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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 - Relapsing Fever Borrelia

TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
RF Borrelia & B.burgdorferi sensu lato RealTime PCR				
[REVISED REPORT: EFFECTIVE APRIL 10 , 2019]				
Relapsing Fever Borrelia Genus*	Serum	Negative	Negative	
* detects RF Borrelia species specific DNA, including but not limited to B. hermsii, B.turicatae, B. miyamotoi, B. parkeri, B. coriaceae, 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 sI specific DNA including but not limited to B. burgdorferi sensu stricto, B. afzelii, B. garinii, B. californiensis, B. mayonii, B. spielmanii and B. valaisiana				

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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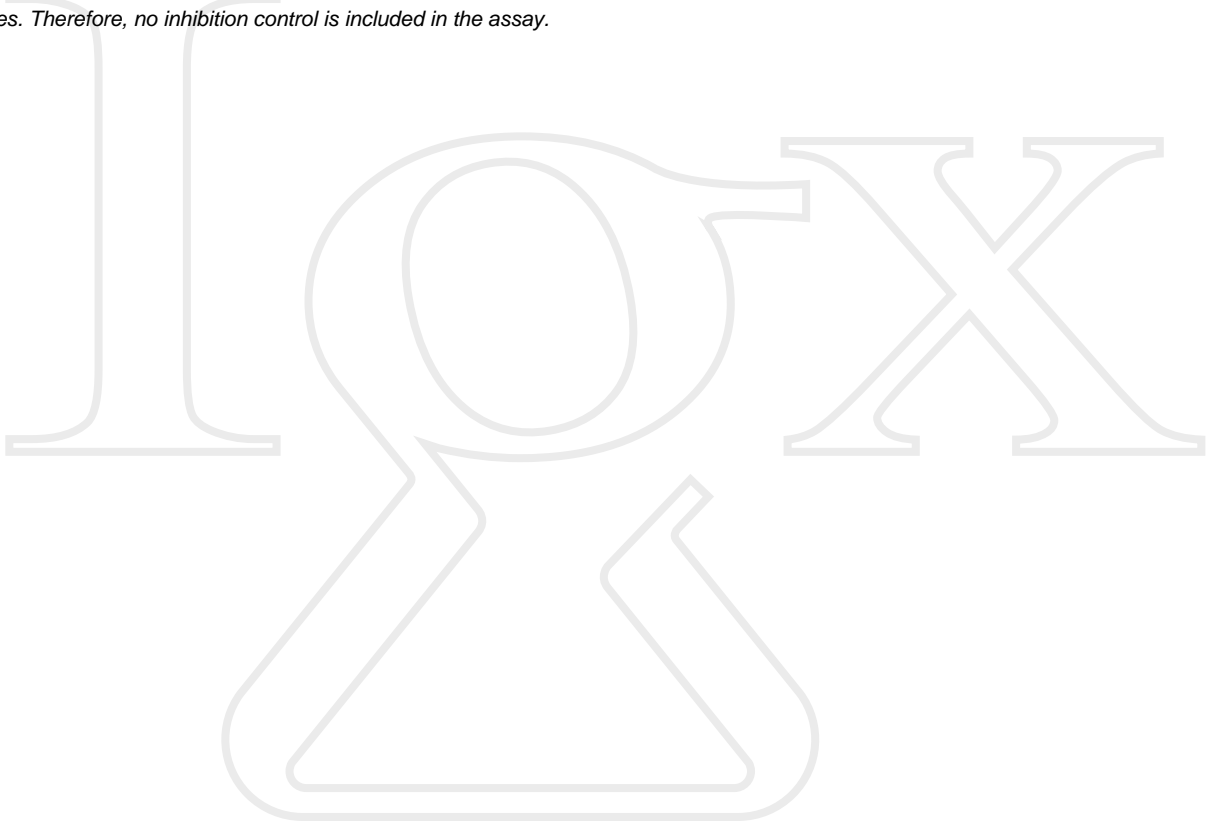
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TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
Borrelia****	Serum	Negative	Negative	

**** 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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