



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: *** [REVISED REPORT: EFFECTIVE APRIL 10, 2019]  Lyme ImmunoBlot IgG detects antibodies to B. burgdorferi strains and species	Serum	<b>Positive</b> Negative										
<b>Band (kDa)</b>	<b>18</b>	<b>23*</b>	<b>28</b>	<b>30</b>	<b>31*</b>	<b>34*</b>	<b>39*</b>	<b>41*</b>	<b>45</b>	<b>58</b>	<b>66</b>	<b>93*</b>
<b>Intensity</b>	-	+	-	-	-	-	-	+	-	-	-	+

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

**INTERPRETATION**

**Positive**

**Negative**

**IGX CRITERIA**

2 or more of the starred bands are present (+): 23\*, 31\*, 34\*, 39\*, 41\*, 93\* kDa

Does not meet IGX criteria for a positive.

**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 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
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**LYME IMMUNOBLOT IGG SPECIATION**

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

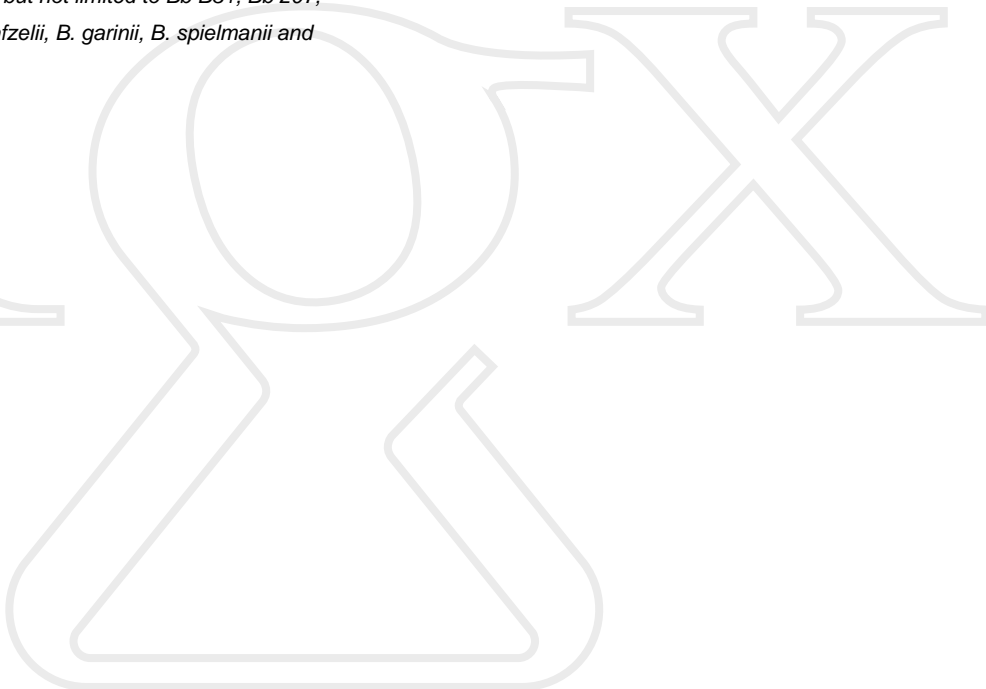
*BbSs: Borrelia burgdorferi sensu stricto includes but not limited to B. burgdorferi B31 and B. burgdorferi 29*  
*BbSl: Borrelia burgdorferi sensu lato includes but not limited to B. mayonii and B. californiensis.*

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		
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*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
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Lyme ImmunoBlot IgM	Serum	<b>Positive</b>		
IGX Criteria:		<b>Positive</b>		
CDC/NYS Criteria:		<b>Positive</b>		

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 [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
<b>Positive</b>	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
<b>Negative</b>	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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B. burgdorferi European(genus)	Serum	Positive		
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		
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*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 IGXSpot	HEP-Whole Blood	<2	Number of Spot :	SFU
			< or = 2 : Negative	
			> or = 3 : Po	

Lyme Multiplex PCR - Serum				
Serum - Genomic	Serum	Negative		
Serum - Plasmid	Serum	Negative		

Lyme Multiplex PCR -Whole Blood				
Whole blood - Genomic	W blood	Negative		
Whole blood - Plasmid	W blood	Negative		

**End of Report**

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