinical serum samples	Bay Area Lyme Foundation
Site 2	37	Clinical serum samples – Cohort 2	IGeneX Inc.
Site 2	230	Clinical serum samples – Cohort 3	IGeneX Inc.
Site 3	211	Clinical serum samples – Cohort 2	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 IgG ImmunoBlot Kit. Performance by cohort is summarized in tables 7 through 9.

Table 7: Performance Summary on prospective banked samples from Bay Area Lyme Foundation (n=290). iDart Lyme IgG ImmunoBlot test versus STTT.

		STTT	
		Positive (+)	Negative (-)
iDart Lyme IgG ImmunoBlot	Positive (+)	19	36
	Negative (-)	1	234
	Total	20	270
	PPA (95% CI)	95.00% (76.39% – 99.11%)	
	NPA (95% CI)	86.67% (82.09% – 90.21%)	

Table 8: Performance Summary on samples from IGeneX Inc. Cohort 2 (n=248). iDart Lyme IgG ImmunoBlot test versus STTT.

		STTT	
		Positive (+)	Negative (-)
iDart Lyme IgG ImmunoBlot	Positive (+)	114	12
	Negative (-)	6	116
	Total	120	128
	PPA (95% CI)	95.00% (89.52% – 97.69%)	
	NPA (95% CI)	90.63% (84.33% – 94.56%)	

Table 9: Performance Summary on samples from IGeneX Inc. Cohort 3 (n=230). iDart Lyme IgG ImmunoBlot test versus STTT.

		STTT	
		Positive (+)	Negative (-)
iDart Lyme IgG ImmunoBlot	Positive (+)	10	7
	Negative (-)	1	212
	Total	11	219
	PPA (95% CI)	90.91% (62.27% – 98.38%)	
	NPA (95% CI)	96.80% (93.55% – 98.44%)	

2. Clinical Sensitivity/Specificity:

CDC Serum Panel:

A Panel of 280 serum samples was 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 10).

Table 10. iDart Lyme IgG ImmunoBlot Kit performance using the CDC Reference Panel

Disease Stage	Stage I		Stage II		Stage III		Overall		Healthy controls		Disease Controls	
N	60		10		20		90		100		90	
Test Kit	iDart	STTT	iDart	STTT	iDart	STTT	iDart	STTT	iDart	STTT	iDart	STTT
Positive	35	18	9	9	20	20	64	47	0	0	0	0
Negative	25	42	1	1	0	0	26	43	100	100	90	90
Sensitivity	58.33%	30.00%	90.00%	90.00%	100%	100%	71.11%	52.22%				
Specificity									100%	100%	100%	100%

3. Other Clinical Supportive Data:

Fresh and Frozen Samples Comparison Study:

72 decoded left-over patient serum samples were tested twice with iDart Lyme IgG ImmunmoBlot Test Kit, pre and post freezing. As shown below in Table 11, after freezing, all IgG positive samples remained positive and all negative samples remained negative. Clinical Performance of iDart™ Lyme IgG ImmunoBlot Kit for fresh and frozen samples are comparable and the test kit can be used on both fresh and frozen samples.

Table 11. : Fresh and Frozen Samples Tested with iDart™Lyme IgG ImmunoBlot Kit

Sample Type	Tested	N	IgG			
			LSA (+)	≥2 bands	IgG (+)	Neg
Fresh Samples	Within 2 weeks of collection (stored refrigerated)	**72**	39	47	33	39
Frozen Samples	After being Frozen (9-44 days)	**72**	39	47	33	39

Antibody Class Specificity:

A study was conducted to demonstrate the specificity of the **goat anti-human IgG Conjugate** used in the **iDart™ Lyme IgG ImmunoBlot Kit**. 10 previously tested patient samples that includes 6 negatives and 4 positives were included study. 3 sets of anti-human IgG conjugate were prepared and tested:

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

The data in Table 12 demonstrates the IgG antibody class specificity performance of **iDart™ Lyme IgG ImmunoBlot Kit**. All positive samples tested with goat anti-human IgG conjugate without treatment with human IgG or with treatment with human IgM remained positive; and all negative samples remained negative.

Table 12. iDart Lyme IgG ImmunoBlot Antibody Class Specificity Study results

Sample #	Goat anti-human antibody treated with								
	None			Human IgM			Human IgG		
	LSA	Band Group	Result	LSA	Band Group	Result	LSA	Band Group	Result
1	P	P	P	P	P	P	N	N	N
2	N	P	N	N	P	N	N	N	N
3	P	P	P	P	P	P	N	N	N
4	P	P	P	P	P	P	N	N	N
5	P	P	P	P	P	P	N	N	N
6	N	N	N	N	N	N	N	N	N
7	N	P	N	N	P	N	N	N	N
8	N	P	N	N	P	N	N	N	N
9	N	N	N	N	N	N	N	N	N
10	N	P	N	N	P	N	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.