

556 Gibraltar Drive Milpitas, CA 95035 T: (800) 832-3200 F: (408) 935-8272 Laboratory Director: Jyotsna S. Shah, Ph.D.

 CLIA:
 05D0643914

 CALIFORNIA:
 CLF 4033

 NPI:
 1396837605

www.igenex.com

## **REFERRING PHYSICIAN**

TEST DOCTOR

### TEST PATIENT DOB: Gender: Accession: Patient ID:

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

# **BORRELIOSIS - Relapsing Fever Borrelia**

TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS		
RFBorrelia & B.burgdorferi sensu l	ato RealTime	PCR				
[REVISED REPORT: EFFECTIVE	APRIL 10 , 20	19]				
Relapsing Fever Borrelia Genus*	Serum	Negative	Negative			
* detects RF Borrelia species specific DN/ to B. hermsii, B.turicatae, B. miyamotoi, B B. turcica and B. recurrent						
RF Borrelia Subgroup Species**	Serum	Negative	Negative			
** detects RF Borrelia subgroup species specific DNA including but not limited to B. turicatae, B. miyamotoi, B. parkeri, B. coriaceae and B. recurrentis						
Borrelia burgdorferi sensu lato***	Serum	Negative	Negative			
*** detects B. burgdorferi sl specific DNA i to B. burgdorferi sensu stricto, B. afzelii, B californiensis, B. mayonii, B. spielmanii an	. garinii, B.	ted				

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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EST	SPECIMEN	RESULT	REFERENCE RANGE	UNIT
orrelia****	Serum	Negative	Negative	
**** detects Borrelia specific DNA il	ncluding but not limited to B.			
chiliensis, B. sinica and B. japonica	1			
DISCLAIMER: Diagnostic value of	a negative result is questiona	able due		
to low or nonexistent number of Bo	rrelia organisms in patients w	vith		
Lyme disease				
LIMITATION: An inhibition study wa	as performed on about 2000			
clinical samples that included fresh	whole blood, fresh serum,			
frozen urine and frozen CSF sample	les. The inhibition for all sam	ple		
types was well controlled and only	occurred in less than 1% of			
samples. Therefore, no inhibition co	ontrol is included in the assay	1.		
RFBorrelia & B.burgdorferi se [REVISED REPORT: EFFEC Relapsing Fever Borrelia Ger	TIVE APRIL 10 , 201 nus* W blood	9] Negative	Negative	
[REVISED REPORT: EFFEC Relapsing Fever Borrelia Ger * detects RF Borrelia species speci	TIVE APRIL 10 , 201 nus* W blood	9] Negative	Negative	
[REVISED REPORT: EFFEC	TIVE APRIL 10 , 201 nus* W blood	9] Negative	Negative	
[REVISED REPORT : EFFEC Relapsing Fever Borrelia Ger * detects RF Borrelia species speci to B. hermsii, B.turicatae, B. miyarr B. turcica and B. recurren	TIVE APRIL 10 , 201 nus* W blood ific DNA, including but not lim notoi, B. parkeri, B. coriaceae	9] Negative <sup>hite</sup>	Negative	
[REVISED REPORT : EFFEC Relapsing Fever Borrelia Ger * detects RF Borrelia species speci to B. hermsii, B.turicatae, B. miyam	TIVE APRIL 10 , 201 nus* W blood ific DNA, including but not lim notoi, B. parkeri, B. coriaceae	9] Negative	Negative	
[REVISED REPORT : EFFEC Relapsing Fever Borrelia Ger * detects RF Borrelia species speci to B. hermsii, B.turicatae, B. miyam B. turcica and B. recurren RF Borrelia Subgroup Specie ** detects RF Borrelia subgroup sp not limited to B. turicatae, B. miyam	TIVE APRIL 10 , 201 hus* W blood ific DNA, including but not lim notoi, B. parkeri, B. coriaceae es** W blood recies specific DNA including	9] Negative <sup>bite</sup> Negative		
[REVISED REPORT : EFFEC Relapsing Fever Borrelia Ger * detects RF Borrelia species speci to B. hermsii, B.turicatae, B. miyam B. turcica and B. recurren RF Borrelia Subgroup Species ** detects RF Borrelia subgroup sp	TIVE APRIL 10 , 201 hus* W blood ific DNA, including but not lim notoi, B. parkeri, B. coriaceae es** W blood recies specific DNA including	9] Negative <sup>bite</sup> Negative		
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[REVISED REPORT : EFFEC Relapsing Fever Borrelia Ger * detects RF Borrelia species speci to B. hermsii, B.turicatae, B. miyam B. turcica and B. recurren RF Borrelia Subgroup Specie ** detects RF Borrelia subgroup sp not limited to B. turicatae, B. miyam	TIVE APRIL 10 , 201 hus* W blood ific DNA, including but not lim notoi, B. parkeri, B. coriaceae es** W blood recies specific DNA including notoi, B. parkeri, B. coriaceae	9] Negative <sup>bite</sup> Negative	Negative	
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TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
Borrelia****	W blood	Negative	Negative	

\*\*\*\* detects Borrelia specific DNA including but not limited to B.

chiliensis, B. sinica and B. japonica

DISCLAIMER: Diagnostic value of a negative result is questionable due to low or nonexistent number of Borrelia organisms in patients with

Lyme disease

LIMITATION: An inhibition study was performed on about 2000 clinical samples that included fresh whole blood, fresh serum,

frozen urine and frozen CSF samples. The inhibition for all sample

types was well controlled and only occurred in less than 1% of

samples. Therefore, no inhibition control is included in the assay.



## **End of Report**

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