510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K252627

B Applicant

Inanovate Inc.

C Proprietary and Established Names

Lyme-ID IgG Test; Bio-ID800

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LSR	Class II	21 CFR 866.3830 - Treponema Pallidum Treponemal Test Reagents	MI - Microbiology
NSU	Class II	21 CFR 862.2570 - Instrumentation for clinical multiplex test systems	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the Lyme-ID IgG Test on the Bio-ID800 analyzer.

B Measurand:

Anti-*Borrelia burgdorferi* antibodies.

C Type of Test:

Protein Microarray

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Inanovate Lyme-ID IgG Test is an in vitro qualitative microarray assay for the detection of 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 Lyme-ID IgG Test 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 Inanovate Lyme-ID IgG Test Kit must be used with Inanovate's Bio-ID800 instrument and Lyme-ID software.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

The Lyme-ID IgG Test runs on the Bio-ID-800 analyzer.

IV Device/System Characteristics:

A Device Description:

The Lyme-ID IgG Test is a qualitative protein microarray assay design to detect antibodies to *B. burgdorferi*, the causative agent of Lyme disease in the United States. The Lyme-ID IgG Test detects human serum IgG antibodies against *Borrelia burgdorferi* cell lysate, OspC, and VlsE. The Lyme-ID IgG Test runs in the analyzer Bio-ID-800. This system utilizes fluorescent-based reactions and microfluidics to generate and measure signal from multiple analytes located in the Lyme-ID IgG Test. The Bio-ID800 is a benchtop instrument designed to detect analytes using microarrays embedded in a self-contained, multichannel, microfluidics cartridge, which is specific to the Lyme-ID IgG Test. The test system combines two immunoassays into a single Modified Two-Tiered test (MTTT) methodology, giving results using the Longitudinal Assay Screening (LAS) system.

The Bio-ID-800 system utilizes fluorescent-based reactions and microfluidics to generate and measure signal from multiple analytes located in the Lyme-ID IgG Test. The Bio-ID800 is a benchtop instrument designed to detect analytes using microarrays embedded in a self-contained, multichannel, microfluidics cartridge, which is specific to the Lyme-ID IgG Test (see figure 1). Target analyte measurements occur through fluorescence detection in a cyclical process. The

Bio-ID800 benchtop device is controlled by a PC and assay specific software for hardware control and data analysis.

LAS utilizes multiple cycles of flowing small volumes of sample and fluorescently labeled Detection Reagent across a planar microarray field. The microarray within the microarray field consists of capture spots which interact with the flowing reagent and sample to fluoresce when the Bio-ID800 laser targets the microarray field. Images are collected using the laser, optics, and PMT to capture fluorescence signal from each spot.

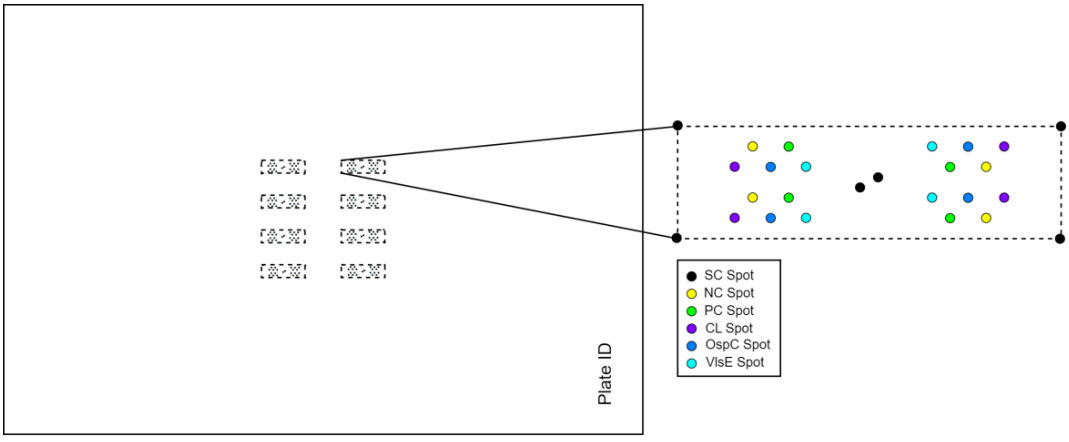
Data captured during the cycles are then used by the Lyme-ID software to calculate the increase of signal over time, or LAS curve. The resultant LAS curve is then analyzed by the software to provide values (Area Under the Curve or AUC and r^2) representing the presence of target analytes to distinguish between positive, negative, and false positive reactions. The profile of a signal generated by non-specific binding in a test will often differ from the LAS profile of a true signal from a target analyte.

B Principle of Operation:

Designed as a modified solid-phase ELISA, the Lyme-ID IgG Test is a protein microarray assay. Each microarray contains spots that correspond to a whole cell lysate sample of *Borrelia burgdorferi* B31 strain in addition to antigens Outer Surface Protein C (OspC) and Variable Lipoprotein Surface-Exposed (VlsE) bound to the glass surface of the Lyme-ID (IgG/IgM) Test cartridge.

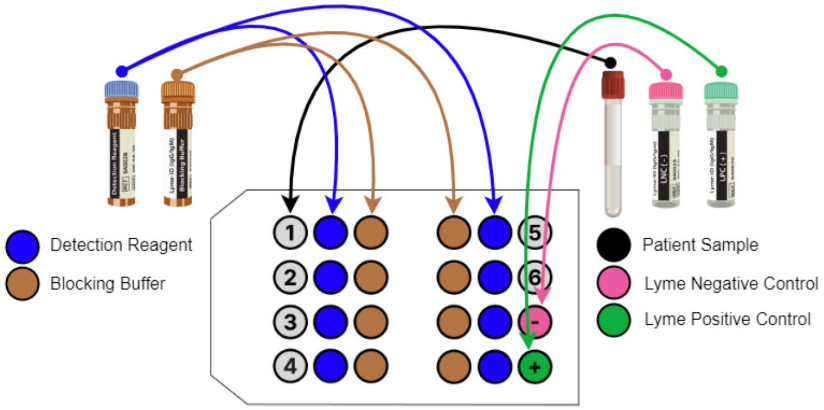
A negative control spot, positive control spot, and six signal control spots are applied to each microarray to ensure that the assay performs properly and to verify the validity of individual sample test results (see Figure 1 below). Each cartridge contains eight protein microarrays sufficient to test a total of six patient samples, the positive control, and the negative control (See Figure 2).

Figure 1. Microarray print layout. SC Spot: Signal Control spot: NC Spot: Negative Control spot; PC Spot: Positive Control spot; CL Spot: *B. burgdorferi* Cell Lysate antigen; OspC Spot: *B. burgdorferi* OspC antigen, VlsE Spot: *B. burgdorferi* VlsE antigen.



During each test, the diluted test serum of each sample is added to one microarray (see Figure 2). If *B. burgdorferi* specific antibodies are present in the test sample, they will bind to the antigens immobilized on the glass surface. During the next step, fluorescently labelled detection antibodies are flowed across the microarray which recognize *B. burgdorferi* specific antibodies already bound to the antigens on the glass surface. The fluorescently labelled detection antibodies emit a fluorescent signal detected and measured by the Bio-ID800 instrument. These steps (or cycles) are performed with fluorescent signal measurements collected over a number of timepoints, ultimately generating a curve reflective of the change in fluorescent signal over time. From this curve, an area under the curve (AUC) value and r^2 are calculated providing an indirect measurement of *B. burgdorferi* specific antibodies present in the patient specimen.

Figure 2. Cartridge Loading Summary



Kit components

Lyme-ID IgG Test components are listed in Table 1 below.

Table 1. Components of the Lyme-ID IgG Test

Quantity	Amount Provided/Used	Description	Part Number	Storage Conditions
1x	each	**Test Cartridge** Contains antigen microarray printed on glass surface, ready to use	820068	15 – 25ºC
1x	10 mL	**Assay Buffer (white cap)** Sample diluent containing 9.9 mL diluent, ≤ 0.05% sodium azide (as preservative), ≤ 0.5% Tween 20, and ≤ 0.1% caprine-derived serum	840027	15 – 25ºC
1x	1.8 mL	**Blocking Buffer (amber cap)** Sample containing 1.728 mL PBS 1X, ≤ 0.05% sodium azide (as preservative), ≤ 0.005% 555-cadaverine, and ≤ 3% caprine-derived serum	840026	15 – 25ºC
1x	1.8 mL	**Detection Reagent (blue cap)** Assay Buffer (840027) containing caprine-derived Cy3	840028	15 – 25ºC

		labeled F(ab)^2 fragment anti-human to ≤ 0.0008 mg/mL of anti-IgG and ≤ 0.0006 mg/mL of anti-IgM		
1x	0.025 mL	**Lyme Positive Control, LPC (+) (green cap)** Human derived serum containing ≤ 0.01251 mL Assay Buffer (840027), ≥ 0.00625 mL Lyme IgG Positive Control and ≥ 0.00625 mL Lyme IgM Positive Control	840030	15 – 25ºC
1x	0.025 mL	**Lyme Negative Control, LNC (-) (pink cap)** Assay Buffer (840027) and ≤ 38% human derived serum or plasma multi-marker negative control	840029	15 – 25ºC
1x	Each	**Lyme-ID (IgG/IgM) Test Kit – Instructions for Use**	820069	N/A
1x	Each	**Quick Reference Guide**	820105	N/A

Interpretation of Results

1. After the completion of the assay, the Lyme-ID software performs an analysis of each antigen spot of each sample (including the LPC and LNC) to determine if the assay ran successfully.
2. For each antigen spot of each sample (including the LPC and LNC), a mean AUC value is calculated from all valid spot replicates.
3. The mean AUC values of the VlsE, OspC, and Cell Lysate antigen spots of the LPC are multiplied by unique Normalization Factors to establish assay specific positive cutoff values.
4. Mean AUC values of the VlsE, OspC, and Cell Lysate antigen spots of each patient specimen are then evaluated against the corresponding positive cutoff values.
5. A sample antigen spot is considered POSITIVE if the AUC value and r^2 are greater than or equal to the corresponding positive cutoff value.
6. A sample antigen spot is considered NEGATIVE if the AUC value and r^2 are less than the corresponding positive cutoff value.
7. The results of each antigen spot from each sample are reviewed by the Lyme-ID software against the algorithm described in Table 1 below to determine the reported result.
8. The Reported Result for each patient specimen will be one of the following:
   - Positive – Lyme antibodies detected,
   - Negative – Lyme antibodies not detected,
   - Invalid – Invalid sample / No sample present.

Table 2. Lyme-ID IgG Test Result interpretation

VlsE AUC Result	OspC AUC Result	Cell Lysate AUC Result	Reported Result
+	+	+	POSITIVE
+	-	+	POSITIVE
-	+	+	POSITIVE
+	+	-	NEGATIVE
+	-	-	NEGATIVE
-	+	-	NEGATIVE
-	-	+	NEGATIVE
-	-	-	NEGATIVE

C Instrument Description Information:

1. Instrument Name:
   Bio-ID800 analyzer

2. Specimen Identification:
   When ready to load samples on cartridge after the software loads operators scan in the test kit barcode, Lyme Negative Control (LNC) and Lyme Positive Control barcodes, and all specimen ID barcodes. If barcodes are not able to populate, operators manually enter the serial and lot numbers.

3. Specimen Sampling and Handling:
   Specimen type: Serum

4. Calibration:
   The Lyme Positive Control or LPC (+) is used to calibrate assay cutoff values for each of the antigens (Cell lysate, OspC, and VlsE) in each run.

   This instrument requires annual calibration and quality control procedures that are to be performed ONLY by a qualified technician from Inanovate Inc. There are no user-level calibration or quality control checks. The software will prevent operation after 1 year has elapsed without calibration. One month prior to calibration, the software will provide a warning of the upcoming calibration expiration.

5. Quality Control:
   Control spots are printed on the microarray assay surface to control for location of spots printed in the microarray and validity of the run. These include a signal control (SC) spot, a Negative Control (NC) spot, and a Positive Control (PC) spot.

   Additionally, the kit contains a Lyme Negative Control tube (LNC) and a Lyme Positive Control tube (LPC).

V Substantial Equivalence Information:

A Predicate Device Name(s):

Viramed Borrela All-In-One ViraChip Test Kit

B Predicate 510(k) Number(s):

K220016

C Comparison with Predicate(s):

Device & Predicate Device(s):	K243754	K220016
Device Trade Name	Lyme-ID IgG Test	Viramed Borrelia All-In-One ViraChip Test Kit
General Device Characteristic		

Similarities		
Intended Use/Indications For Use	The Inanovate Lyme-ID IgG Test is an *in vitro* qualitative microarray assay for the detection of 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 Lyme-ID IgG Test 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 Inanovate Lyme-ID IgG Test Kit must be used with Inanovate's Bio-ID800 instrument and Lyme-ID software.	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.
Sample type	Serum	Same
Controls	Lyme Positive Control (LPC), Lyme Negative Control (LNC)	Positive Control Serum, Negative Control Serum
Assay Type	Qualitative	Same
Result Generation	Automated	Same
General Device Characteristic Differences		
Assay Technology	Protein microarray assay within microfluidic cartridge	Antigen coated wells (microarray)
Antibodies detected	IgG	IgG and IgM
Sample volume	Samples diluted: 1:150 and 200 µL added per well	Samples diluted 1:76 and 100 µL added per well
Procedural Steps	Dilute samples and controls.	Wash after Sample and Conjugate

	Pipette sample and controls into designated well. Transfer Blocking Buffer and Detection Reagent into designated wells. Place in the Bio-ID800 and begin assay run.	Step
Antigens	OspC, VlsE, *B. burgdorferi* Cell Lysate	VlsE, 93 kD, 58 kD, 45 kD, 39 kD, 30 kD, 23 kD, 21 kD, 19 kD, 18 kD, and 17 kD
Instrumentation	Bio-ID800	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 Food and Drug Administration Staff.

ANSI AAMI HE75:2009/(R)2018. Human factors engineering - Design of medical devices.

CLSI AUTO11-A2. Information Technology Security of in vitro Diagnostic Instruments and software Systems; Approved Standard, Second Edition

ISO 14971:2019

ISO 15223-1:2016. Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied.

CLSI EP17-A2. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition.

IEC 61010-1 Edition 3.1 Edition 3.1. 2017-01 Consolidated version. Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)] - Note: This standard is recognized with relevant US national differences applied see reference #1 in Relevant FDA Guidance and/or Supportive Publication section.

IEC 61326-1 Edition 3.0 2020-10. Electrical equipment for measurement control and laboratory use - EMC requirements - Part 1: General requirements.

ANSI AAMI IEC 62304:2006/A1:2016. Medical device software - Software life cycle processes [Including Amendment 1 (2016).

ANSI AAMI IEC 62366-12015+AMDI:2020 (Consolidated Text). Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1.

CLSI EP07 3rd Edition. Interference Testing in Clinical Chemistry.

CLSI EP15-A3. User Verification of Precision and Estimation of Bias; Approved Guideline - Third Edition.

IEC 60825-1 Edition 2.0 2007-03. Safety of laser products - Part 1: Equipment classification and requirements [Including: Technical Corrigendum 1 (2008) Interpretation Sheet 1 (2007) Interpretation.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Within-Laboratory Precision/Repeatability: The within-laboratory precision of the Lyme-ID IgG Test was evaluated in a study that included six anti-*B. burgdorferi* human serum samples at different analyte concentrations (one negative, one high negative, two low positive, and two moderate positive) and the Lyme Positive control.

   Testing was performed at one site with each sample tested in replicates of two with two runs per day generating a total of 80 replicates per sample. Final positive and negative agreement was 100% for all specimens. Study results are summarized in Table 3 below.

   Table 3. Summary of the Within-Laboratory precision for the Lyme-ID IgG Test

Sample	Lyme Status	n	Lyme-ID IgG Test	Positive	Negative	% Agreement
LPC	Positive	80	Positive	80	0	100%
63483	Moderately Pos	80	Positive	80	0	100%
66978	Moderately Pos	80	Positive	80	0	100%
134596	Low Pos	80	Positive	80	0	100%
134592	Low Pos	80	Positive	80	0	100%
44929	High Neg	80	Negative	13	67	84%
40239	Negative	80	Negative	0	80	100%

2. Reproducibility: The reproducibility of the Lyme-ID IgG Test was evaluated in a study that included six anti-*B. burgdorferi* human serum samples at different analyte levels: two negative, two low positive, and two positive samples.

   The study was conducted across three sites, with two operators per site over five non-consecutive days. On each of the five days, each operator performed two runs, and each run included two replicates per sample, generating a total of 60 replicates per sample (2 runs x 2 operators x 1 replicates x 5 days x 3 sites). Final agreement for samples included in the study are summarized in table below.

   Table 4. Summary of the Reproducibility Study Results

Expected	sample ID	n	Positive	Negative	Invalid Runs	Valid Runs	% Agreement
Negative	21767	60	0	59	1	59	100%
Negative	21769	60	0	59	1	59	100%
Borderline	44927	60	30	29	1	59	51%

Low Positive	137042	60	58	1	1	59	98%
Positive	63483	60	58	1	1	59	98%
Positive	66978	60	60	0	0	60	100%

3. Linearity:

Not Applicable

4. Analytical Specificity/Interference:

Cross-reactivity

Potential cross-reactivity of the Lyme-ID IgG Test was evaluated in a study that tested leftover patient sera containing antibodies to potentially cross-reacting conditions (viral, bacterial, and protozoan infections as well as autoimmune disorders). Samples with a positive result with the Lyme-ID IgG Test were tested with Standard Two-Tiered (STTT) methodology to confirm presence of anti-*Borrelia burgdorferi* IgG antibodies. The table below summarizes the potential cross-reactants tested and study results.

Table 5. Cross-reactivity study results for Lyme-ID IgG Test.

Disease Condition	Immunoglobulin Type	Positive Result / Number Tested	% Cross Reactive
Anaplasmosis	N/A	2/9[a]	22.20%
Ehrlichiosis	N/A	2/10	20.00%
Helicobacter pylori	N/A	1/9	11.10%
Leptospira spp.	N/A	0/9	0%
Syphilis	N/A	2/10	20.00%
Toxoplasmosis	N/A	0/10	0%
Babesiosis	IgG/IgM	5/11[b]	45.40%
Parvovirus	N/A	0/10	0%
Influenza A	N/A	0/10	0.00%
Rubella	IgG	0/10	0%
Herpes Simplex	IgG	1/7	14.30%
CMV	IgG	2/10	20.00%
CMV	IgM	1/10	10.00%
EBV	IgG	1/10[c]	10.00%
VZV	IgG	0/10	0%
Rheumatoid Arthritis	N/A	0/10	0%
Fibromyalgia	N/A	0/10	0%
Multiple Sclerosis	N/A	0/10	0%
Total		17/177	9.60%

[a] Two positive samples also tested Lyme Positive through STTT.
[b] One of five positive samples also tested Lyme Positive through STTT.
[c] One positive sample also tested Lyme Positive through STTT.

Interference

The potential interfering effect of endogenous substances in patient samples when using the Lyme-ID (IgG/IgM) Test was evaluated with five replicates each of contrived samples prepared from two samples positive for *Borrelia* antibodies and a single negative sample. Samples were spiked with the endogenous substances at the final concentrations listed in the table below. No interference was observed at the concentrations tested.

Table 6. Endogenous Interference substances included in the study.

Interferent	Concentration
Albumin	1.25, 2.50, 3.75, and 5.00 g/dL
Bilirubin	3.75, 7.50, 11.25, and 15 mg/dL
Hemoglobin	5, 10, 15, 20 g/dL
Cholesterol	100, 200, 300, and 400 mg/dL
Intralipid	200, 400, 600, 800 mg/dL
Triglycerides	125, 250, 375, 500 mg/dL

5. Assay Reportable Range:
   Not Applicable

6. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Sample Freeze/Thaw Stability: The stability of antibodies detected by the Lyme ID-IgG test in human serum samples was evaluated after storage at ≤-65°C and following three freeze/thaw cycles. Sixty unique clinical serum samples were included in the study. Thirty samples were confirmed positive, and thirty sample were confirmed negative prior to initiation of the study. All samples were tested fresh at baseline and after one, two, and three freeze/thaw cycles. The study results support testing samples after no more than one freeze/thaw cycle.

   Store serum samples between 2-8°C for no longer than 5 days. Specimens may be stored frozen at -20°C (or below) for long term storage, avoiding multiple freeze and thaw cycles.

7. Detection Limit:
   Not applicable.

8. Assay Cut-Off:
   The cutoff algorithm for each analyte considers their resultant LAS curve parameters, AUC, and r^2 values. The absolute assay cutoff for each of the analytes detected by the Lyme-ID IgG Test (Cell Lysate, OspC, and VlsE) was determined by testing 92 samples from the CDC Research Panel II and the Lyme Positive and Negative Controls. The absolute Cutoff value for each analyte represents the AUC value that correlates to the lowest value expected to be obtained from a Lyme Positive sample and the minimum curve r^2.

9. Accuracy (Instrument):
   Not applicable

10. Carry-Over:
    Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:
   Not applicable

2. Matrix Comparison:
   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

The Lyme-ID IgG Test clinical performance was evaluated through a prospective clinical study. A total of 150 serum samples from individuals suspected of having Lyme disease were collected from two clinical sites and distributed between three separate testing sites. Participants included individuals of all ages who meet the inclusion and exclusion criteria. A subset of samples from one of the sites was collected as known positive samples based on testing with another FDA cleared serology test (n=19). Performance for this cohort was calculated separately from the prospective cohort. Comparator testing with an FDA-cleared EIA and immunoblot as part of a Standard Two-Tiered Testing (STTT) methodology was conducted at a reference laboratory. Samples were subsequently blinded and randomized prior to testing with the Lyme-ID IgG Test across three testing locations. In the prospective cohort, a total of 28 Lyme positive samples and 103 Lyme negative samples with the comparator device were included in the Lyme-ID IgG performance calculations. Three out of 19 samples in the known positive cohort were STTT positive only for IgM antibodies and thus excluded from performance calculations (n=16). Table 8 below summarizes the performance of the Lyme-ID IgG Test as Positive Percent Agreement (PPA), Negative Percent Agreement (NPA), and their corresponding two-sided 95% Confidence Interval (CI) in the prospective sample cohort. Table 9 below summarizes the results observed in the known positive sample cohort.

Table 7: Lyme-ID IgG Test performance in prospectively collected samples

		STTT Results (IgG)		
		Positive	**Negative**	**Total**
Lyme-ID-IgG Test	**Positive**	27	5*	32
	Negative	1	98	99
	Total	28	103	131
	PPA (95% CI)	96.43% (82.29% – 99.37%)		
	NPA (95% CI)	95.15% (89.14% – 97.91%)		

* Three out of five false positive samples with candidate device were STTT positive for anti-*B. burgdorferi* IgM antibodies.

Table 8: Lyme-ID IgG Test performance in known positive samples

	% Agreement with Expected Results
Lyme-ID IgG Test	100% (16/16)
95% CI	100% (80.64% – 100%)

Additionally, the CDC Premarket panel containing 280 samples was tested with the Lyme-ID IgG Test and the STTT comparator methods. This panel contains samples collected 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. The tables below summarize the results of the Lyme-ID IgG Test when testing the CDC Premarket panel.

Table 9: CDC Premarket panel results – Performance by Disease Stage

	Lyme Stage I (60)		Lyme Stage II (10)		Lyme Stage III (20)	
	Lyme-ID	STTT (VIDAS/WB)	Lyme-ID	STTT (VIDAS/WB)	Lyme-ID	STTT (VIDAS/WB)
Positive	49	19	10	6	20	20
Negative	11	41	0	4	0	0
Sensitivity or PPA	81.7%	31.7%	100%	60.0%	100%	100%

Table10: CDC Premarket panel results – Performance in Controls

	Healthy Controls (Endemic, 50)		Healthy Controls (Non-Endemic,50)		Disease Controls (90)	
	Lyme-ID	STTT (VIDAS/WB)	Lyme-ID	STTT (VIDAS/WB)	Lyme-ID	STTT (VIDAS/WB)
Positive	0	0	4	0	8	0
Negative	50	50	46	50	82	90
Specificity or NPA	100%	100%	92.0%	100%	91.1%	100%

2. Clinical Specificity:
   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   Not applicable

D Clinical Cut-Off:
Not applicable.

E Expected Values/Reference Range:
The incidence of IgG antibodies to *B. burgdorferi* antigens in patients tested by the Lyme-ID test is summarized in table 14 below.

Table 11: Observed Reactivity of Lyme ID test

Cohort	Samples tested	Lyme-ID positive	Prevalence
Prospective cohort	131	32	24.43%

F Other Supportive Instrument Performance Characteristics Data:
Not applicable.

VIII Proposed Labeling:
The labeling supports the finding of substantial equivalence for this device.

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