IMMUNOSCIENCES LAB, INC.
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LOS ANGELES, CA 90035
TEL: (310) 657-1077 FAX: (310) 657-1053
E-MAIL: immunsci@gmail.com

REFERRING PHYSICIAN

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RESEARCH
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PATIENT NAME: SAMPLE, REPORT

AGE: 37Y SEX: F

ACCESSION NO.	D.O.B.	COLLECTION DATE	LOG-IN DATE	TEST DATE	REPORT DATE
AAAA25	08/11/1984	11/5/2021	12/21/2021	12/21/2021	12/21/2021

TEST	RESULTS NORMAL	RESULTS ABNORMAL	REFERENCE RANGE	UNITS
IMMUNOSEROLOGY OF LYME				
IgG B. burgdorferi AG	0.5		<0.81	INDEX
IgM B. burgdorferi AG	0.5		<0.81	INDEX
IgG OUTER SURFACE P. A+C	0.5		<0.81	INDEX
IgM OUTER SURFACE P. A+C	0.5		<0.81	INDEX
IgG OUTER SURFACE P. E	0.5		<0.81	INDEX
IgM OUTER SURFACE P. E	0.5		<0.81	INDEX
IgG LFA ANTIGEN + CK10	0.5		<0.81	INDEX
IgM LFA ANTIGEN + CK10	0.5		<0.81	INDEX
IgG IMMUNODOMINANT P. C6	0.5		<0.81	INDEX
IgM IMMUNODOMINANT P. C6		1.1	<0.81	INDEX
IgG VARIABLE MAJOR PRO. E		1.1	<0.81	INDEX
IgM VARIABLE MAJOR PRO. E	0.5		<0.81	INDEX
IgG B. burg sensu stricto	0.5		<0.81	INDEX
IgM B. burg sensu stricto	0.5		<0.81	INDEX
IgG B. garinii	0.5		<0.81	INDEX
IgM B. garinii		0.9	<0.81	INDEX
IgG B. afzelii		0.9	<0.81	INDEX
IgM B. afzelii		0.9	<0.81	INDEX
IgG B. miyamotoi		0.9	<0.81	INDEX
IgM B. miyamotoi		0.9	<0.81	INDEX
IgG BABESIA		0.9	<0.81	INDEX

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TEST	RESULTS NORMAL	RESULTS ABNORMAL	REFERENCE RANGE	UNITS
IgM BABESIA		0.9	<0.81	INDEX
IgG EHRLICHIA		0.9	<0.81	INDEX
IgM EHRLICHIA		0.9	<0.81	INDEX
IgG BARTONELLA		0.9	<0.81	INDEX
IgM BARTONELLA		0.9	<0.81	INDEX

RESULTS REPORTED AS 0.81-1.199 INDEX ARE CONSIDERED EQUIVOCAL.

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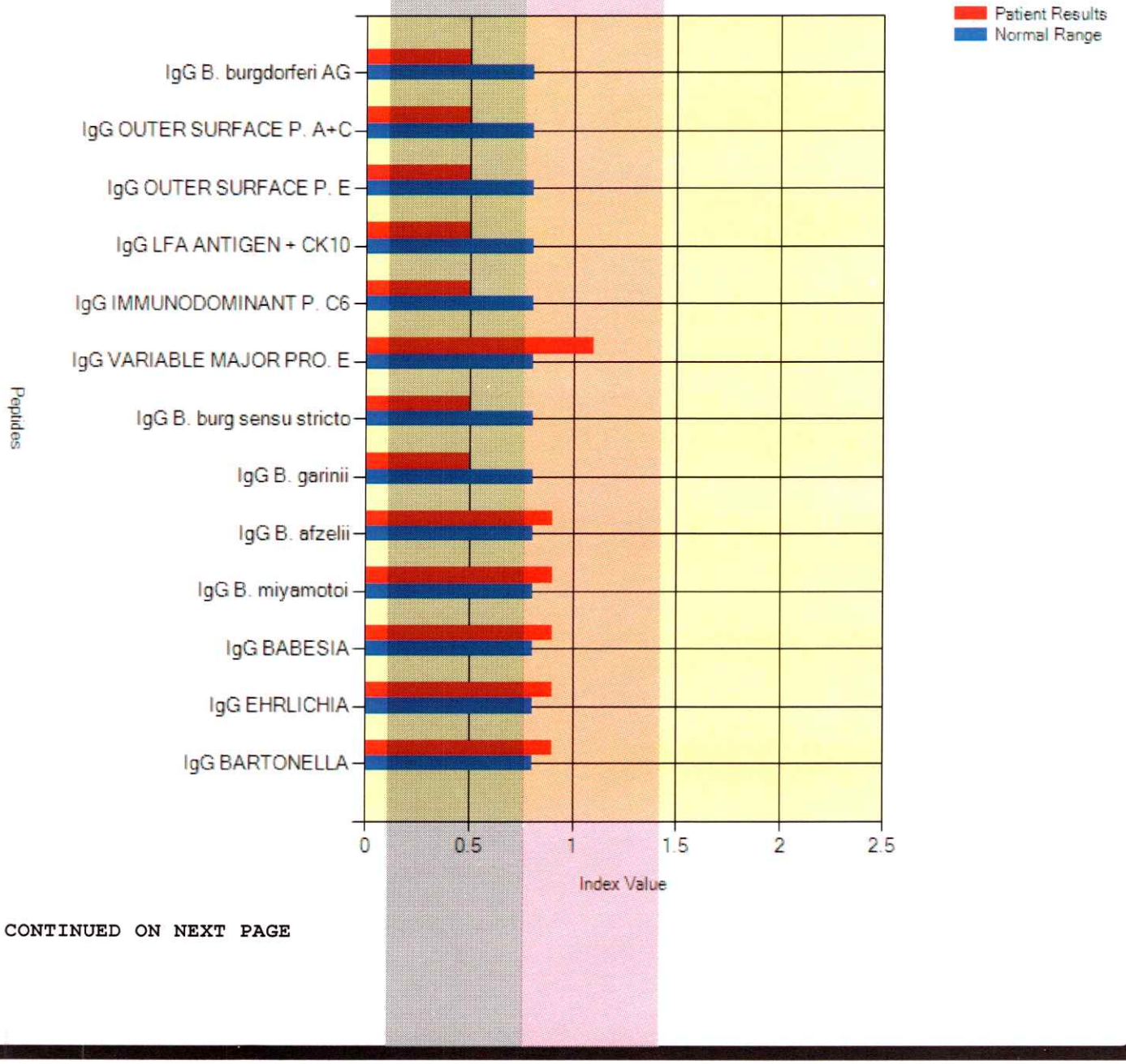
TEST	RESULTS NORMAL	RESULTS ABNORMAL	REFERENCE RANGE	UNITS

LYME MULTI-PEPTIDE IgG ELISA ASSAY



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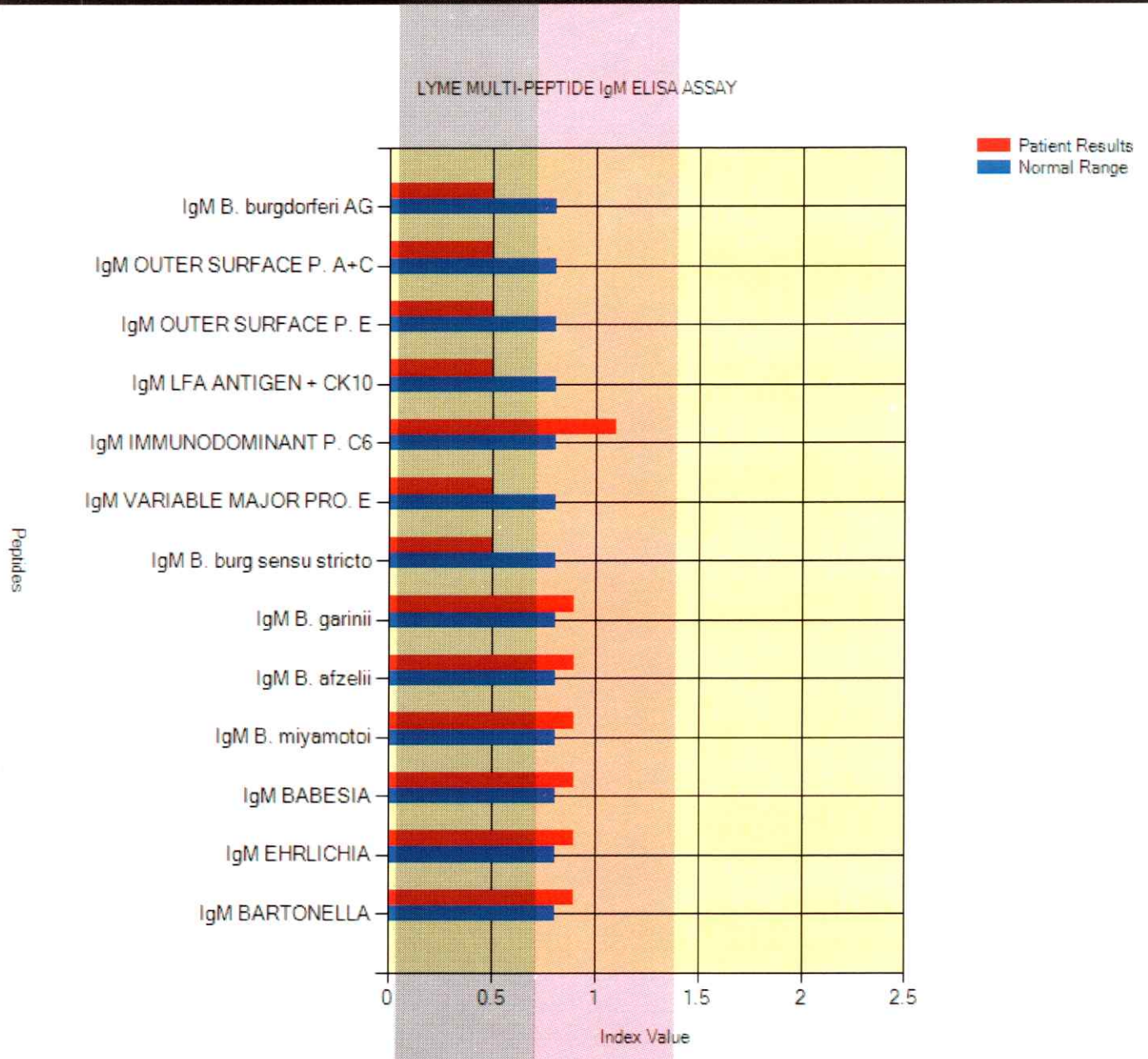
TEST	RESULTS NORMAL	RESULTS ABNORMAL	REFERENCE RANGE	UNITS



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TEST	RESULTS NORMAL	RESULTS ABNORMAL	REFERENCE RANGE	UNITS

Prompt diagnosis and treatment of Lyme disease is the key to avoiding chronic Lyme borreliosis and its serious effects on the human system. Thus, it is crucial to combine clinical symptomatology with the most sensitive technique available to diagnose Lyme disease. ISL applies the commercially available ELISA, Western Blot and our patented multi-peptide ELISA assessments. The chronic nature of Lyme disease and antigenic diversity of spirochetes suggest that antigenic variations play an important role in immune invasion. Peptides from different components of Borrelia during life cycles are tested along with proteins and peptides from Borrelia subspecies and co-infections in order to differentiate similar or associative disorders.

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FOR ADDITIONAL INFORMATION SEE INTERPRETATION GUIDE.
****

* * LIMITATIONS * *

*Antibodies against tick-borne antigens or peptides alone are not indicative of any specific condition or disease. Test results should be used in conjunction with pertinent clinical information.
*Specimens received as hemolytic, lipemic, bacterially contaminated, or heat inactivated, are rejected for analysis.
****
The Lyme Multi-Peptide Elisa Panel is a lab-developed test at ISL.
****

* * * * *

The performance characteristics of this test were established through validation by Immunosciences Lab., Inc. It has not been cleared or approved by the US Food and Drug Administration. Immunosciences Lab., Inc. is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing.

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TEST	RESULTS NORMAL	RESULTS ABNORMAL	REFERENCE RANGE	UNITS

INTERPRETATION OF RESULTS FOR MULTI-PEPTIDE ELISA

Antibody against	Indication
B. burgdorferi antigens	Elevated IgM or IgG antibody against B. burgdorferi antigens may indicate recent or past exposure to the spirochete or cross-reactive antigens.
Outer Surface Protein A (OspA), 30/31 KDa	Elevated IgM or IgG against OspA may indicate exposure to the spirochete or cross-reactive antigens. Arthritic episodes observed in some patients may confirm exposure to the organism.
Outer Surface Protein C (OspC), 23 KDa	Both IgM and IgG are produced against OspC during the early stages of Lyme disease. Elevation in antibody against OspC may indicate recent exposure to B. burgdorferi or cross-reactive antigens.
Outer Surface Protein E (OspE), 26 KDa	IgM and IgG antibodies against OspE are detected in patients with ongoing Lyme disease. Simultaneous detection of antibodies against OspE and B. burgdorferi antigens may indicate exposure to an agent of Lyme disease or its cross-reactive antigens.
Leukocyte Function Associated Antigen (LFA)	Detection of high levels of antibodies against LFA, its cross-reactive antigen (OspA) and Cytokeratin-10 may indicate chronic Lyme arthritis, rheumatoid arthritis, psoriatic arthritis, lupus or other autoimmune disorders due to exposure to the Lyme spirochete.
C6 Peptide originated from Immunodominant Protein, 43 KDa	Elevated levels of antibodies against flagellar antigen or C6 Peptide may indicate exposure to B. b. sensu lato, B. b. sensu stricto, B. garinii or their cross-reactive antigens during the early stages, and persistently through the course of infection. The C6 antibodies are also detected in patients with neuroborreliosis.

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TEST	RESULTS NORMAL / ABNORMAL	REFERENCE RANGE	UNITS
Variable Major Protein E (VmpE), 34 KDa	IgM and/or IgG antibodies against VmpE, which present in almost all subspecies of Borrelia, may indicate recent or late exposure to B. burgdorferi, its subspecies, or their cross-reactive anrtigens.		
Borrelia subspecies: B. b. sensu stricto, B. garinii, B. afzelii, B. miyamotoi	Elevated antibodies against Borrelial outer protein or Decorin Binding Protein indicates not only exposure to one of these subspecies but the presence of chronic Lyme which may have resulted in neuroborreliosis or Lyme arthritis. Elevated antibodies against Variable Major Protein (Vmp) of B. miyamotoi may indicate exposure to hard tick-borne relapsing fever.		
Babesia microti, B. equi, B. bovis	Antibody elevation against Babesia antigens, particularly in individuals with reduced immune function, anemia, hemoglobinuria, elevated liver enzymes, jaundice and kidney malfunction may indicate exposure to the organism and host immune response against this intracellular protozoan or its cross-reactive antigens.		
Ehrlichia phagocytophila, Anaplasma marginale, Major Surface Protein 2	Elevation in IgM or IgG antibodies against Major Surface Protein 2 of Ehrlichia may indicate exposure to this microorganism or cross-reactive antigens such as human F-actin		
Bartonella henselae	Elevation in IgM or IgG antibodies against Bartonella henselae, especially in individuals who have had direct contact with cats and dogs and exhibit symptoms of fatigue, myalgia, arthralgia, and/or neurologic abnormalities may indicate exposure to Bartonella or its cross-reactive antigens.		

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LYME DISEASE BY LINE BLOT

TEST	RESULTS NORMAL	RESULTS ABNORMAL	REFERENCE RANGE	UNITS
IgG BANDS PRESENT	0		0-4	
p 18 IgG BANDS	NEGATIVE		NEGATIVE	
p 23 IgG BANDS	NEGATIVE		NEGATIVE	
p 28 IgG BANDS	NEGATIVE		NEGATIVE	
p 30 IgG BANDS	NEGATIVE		NEGATIVE	
p 31 IgG BANDS	NEGATIVE		NEGATIVE	
p 39 IgG BANDS	NEGATIVE		NEGATIVE	
p 41 IgG BANDS	NEGATIVE		NEGATIVE	
p 45 IgG BANDS	NEGATIVE		NEGATIVE	
p 58 IgG BANDS	NEGATIVE		NEGATIVE	
p 66 IgG BANDS	NEGATIVE		NEGATIVE	
p 93 IgG BANDS	NEGATIVE		NEGATIVE	
IgM BANDS PRESENT	0		0-1	
p 23 IgM BANDS	NEGATIVE		NEGATIVE	
p 39 IgM BANDS	NEGATIVE		NEGATIVE	
p 41 IgM BANDS	NEGATIVE		NEGATIVE	

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TEST	RESULTS NORMAL	RESULTS ABNORMAL	REFERENCE RANGE	UNITS

Lyme disease is transmitted through the bite of a tick infected with the spirochete, Borrelia burgdorferi. Lyme disease is associated with neurologic or cardiac symptoms (stage 2) or arthritic symptoms (stage 3). In some cases, these secondary symptoms may occur even though the patient does not remember a tick bite or rash. Diagnosis of the patient based on clinical grounds alone is difficult unless the typical ECM lesions are present. Currently, detection of B. burgdorferi antibodies best identify patient exposure to the agent. To avoid the problems associated with measurement of antibodies to the whole organism, the Line Blot Lyme Test separately measures the level of response to the two major components of the spirochete, the outer surface membrane and the flagellar antigens.

Based on recent CDC/ASTPHLD criteria, an IgG blot is considered positive or reactive if five (5) of the following bands are present:

p18, p23, p28, p30, p39, p41, p45, p58, p66 and p93

Based on recent CDC/ASTPHLD criteria, an IgM blot is considered positive or reactive if two (2) of the following bands are present:

p23, p39 and p41

*Specimens received as hemolytic, lipemic, bacterially contaminated, or heat inactivated, are rejected for analysis.

Gopal Krishnan, PhD,HCLD (ABB), Lab Director

A.Vojdani, PhD,CLS, Tech Dir