510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K220016

B Applicant

Viramed Biotech AG

C Proprietary and Established Names

Viramed Borrelia All-In-One ViraChip Test Kit

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LSR	Class II	21 CFR 866.3830 - Treponema Pallidum Treponemal Test Reagents	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for a new device.

B Measurand:

Anti-*Borrelia burgdorferi* (IgG and IgM) antibodies

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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

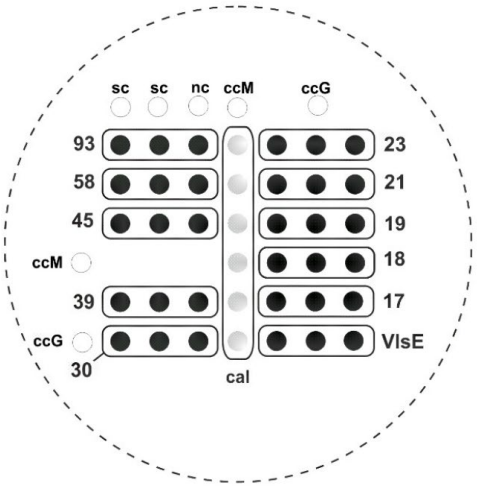
ViraChip Reader and the ViraChip Software

IV Device/System Characteristics:

A Device Description:

The Viramed Biotech AG Borrelia All-In-One ViraChip Test Kit is a protein microarray assay. A protein microarray can be considered as a modified solid-phase enzyme linked immunosorbent assay. Isolated *B. burgdorferi* antigens are bound to a solid phase nitrocellulose support membrane. Purified *B. burgdorferi* VlsE and *B. burgdorferi* antigens with the following molecular weights are used: 93 kDa, 58 kDa, 45 kDa, 39 kDa, 30 kDa, 23 kDa, 21 kDa, 19 kDa, 18 kDa and 17 kDa. The antigens were immobilized as individual spot triplets onto the nitrocellulose membrane. Positions of the spots are exactly defined and can be assigned to the antigen reliably. A negative control (nc), two serum controls (sc), four conjugate controls (ccG and ccM), and six calibrator controls (cal) are also applied to each microarray. One microarray is fixed on the bottom of each cavity of a standard microtiter plate. The cavities are single breakable wells in a holding frame with 96 positions. A schematic of the Borrelia All-In-One ViraChip is shown below.

Figure 1. Borrellia All-In-One ViraChip Microarray



B Principle of Operation:

For each test to be performed, the diluted test serum sample is added to one microarray. If specific antibodies that recognize an antigen are present, they will bind to the specific antigens on the microarray. After incubation, the microarray is washed to remove unbound antibodies. Alkaline phosphatase-conjugated anti-human antibodies (conjugate) are then added to each microarray and incubated. If host antibodies are present, the conjugate will bind to the antibodies attached to the specific antigens. The microarray is washed to remove unbound conjugate and the substrate solution is added. If the enzyme/antibody complex is present, the substrate will undergo a precipitation and color change. After an incubation period, the reaction is stopped and the presence of precipitated substrate is visualized at specific locations on the microarray. The presence of a colored precipitation at various locations on the microarray is an indirect measurement of *Borrelia burgdorferi* specific antibodies in the patient specimen. Visualized spots from the reaction are compared for intensity with the integrated calibrator controls for evaluation.

Spot intensity measurements are performed by the ViraChip Reader and that the assay result is interpreted by the ViraChip Software. The assay result interpretation algorithm is described in the table below. Test results are considered positive if the VlsE spot triplet is positive or equivocal and at least one additional spot triplet is positive. For all test results, the VlsE spots and intensities are shown in the ViraChip Software on the screen, in the print-outs from the ViraChip Software, and in the exported files. All other antigen spots and their corresponding intensities are only reported if the VlsE spot triplet is positive or equivocal. If the VlsE spot triplet is negative, all other antigen spots are masked by white circles.

Table 1. Borrelia All-In-One ViraChip Interpretation of Results

VlsE Spot Triplet		93 kDa, 58 kDa, 45 kDa, 39 kDa, 30 kDa, 23 kDa, 21 kDa, 19 kDa, 18 kDa and 17 kDa Spot Triplets		Borrelia All-In-One ViraChip Result
Spot Intensities	**Spot Triplet Result**	**Spot Intensities**	**Spot Triplet Result**	
≥ 100 units	Positive	≥ 100 units for at least one spot triplet out of 93, 58, 45, 39, 30, 23, 21, 19, or 17kDa Or ≥ 90 units for spot triplet 18 kDa	Positive	Positive
		< 100 units for all spot triplets AND < 90 units for spot triplet 18 kDa	Negative	Negative
≥ 60 and < 100 units	Equivocal	≥ 100 units for at least one spot triplet out of 93, 58, 45, 39, 30, 23, 21, 19, or 17kDa Or ≥ 90 units for spot triplet 18 kDa	Positive	Positive
		< 100 units for all spot triplets AND < 90 units for spot triplet 18 kDa	Negative	Negative
< 60 units	Negative	Not interpreted	Not interpreted	Negative

V Substantial Equivalence Information:

A Predicate Device Name(s):
Borrelia B31 ViraChip IgG Test Kit, Borrelia B31 ViraChip IgM Test Kit, ZEUS ELISA Borrelia VlsE1/PepC10 IgG/IgM Test System

B Predicate 510(k) Number(s):
K163504, K163695, K113397

C Comparison with Predicate(s):

Device & Predicate Device(s):	K220016	K163504	K163695
Device Trade Name	Viramed Borrelia All-In-One ViraChip Test Kit	Borrelia B31 ViraChip IgG Test Kit	Borrelia B31 ViraChip IgM Test Kit
General Device Characteristic Similarities			
Intended Use/Indications For Use	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	The Viramed Biotech AG Borrelia B31 ViraChip IgG Test Kit is an in vitro qualitative protein microarray assay for the detection of IgG antibodies to *Borrelia burgdorferi* in human serum. It is intended for use in the testing of human serum samples which have been found positive or equivocal using an EIA or IFA test procedure for *B. burgdorferi* antibodies. Positive results from this assay are supportive evidence of infection with *B. burgdorferi*, the causative agent for Lyme disease. The Borrelia B31 ViraChip IgG Test Kit must be used with a ViraChip Reader and the ViraChip Software.	The Viramed Biotech AG Borrelia B31 ViraChip IgM Test Kit is an in vitro qualitative protein microarray assay for the detection of IgM antibodies to *Borrelia burgdorferi* in human serum. It is intended for use in the testing of human serum samples which have been found positive or equivocal using an EIA or IFA test procedure for *B. burgdorferi* antibodies. Positive results from this assay are supportive evidence of infection with *B. burgdorferi*, the causative agent for Lyme disease. The Viramed Biotech AG Borrelia B31 ViraChip IgM Test Kit must be used with a ViraChip Reader and the ViraChip Software.

	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.		
Assay Design	Antigen Coated wells (Microarrays)	Same	Same
Reagents	10X Wash Buffer, Sample Buffer, Sample Buffer, Chromogen/Substrate Solution	Same	Same
Sample Volume	Samples diluted 1:76 and 100 µL added per well	Same	Same
Procedural Steps	Wash after Sample and Conjugate Step	Same	Same
Controls	Positive Control Serum, Negative Control Serum	Same	Same
Result Generation	Automated with ViraChip Reader	Same	Same
General Device Characteristic Differences			
Antigens	VlsE, 93 kD, 58 kD, 45 kD, 39 kD, 30 kD, 23 kD, 21 kD, 19 kD, 18 kD, and 17 kD	93 kD, 66 kD. 58 kD, 45 kD, 41 kD, 39 kD, 30 kD, 28 kD, 23 kD, and 18 kD	41 kD, 39 kD, and 23 kD
Antibodies Detected	IgG and IgM	IgG	IgM

Device & Predicate Device(s):	K220016	K113397
Device Trade Name	Viramed Borrelia All-In-One ViraChip Test Kit	ZEUS ELISA Borrelia VlsE1/PepC10 IgG/IgM Test System
General Device Characteristic Similarities		
Intended Use/Indications For Use	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	The ZEUS ELISA Borrelia VIsE1/PepClO lgG/lgM Test System is intended for the qualitative detection of IgG and IgM class antibodies to VIsE1 and pepC10 antigens from *Borrelia burgdorferi* in human serum. The assay is intended for testing serum samples from symptomatic patients or those with a history of Lyme Borreliosis. All positive and equivocal specimens should be tested with a second-tier test such as Western Blot, which if positive, is supportive evidence of infection with *Borrelia burgdorferi*. Diagnosis of Lyme Borreliosis should be made based on the presence of *B. burgdorferi* antibodies, history, symptoms, and other laboratory data. Negative first or second tier results should not be used to exclude Borreliosis. This kit is for in vitro diagnostic use.

	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.	
Antibodies Detected	IgG and IgM	Same
Controls	Positive Control Serum, Negative Control Serum	Same
General Device Characteristic Differences		
Antigens	VlsE, 93 kD, 58 kD, 45 kD, 39 kD, 30 kD, 23 kD, 21 kD, 19 kD, 18 kD, and 17 kD	Recombinant VlsE antigen and synthetic pepC10 antigen
Assay Design	Antigen Coated wells (Microarrays)	ELISA
Procedural Steps	Wash after Sample and Conjugate Step	Wash between sample and conjugate incubation steps, incubate with substrate
Reagents	10X Wash Buffer, Sample Buffer, Sample Buffer, Chromogen/Substrate Solution	Calibrator, SAVe Diluent, TMB substrate solution, Stop Solution, Wash buffer concentrate
Result Generation	Automated with ViraChip Reader	ELISA microwell reager, 450 nm
Sample Volume	Samples diluted 1:76 and 100 µL added per well	Sample diluted 1:21 in SAVe Diluent

VI Standards/Guidance Documents Referenced:

M34-1A: Western Blot Assay for Antibodies to Borrelia Burgdorferi; Approved Guideline

EP05-A3 Evaluation of Precision Performance of Quantitative Measurement Methdos; Approved Guideline- Third Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision Study

A panel of eight specimens was tested by the Borrelia All-In-One ViraChip in two replicates by two operators per day over 12 days for a total of 48 tests for each specimen. Samples were selected based on FDA cleared *B. burgdorferi* antibody ELISA results, including one low negative, one moderate negative, one high negative one low positive, two moderate positive, and one high positive sample. The relative intensity of each antigen was classified as distinct signal with the thresholds as described in the interpretation criteria. Final positive and negative agreement was 100% for all specimens with the exception of a high negative specimen which exhibited a positive result for 6/48 replicates.

Table 2. Precision Study Results Summary

			Antigens										
Sample	**Reactivity**	**Test results**	**VlsE**	**p93**	**p58**	**p45**	**p39**	**p30**	**p23**	**p21**	**p19**	**p18**	**p17**
High Pos	Poss test results	**48**											
	Neg test results	0											
	Distinct signals		48	0	45	0	48	48	48	48	10	48	0
	% distinct signals		100%	0%	94%	0%	100%	100%	100%	100%	21%	100%	0%
Mod. Pos	Pos test results	**48**											
	Neg test results	0											
	Distinct signals		48	0	0	48	0	48	0	45	48	48	48
	% distinct signals		100%	0%	0%	100%	0%	100%	0%	94%	100%	100%	100%
Mod Pos	Pos test results	**48**											
	Neg test results	0											
	Distinct signals		48	48	48	0	48	0	0	48	0	48	0
	% distinct signals		100%	100%	100%	0%	100%	0%	0%	100%	0%	100%	0%
Mod Pos	Pos test results	**48**											
	Neg test results	0											
	Distinct signals		48	0	0	0	46	0	48	5	0	48	0
	% distinct signals		100%	0%	0%	0%	96%	0%	100%	10%	0%	100%	0%
Los Pos	Pos test results	**48**											
	Neg test results	0											
	Distinct signals		48	0	0	0	0	0	48	0	0	0	0
	% distinct signals		100%	0%	0%	0%	0%	0%	100%	0%	0%	0%	0%
High Neg	Pos test results	**6**											
	Neg test results	42											
	Distinct signals		6	0	48	0	0	0	0	0	0	0	0
	% distinct signals		13%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%
Mod Neg	Pos test results	**0**											
	Neg test results	48											
	Distinct signals		0	0	0	0	0	0	0	0	0	0	0
	% distinct signals		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Low Neg	Pos test results	**0**											
	Neg test results	48											
	Distinct signals		0	0	0	0	0	0	0	0	0	0	0
	% distinct signals		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%

Reproducibility Study

Eight specimens were tested in three replicates by two operators over five days across three independent sites for a total of 90 tests for each specimen. Samples were selected based on FDA cleared *B. burgdorferi* antibody ELISA results, including one low negative, one moderate negative, one high negative sample and one low positive, two moderate positive, one high positive sample. Final positive or negative agreement was 100% for all specimens with the exception a low positive sample which produced a positive result for 77/90 replicates (positive agreement 85.5%). Similarly, a high negative sample exhibited a positive result for 2/88 replicates (negative agreement 97.8%).

Table 3. Reproducibility Study Results Summary

			Antigens										
Sample	**Reactivity**	**Test results**	**VlsE**	**p93**	**p58**	**p45**	**p39**	**p30**	**p23**	**p21**	**p19**	**p18**	**p17**
High Pos	Poss test results	**90**											
	Neg test results	0											
	Distinct signals		90	0	74	0	90	54	90	90	6	90	0
	% distinct signals		100%	0%	82%	0%	100%	60%	100%	100%	7%	100%	0%
Mod. Pos	Pos test results	**90**											
	Neg test results	0											
	Distinct signals		90	0	0	90	1	90	5	85	90	90	90
	% distinct signals		100%	0%	0%	100%	1%	100%	6%	94%	100%	100%	100%
Mod Pos	Pos test results	**90**											
	Neg test results	0											
	Distinct signals		90	90	90	1	90	0	0	86	1	90	0
	% distinct signals		100%	100%	100%	1%	100%	0%	0%	96%	1%	100%	0%
Mod Pos	Pos test results	**90**											
	Neg test results	0											
	Distinct signals		90	0	0	0	82	0	90	6	0	76	0
	% distinct signals		100%	0%	0%	0%	91%	0%	100%	7%	0%	84%	0%
Low Pos	Pos test results	77											
	Neg test results	13											
	Distinct signals		90	0	0	2	0	0	77	0	0	0	0
	% distinct signals		100%	0%	0%	2%	0%	0%	86%	0%	0%	0%	0%
High Neg	Pos test results	**2**											
	Neg test results	88											
	Distinct signals		2	0	89	0	0	0	0	0	0	0	0
	% distinct signals		2%	0%	99%	0%	0%	0%	0%	0%	0%	0%	0%
Mod Neg	Pos test results	**0**											
	Neg test results	90											
	Distinct signals		0	0	0	0	0	0	0	0	0	0	0
	% distinct signals		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Low Neg	Pos test results	**0**											
	Neg test results	90											
	Distinct signals		1	0	0	0	0	0	0	0	0	0	0
	% distinct signals		1%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Analytical Specificity Study: For determination of analytical specificity, 100 sera form normal blood donor individuals representing endemic and non-endemic geographic regions of the United States were tested for *B. burgdorferi* antibodies by the Borrelia All-In-One ViraChip.

Table 4. Analytical Specificity Study Results Summary

	Total	Negative	Positive	% Positive	% Negative
Endemic	50	46	4	8%	92%
Non-endemic	50	50	0	0%	100%
All Specimens	100	96	4	4%	96%

Cross-Reactivity Study: A total of 203 sera determined to contain antibodies to other infectious disease agents were evaluated on the Borrelia All-In-One ViraChip. The results are shown in the table below.

Table 5. Cross-Reactivity Study Results Summary

Disease State Sera	Total	Borrelia All-In-One ViraChip Positive	% Cross-reactivity
Autoimmune[1]	10	0	0%
Babesia microti	9	4[2]	44.4%
Borrelia hermsii	6	0	0%
Celiac disease[1]	10	0	0%
Chlamydia trachomatis	15	1	6.7%
Cytomegalovirus	11	3[3]	27.3%
Epstein–Barr virus	10	0	0%
Ehrlichia chaffeensis	11	2	18.2%
Fibromyalgia	2	0	0%
Helicobacter pylori	10	0	0%
Herpes simplex virus	10	0	0%
Influenza A	10	1	10%
Leptospira interrogans	10	0	0%
Lupus[1]	10	0	0%
Parvovirus B19	10	0	0%
Rheumatoid arthritis[1]	10	0	0%
Rickettsia spp.	10	2[2]	20%
Rubella virus	10	1	10%
Toxoplasma gondii	10	1	10%
Treponema pallidum	10	0	0%
Varicella zoster virus	9	1	11.1%

[1]Autoimmune diseases are not an infectious disease but can produce autoimmune antibodies with varied known and unknown specificity.
[2]Possible co-infection with *B. burgdorferi.* 2/4 positive *B. microti* samples were also positive using STTT methodology. 1/2 positie *Rickettsia* spp. samples were also positive by STTT methodology.
[3]6/10 samples were positive by STTT methodology

Interfering Substances: Hemolyzed, lipemic, icteric, or microbially contaminated sera should not be used for testing by the Borrelia All-In-One ViraChip. In addition the effect of elevated bilirubin and triglycerides on test results is not established.

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 ViraChip test system is defined for each antigen individually by multiplying the mean intensity of the calibrator spots with an antifen specific factor. Specific antigen factors were adjusted for each antigen according to concordance with pre-characterized blood donor sera. Using Receiver Operating Characteristic analysis, the antigen specific cut-off factors were optimized for both maximum sensitivity and specificity for each antigen.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Prospective Study: 113 specimens from three independent commercial clinical testing laboratories were evaluated with the Viramed Borrelia All-In-One ViraChip and comparator *B. burgdorferi* antibody testing following a Standard Two-Tiered Testing (STTT) methodology in which samples with positive or equivocal results from the ZEUS ELISA Borrelia VlsE1/pepC10 IgG/IgM Test System (K113397) were subsequently tested with the Borrelia B31 ViraChip IgG test kit (K163504) and Borrelia B31 ViraChip IgM test kit (K163695). The percent agreement between the Viramed Borrelia All-In-One ViraChip results and STTT results are shown below.

   Table 6. Prospective Study Results – Comparison with STTT

Borrelia All-In-One ViraChip	STTT Results (IgG and/or IgM)		
	Positive	Negative	Total
Positive	41	16	57
Negative	3	53	56
Total	44	69	113

   Positive Percent Agreement: 93.2% (41/44) 95% CI: 81.8-97.7%
   Negative Percent Agreement: 76.8% (53/69) 95% CI: 65.6-85.2%

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Sensitivity Study: Staged clinically defined sera sourced from Massachusetts General Hospital were evaluated with the Viramed Biotech AG Borrelia All-In-One ViraChip and the STTT methodology described in VII.B.1 above. Results are summarized below.

Table 7. Sensitivity Study Results – Comparison with STTT

	Early Lyme (N = 5)		Disseminated Lyme (N = 19)		Lyme Arthritis (N = 37)	
	Viramed	**STTT**	**Viramed**	**STTT**	**Viramed**	**STTT**
Positive	2	4	19	19	35	35
Negative	3	1	0	0	2	2
Sensitivity or PPA	40%	80%	100%	100%	95%	95%

CDC Serum Panel: A Lyme disease panel containing 90 clinically defined positive samples was obtained from the Centers for Disease Control and Prevention. These samples were evaluated with the Viramed Borrelia All-In-One ViraChip and the STTT methodology.

Table 8. CDC Reference Panel Testing Results – Comparison with STTT

	Stage I (N = 60)		Stage II (N = 10)		Stage III (N = 20)		Healthy Controls (N = 100)		Disease Controls (N = 90)	
	Viramed	**STTT**	**Viramed**	**STTT**	**Viramed**	**STTT**	**Viramed**	**STTT**	**Viramed**	**STTT**
Positive	54	37	10	9	20	20	1	0	2	0
Negative	6	23	0	10	0	0	99	100	88	90
Sensitivity or PPA	90%	61.7%	100%	90%	100%	100%	99%	100%	98%	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 and IgM antibodies to *B. burgdorferi* antigens in different patient populations tested by the Viramed Borrelia All-In-One ViraChip test are shown in the table below.

Table 9. Expected Reactivities Among Viramed Borrelia All-In-One ViraChip Antigen Spots

	Antigens (% incidence)										
Viramed Borrelia All-In-One ViraChip	**VlsE**	**p93**	**p58**	**p45**	**p39**	**p30[1]**	**p23**	**p21**	**p19**	**p18**	**p17**
Early Lyme Disease	89.2%	0.0%	3.1%	7.7%	24.6%	46.2%	80.0%	15.4%	0.0%	30.8%	7.7%
Cardiac Lyme	100%	0.0%	0.0%	33.3%	66.7%	66.7%	66.7%	66.7%	0.0%	66.7%	0.0%
Disseminated Lyme Disease	100%	0.0%	10.5%	31.6%	36.8%	63.2%	100%	36.8%	0.0%	68.4%	31.6%
Neurologic Lyme	100%	0.0%	0.0%	0.0%	28.6%	71.4%	100%	42.9%	0.0%	57.1%	0.0%
Prospective Study	68.1%	5.3%	8.8%	4.4%	26.5%	27.4%	41.6%	15.9%	1.8%	23.9%	5.3%
Non-Endemic Blood Donors	1.0%	1.0%	0.0%	0%	0.0%	1.0%	1.0%	0.0%	0.0%	1.0%	0%
Endemic Blood Donors	12.0%	0.0%	1.0%	0%	1.0%	3.0%	4.0%	2.0%	0.0%	1.0%	2.0%

[1]According to the interpretation criteria, p30 is counted only for a positive first test result (i.e, VlsE ≥ 100) not an equivocal first test result.

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.