Tickborne

VibrantWellness
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Final Report Date:	10-01-2018 15:47	**Specimen Collected:**	09-30-2018 15:47
Accession ID:	1810010044	**Specimen Received:**	10-01-2018 09:47

LAST NAME	FIRST NAME	MIDDLE NAME	GENDER	DATE OF BIRTH	ACCESSION ID
LYME TBRF	DEMO		MALE	1996-04-19	1810010044

PATIENT

Name: DEMO LYME TBRF
Date of Birth: 1996-04-19
Gender: Male
Age: 22
Height: 6'1" Weight: 169.0 lbs

Telephone #: 666-666-8888
Street Address: 1021 HOWARD AVENUE SUITE B
City: SAN CARLOS
State: CA Zip #: 94070
Email: demo@demo.com

Fasting: FASTING

PROVIDER

Practice Name: Demo Client, MD
Provider Name: Demo Client, MD (999994)
Street Address: 1021 HOWARD AVENUE
City: SAN CARLOS
State: CA
Zip #: 94070
Telephone #: 800-842-7268
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Your **Vibrant Wellness TickBorne Diseases panel** results are enclosed. These results are intended to help you make healthy lifestyle and dietary choices in consultation with your healthcare provider. It is intended to be used as a tool to encourage informed nutritional and health changes.

The Vibrant TickBorne Diseases panel tests for IgG and IgM antibodies for Borreliosis/Lyme disease as well as co-infection(s) with other tick-borne illnesses along with detection of DNA of the species causing these infections. The Vibrant Immunochip test is a qualitative and semiquantitative assay that detects IgG and IgM antibodies in human serum. The PCR Test is a real-time PCR Assay designed for qualitative detection of infectious group- specific DNA in clinical samples.

Interpretation of Report: The test results of antibody levels to the individual antigens are calculated by comparing the average intensity of the individual antibody to that of a reference population and cut-off chosen for each protein. Reference ranges have been established using a well characterized set of 188 serum samples and antibodies to specific bacteria tested. The results are displayed as In Control, Moderate, or High Risk for each antigen tested. The PCR panel reports results as Detected or Not Detected for each species tested.Interpretation for the results is obtained by using all the antigens tested and provided below the panel results. As with all testing, results should be interpreted in light of a patient's history, physical examination, and/or results of other diagnostic testing.

The Vibrant Wellness platform provides tools for you to track and analyze your general wellness profile. Testing for the TickBorne Diseases panel is performed by Vibrant America, a CLIA certified lab CLIA#:05D2078809 and Vibrant Genomics LLC, a CLIA certified lab CLIA# 05D2098445. Vibrant Wellness provides and makes available this report and any related services pursuant to the Terms of Use Agreement (the "Terms") on its website at www.vibrant-wellness.com. By accessing, browsing, or otherwise using the report or website or any services, you acknowledge that you have read, understood, and agree to be bound by these terms. If you do not agree to accept these terms, you shall not access, browse or use the report or website. The statements in this report have not been evaluated by the Food and Drug Administration and are only meant to be lifestyle choices for potential risk mitigation. Please consult your physician for medication, treatment, or lifestyle management. This product is not intended to diagnose, treat, or cure any disease.

Comments provided by Vibrant Wellness are for educational purposes only and not intended to be used as or substituted for medical advice. We do not treat or cure medical conditions. Vibrant Wellness does not replace the care of a medical practitioner or counselor and does not recommend self- diagnosis or self- medication. Depending on the nature of your testing, if you receive a high risk or moderate risk result, confirmatory testing may be recommended and you will be encouraged to seek medical attention for additional follow up. Vibrant Wellness does not provide clinical consultations for Lyme Disease treatments.
Vibrant Wellness shall not be liable to you or anyone else for loss or injury caused in whole or part by procuring, compiling, interpreting, delivering, or reporting information through this report. Also, in no event shall Vibrant Wellness be held liable to you or anyone else for any decisions made or action taken or not taken by you in reliance on such information.

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Borreliosis

Borreliosis is caused by two groups of Borrelia: Borrelia burgdorferi group and the Tick-Borne Relapsing Fever (TBRF) Borrelia group.

The Vibrant Lyme Immunochip test is a qualitative and semi-quantitative assay that detects Borrelia burgdorferi in human serum. The assay is designed to detect IgG and IgM antibodies to major Borrelia burgdorferi sensu lato specific antigens, including Borrelia burgdorferi B31, Borrelia burgdorferi 297, Borrelia afzelii, Borrelia garinii, Borrelia spielmanii, and Borrelia valaisiana. The Lyme PCR test is a real-time PCR assay designed for qualitative detection of Borrelia burgdorferi group specific DNA, including Borrelia mayonii and Borrelia andersonii in clinical samples.

The Vibrant TBRF Immunochip test is a qualitative and semi-quantitative assay that detects TBRF-related Borrelia IgG and IgM antibodies in human serum. The TBRF PCR test is a real-time PCR assay designed for qualitative detection of TBRF Borrelia group specific DNA in clinical samples. The TBRF group includes B. miyamotoi, B. hermsii, B. coriaceae, B. lonestari and B. anserine, etc

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Lyme Immunochip IgM

Test name	In Control ≤10.0	Moderate 10.1~20.0	High Risk ≥20.1	Previous (09/01/2018)
Borrelia burgdorferi VlsE1 IgM (kU/L)	1.5			3.9
Borrelia burgdorferi C6 peptide IgM (kU/L)	0.4			0.9
Borrelia burgdorferi spp. 18 kDa IgM (kU/L)	0.6			4.1
Borrelia burgdorferi spp. 23-25 kDa IgM (kU/L)	1.8			2.6
Borrelia burgdorferi spp. 28 kDa IgM (kU/L)	4.3			3.3
Borrelia burgdorferi spp. 30 kDa IgM (kU/L)	0.6			5.1
Borrelia burgdorferi spp. 31 kDa IgM (kU/L)	0.7			2.4
Borrelia burgdorferi spp. 34 kDa IgM (kU/L)	0.6			2.2
Borrelia burgdorferi spp. 39 kDa IgM (kU/L)	0.9			3.2
Borrelia burgdorferi spp. 41 kDa IgM (kU/L)	0.6			1.6
Borrelia burgdorferi spp. 45 kDa IgM (kU/L)	0.6			1.5
Borrelia burgdorferi spp. 58 kDa IgM (kU/L)	1.0			1.9
Borrelia burgdorferi spp. 66 kDa IgM (kU/L)	0.4			1.4
Borrelia burgdorferi spp. 83-93 kDa IgM (kU/L)	0.2			0.6

Test Interpretation

By CDC criteria, Lyme IgM is reported positive if VlsE1 or C6 peptide is positive and two of the following three antigens are positive: 23-25, 39 and 41 kDa.
By Vibrant criteria, Lyme IgM is reported positive if VlsE1 or C6 peptide is borderline or positive and two of the following antigens are borderline or positive: 23-25, 31, 34, 39, 41 and 83-93 kDa. Lyme IgM is reported as indeterminate if VlsE1 or C6 peptide is borderline or positive and if one of the following antigens are borderline or positive: 23-25, 31, 34, 39, 41 and 83-93 kDa. This interpretation is based on internal validation studies.

Test Name	Current	Previous (09/01/2018)	Comment
CDC Lyme IgM Result	NEGATIVE	NEGATIVE	
Vibrant Lyme IgM Result	NEGATIVE	NEGATIVE	

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Lyme Immunochip IgG

Test name	In Control ≤10.0	Moderate 10.1~20.0	High Risk ≥20.1	Previous (09/01/2018)
Borrelia burgdorferi VlsE1 IgG (kU/L)	1.5			1.4
Borrelia burgdorferi C6 peptide IgG (kU/L)			>30.0	2.5
Borrelia burgdorferi spp. 18 kDa IgG (kU/L)			20.6	7.6
Borrelia burgdorferi spp. 23-25 kDa IgG (kU/L)			25.4	8.9
Borrelia burgdorferi spp. 28 kDa IgG (kU/L)			20.5	6.0
Borrelia burgdorferi spp. 30 kDa IgG (kU/L)	6.7			4.1
Borrelia burgdorferi spp. 31 kDa IgG (kU/L)	4.3			1.9
Borrelia burgdorferi spp. 34 kDa IgG (kU/L)	3.4			2.4
Borrelia burgdorferi spp. 39 kDa IgG (kU/L)	6.7			4.5
Borrelia burgdorferi spp. 41 kDa IgG (kU/L)			26.1	8.1
Borrelia burgdorferi spp. 45 kDa IgG (kU/L)	3.3			3.6
Borrelia burgdorferi spp. 58 kDa IgG (kU/L)			21.4	7.8
Borrelia burgdorferi spp. 66 kDa IgG (kU/L)	8.5			3.5
Borrelia burgdorferi spp. 83-93 kDa IgG (kU/L)	5.8			4.6

Test Interpretation

By CDC criteria, Lyme IgG is reported positive if VlsE1 or C6 peptide is positive and five of the following ten antigens are positive: 18, 23-25, 28, 30, 39, 41, 45, 58, 66, and 83-93 kDa.
By Vibrant criteria, Lyme IgG is reported positive if VlsE1 or C6 peptide is borderline or positive and two of the following antigens are borderline or positive: 23-25, 31, 34, 39, 41 and 83-93 kDa. Lyme IgG is reported as indeterminate if VlsE1 or C6 peptide is borderline or positive and if one of the following antigens are borderline or positive: 23-25, 31, 34, 39, 41 and 83-93 kDa. This interpretation is based on internal validation studies.

Test Name	Current	Previous (09/01/2018)	Comment
CDC Lyme IgG Result	POSITIVE	NEGATIVE	IgG antibodies to significant Borrelia burgdorferi proteins were detected suggestive of probable exposure.
Vibrant Lyme IgG Result	POSITIVE	NEGATIVE	

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Lyme PCR

Test Name	Current Result	Previous Result (09/01/2018)
Borrelia burgdorferi spp.	NOT DETECTED	NOT DETECTED
Borrelia afzelii	NOT DETECTED	NOT DETECTED
Borrelia garinii	NOT DETECTED	NOT DETECTED

TBRF Immunochip IgM

Test name	In Control ≤10.0	Moderate 10.1~20.0	High Risk ≥20.1	Previous (09/01/2018)
Borrelia miyamotoi IgM (kU/L)	0.4			0.8
Borrelia hermsii IgM (kU/L)	1.6			3.2
Borrelia turicatae IgM (kU/L)	0.3			2.2

Test Interpretation

By Vibrant criteria, TBRF IgM is reported positive if two TBRF-specific antigens are borderline or positive and reported as indeterminate if one TBRF-specific antigen is borderline or positive.

Test Name	Current	Previous (09/01/2018)	Comment
Vibrant TBRF IgM Result	NEGATIVE	NEGATIVE	

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TBRF Immunochip IgG

Test name	In Control ≤10.0	Moderate 10.1~20.0	High Risk ≥20.1	Previous (09/01/2018)
Borrelia miyamotoi IgG (kU/L)	2.4			1.7
Borrelia hermsii IgG (kU/L)	3.9			2.4
Borrelia turicatae IgG (kU/L)	5.2			0.6

Test Interpretation

By Vibrant criteria, TBRF IgG is reported positive if two TBRF-specific antigens are borderline or positive and reported as indeterminate if one TBRF-specific antigen is borderline or positive.

Test Name	Current	Previous (09/01/2018)	Comment
Vibrant TBRF IgG Result	NEGATIVE	NEGATIVE	

TBRF PCR

Test Name	Current Result	Previous Result (09/01/2018)
Borrelia TBRF spp.	NOT DETECTED	NOT DETECTED
Borrelia lonestari	NOT DETECTED	NOT DETECTED
Borrelia miyamotoi	NOT DETECTED	NOT DETECTED

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Risk and Limitations

Lyme Immunochip IgM

Antibiotic therapy given early in the disease may prevent the development of an antibody response. A positive result for 31 and/or 34 kDa antigens may be present in Lyme-vaccinated individuals and the use of this assay has not been evaluated for this group. Some viral and autoimmune antibodies may cross-react with 31, 41, and 83-93 kDa antigens. Lipemic, hemolyzed, bilirubinemic, or turbid samples may produce artifactual results.

Diagnosis should not be based on laboratory tests alone. Results should be interpreted in conjunction with clinical symptoms and patient history. Patients with other spirochetal disease and/or who test positive for rheumatoid factor or Epstein Barr virus may have cross-reacting antibodies and may have a positive result for 31, 41, and/or 83 kDa antigens. Positive results for 31 kDa antigens may be present after Lyme vaccination in uninfected persons. A negative Immunochip does not exclude the possibility of infection with B. burgdorferi. Vibrant interpretation is based on internal validation studies. The results of this test must be interpreted in relation to patient's clinical history, epidemiological data, stages of disease, clinical symptoms, or other laboratory results. Presence of any of the following bands: 23-25, 31, 34, 39 and 83-93 kDa as indeterminate, or if only one of these bands is present in a negative report, may have clinical significance. Therefore, we recommend retesting in 4-6 weeks.

Lyme Immunochip IgG

Positive results for 31 and/or 34 kDa may be present after Lyme vaccination in uninfected persons. A negative Lyme Immunochip IgG does not exclude the possibility of infection with B. burgdorferi. Vibrant interpretation is based on internal validation studies. The results of this test must be interpreted in relation to patient's clinical history, epidemiological data, stage of disease, clinical symptoms, or other laboratory results.

Lyme PCR

A negative PCR result does not preclude the presence of the organism or active Lyme disease. Results should be interpreted in conjunction with other laboratory and clinical findings. Test results can only help the physician in confirming clinical diagnosis.

TBRF Immunochip IgM

A positive result suggests exposure to TBRF Borrelia. A negative TBRF Immunochip does not exclude the possibility of infection with TBRF Borrelia. Vibrant interpretation is based on internal validation studies. The results of this test must be interpreted in relation to patient's clinical history, epidemiological data, stages of disease, clinical symptoms, or other laboratory results. Indeterminate result may have clinical significance. Therefore, we recommend testing with another method and/or retesting in 4-6 weeks. For diagnostic purposes, Immunochip test results should be used in conjunction with clinical symptoms and other evidence available to the diagnosing physician. If the test result is indeterminate, testing with another method or retesting in 6-8 weeks is recommended.

TBRF Immunochip IgG

A negative TBRF Immunochip does not exclude the possibility of infection with TBRF Borrelia. Vibrant interpretation is based on internal validation studies. The results of this test must be interpreted in relation to patient's clinical history, epidemiological data, stages of disease, clinical symptoms, or other laboratory results. Indeterminate result may have clinical significance. Therefore, we recommend testing with another method and/or retesting in 4-6 weeks.

TBRF PCR

Results should be interpreted in conjunction with other laboratory and clinical findings. Test results can only help the physician in confirming clinical diagnosis.

Immunochip tests were developed and their performance characteristics determined by Vibrant America Clinical Laboratory as a Lab Developed Test (LDT). PCR tests were developed and their performance characteristics determined by Vibrant Genomics as a Lab Developed Test (LDT). It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.