

556 Gibraltar Drive Milpitas, CA 95035 T: (800) 832-3200

F: (408) 935-8272

www.igenex.com

Laboratory Director: Jyotsna S. Shah, Ph.D.

CLIA: 05D0643914

CALIFORNIA: CLF 4033 NPI: 1396837605

REFERRING PHYSICIAN

TEST DOCTOR

TEST PATIENT

DOB: Gender: Accession: Patient ID:

Collected: Received: Reported: Reprinted: Amended: Corrected:

BORRELIOSIS - Lyme Disease

TEST SPECIMEN RESULT REFERENCE RANGE **UNITS**

Lyme ImmunoBlot IgG

IGX Criteria: CDC/NYS Criteria: **Positive**

Negative

[REVISED REPORT: EFFECTIVE APRIL 10, 2019]

Lyme ImmunoBlot IgG detects antibodies to B. burgdorferi strains and

species

Positive

Band (kDa)	18	23*	28	30	31*	34*	39*	41*	45	58	66	93*
Intensity	-	+	-	-	-	-	-	+	-	-	-	+

Band Intensity: Positive: + to ++++, Indeterminate: Ind, Negative: (-)

INTERPRETATION **IGX CRITERIA**

2 or more of the starred bands are present (+): 23*,

Serum

31*, 34*, 39*, 41*, 93* kDa

CDC/NYS CRITERIA

5 or more of the following bands are present (+): 18, 23*, 28, 30, 39*,

41*, 45, 58, 66, 93* kDa

Does not meet IGX criteria for a **Negative**

positive.

Does not meet CDC/NYS criteria for

a positive.

LIMITATION: Bands 31* and 34* kDa are present in Lyme vaccinated patients. Viral antibodies cross react with the 93 kDa antigen.

Testing performed at IGeneX 556 Gibraltar Drive Milpitas CA 95035 (800) 832-3200

Diagnosis should not be based on laboratory results alone. Results should be interpreted in conjunction with clinical symptoms and patient history.

NOTE: Western Blots, ImmunoBlots, Lyme Dot Blot, Epitope, PCR, IFA, FISH, C. pneumoniae IgG/IgA, CD57, IGXSpot, Broad Coverage Antibody, COVID-19 Test - These tests were developed and their performance characteristics determined by IGeneX, Inc. They have not been cleared or approved by the FDA. The FDA has determined that such approval is not necessary. These tests are used for clinical purposes and should not be regarded as investigational or for research. IGeneX, Inc. is licensed by CMS and NYS to perform high complexity clinical laboratory testing.



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TEST SPECIMEN RESULT REFERENCE RANGE **UNITS**

LYME IMMUNOBLOT IGG SPECIATION

B. burgdorferi US(genus) Positive Serum B. burgdorferi US spp Serum Negative

BbSs: Borrelia burgdorferi sensu stricto includes but not limited to

B. burgdorferi B31 and B. burgdorferi 29

BbSI: Borrelia burgdorferi sensu lato includes but not limited to B.

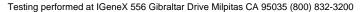
mayonii and B. californiensis.

B. burgdorferi European(genus) Serum Negative B. burgdorferi European Spp Serum Negative

Borrelia burgdorferi European species include but not limited to B. afzelii, B. garinii, B. spielmanii and B. valaisiana.

B. burgdorferi Species Serum Positive

B. burgdorferi species include but not limited to Bb B31, Bb 297, mayonii, B. californiensis, B. afzelii, B. garinii, B. spielmanii and B. valaisian



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TEST SPECIMEN RESULT REFERENCE RANGE UNITS

Lyme ImmunoBlot IgM

Serum

IGX Criteria: CDC/NYS Criteria:

Positive Positive

[REVISED REPORT: EFFECTIVE APRIL 10, 2019]

Lyme ImmunoBlot IgM detects antibodies to B. burgdorferi strains and species

Band (kDa)	31*	34*	39*	41*	93
Intensity	+	+	-	+	IND

Band Intensity: Positive: + to ++++, Indeterminate: Ind, Negative: (-)

INTERPRETATION IGX CRITERIA

CDC/NYS CRITERIA

Positive

Negative

2 or more of the starred bands are present (+): 23*, 31*, 34*, 39*, 41* kDa 2 or more of the following bands are present (+): 23*, 39*, 41* kDa

Does not meet IGX criteria for a

positive.

Does not meet CDC/NYS criteria for

a positive.

LIMITATION:

Bands 31* and 34* kDa are present in Lyme vaccinated patients. Viral

antibodies cross react with the 93 kDa antigen.



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TEST SPECIMEN RESULT REFERENCE RANGE **UNITS**

LYME IMMUNOBLOT IGM SPECIATION

B. burgdorferi US(genus) Serum Positive B. burgdorferi US Spp Serum Negative

BbSs: Borrelia burgdorferi sensu stricto includes but not limited to

B. burgdorferi B31 and B. burgdorferi 29

BbSI: Borrelia burgdorferi sensu lato includes but not limited to B. mayonii and B. californiensis.

B. burgdorferi European(genus) Positive Serum B. burgdorferi European Spp Serum Negative

Borrelia burgdorferi European species include but not limited to B. afzelii, B. garinii, B. spielmanii and B. valaisiana.

Serum B. burgdorferi Species Positive

B. burgdorferi species include but not limited to Bb B31, Bb 297, mayonii, B. californiensis, B. afzelii, B. garinii, B. spielmanii and B. valaisian

B. burgdorferi IFA - G/M/A

Serum 40 Negative: <40 Equivocal: 40

Positive: > or = 80

End of Report

Testing performed at IGeneX 556 Gibraltar Drive Milpitas CA 95035 (800) 832-3200

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