510(k) Summary

I. BACKGROUND INFORMATION:

A. 510(k) Number

K252627

B. Applicant

Inanovate Inc.
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C. Contact Person

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D. Date Prepared

August 19, 2025

E. Proprietary and Established Names

Lyme-ID IgG Test, Bio-ID800

F. Regulatory Information

Product Code(s):	LSR, NSU
Reagent Classification:	Class II
Regulation Section:	21 CFR 866.3830 - Treponema Pallidum Treponemal Test Reagents
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 *Borreliella burgdorferi* (*B. burgdorferi*)

C. Type of Test:

Enzyme Immunoassay

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 *Borreliella 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 must be used with Inanovate's Bio-ID800 instrument and Lyme-ID Software.

C. Special Conditions for Use Statement(s):

For prescription use only

D. Special Instrument Requirements:

Bio-ID800 Instrument and Lyme-ID Software

IV. DEVICE/SYSTEM CHARACTERISTICS:

A. Device Description:

Designed as a modified solid-phase ELISA, the Lyme-ID IgG Test is a protein microarray assay. A whole cell lysate sample of *B. burgdorferi*, along with antigens Outer Surface Protein C (OspC) and Variable Lipoprotein Surface-Exposed (VlsE) are bound to the glass surface of the Lyme-ID IgG Test cartridge. The antigens are immobilized as individual spots onto the glass surface. Positions of the spots are exactly defined and can be assigned to each antigen reliably. 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 reliability of individual sample results.

The Bio-ID800 Instrument is a bench-top analyzer which contains an optics system for detecting and reading fluorescence produced during the assay, pressure system for flowing reagents through the microfluidics channels in the cartridge, and a manifold for clamping the cartridge and aligning the cartridge over the optics scan area. The optics system excites the fluorescent reagent for analyte detection using a

532nm wavelength laser projected through a series of mirrors and expanders to a scan lens located directly under the stage for the cartridge. This enables the assay area of the cartridge to be scanned for fluorescence through an aperture and read as it returns down an optics path to a photomultiplier tube (PMT). The PMT converts the collected fluorescent light into a corresponding output voltage that is read by a high-speed data acquisition card. Reagent and sample flow rates are pulsed using high-speed valves connected to externally sourced compressed air through a series of regulators and sensors. Assay reaction temperature is controlled using filtered fans and vents to maintain the chamber at room temp with a negative pressure at the cartridge loading door.

The cartridge contains up to six patient samples and two controls (positive and negative), detection reagent, and blocking buffer wells all connected by microfluidic channels to an assay array field. As reagents or samples flow through the field, they are collected in waste wells, so that no waste leaves the cartridge. Each cartridge consists of a glass plate (containing the protein and cell lysate antigens, along with positive and negative control spots), a PDMS polymer assay reservoir which contains the microfluidic flow paths molded into the bottom, and a protective frame that aids in the alignment.

The Lyme-ID Software controls the Bio-ID800 and communicates with the instrument to collect data into a database, enabling both storage of the assay data and analysis. The software enables self-tests of the instrument and communication through the user interface with the user and instrument for warnings, errors, and prompts. During assay performance, the control of the valves for pressurizing cartridges is controlled by the software. Signal generated through the PMT is interpreted using a statistical average function and stored by the software as an image file. The software then analyzes the image files to ensure the test was performed without error and analyzes the data collected from the analytes to compute the positive or negative status of the sample. Results are then printed from the computer with a standalone printer.

B. Principle of Operation:

During each test, the diluted test serum of each sample is added to one microarray. 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 flow across the microarray, binding to *B. burgdorferi* specific antibodies bound to the antigens on the glass surface. Once bound, 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 is calculated providing an indirect measurement of *B. burgdorferi* specific antibodies present in the patient specimen (sample). After completion of each assay, the Lyme-ID software performs an analysis of each antigen spot of each sample (including the positive and negative control samples) to determine if the assay ran successfully. The results of each antigen spot from each sample are reviewed by the Lyme-ID software against the algorithm below in Table 1 to determine the Lyme Disease Evaluation – Report Result.

Table 1. Lyme Disease Evaluation			
Cell Lysate Result	**OspC Result**	**VlsE Result**	**Reported Result**
+	+	+	POSITIVE
+	+	-	POSITIVE
+	-	+	POSITIVE
+	-	-	NEGATIVE
-	+	+	NEGATIVE
-	+	-	NEGATIVE
-	-	+	NEGATIVE
-	-	-	NEGATIVE

The Lyme-ID IgG Test meets the CDC's Modified Two-Tiered Test (MTTT) methodology requirement The Lyme-ID IgG Test detects human serum IgG antibodies against B. burgdorferi cell lysate, OspC, and VlsE. The test system simplifies the MTTT method by combining the two tiers of testing into one test, giving results for all three targets simultaneously.

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:**
	Lyme-ID IgG Test	**Viramed Borrelia All-In-One ViraChip Test Kit (K220016)**
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 *Borreliella 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 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.
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	Antigen Spotted Glass (Microarrays)	Antigen Coated Wells (Microarrays)
Antigens	VlsE, OspC, and whole cell extract of B. burgdorferi	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
Sample Volume	Samples diluted 1:150 and 200 µL added per well	Samples diluted 1:76 and 100 µL added per well
Reagents	Assay Buffer, Blocking Buffer, Fluorescent Detection Reagent	10X Wash Buffer, Sample Buffer, Chromogen/Substrate Solution
Procedural Steps	Pressure driven flow of sample and detection reagent through microarray over multiple cycles	Wash after sample and conjugate step
Result Generation	Automated with Bio-ID800 Instrument and Lyme-ID Software	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. Precision/Reproducibility:

a. Precision: A panel of six samples was tested by the Lyme-ID IgG Test in four replicates per day (two replicates per run, two runs per day) over 20 days for a total of 80 replicates for each specimen. Samples selected for the panel included two moderate positive, two low positive, one high negative and one negative specimen. Final positive and negative agreement was 100% for all specimens with the exception of a high negative sample which exhibited a positive result in 13/80 replicates. Results are shown below in Table 2.

Table 2. Precision Study Results Summary				
Sample	**Test results**	**Positive test results**	**Negative test results**	**% Agreement**
Moderate Positive	80	80	0	100%
Moderate Positive	80	80	0	100%

Low Positive	80	80	0	100%
Low Positive	80	80	0	100%
High Negative	80	13	67	84%
Negative	80	0	80	100%

b. Reproducibility: A panel of six samples was tested by the Lyme-ID IgG Test in four replicates per day (two operators each completing two runs per day, one replicate per run) over five days for a total of 20 replicates for each specimen. This was repeated at two external sites (separate from the manufacturer's site), each with two new operators, for a total of 59 valid replicates for each specimen (except for one of the moderate positive samples which had 60 valid replicates). Samples selected for the panel included two moderate positive, one low positive, one borderline (expected to test positive approximately 50% of the time), and two negative samples. Results are shown below in Table 3.

Table 3. Reproducibility Study Results Summary

Sample	Test results	Positive test results	Negative test results	% Agreement
Moderate Positive	60	60	0	100%
Moderate Positive	59	58	1	98%
Low Positive	59	58	1	98%
Borderline	59	30	29	51%
Negative	59	0	59	100%
Negative	59	0	59	100%

2. Linearity:

   Not applicable.

3. Cross-Reactivity/Interference:

   a. Cross-Reactivity Study: A total of 175 sera determined to contain antibodies to other infectious disease agents were evaluated on the Lyme-ID IgG Test. Results are shown below in Table 4.

Table 4. Cross-Reactivity Study Results Summary

Disease Condition	Total Number Tested	Number of Positive Results	% Cross Reactive
Anaplasmosis	9	2[a]	22.2%
Babesiosis	11	5[b]	45.4%
Ehrlichiosis	10	2	20%
CMV (IgG)	10	2	20%

CMV (IgM)	10	1	10%
EBV	10	1[c]	10%
Fibromyalgia	10	0	0%
Helicobacter Pylori	9	1	11.1%
Herpes Simplex	7	1	14.3%
Influenza A	10	0	0%
Leptospira	9	0	0%
Multiple Sclerosis	10	0	0%
Parvovirus	10	0	0%
Rheumatoid Arthritis	10	0	0%
Rubella	10	0	0%
Syphilis	10	2	20%
Toxoplasmosis	10	0	0%
VZV	10	0	0%

[a]Two positive samples also tested Lyme Positive through STTT, possible co-infection with Lyme antibodies.
[b]One of five positive samples also tested Lyme Positive through STTT, possible co-infection with Lyme antibodies.
[c]One positive sample also tested Lyme Positive through STTT, possible co-infection with Lyme antibodies.

b. Interference from Endogenous Analytes: The potential interfering effect of endogenous substances in patient samples using the Lyme-ID IgG Test was evaluated using one moderate positive, one low positive, and one negative Lyme sample. Samples were spiked with the endogenous substances at the concentrations listed in Table 5 below. All samples were tested in a minimum of five replicates. No interference was observed in the tested samples, even at the highest concentration of each analyte.

Table 5 – Effect of Interfering Substances on Lyme-ID IgG Test

Interfering Substance	Concentrations Tested	Effect on Lyme-ID IgG Test
Albumin	1.25g/dL, 2.5g/dL, 3.75g/dL, 5.0g/dL	No effect
Bilirubin	3.75mg/dL, 7.5mg/dL, 11.25mg/dL, 15.0mg/dL	No effect
Cholesterol	100mg/dL, 200mg/dL, 300mg/dL, 400mg/dL	No effect
Hemoglobin	5g/dL, 10g/dL, 15g/dL, 20g/dL	No effect
Intralipid	200mg/dL, 400mg/dL, 600mg/dL, 800mg/dL	No effect
Triglycerides	125mg/dL, 250mg/dL, 375mg/dL, 500mg/dL	No effect

4. Assay Reportable Range:
   Not applicable.

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

6. Detection Limit:
   Not applicable.

7. Assay Cut-Off:
   The cut-off of the Lyme-ID IgG Test is defined for each antigen individually by multiplying the mean intensity of the Lyme Positive Control with an antigen specific factor (Normalization Factor). Specific antigen factors are established for each kit lot according to the performance of the Lyme Positive Control sample when compared to established absolute cutoff values for the test. Absolute cutoff values were validated with pre-characterized blood serum and were optimized for both maximum sensitivity and specificity for each antigen.

B. Clinical Studies:

1. Method Comparison with comparator (STTT):
   The performance of the Lyme-ID IgG Test for detection of *Borrelial*-specific antibodies was compared to FDA-cleared EIA and immunoblot as part of the standard two-tier test methodology (STTT). A total of 150 serum samples were collected from two clinical sites and distributed between three separate testing sites. Table 6 below summarizes the distribution of samples per collection site.

Table 6: Sample distribution by clinical site and cohort.

Table 6 – Sample distribution by clinical site and cohort.			
	Number of Samples	Sample Type and Cohort	Clinical Sites Providing Samples
Site 1	131	Clinical serum samples – Cohort 1	Sanford Health
Site 2	19	Clinical serum samples – Cohort 2	Northwell Health

Samples were randomized, blinded, and distributed to each of three testing sites and tested per the instructions for use for the Lyme-ID IgG Test. Performance by cohort is summarized below in Tables 7 and 8.

Table 7: Performance summary of prospectively collected samples from Sanford Health (n=131)

with results of Lyme-ID IgG Test compared to results of STTT method.

Table 7 – Sanford Health cohort performance table				
		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)	96.4% (82.3%, 99.4%)		
	NPA (95% CI)	95.1% (89.1%, 97.9%)		

Table 8: Performance summary of prospectively collected samples from Northwell Health (n=16) with results of Lyme-ID IgG Test compared to results of STTT method.

Table 8: Lyme-ID IgG Test performance in known positive samples		
		Positive*
Lyme-ID IgG Test	Positive	16
	Negative	0
	Total	16
	PPA (95% CI)	100% (80.6%, 100%)

*Three samples positive with Lyme-ID IgG Test were positive for *anti-B. burgdorferi* IgM antibodies and negative for *anti-B. burgdorferi* IgG antibodies when tested by STTT method

2. Clinical Sensitivity/Specificity:

CDC Serum Panel: A panel of 280 serum samples provided by the CDC was tested with the Lyme-ID IgG Test. Samples within this panel 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 were analyzed and compared to results from both a STTT and MTTT method.

The sensitivity of the Lyme-ID IgG Test when testing the CDC Reference Panel was 81.7% in stage I Lyme disease samples, 100% in stage II samples, and 100% in stage III samples. Results are shown below in Table 9.

Table 9. Sensitivity of Inanovate's Lyme-ID IgG Test (CDC Reference Panel)						
	Lyme Stage I (60)		Lyme Stage II (10)		Lyme Stage III (20)	
	Lyme-ID	STTT	Lyme-ID	STTT	Lyme-ID	STTT
Positive	49	19	10	6	20	20
Negative	11	41	0	4	0	0
Sensitivity	81.7%	31.7%	100.0%	60.0%	100.0%	100.0%

The specificity of the Lyme-ID IgG Test when testing the CDC Reference Panel was 100% in endemic healthy control samples, 92% in non-endemic healthy control samples and 91.1% in disease control samples. Results are shown below in Table 10.

Table 10. Specificity of Inanovate's Lyme-ID IgG Test (CDC Reference Panel)						
	Healthy Controls (Endemic, 50)		Healthy Controls (Non-Endemic, 50)		Disease Controls (90)	
	Lyme-ID	STTT	Lyme-ID	STTT	Lyme-ID	STTT
Positive	0	0	4	0	8	0
Negative	50	50	46	50	82	90
Specificity	100.0%	100.0%	92.0%	100.0%	91.1%	100.0%

3. Other Clinical Supportive Data:

Sample stability study: 60 decoded remnant patient serum samples were tested fresh (no freeze-thaw cycles) and again after one, two, and three freeze-thaw cycles. Lyme Diagnosis as determined by the Lyme-ID IgG Test was measured at each timepoint and any changes in diagnosis between timepoints was examined further. No effects of one, two, or three freeze-thaw cycles on any of the samples was observed. Clinical performance of the Lyme-ID IgG Test for fresh and frozen samples was comparable, confirming that the Lyme-ID IgG Test can be used with both fresh and frozen samples.

C. Clinical Cut-Off:

Not applicable.

D. 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 11 below.

Table 11: Observed Reactivity of Lyme ID test

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

VIII. PROPOSED LABELING:

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

IX. CONCLUSION:

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