

Phone (301) 916-0173

Fax (301) 916-0175

Toll Free 1-877-CLONGEN

www.clongen.com

Laboratory Director: Ahmed Kilani, Ph.D., MT(ASCP)

CLIA#21D1032144 MD#1206

Date:

Patient Name: John Doe Date of Birth: 1/14/2009

Address: 111 Pasture Lane

Phone:

Accession number: Collected on: Received on: Physician: Dr. LymebyWestern Fax: Phone:

## **Final Report**

### Criteria for a positive result:

- ❖ For the IgM strips score as positive any sample that has 2 or more of the following guide bands: p23kDa, p39 or p41.
- For the IgG strips score as positive any sample that has 5 or more of the following guide bands: p18kDa, p23, p28, p30, p39, p41, p45, p58, p66, or p93.
- Any positive strip is presumptive evidence of exposure to *B. burgdorferi*. Individuals with positive blots should be referred for medical evaluation and additional testing.

# Borrelia burgdorferi Western Blot Results: (Bands were scored from +1 to +4 where +1 is weakest and +4 is strongest reaction):

IgG Band	Result	IgM Band	Result
93	+3	93	-
75	•	75	
66	+2	66	
60	+1	60	
58	•	58	-
45	+1	45	-
41	+4	41	
39	+4	39	-
34	ı	34	
31	+2	31	
30	ı	30	
28	+3	28	-
23	-	23	-
18	+4	18	-

IgG: Positive\*

IgM: Negative (Normal)

<sup>\*</sup>It is recommended that the patient seek medical attention.

#### 12321 Middlebrook Road, Suite 120, Germantown, MD 20874

Phone (301) 916-0173 Fax (301) 916-0175

Toll Free 1-877-CLONGEN

www.clongen.com

Laboratory Director: Ahmed Kilani, Ph.D., MT(ASCP)

CLIA#21D1032144 MD#1206

Date:

Patient Name: John Doe

Address: 111 Pasture Lane Rockville, MD 20853

Physician: Dr. LymebyWestern, MD

Date of Birth:

Phone:

Accession number:

Collected on:

Received on: Phone:

Fax:

Final Report

### Samples collected and tested:

Serum collected in a serum separator tube was received. Tests requested:

1. Lyme Disease by Western Blot (IgG & IgM)

### **Background on Lyme Serology Testing:**

#### **Western Blot Test:**

The test detects IgM and IgG antibodies to *Borrelia burgdorferi* in human serum. It is intended for use in testing human samples that tested positive or were equivocal for Lyme Disease using an enzyme immunoassay or an immunofluorescence procedure. Positive results from the Western Blot assay are supportive evidence of infection with *Borrelia burgdorferi*, the causative agent of Lyme Disease. The test detects IgG and IgM. Controls were included in the assay and performed as expected. The immune response with *Borrelia burgdorferi* varies considerably. In general, seroconversion occurs in the first few weeks after the onset of erythema migrans (EM). IgM is produced initially and is later followed by class switching to IgG. Both IgM and IgG may diminish over time or remain at detectable levels.

Images of the western blots are shown on the next two pages.

**Final Results:** 

IaG: Positive\*

IgM: Negative (Normal)

\*It is recommended that the patient seek medical attention.

Laboratory Director: Ahmed Kilani, Ph.D., MT(ASCP)

**Date** 

# **CLONGEN**

12321 Middlebrook Road, Suite 120, Germantown, MD 20874

Committed to Scientific Excellen

Committed to Scientific Excellence

Phone (301) 916-0173 Fax (301) 916-0175 Toll Free 1-877-CLONGEN

www.clongen.com

Sample #:

Patient Name:

Patient Birthdate:

Examiner:

Date Evaluted:

Test: Borrelia B31 ViraBlot® IgG

Strip #:

# **Final Report**

### Lyme IgG Western Blot

Report Date:

This is a membrane immunoassay based on the Western Blot method. As recommended by the CDC, all samples which test positive or equivocal on a serological screening test should be re-tested on a Borrelia burgdorferi Western Blot. The B. burgdorferi IgG Western Blot assay is recommended for the evaluation of sera from patients believed to be exposed to B. burgdorferi.

Results for IgG antibodies to significant B. burgdorferi proteins (size and intensity):

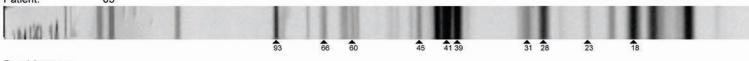
Bands,kD

Intensity, % of Cut-off

93 66 60 58 45 41 39 34 31 30 28 23 18 214 107 088 - 120 303 298 - 139 - 247 052 273

Patient:

05



Band-Locator:



Results for this specimen:

positive

Result Interpretation:

IgG Result

CDC Criteria (Antibody, CDC)\*

Negative (Non-Reactive)

No bands or less than five bands from: 18,23,28,30,39,41,45,58,66,93 kD

Equivocal

N/A

Positive (Reactive)

Five or more bands from: 18,23,28,30,39,41,45,58,66,93 kD

### Negative Results (Non-Reactive):

IgG antibodies to significant Borrelia burgdorferi proteins were NOT detected.

#### Positive Results (Reactive):

IgG antibodies to significant Borrelia burgdorferi proteins were detected; presumptive evidence of probable exposure.

REMARKS:

aboratory Director (Ahmed Kilani, Ph.D.	MT (ASCP) CLIA#21D1032144 MD#1206)	Date:



12321 Middlebrook Road, Suite 120, Germantown, MD 20874

Committed to Scientific Excellence

Dhone (201) 016 0173 Fey (201) 0:

Phone (301) 916-0173 Fax (301) 916-0175 Toll Free 1-877-CLONGEN

www.clongen.com

Patient Name:

Patient Birthdate:

Sample #:

Examiner:

Date Evaluted:

Test: Borrelia B31 ViraBlot® IgM

Strip #:

# **Final Report**

### Lyme IgM Western Blot

Report Date:

This is a membrane immunoassay based on the Western Blot method. As recommended by the CDC, all samples which test positive or equivocal on a serological screening test should be re-tested on a Borrelia burgdorferi Western Blot. The B. burgdorferi IgM Western Blot assay is recommended for the evaluation of sera from patients believed to be exposed to B. burgdorferi.

Results for IgM antibodies to significant B. burgdorferi proteins (size and intensity):

Bands,kD

Intensity, % of Cut-off

93 66 60 41 39 28 23 - - - 037 - - 026

Patient

05



Band-Locator:



Results for this specimen: negative

Result Interpretation:

IgM Result CDC Criteria (Antibody, CDC\*)

Negative (Non-reactive) No bands or less than two bands from: 23,39,41 kD

Equivocal N/A

Positive (Reactive) Two or more bands from: 23,39,41 kD

### Negative Results (Non-Reactive):

IgM antibodies to significant Borrelia burgdorferi proteins were NOT detected.

#### Positive Results (Reactive):

IgM antibodies to significant Borrelia burgdorferi proteins were detected; presumptive evidence of probable exposure.

REMARKS:

Laboratory Director	(Ahmed Kilani, Ph.D.,	MT (ASCP)	, CLIA#21D1032144,	MD#1206):	Da	ate
Laboratory Director	( timilou randin, r n.D.,	1111 (1001)	, OLI WEID TOOL ITT,	11101112001.		^