Vibrant Tickborne Diseases Panel Validation Report

1 Intended Use

Vibrant Tickborne Diseases Antibody Panel kit is designed for the *in vitro* measurement of specific IgG and IgM autoantibodies against the Borreliosis/Lyme disease as well as co-infection(s) and opportunistic infections with other tick-borne illnesses specific antigens present in human serum/ blood (EDTA)/ dried blood spot (DBS).

2 Test Principle

The kit contains pillar plate and reagents required to run the assay. The pillar plate comprises of multiple individual immunochips for each specific antigen tested. Antibodies specific to the antigens if present in the serum/blood/eluted blood from DBS will recognize the antigens attached on the chips and form antibody-antigen complex. An enhanced IgM assay is performed by incubating the sample with a purified goat anti-human IgG antibody for the removal of human IgG prior to testing for specific IgM antibodies. Unbound antibody and other substances are removed by washing using wash buffer. The chips are then incubated with anti-human IgG HRP and anti-human IgM HRP antibodies. The chips are then washed using wash buffer and dried. The plate is then immersed in a chemiluminescent substrate solution and is imaged using a Bio CCD Chemiluminescence imager. The intensity of specific chips are then calculated and converted into qualitative and semi-quantitative results for the individual antigens tested. This interpretation is performed by comparison with calibrators, controls and cut-off values. The sample is considered to be negative if the concentration of the antibody is less than the cut-off value chosen. The sample is considered to be positive if the concentration of the antibody is greater than the cut-off value chosen.

3 Performance Characteristics

1. Performance Characteristics

The kit comprises of calibrators, positive and negative controls which are used for every assay performed. The studies are analyzed after every plate tested passes the acceptance criteria for controls and calibrators ranges assigned during assay design.

2. Precision

A. Repeatability/Reproducibility

The simple precision (repeatability) of Tickborne Diseases Antibody Panel kit was determined by running 3 samples 10 times within the same run and analyzed.

The complex precision (reproducibility) of Tickborne Diseases Antibody Panel kit was assayed in 2 replicates of 3 samples twice daily over 5 days and analyzed.

One positive and one negative control were included in each run. The data were analyzed for within-run, between run/day variations. Total precision and percent coefficient of variation are

summarized below:

Simple Precision (Repeatability)	Sample 1	Sample 2	Sample 3
Borrelia burgdorferi VlsE1 IgM	7.7%	7.0%	3.8%
Borrelia burgdorferi C6 peptide IgM	7.0%	4.9%	5.6%
Borrelia burgdorferi p18 (DbpB) IgM	7.1%	4.4%	1.9%
Borrelia burgdorferi p23-25 (OspC) IgM	8.8%	5.0%	6.2%
Borrelia burgdorferi p28 IgM	5.1%	5.3%	6.4%
Borrelia burgdorferi p30 IgM	6.0%	6.1%	5.8%
Borrelia burgdorferi p31 (OspA) IgM	8.3%	2.7%	5.9%
Borrelia burgdorferi p34 (OspB) IgM	6.5%	6.2%	6.2%
Borrelia burgdorferi p39 (BmpA) IgM	6.6%	4.9%	4.9%
Borrelia burgdorferi p41 IgM	4.5%	6.3%	5.4%
Borrelia burgdorferi p45 IgM	5.3%	6.1%	4.5%
Borrelia burgdorferi p58 IgM	5.3%	5.7%	5.6%
Borrelia burgdorferi p66 IgM	6.4%	5.9%	4.0%
Borrelia burgdorferi p83-93 IgM	8.6%	5.5%	6.4%
Borrelia burgdoferi B31 WCS IgM	5.7%	4.7%	6.0%
Borrelia burgdoferi 297 WCS IgM	4.5%	5.3%	6.4%
Borrelia mayonii IgM	5.8%	6.9%	6.5%
Borrelia afzelii BmpA IgM	6.9%	6.0%	6.6%
Borrelia afzelii DbpA IgM	7.1%	4.5%	5.9%
Borrelia afzelii OspA IgM	9.5%	3.7%	4.6%
Borrelia afzelii OspC IgM	6.8%	5.9%	5.5%
Borrelia afzelii p100 IgM	5.7%	5.9%	6.3%
Borrelia garinii DbpA IgM	7.7%	5.4%	6.3%
Borrelia garinii OspC IgM	6.7%	3.5%	6.4%
Borrelia bavariensis DbpA IgM	7.6%	4.7%	6.1%
Borrelia bavariensis p58 IgM	5.9%	5.5%	6.3%
Borrelia bavariensis VlsE1 IgM	8.6%	5.6%	6.2%
Borrelia spielmanii DbpA IgM	6.0%	5.2%	4.1%
Borrelia spielmanii OspC IgM	6.1%	5.9%	5.0%
Borrelia burgdorferi VlsE1 IgG	4.9%	4.8%	6.0%
Borrelia burgdorferi C6 peptide IgG	6.0%	6.6%	4.7%
Borrelia burgdorferi p18 (DbpB) IgG	7.4%	2.7%	5.8%
Borrelia burgdorferi p23-25 (OspC) IgG	6.8%	5.7%	4.7%
Borrelia burgdorferi p28 IgG	5.5%	7.3%	6.6%
Borrelia burgdorferi p30 IgG	4.4%	5.2%	5.1%
Borrelia burgdorferi p31 (OspA) IgG	7.0%	5.1%	5.2%
Borrelia burgdorferi p34 (OspB) IgG	8.6%	4.3%	6.7%
Borrelia burgdorferi p39 (BmpA) IgG	6.9%	4.7%	4.8%

Simple Precision (Repeatability)	Sample 1	Sample 2	Sample 3
Borrelia burgdorferi p41 IgG	6.6%	5.2%	6.2%
Borrelia burgdorferi p45 IgG	6.3%	5.4%	5.3%
Borrelia burgdorferi p58 IgG	5.3%	5.9%	4.2%
Borrelia burgdorferi p66 IgG	6.1%	3.6%	6.2%
Borrelia burgdorferi p83-93 IgG	5.6%	5.2%	5.3%
Borrelia burgdoferi B31 WCS IgG	8.3%	4.0%	5.7%
Borrelia burgdoferi 297 WCS IgG	6.1%	5.7%	5.0%
Borrelia mayonii IgG	6.0%	5.1%	4.7%
Borrelia afzelii BmpA IgG	7.9%	6.0%	3.7%
Borrelia afzelii DbpA IgG	6.2%	6.4%	4.8%
Borrelia afzelii OspA IgG	4.3%	5.4%	6.8%
Borrelia afzelii OspC IgG	6.6%	5.3%	4.3%
Borrelia afzelii p100 IgG	5.4%	6.0%	6.3%
Borrelia garinii DbpA IgG	4.6%	5.7%	5.7%
Borrelia garinii OspC IgG	8.1%	5.7%	5.3%
Borrelia bavariensis DbpA IgG	5.6%	5.8%	4.8%
Borrelia bavariensis p58 IgG	5.7%	4.1%	6.5%
Borrelia bavariensis VlsE1 IgG	7.5%	4.8%	5.7%
Borrelia spielmanii DbpA IgG	8.5%	4.0%	5.8%
Borrelia spielmanii OspC IgG	5.9%	6.3%	6.9%
Borrelia andersonii IgM	7.7%	5.5%	4.7%
Borrelia maritima IgM	8.1%	7.1%	6.4%
Borrelia californiensis IgM	6.3%	6.6%	5.7%
Borrelia bissettiae IgM	5.9%	4.4%	4.7%
Borrelia lusitaniae IgM	7.9%	4.0%	6.0%
Borrelia valaisiana IgM	8.3%	5.2%	5.6%
Borrelia yangtzensis IgM	6.5%	6.3%	6.1%
Borrelia turcica IgM	6.3%	5.2%	6.5%
Borrelia andersonii IgG	6.6%	4.8%	5.7%
Borrelia maritima IgG	7.0%	5.4%	6.3%
Borrelia californiensis IgG	7.8%	4.3%	5.6%
Borrelia bissettiae IgG	9.2%	6.3%	6.0%
Borrelia lusitaniae IgG	5.0%	5.7%	6.5%
Borrelia valaisiana IgG	5.8%	5.9%	4.9%
Borrelia yangtzensis IgG	8.1%	4.5%	5.5%
Borrelia turcica IgG	8.2%	7.3%	5.2%
Borrelia hermsii IgM	7.0%	3.4%	5.0%
Borrelia turicatae IgM	3.8%	5.4%	8.5%
Borrelia hermsii IgG	5.5%	6.5%	4.4%
Borrelia turicatae IgG	7.4%	4.3%	5.5%

Simple Precision (Repeatability)	Sample 1	Sample 2	Sample 3
Borrelia miyamotoi IgM	8.5%	3.9%	4.6%
Borrelia miyamotoi IgG	6.1%	4.2%	4.5%
Babesia microti IRA IgM	7.1%	4.9%	4.8%
Babesia microti p32 IgM	6.9%	5.4%	5.0%
Babesia microti p41 IgM	8.5%	5.4%	5.8%
Babesia microti WCS IgM	5.7%	5.3%	5.6%
Babesia duncani IgM	6.7%	4.2%	4.6%
Babesia microti IRA IgG	5.8%	5.3%	4.5%
Babesia microti p32 IgG	8.7%	5.4%	5.2%
Babesia microti p41 IgG	7.2%	6.8%	5.2%
Babesia microti WCS IgG	7.1%	6.2%	4.3%
Babesia duncani IgG	6.9%	3.9%	5.2%
Bartonella henselae 17 kDa IgM	7.9%	4.8%	4.4%
Bartonella henselae 26 kDa IgM	7.1%	6.4%	6.8%
Bartonella henselae SucB IgM	7.7%	5.1%	5.4%
Bartonella elizabethae IgM	7.2%	4.9%	5.3%
Bartonella vinsonii IgM	8.3%	6.5%	7.6%
Bartonella quintana IgM	5.4%	6.1%	3.2%
Bartonella henselae 17 kDa IgG	5.9%	6.5%	6.7%
Bartonella henselae 26 kDa IgG	6.8%	5.7%	2.8%
Bartonella henselae SucB IgG	5.0%	5.4%	4.5%
Bartonella elizabethae IgG	8.4%	5.5%	4.9%
Bartonella vinsonii IgG	7.4%	5.0%	5.3%
Bartonella quintana IgG	8.1%	4.6%	5.7%
Anaplasma phagocytophilum Msp5 IgM	8.4%	4.5%	4.8%
Anaplasma phagocytophilum Msp2 (p44) IgM	7.8%	5.8%	5.1%
Anaplasma phagocytophilum OmpA IgM	6.4%	4.5%	6.1%
Anaplasma phagocytophilum Msp5 IgG	7.5%	4.7%	4.7%
Anaplasma phagocytophilum Msp2 (p44) IgG	6.6%	8.0%	5.6%
Anaplasma phagocytophilum OmpA IgG	5.3%	4.4%	4.8%
Ehrlichia chaffeensis IgM	7.6%	4.7%	6.4%
Ehrlichia chaffeensis IgG	6.5%	5.7%	5.4%
Rickettsia typhi OmpB IgM	5.6%	7.7%	5.7%
Rickettsia typhi Surface antigen IgM	4.1%	4.9%	5.7%
Rickettsia typhi OmpB IgG	9.2%	5.4%	5.1%
Rickettsia typhi Surface antigen IgG	6.0%	6.2%	5.1%
Powassan Virus IgM	5.7%	4.5%	4.4%
Powassan Virus IgG	7.1%	6.9%	5.3%
Tickborne Encephalitis Virus IgM	6.5%	4.2%	7.1%
Tickborne Encephalitis Virus IgG	7.1%	6.1%	5.4%

Simple Precision (Repeatability)	Sample 1	Sample 2	Sample 3
West Nile Virus IgM	8.6%	5.0%	6.2%
West Nile Virus IgG	5.3%	5.6%	4.7%
Chlamydophila pneumoniae IgM	7.2%	4.3%	5.4%
Chlamydophila pneumoniae IgG	5.6%	6.4%	4.7%
Coxsackie Virus IgM	3.2%	4.4%	5.5%
Coxsackie Virus IgG	7.7%	2.9%	6.0%
Parvovirus B19 VLP VP2 IgM	9.3%	7.6%	5.9%
Parvovirus B19 VLP VP1/Vp2 Co Capsid IgM	7.8%	7.0%	5.5%
Parvovirus B19 VLP VP2 IgG	6.4%	6.1%	3.7%
Parvovirus B19 VLP VP1/Vp2 Co Capsid IgG	6.8%	5.0%	6.4%
Mycoplasma pneumoniae IgM	7.2%	7.2%	5.4%
Mycoplasma pneumoniae IgG	5.5%	6.1%	6.2%
Toxoplasma gondii Crude Extract IgM	6.9%	6.8%	5.9%
Toxoplasma gondii MIC3 IgM	7.1%	5.5%	3.9%
Toxoplasma gondii p24 IgM	6.9%	5.4%	4.7%
Toxoplasma gondii p29 IgM	6.9%	5.7%	5.2%
Toxoplasma gondii p30 IgM	8.8%	4.1%	5.3%
Toxoplasma gondii Crude Extract IgG	6.7%	5.4%	6.2%
Toxoplasma gondii MIC3 IgG	7.3%	5.8%	3.1%
Toxoplasma gondii p24 IgG	6.9%	3.7%	4.2%
Toxoplasma gondii p29 IgG	5.6%	5.6%	5.6%
Toxoplasma gondii p30 IgG	6.1%	5.7%	6.1%

Complex Precision (Reproducibility)	Sample 1	Sample 2	Sample 3
Borrelia burgdorferi VlsE1 IgM	4.8%	3.7%	4.2%
Borrelia burgdorferi C6 peptide IgM	8.5%	5.8%	4.3%
Borrelia burgdorferi p18 (DbpB) IgM	7.4%	6.2%	6.4%
Borrelia burgdorferi p23-25 (OspC) IgM	6.3%	4.1%	7.3%
Borrelia burgdorferi p28 IgM	9.4%	3.8%	5.0%
Borrelia burgdorferi p30 IgM	7.4%	4.4%	4.7%
Borrelia burgdorferi p31 (OspA) IgM	5.6%	5.4%	2.3%
Borrelia burgdorferi p34 (OspB) IgM	5.0%	4.4%	7.0%
Borrelia burgdorferi p39 (BmpA) IgM	7.6%	4.3%	5.5%
Borrelia burgdorferi p41 IgM	6.5%	5.3%	5.0%
Borrelia burgdorferi p45 IgM	8.6%	4.1%	5.0%
Borrelia burgdorferi p58 IgM	7.9%	6.6%	5.5%
Borrelia burgdorferi p66 IgM	6.9%	5.7%	3.9%
Borrelia burgdorferi p83-93 IgM	7.1%	5.7%	5.3%
Borrelia burgdoferi B31 WCS IgM	4.8%	5.5%	5.1%
Borrelia burgdoferi 297 WCS IgM	6.5%	6.4%	6.3%
Borrelia mayonii IgM	9.1%	4.8%	5.1%

Complex Precision (Reproducibility)	Sample 1	Sample 2	Sample 3
Borrelia afzelii BmpA IgM	9.0%	5.1%	5.7%
Borrelia afzelii DbpA IgM	6.8%	5.8%	5.7%
Borrelia afzelii OspA IgM	5.5%	4.8%	5.3%
Borrelia afzelii OspC IgM	8.8%	5.2%	4.5%
Borrelia afzelii p100 IgM	6.6%	5.6%	4.2%
Borrelia garinii DbpA IgM	5.7%	4.9%	4.5%
Borrelia garinii OspC IgM	6.4%	5.9%	5.3%
Borrelia bavariensis DbpA IgM	8.2%	3.5%	6.6%
Borrelia bavariensis p58 IgM	8.2%	6.9%	6.8%
Borrelia bavariensis VlsE1 IgM	7.8%	5.0%	4.5%
Borrelia spielmanii DbpA IgM	7.2%	5.9%	5.9%
Borrelia spielmanii OspC IgM	5.1%	4.7%	6.4%
Borrelia burgdorferi VlsE1 IgG	6.3%	5.5%	6.7%
Borrelia burgdorferi C6 peptide IgG	6.9%	6.5%	5.6%
Borrelia burgdorferi p18 (DbpB) IgG	5.4%	7.5%	4.6%
Borrelia burgdorferi p23-25 (OspC) IgG	6.7%	5.8%	6.8%
Borrelia burgdorferi p28 IgG	5.9%	5.9%	3.9%
Borrelia burgdorferi p30 IgG	4.7%	4.8%	4.1%
Borrelia burgdorferi p31 (OspA) IgG	6.8%	4.3%	6.0%
Borrelia burgdorferi p34 (OspB) IgG	7.0%	5.9%	4.8%
Borrelia burgdorferi p39 (BmpA) IgG	5.4%	4.5%	5.5%
Borrelia burgdorferi p41 IgG	6.6%	6.1%	5.9%
Borrelia burgdorferi p45 IgG	6.0%	4.0%	6.6%
Borrelia burgdorferi p58 IgG	7.4%	5.3%	7.2%
Borrelia burgdorferi p66 IgG	7.6%	4.8%	6.1%
Borrelia burgdorferi p83-93 IgG	6.2%	6.2%	5.7%
Borrelia burgdoferi B31 WCS IgG	6.8%	6.2%	4.9%
Borrelia burgdoferi 297 WCS IgG	8.3%	5.0%	5.5%
Borrelia mayonii IgG	6.1%	5.7%	5.6%
Borrelia afzelii BmpA IgG	6.8%	4.8%	5.8%
Borrelia afzelii DbpA IgG	3.7%	6.3%	4.0%
Borrelia afzelii OspA IgG	5.9%	5.5%	4.3%
Borrelia afzelii OspC IgG	8.2%	4.1%	6.1%
Borrelia afzelii p100 IgG	5.5%	5.3%	6.1%
Borrelia garinii DbpA IgG	8.5%	4.5%	5.9%
Borrelia garinii OspC IgG	6.0%	6.3%	4.9%
Borrelia bavariensis DbpA IgG	4.1%	6.3%	5.2%
Borrelia bavariensis p58 IgG	7.9%	5.4%	4.0%
Borrelia bavariensis VlsE1 IgG	7.9%	6.8%	4.8%
Borrelia spielmanii DbpA IgG	5.7%	4.5%	6.0%

Complex Precision (Reproducibility)	Sample 1	Sample 2	Sample 3
Borrelia spielmanii OspC IgG	6.5%	6.0%	6.0%
Borrelia andersonii IgM	4.5%	5.6%	4.0%
Borrelia maritima IgM	5.8%	5.0%	5.6%
Borrelia californiensis IgM	4.8%	6.5%	6.2%
Borrelia bissettiae IgM	5.0%	6.5%	6.0%
Borrelia lusitaniae IgM	8.3%	3.7%	5.3%
Borrelia valaisiana IgM	7.9%	4.8%	7.0%
Borrelia yangtzensis IgM	6.1%	5.7%	6.1%
Borrelia turcica IgM	6.8%	5.2%	7.6%
Borrelia andersonii IgG	6.5%	6.0%	4.6%
Borrelia maritima IgG	5.2%	7.3%	5.7%
Borrelia californiensis IgG	5.8%	6.3%	5.0%
Borrelia bissettiae IgG	7.1%	5.4%	5.8%
Borrelia lusitaniae IgG	6.3%	6.5%	3.6%
Borrelia valaisiana IgG	7.5%	5.8%	3.6%
Borrelia yangtzensis IgG	5.8%	4.3%	6.1%
Borrelia turcica IgG	5.4%	5.1%	4.7%
Borrelia hermsii IgM	7.8%	4.5%	6.5%
Borrelia turicatae IgM	7.3%	5.3%	4.5%
Borrelia hermsii IgG	5.4%	3.9%	5.3%
Borrelia turicatae IgG	6.8%	5.7%	6.0%
Borrelia miyamotoi IgM	5.1%	5.1%	6.8%
Borrelia miyamotoi IgG	5.9%	4.6%	6.9%
Babesia microti IRA IgM	6.0%	5.4%	5.4%
Babesia microti p32 IgM	8.8%	4.5%	5.5%
Babesia microti p41 IgM	6.9%	4.7%	5.1%
Babesia microti WCS IgM	6.8%	6.3%	5.5%
Babesia duncani IgM	7.4%	6.1%	4.4%
Babesia microti IRA IgG	5.7%	5.6%	5.1%
Babesia microti p32 IgG	4.6%	4.2%	5.7%
Babesia microti p41 IgG	8.7%	5.3%	3.2%
Babesia microti WCS IgG	7.8%	5.7%	5.6%
Babesia duncani IgG	8.1%	3.8%	6.8%
Bartonella henselae 17 kDa IgM	5.4%	5.1%	6.0%
Bartonella henselae 26 kDa IgM	7.7%	6.4%	4.9%
Bartonella henselae SucB IgM	8.2%	5.4%	4.0%
Bartonella elizabethae IgM	7.9%	5.8%	5.3%
Bartonella vinsonii IgM	7.1%	6.0%	4.4%
Bartonella quintana IgM	7.1%	5.9%	4.6%
Bartonella henselae 17 kDa IgG	7.0%	4.0%	6.9%

Complex Precision (Reproducibility)	Sample 1	Sample 2	Sample 3
Bartonella henselae 26 kDa IgG	5.9%	7.0%	5.1%
Bartonella henselae SucB IgG	7.6%	4.1%	5.7%
Bartonella elizabethae IgG	9.6%	6.5%	5.6%
Bartonella vinsonii IgG	6.7%	7.0%	5.1%
Bartonella quintana IgG	6.7%	5.1%	5.3%
Anaplasma phagocytophilum Msp5 IgM	7.8%	6.3%	5.0%
Anaplasma phagocytophilum Msp2 (p44) IgM	8.0%	4.4%	6.4%
Anaplasma phagocytophilum OmpA IgM	4.4%	4.4%	3.9%
Anaplasma phagocytophilum Msp5 IgG	6.8%	4.5%	7.3%
Anaplasma phagocytophilum Msp2 (p44) IgG	6.3%	4.8%	5.6%
Anaplasma phagocytophilum OmpA IgG	4.6%	4.9%	4.5%
Ehrlichia chaffeensis IgM	6.5%	5.8%	5.8%
Ehrlichia chaffeensis IgG	6.5%	6.2%	5.3%
Rickettsia typhi OmpB IgM	7.1%	6.8%	5.0%
Rickettsia typhi Surface antigen IgM	5.8%	4.6%	5.3%
Rickettsia typhi OmpB IgG	7.7%	4.7%	6.0%
Rickettsia typhi Surface antigen IgG	7.8%	6.5%	3.6%
Powassan Virus IgM	8.0%	4.1%	3.8%
Powassan Virus IgG	6.3%	7.4%	4.3%
Tickborne Encephalitis Virus IgM	5.2%	4.4%	5.2%
Tickborne Encephalitis Virus IgG	6.9%	6.8%	4.1%
West Nile Virus IgM	6.4%	4.9%	5.6%
West Nile Virus IgG	6.4%	4.9%	4.9%
Chlamydophila pneumoniae IgM	6.6%	6.6%	4.8%
Chlamydophila pneumoniae IgG	6.3%	3.2%	5.7%
Coxsackie Virus IgM	5.8%	4.7%	6.1%
Coxsackie Virus IgG	7.6%	4.8%	5.3%
Parvovirus B19 VLP VP2 IgM	6.4%	4.1%	5.7%
Parvovirus B19 VLP VP1/Vp2 Co Capsid IgM	8.7%	7.7%	5.0%
Parvovirus B19 VLP VP2 IgG	7.8%	5.0%	5.5%
Parvovirus B19 VLP VP1/Vp2 Co Capsid IgG	5.5%	6.2%	4.9%
Mycoplasma pneumoniae IgM	8.8%	5.2%	4.4%
Mycoplasma pneumoniae IgG	7.1%	4.8%	5.3%
Toxoplasma gondii Crude Extract IgM	7.4%	5.6%	5.9%
Toxoplasma gondii MIC3 IgM	7.3%	5.4%	6.6%
Toxoplasma gondii p24 IgM	7.5%	4.1%	6.1%
Toxoplasma gondii p29 IgM	6.5%	5.9%	6.1%
Toxoplasma gondii p30 IgM	6.5%	5.9%	4.8%
Toxoplasma gondii Crude Extract IgG	7.2%	5.1%	3.9%
Toxoplasma gondii MIC3 IgG	6.4%	5.1%	6.5%

Complex Precision (Reproducibility)	Sample 1	Sample 2	Sample 3
Toxoplasma gondii p24 IgG	7.9%	6.3%	5.0%
Toxoplasma gondii p29 IgG	5.2%	4.1%	6.5%
Toxoplasma gondii p30 IgG	8.2%	6.9%	5.2%

B. Analytical Specificity

An interfering substances study was conducted to evaluate the potential interference of specific endogenous and exogenous substances with Tickborne Diseases Antibody Panel kit. No interference was observed with any of the substances tested. The substances and the maximum levels tested are shown in the table below:

Substance	Concentration
Bilirubin	40 mg/dl
Cholesterol	500 mg/dl
Triglycerides	1000 mg/dl
Rheumatoid Factor (RF)	2000 IU/ml
Cholesterol	100 mg/ml
EDTA	50 mg/ml

C. Reference Range and Interpretation

Calibration - The calibrator within this test system has been assigned a Correction Factor (CF) for the generation of calibrator value and the unit values. Based on testing of specimens, a maximum normal unit value has been determined and correlated to the calibrator.

Calculation - All calculations are based on raw signal intensity. The cutoff value is determined for positive samples and correlated it to the calibrator to determine the Correction Factor (CF). The CF allows for the determination of the cutoff value for positive samples. It will also correct for slight day-to-day variations in test results. The CF is determined individually for each different lot of components. To obtain the cutoff value, CF is multiplied by the mean signal of the calibrators determined in each assay. The calculation is done automatically to determine the index value for each test in the assay system.

Reference Ranges - Reference ranges have been established using a sample cohort comprising of 300 samples for each antigen tested. The upper 97.5% percentile and upper 99% percentile were calculated for each analyte and was set to 10 units and 20 units respectively.

Interpretations - Index values for all analytes are interpreted as follows-

Result	Index Value (units)
Negative	0 - 10
Borderline/Moderate	10.1 - 20
Positive	20.1 - 30

Tickborne Panel Interpretation

Test interpretation for Borrelia burgdorferi based on multiple bands is reported according to the CDC/IDSA criteria as well as Alternate criteria established by running clinical samples.

By CDC criteria Lyme IgM is reported positive if VlsE1 or C6 peptide or WCS (Whole cell sonicate) is positive and two of the following three antigens are positive: 23-25kDa, 39kDa and 41kDa. In the alternate criteria IgM is reported positive if VlsE1 or C6 peptide or WCS (Whole cell sonicate) is borderline or positive and any two of the following antigens are borderline or positive: 23-25kDa, 31kDa, 34kDa, 39kDa, 41kDa and 83-93kDa.

Similarly, by CDC criteria Lyme IgG is reported positive if VlsE1 or C6 peptide or WCS (Whole cell sonicate) is positive and any five of the following ten antigens are positive: 18kDa, 23-25kDa, 28kDa, 30kDa, 39kDa, 41kDa, 45kDa, 58kDa, 66kDa and 83-93kDa. In the alternate criteria IgG is reported positive if VlsE1 or C6 peptide or WCS is borderline or positive and two of the following antigens are borderline or positive: 18kDa, 23-25kDa, 28kDa, 30kDa, 31kDa, 34kDa, 39kDa, 41kDa, 45kDa, 58kDa, 66kDa and 83-93kDa.

The alternate criteria was established using a training set of 90 Lyme positive samples and 196 negative samples. ROC curve was established for each antigen and the ones with highest sensitivity and specificity were used to setup the alternate criteria. This criteria was then verified and validated using a large clinical sample cohort detailed in the clinical study section of this report.

D. Accuracy/Trueness

A method comparison study was performed using a panel of 100 samples with known results for each antigen tested. The comparison methods included ELISA, Western Blot and specific antibodies to all antigens tested. Results obtained are as follows-

Test Name	N Positive	N Negative	Overall Agreement (%)
Borrelia burgdorferi VlsE1 IgM	43	57	100%
Borrelia burgdorferi C6 peptide IgM	32	68	100%
Borrelia burgdorferi p18 (DbpB) IgM	53	47	100%
Borrelia burgdorferi p23-25 (OspC) IgM	46	54	100%
Borrelia burgdorferi p28 IgM	37	63	100%
Borrelia burgdorferi p30 IgM	44	56	100%
Borrelia burgdorferi p31 (OspA) IgM	37	63	100%
Borrelia burgdorferi p34 (OspB) IgM	49	51	100%
Borrelia burgdorferi p39 (BmpA) IgM	41	59	100%
Borrelia burgdorferi p41 IgM	42	58	100%
Borrelia burgdorferi p45 IgM	47	53	100%
Borrelia burgdorferi p58 IgM	39	61	100%
Borrelia burgdorferi p66 IgM	40	60	99%
Borrelia burgdorferi p83-93 IgM	45	55	100%

Test Name	N Positive	N Negative	Overall Agreement (%)
Borrelia burgdoferi B31 WCS IgM	38	62	100%
Borrelia burgdoferi 297 WCS IgM	49	51	100%
Borrelia mayonii IgM	34	66	100%
Borrelia afzelii BmpA IgM	41	59	100%
Borrelia afzelii DbpA IgM	43	57	100%
Borrelia afzelii OspA IgM	51	49	100%
Borrelia afzelii OspC IgM	38	62	100%
Borrelia afzelii p100 IgM	43	57	100%
Borrelia garinii DbpA IgM	50	50	100%
Borrelia garinii OspC IgM	44	56	100%
Borrelia bavariensis DbpA IgM	38	62	98%
Borrelia bavariensis p58 IgM	49	51	100%
Borrelia bavariensis VlsE1 IgM	45	55	100%
Borrelia spielmanii DbpA IgM	44	56	100%
Borrelia spielmanii OspC IgM	51	49	100%
Borrelia burgdorferi VlsE1 IgG	47	53	100%
Borrelia burgdorferi C6 peptide IgG	43	57	100%
Borrelia burgdorferi p18 (DbpB) IgG	37	63	100%
Borrelia burgdorferi p23-25 (OspC) IgG	33	67	100%
Borrelia burgdorferi p28 IgG	46	54	100%
Borrelia burgdorferi p30 IgG	41	59	100%
Borrelia burgdorferi p31 (OspA) IgG	34	66	100%
Borrelia burgdorferi p34 (OspB) IgG	51	49	100%
Borrelia burgdorferi p39 (BmpA) IgG	39	61	100%
Borrelia burgdorferi p41 IgG	33	67	100%
Borrelia burgdorferi p45 IgG	47	53	100%
Borrelia burgdorferi p58 IgG	48	52	100%
Borrelia burgdorferi p66 IgG	52	48	100%
Borrelia burgdorferi p83-93 IgG	32	68	100%
Borrelia burgdoferi B31 WCS IgG	38	62	100%
Borrelia burgdoferi 297 WCS IgG	45	55	100%
Borrelia mayonii IgG	33	67	100%
Borrelia afzelii BmpA IgG	44	56	100%
Borrelia afzelii DbpA IgG	47	53	98%
Borrelia afzelii OspA IgG	32	68	100%
Borrelia afzelii OspC IgG	50	50	100%
Borrelia afzelii p100 IgG	50	50	100%
Borrelia garinii DbpA IgG	41	59	100%
Borrelia garinii OspC IgG	37	63	100%
Borrelia bavariensis DbpA IgG	39	61	100%

Test Name	N Positive	N Negative	Overall Agreement (%)
Borrelia bavariensis p58 IgG	36	64	100%
Borrelia bavariensis VlsE1 IgG	44	56	100%
Borrelia spielmanii DbpA IgG	50	50	100%
Borrelia spielmanii OspC IgG	53	47	100%
Borrelia andersonii IgM	40	60	100%
Borrelia maritima IgM	49	51	100%
Borrelia californiensis IgM	47	53	100%
Borrelia bissettiae IgM	53	47	100%
Borrelia lusitaniae IgM	47	53	99%
Borrelia valaisiana IgM	37	63	100%
Borrelia yangtzensis IgM	32	68	100%
Borrelia turcica IgM	41	59	100%
Borrelia andersonii IgG	47	53	100%
Borrelia maritima IgG	38	62	100%
Borrelia californiensis IgG	48	52	100%
Borrelia bissettiae IgG	42	58	100%
Borrelia lusitaniae IgG	33	67	100%
Borrelia valaisiana IgG	45	55	100%
Borrelia yangtzensis IgG	42	58	100%
Borrelia turcica IgG	35	65	100%
Borrelia hermsii IgM	48	52	100%
Borrelia turicatae IgM	53	47	100%
Borrelia hermsii IgG	43	57	100%
Borrelia turicatae IgG	51	49	99%
Borrelia miyamotoi IgM	40	60	100%
Borrelia miyamotoi IgG	38	62	100%
Babesia microti IRA IgM	42	58	100%
Babesia microti p32 IgM	32	68	100%
Babesia microti p41 IgM	35	65	100%
Babesia microti WCS IgM	44	56	100%
Babesia duncani IgM	34	66	100%
Babesia microti IRA IgG	50	50	100%
Babesia microti p32 IgG	37	63	100%
Babesia microti p41 IgG	36	64	100%
Babesia microti WCS IgG	48	52	100%
Babesia duncani IgG	48	52	100%
Bartonella henselae 17 kDa IgM	49	51	100%
Bartonella henselae 26 kDa IgM	37	63	100%
Bartonella henselae SucB IgM	50	50	100%
Bartonella elizabethae IgM	47	53	100%

Test Name	N Positive	N Negative	Overall Agreement (%)
Bartonella vinsonii IgM	47	53	100%
Bartonella quintana IgM	39	61	100%
Bartonella henselae 17 kDa IgG	34	66	100%
Bartonella henselae 26 kDa IgG	40	60	100%
Bartonella henselae SucB IgG	49	51	100%
Bartonella elizabethae IgG	45	55	100%
Bartonella vinsonii IgG	41	59	100%
Bartonella quintana IgG	53	47	100%
Anaplasma phagocytophilum Msp5 IgM	38	62	100%
Anaplasma phagocytophilum Msp2 (p44) IgM	37	63	100%
Anaplasma phagocytophilum OmpA IgM	38	62	100%
Anaplasma phagocytophilum Msp5 IgG	47	53	100%
Anaplasma phagocytophilum Msp2 (p44) IgG	40	60	100%
Anaplasma phagocytophilum OmpA IgG	51	49	100%
Ehrlichia chaffeensis IgM	46	54	100%
Ehrlichia chaffeensis IgG	50	50	100%
Rickettsia typhi OmpB IgM	43	57	100%
Rickettsia typhi Surface antigen IgM	50	50	100%
Rickettsia typhi OmpB IgG	32	68	100%
Rickettsia typhi Surface antigen IgG	44	56	100%
Powassan Virus IgM	34	66	100%
Powassan Virus IgG	51	49	100%
Tickborne Encephalitis Virus IgM	32	68	100%
Tickborne Encephalitis Virus IgG	40	60	100%
West Nile Virus IgM	38	62	100%
West Nile Virus IgG	48	52	100%
Chlamydophila pneumoniae IgM	38	62	100%
Chlamydophila pneumoniae IgG	37	63	100%
Coxsackie Virus IgM	40	60	100%
Coxsackie Virus IgG	42	58	100%
Parvovirus B19 VLP VP2 IgM	52	48	100%
Parvovirus B19 VLP VP1/Vp2 Co Capsid IgM	45	55	99%
Parvovirus B19 VLP VP2 IgG	33	67	100%
Parvovirus B19 VLP VP1/Vp2 Co Capsid IgG	40	60	100%
Mycoplasma pneumoniae IgM	49	51	100%
Mycoplasma pneumoniae IgG	40	60	100%
Toxoplasma gondii Crude Extract IgM	36	64	100%
Toxoplasma gondii MIC3 IgM	47	53	100%
Toxoplasma gondii p24 IgM	35	65	100%
Toxoplasma gondii p29 IgM	53	47	100%

Test Name	N Positive	N Negative	Overall Agreement (%)
Toxoplasma gondii p30 IgM	50	50	100%
Toxoplasma gondii Crude Extract IgG	48	52	98%
Toxoplasma gondii MIC3 IgG	53	47	100%
Toxoplasma gondii p24 IgG	43	57	100%
Toxoplasma gondii p29 IgG	42	58	100%
Toxoplasma gondii p30 IgG	50	50	100%

E. Matrix Comparison Study

The purpose of this study was to compare two methods for blood collection (venipuncture and finger prick) and three sample matrices (serum, blood and DBS) that can be used in Vibrant Tickborne Diseases Panel testing. A matched set of 180 samples which includes 1 serum (SST), 1 blood (EDTA) and 1 dried blood (DBS) for each sample were tested on the Vibrant Tickborne Diseases Panel to evaluate the matrix effects and the results are summarized below:

Test Name	SST vs EDTA		SST vs DBS	
	Slope	Cor. (R2)	Slope	Cor. (R2)
Borrelia burgdorferi VlsE1 IgM	0.92	0.95	0.98	0.97
Borrelia burgdorferi C6 peptide IgM	1.06	0.99	1.09	0.96
Borrelia burgdorferi p18 (DbpB) IgM	1.09	0.95	0.96	0.98
Borrelia burgdorferi p23-25 (OspC) IgM	0.94	0.99	1.05	0.97
Borrelia burgdorferi p28 IgM	1.05	0.96	1.08	0.99
Borrelia burgdorferi p30 IgM	0.95	0.95	0.94	0.99
Borrelia burgdorferi p31 (OspA) IgM	1.02	0.98	0.99	0.95
Borrelia burgdorferi p34 (OspB) IgM	0.99	0.97	0.97	0.99
Borrelia burgdorferi p39 (BmpA) IgM	1.03	0.96	1.02	0.96
Borrelia burgdorferi p41 IgM	1.03	0.96	1.03	0.99
Borrelia burgdorferi p45 IgM	0.95	0.96	1.06	0.99
Borrelia burgdorferi p58 IgM	1.05	0.95	0.94	0.96
Borrelia burgdorferi p66 IgM	0.96	0.95	0.97	0.99
Borrelia burgdorferi p83-93 IgM	1.07	0.95	1.06	0.98
Borrelia burgdoferi B31 WCS IgM	0.98	0.98	0.98	0.97
Borrelia burgdoferi 297 WCS IgM	0.99	0.96	1.09	0.99
Borrelia mayonii IgM	0.94	0.95	0.97	0.99
Borrelia afzelii BmpA IgM	1.01	0.95	1.03	0.97
Borrelia afzelii DbpA IgM	0.98	0.96	0.92	0.95
Borrelia afzelii OspA IgM	0.92	0.96	1.06	0.97
Borrelia afzelii OspC IgM	1.03	0.99	0.96	0.97
Borrelia afzelii p100 IgM	1.03	0.99	1.04	0.97
Borrelia garinii DbpA IgM	0.98	0.99	0.93	0.99

Test Name	SST vs EDTA		SST vs DBS	
	Slope	Cor. (R2)	Slope	Cor. (R2)
Borrelia garinii OspC IgM	1.04	0.99	0.98	0.95
Borrelia bavariensis DbpA IgM	1.06	0.96	1.09	0.96
Borrelia bavariensis p58 IgM	1.05	0.98	0.96	0.99
Borrelia bavariensis VlsE1 IgM	0.93	0.98	1.04	0.99
Borrelia spielmanii DbpA IgM	1.09	0.98	1.01	0.98
Borrelia spielmanii OspC IgM	0.93	0.96	1.02	0.96
Borrelia burgdorferi VlsE1 IgG	0.94	0.97	0.94	0.99
Borrelia burgdorferi C6 peptide IgG	0.93	0.95	0.97	0.95
Borrelia burgdorferi p18 (DbpB) IgG	0.95	0.98	0.99	0.95
Borrelia burgdorferi p23-25 (OspC) IgG	1.04	0.99	1.05	0.99
Borrelia burgdorferi p28 IgG	1.06	0.95	1.07	0.97
Borrelia burgdorferi p30 IgG	0.94	0.99	0.99	0.96
Borrelia burgdorferi p31 (OspA) IgG	0.94	0.99	0.93	0.97
Borrelia burgdorferi p34 (OspB) IgG	0.97	0.95	0.98	0.97
Borrelia burgdorferi p39 (BmpA) IgG	1.03	0.97	0.99	0.95
Borrelia burgdorferi p41 IgG	1.04	0.99	1.02	0.98
Borrelia burgdorferi p45 IgG	0.94	0.99	1.04	0.96
Borrelia burgdorferi p58 IgG	1.05	0.96	1.03	0.97
Borrelia burgdorferi p66 IgG	1.02	0.98	1.00	0.96
Borrelia burgdorferi p83-93 IgG	0.99	0.99	0.91	0.96
Borrelia burgdoferi B31 WCS IgG	1.00	0.99	0.92	0.95
Borrelia burgdoferi 297 WCS IgG	0.91	0.96	1.00	0.95
Borrelia mayonii IgG	1.09	0.96	0.99	0.98
Borrelia afzelii BmpA IgG	1.07	0.99	1.03	0.99
Borrelia afzelii DbpA IgG	0.93	0.97	1.03	0.96
Borrelia afzelii OspA IgG	1.03	0.97	0.95	0.99
Borrelia afzelii OspC IgG	0.98	0.98	0.95	0.96
Borrelia afzelii p100 IgG	0.95	0.99	1.09	0.95
Borrelia garinii DbpA IgG	1.02	0.97	1.01	0.98
Borrelia garinii OspC IgG	0.96	0.99	1.03	0.99
Borrelia bavariensis DbpA IgG	1.01	0.98	1.00	0.95
Borrelia bavariensis p58 IgG	0.97	0.95	1.08	0.99
Borrelia bavariensis VlsE1 IgG	1.07	0.96	1.09	0.96
Borrelia spielmanii DbpA IgG	1.02	0.97	1.07	0.97
Borrelia spielmanii OspC IgG	1.03	0.98	1.03	0.98
Borrelia andersonii IgM	0.93	0.98	1.01	0.96
Borrelia maritima IgM	1.09	0.99	1.02	0.95
Borrelia californiensis IgM	0.91	0.95	0.99	0.96
Borrelia bissettiae IgM	1.08	0.96	0.97	0.97

Test Name	SST vs EDTA		SST vs DBS	
	Slope	Cor. (R2)	Slope	Cor. (R2)
Borrelia lusitaniae IgM	0.97	0.95	1.03	0.96
Borrelia valaisiana IgM	1.00	0.97	1.02	0.99
Borrelia yangtzensis IgM	0.96	0.97	0.93	0.95
Borrelia turcica IgM	0.91	0.97	1.01	0.95
Borrelia andersonii IgG	1.07	0.98	0.98	0.96
Borrelia maritima IgG	1.05	0.96	1.04	0.98
Borrelia californiensis IgG	1.02	0.97	0.99	0.96
Borrelia bissettiae IgG	0.94	0.95	0.92	0.99
Borrelia lusitaniae IgG	1.05	0.98	0.95	0.96
Borrelia valaisiana IgG	0.91	0.98	0.95	0.99
Borrelia yangtzensis IgG	1.05	0.98	0.99	0.97
Borrelia turcica IgG	1.07	0.97	1.07	0.98
Borrelia hermsii IgM	1.04	0.97	1.03	0.97
Borrelia turicatae IgM	1.09	0.97	1.04	0.95
Borrelia hermsii IgG	1.09	0.98	1.05	0.97
Borrelia turicatae IgG	0.91	0.97	1.09	0.97
Borrelia miyamotoi IgM	0.92	0.95	1.05	0.98
Borrelia miyamotoi IgG	1.07	0.97	0.98	0.95
Babesia microti IRA IgM	1.08	0.99	1.05	0.96
Babesia microti p32 IgM	0.95	0.98	0.92	0.97
Babesia microti p41 IgM	1.05	0.99	1.04	0.96
Babesia microti WCS IgM	1.08	0.97	0.91	0.99
Babesia duncani IgM	1.09	0.99	0.97	0.98
Babesia microti IRA IgG	0.91	0.99	1.03	0.99
Babesia microti p32 IgG	1.08	0.96	0.95	0.98
Babesia microti p41 IgG	1.01	0.98	1.03	0.95
Babesia microti WCS IgG	0.94	0.99	0.95	0.99
Babesia duncani IgG	0.96	0.95	0.93	0.95
Bartonella henselae 17 kDa IgM	1.06	0.96	1.04	0.98
Bartonella henselae 26 kDa IgM	1.05	0.96	1.02	0.95
Bartonella henselae SucB IgM	1.02	0.99	1.06	0.99
Bartonella elizabethae IgM	0.96	0.98	0.99	0.95
Bartonella vinsonii IgM	1.07	0.99	1.09	0.96
Bartonella quintana IgM	0.91	0.97	0.92	0.96
Bartonella henselae 17 kDa IgG	0.98	0.95	1.00	0.99
Bartonella henselae 26 kDa IgG	1.01	0.97	1.04	0.95
Bartonella henselae SucB IgG	0.94	0.98	1.04	0.96
Bartonella elizabethae IgG	1.03	0.95	0.92	0.97
Bartonella vinsonii IgG	1.03	0.95	1.05	0.97

Test Name	SST vs EDTA		SST vs DBS	
	Slope	Cor. (R2)	Slope	Cor. (R2)
Bartonella quintana IgG	0.93	0.97	0.91	0.95
Anaplasma phagocytophilum Msp5 IgM	1.08	0.95	1.05	0.95
Anaplasma phagocytophilum Msp2 (p44) IgM	1.00	0.98	1.04	0.95
Anaplasma phagocytophilum OmpA IgM	0.97	0.95	1.07	0.96
Anaplasma phagocytophilum Msp5 IgG	1.09	0.97	0.96	0.97
Anaplasma phagocytophilum Msp2 (p44) IgG	0.97	0.95	1.02	0.98
Anaplasma phagocytophilum OmpA IgG	0.94	0.99	0.99	0.97
Ehrlichia chaffeensis IgM	0.96	0.95	1.07	0.96
Ehrlichia chaffeensis IgG	1.00	0.95	1.01	0.99
Rickettsia typhi OmpB IgM	1.06	0.96	1.08	0.97
Rickettsia typhi Surface antigen IgM	1.08	0.97	0.94	0.97
Rickettsia typhi OmpB IgG	1.03	0.98	1.09	0.95
Rickettsia typhi Surface antigen IgG	0.92	0.99	1.02	0.95
Powassan Virus IgM	0.94	0.99	1.08	0.95
Powassan Virus IgG	1.04	0.96	0.97	0.96
Tickborne Encephalitis Virus IgM	0.98	0.96	1.05	0.97
Tickborne Encephalitis Virus IgG	0.96	0.98	0.94	0.96
West Nile Virus IgM	1.05	0.98	0.95	0.97
West Nile Virus IgG	1.05	0.98	1.07	0.98
Chlamydophila pneumoniae IgM	1.06	0.97	1.02	0.96
Chlamydophila pneumoniae IgG	0.92	0.99	1.08	0.98
Coxsackie Virus IgM	0.98	0.97	1.01	0.99
Coxsackie Virus IgG	1.04	0.96	1.03	0.95
Parvovirus B19 VLP VP2 IgM	1.02	0.96	1.03	0.99
Parvovirus B19 VLP VP1/Vp2 Co Capsid IgM	1.07	0.99	0.95	0.97
Parvovirus B19 VLP VP2 IgG	0.95	0.97	0.99	0.99
Parvovirus B19 VLP VP1/Vp2 Co Capsid IgG	1.00	0.97	0.92	0.97
Mycoplasma pneumoniae IgM	1.01	0.99	1.01	0.95
Mycoplasma pneumoniae IgG	0.97	0.95	1.00	0.98
Toxoplasma gondii Crude Extract IgM	1.05	0.96	1.03	0.97
Toxoplasma gondii MIC3 IgM	1.09	0.99	1.01	0.96
Toxoplasma gondii p24 IgM	0.98	0.95	1.08	0.98
Toxoplasma gondii p29 IgM	0.92	0.97	0.98	0.98
Toxoplasma gondii p30 IgM	0.96	0.96	1.02	0.97
Toxoplasma gondii Crude Extract IgG	1.05	0.96	0.95	0.98
Toxoplasma gondii MIC3 IgG	1.04	0.99	1.06	0.95
Toxoplasma gondii p24 IgG	1.04	0.97	0.91	0.97
Toxoplasma gondii p29 IgG	0.98	0.96	0.97	0.95
Toxoplasma gondii p30 IgG	0.96	0.96	0.98	0.97

F. Clinical Study

The clinical study tested a panel of 1052 clinical samples which includes Lyme disease samples along with disease control and healthy control samples. Clinical sensitivity and clinical specificity were calculated and are summarized below.

Disease	Number of samples
Lyme disease	398
Fibromyalgia	26
Rheumatoid arthritis	26
Mononucleosis	17
Syphilis	35
Multiple Sclerosis	30
Severe periodontitis	13
Healthy endemic	238
Healthy non-endemic	269

Disease	CDC Criteria Sensitivity	CDC Criteria Specificity	Alternate Criteria Sensitivity	Alternate Criteria Specificity
Lyme disease	70.40%	N/A	100%	N/A
Fibromyalgia	N/A	100%	N/A	100%
Rheumatoid arthritis	N/A	100%	N/A	100%
Mononucleosis	N/A	100%	N/A	100%
Syphilis	N/A	97.10%	N/A	94.30%
Multiple Sclerosis	N/A	100%	N/A	100%
Severe periodontitis	N/A	100%	N/A	100%
Healthy endemic	N/A	100%	N/A	100%
Healthy non-endemic	N/A	100%	N/A	100%
OVERALL	**70.40%**	**99.80%**	**100%**	**99.70%**

4 Conclusion

This report documents the process results and process parameters obtained during the validation of the standard operating procedure for Vibrant Tickborne Diseases Antibody Panel assay. All validation test results meet their required specifications set by the laboratory.