Amy MacDonald - Testimony in support of **LD 906 An Act To Ensure Physicians Receive Full Diagnostic Test Data Concerning Tick-borne Diseases**

In Person Testimony:

Good afternoon Senator Baldacci, Representative Meyer and Members of the Health and Human Services Committee

My name is Amy MacDonald and I would like to share my personal experience with tick-borne illness testing.

For 10 years, I was a multi-million dollar producing real estate agent at the top of my industry.

Overnight my world changed with the onset of strange symptoms that took 3 years to figure out.

I went from feeling great, being a productive member of society, enjoying raising my 3 beautiful girls, to being unable to function due to extreme head and neck pain and numbness on the right side of my body that would come on without warning...amongst other symptoms.

After 3 years and 3 rounds of negative Lyme test results with my PC, I got a second opinion. This doctor sent my blood sample (taken within 10 days of the last sample my PC took) to a different lab. This lab sent the raw data with the results which showed positive bands for Lyme Disease.

By the time I was properly diagnosed, I was at the chronic stage of Lyme and Bartonella. Despite going through 3 years of treatments, that thankfully got me back to work, I have ongoing issues that will keep me from being the person I once was.

During the course of the last 3 years my partner and I spent over $35,000 out of pocket on treatment expenses not covered by insurance and we lost over $300,000 in income from me not being able to work.

The impact of this bill goes beyond patients. The amount of money my insurance company spent in the 3 years I went undiagnosed was extremely high.

MRI's, CAT Scan's, a Lumbar Puncture, a 4 day stay at Maine General, and a trip to Boston's MS Lahey Clinic cost my insurance company more than a pretty penny.

Multiply this by the hundreds of patients each year in Maine seeking a diagnosis and it is safe to say that hundreds of thousands of dollars could be saved by insurance companies.

The toughest part for me to think about and speak about is the fact that my children have missed out on having an active mom in their life. My youngest daughter doesn't even remember what I was like before I got sick.

All of this is preventable for other Mainers if doctors are simply given the raw data from labs that they are already producing during testing. Let's give doctors all the tools to increase early, correct diagnosis. Without early treatment of tick-borne diseases, you or someone you love, could experience something similar to what I have gone through. After all, I was a normal, productive person, just like you 7 years ago.

Thank you for your time and consideration on this very important bill. I welcome further discussion and am happy to answer any questions you may have.

More Information:

I support **LD 906 An Act To Ensure Physicians Receive Full Diagnostic Test Data Concerning Tick-borne Diseases**

Over the course of three years from 2016 to 2019, I had a wide range of strange symptoms:

- One night in October of 2016 I went to bed fine. When I woke in the morning, the vision in my left eye was extremely blurry. I went to my eye doctor, they gave me a different prescription but didn't seem alarmed that my vision changed overnight. 5 weeks later my vision returned and I went back to my previous prescription.

- Winter 2016/2017 - Lhermitte's sign started–electric zap starting at the base of my skull shooting down my spine. This would hit at any time and would keep me awake at night.

- 2017 - Parts of my body (like one lower leg) would go numb for a period of time (usually a few hours) This happened on a daily basis.

- Fall of 2017 - over the course of a few days the entire right side of my body went numb. I was hospitalized for four days.

- I underwent MRI's, CAT scans, spinal tap/lumbar puncture and I was misdiagnosed with MS

- I was sent to Boston's MS Lahey Clinic and after being assessed told "based on your symptoms, it looks like you have MS but you don't because your brain scan would show it. You fall into the gray area of people we can't figure out.

- I was told by one doctor during this period of time that I should consider getting counseling.

- By 2019, I was having continued numbness, cognitive issues, and extreme head and neck pain where the only thing I could do was wrap my head in ice and pray for the pain to subside.

- In September of 2019, my doctor, Dr. Amy Trelease-Bell, tested me for the third time for Lyme and she got a negative diagnosis. Within 10 day's of my doctors test, Dr. Mari Sawai also tested me and got a positive diagnosis. **The big difference between these two tests was Dr. Mari was given the raw data by the lab to interpret alongside my symptoms and Dr. Trelease-Bell was not.**

- It took 3 years to be diagnosed with Chronic Lyme and Chronic Bartonella. In this time, I ended up with permanent cognitive issues and muscle atrophy on the right side of my body that will likely never return to normal.

I have spent over $35,000 out of pocket on my treatment because insurance doesn't cover it. I was out of work for the better part of 3 years which meant losing over 100k a year in income to my family.

All of this could have been prevented if my doctor received the raw data from the lab because she would have seen that there were some positive bands for Lyme in my system and been able to combine that with my symptoms to make a diagnosis.

The goal of this bill is to simply provide doctors with information that the labs are already producing as an added tool for diagnosing Tick-borne Diseases.

Thank you very much for your time and consideration.

Amy MacDonald

Sept. 2019

Within 10 days of other 2019 lab test

Family Medicine Institute

15 E Chestnut Street, Office FMI
Augusta,ME 04330
(207) 626-1561

Patient: MACDONALD, AMY A

[redacted]

Age/Sex/DOB: 46 yrs F [redacted]
EMRN: 166223*5
OMRN: 2034290
Home: (207) 485-4789
Work: (207) 485-4789

Results

Lab Accession # T49491_2034290
Ordering Provider: Trelease Bell, Amy

Performing Location:

Collected: 9/17/2019 12:18:00PM
Resulted: 9/20/2019 01:56:00PM
Verified By: Trelease Bell, Amy
Auto Verify: N

LYME SCREEN TOTAL

Stage: Final

Test	Result	Units	Flag	Reference Range
LYME SCREEN TOTAL	Non-React.			Non-React.
(NOTE) Qualitative detection of total antibodies (IgG,IgM,IgA). Performed at MGMC Augusta Campus				

Family Medicine Institute

15 E Chestnut Street, Office FMI
Augusta,ME 04330
(207) 626-1561

Patient: MACDONALD, AMY A

[redacted]
H[redacted]

Age/Sex/DOB: 46 yrs F[redacted]
EMRN: 166223*5
OMRN: 2034290
Home: (207) 485-4789
Work: (207) 485-4789

Results

Lab Accession # T49491_2034290
Ordering Provider: Trelease Bell, Amy

Performing Location:

Collected: 9/17/2019 12:18:00PM
Resulted: 9/20/2019 04:49:00PM
Verified By: Trelease Bell, Amy
Auto Verify: N

Tick-Borne Ab Panel, Serum

Stage: Final

Test	Result	Units	Flag	Reference Range
Ehrlichia Chaffeensis (HME) Ab, IgG	<1:64			
Reference range: <1:64				
Unit: titer				
(NOTE)				

----------ADDITIONAL INFORMATION----------
This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Anaplasma phagocytophilum Ab, IgG,S	<1:64			
Reference range: <1:64				
Unit: titer				
(NOTE)				

----------ADDITIONAL INFORMATION----------
This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Babesia microti IgG Ab, S	<1:64			

Test	Result	Units	Flag	Reference Range
Reference range: <1:64				
Unit: titer				
(NOTE)				

----------ADDITIONAL INFORMATION----------
This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Lyme Disease Serology,S	Negative			
Reference range: Negative				
(NOTE)				

No evidence of antibodies to B. burgdorferi detected. False negative results may occur in recently infected patients (<=2 weeks) due to low or undetectable antibody levels to B. burgdorferi. If recent exposure is suspected, a second sample should be collected and tested in 2-4 weeks.

Test Performed by:
Mayo Clinic Laboratories - Rochester Superior Drive
3050 Superior Drive NW, Rochester, MN 55901
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D1040592

Sept. 2019
Within 10 days of other 2019 lab test

Family Medicine Institute

15 E Chestnut Street, Office FMI
Augusta,ME 04330
(207) 626-1561

Patient: MACDONALD, AMY A
[redacted]

Age/Sex/DOB: 46 yrs F [redacted]
EMRN: 166223*5
OMRN: 2034290
Home: (207) 485-4789
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Results

Lab Accession # T49491_2034290
Ordering Provider: Trelease Bell, Amy

Performing Location:

Collected: 9/17/2019 12:18:00PM
Resulted: 9/20/2019 01:56:00PM
Verified By: Trelease Bell, Amy
Auto Verify: N

LYME SCREEN TOTAL

Stage: Final

Test	Result	Units	Flag	Reference Range
LYME SCREEN TOTAL	Non-React.			Non-React.
(NOTE) Qualitative detection of total antibodies (IgG,IgM,IgA). Performed at MGMC Augusta Campus				

Family Medicine Institute

15 E Chestnut Street, Office FMI
Augusta,ME 04330
(207) 626-1561

Patient: MACDONALD, AMY A

[redacted]
H[redacted]

Age/Sex/DOB: 46 yrs F[redacted]
EMRN: 166223*5
OMRN: 2034290
Home: (207) 485-4789
Work: (207) 485-4789

Results

Lab Accession # T49491_2034290
Ordering Provider: Trelease Bell, Amy

Performing Location:

Collected: 9/17/2019 12:18:00PM
Resulted: 9/20/2019 04:49:00PM
Verified By: Trelease Bell, Amy
Auto Verify: N

Tick-Borne Ab Panel, Serum

Stage: Final

Test	Result	Units	Flag	Reference Range
Ehrlichia Chaffeensis (HME) Ab, IgG	<1:64			
Reference range: <1:64				
Unit: titer				
(NOTE)				

----------ADDITIONAL INFORMATION----------
This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Anaplasma phagocytophilum Ab, IgG,S	<1:64			
Reference range: <1:64				
Unit: titer				
(NOTE)				

----------ADDITIONAL INFORMATION----------
This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Babesia microti IgG Ab, S	<1:64			

Test	Result	Units	Flag	Reference Range

Reference range: <1:64
Unit: titer
(NOTE)

----------ADDITIONAL INFORMATION----------
This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Lyme Disease Serology,S Negative
Reference range: Negative
(NOTE)
No evidence of antibodies to B. burgdorferi detected. False negative results may occur in recently infected patients (<=2 weeks) due to low or undetectable antibody levels to B. burgdorferi. If recent exposure is suspected, a second sample should be collected and tested in 2-4 weeks.

Test Performed by:
Mayo Clinic Laboratories - Rochester Superior Drive
3050 Superior Drive NW, Rochester, MN 55901
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D1040592

Raw data included with results

9499744

Lyme IgG Immunoblot Blot

This is a membrane immunoassay based on the Immunoblot 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 Immunoblot. The B. burgdorferi IgG Immunoblot assay is recommended for the evaluation of sera from patients believed to be exposed to B. burgdorferi.

MDL Number: 9499744-1

Date: 10/10/2019

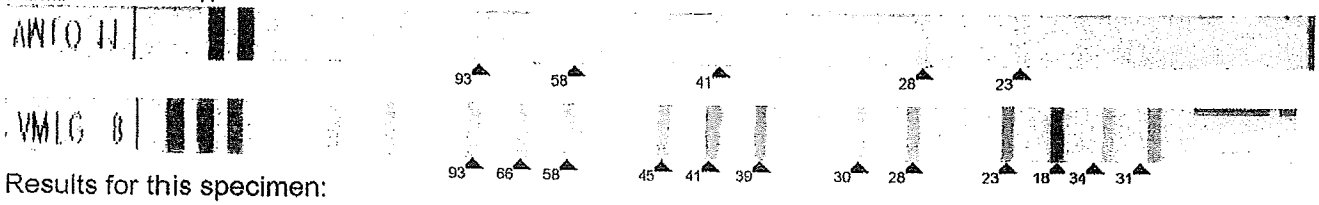
Examiner: LM

Test: Borrelia B31 + OspA/B IgG ViraStripe® IgG

Strip: LOLO1900272-11

Bands,kD	93	58	41	28	23
Intensity, % of Cut-off	062	051	075	072	048

Patient: 11



Results for this specimen:

For results according to the CDC Criteria, please refer to the attached MDL Test Result form.

Result Interpretation:

IgG	Result	CDC Criteria (Antibody, CDC)*	Alternate Criteria (Antibody, Alt)*
	Negative (Non-Reactive)	No bands or less than five bands from: 18,23,28,30,39,41,45,58,66,93 kD	No B. burgdorferi specific bands
	Equivocal	N/A	One or two bands from: 23,31,34,39,93 kD
	Positive (Reactive)	Five or more bands from: 18,23,28,30,39,41,45,58,66,93 kD	Three or more bands from: 23,31,34,39,93 kD

* Bands presented must have an intensity greater or equal to 60% of the cut-off control band.

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.

The Alternate Criteria is based upon a study published by Dr. Richard Tilton (Tilton,R.C., M.N. Sand, M. Manak. 1997. The Western Immunoblot for Lyme Disease: Determination of Sensitivity, Specificity, and Interpretative Criteria with Use of Commerically Available Performance Panels. Clin. Infect. Dis. 25: S31-S34). Reprints are available upon request.

The major differences between the interpretive criteria are:
(1) The Alternative IgG Criteria is based on both the number of bands and the significance of the antibodies detected. For example, OspA (31 kD) and OspB (34 kD) are important bands seen often in late stages of Lyme disease.
Patient:
Patient:

Patient:

MACDONALD, AMY

Ver. 14.10

View:	M		Lyme		
Mail:	Yes	USPS	Fax:	Yes	Manual
	One	Yes		One	No

Medical Director, Mats Sanden, M.D.

MDL#: 9499744 30783
10/10/2019
PATH Final

Lyme IgM Western Blot

This is a membrane immunoassay based on the Immunoblot 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.

MDL Number: 9499744-1

Date: 10/10/2019

Examiner: LM

Test: Borrelia B31 + OspA/B IgM ViraStripe® IgM

Strip: LLLL1900272-11

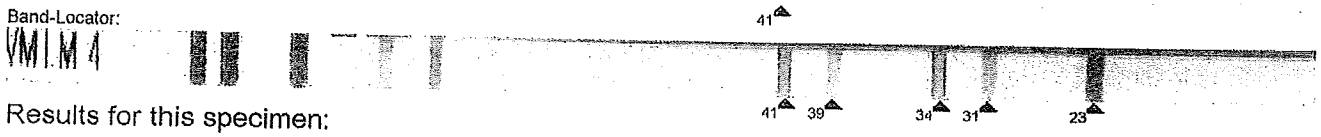
Bands,kD

Intensity, % of Cut-off

41					
028					

Patient

Band-Locator:



Results for this specimen:

For results according to the CDC Criteria, please refer to the attached MDL Test Result form.

Result Interpretation:

IgM	Result	CDC Criteria (Antibody, CDC*)	Alternate Criteria (Antibody, Alt*)
	Negative (Non-reactive)	No bands or less than two bands from: 23,39,41 kD	No B. burgdorferi specific bands
	Equivocal	N/A	One band from: 23,31,34,39,41 kD
	Positive (Reactive)	Two or more bands from: 23,39,41 kD	Two or more bands from: 23,31,34,39,41 kD

* Bands presented must have an intensity greater or equal to 60% of the cut-off control band.

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.

The Alternate Criteria is based upon a study published by Dr. Richard Tilton (Tilton,R.C., M.N. Sand, M. Manak. 1997. The Western Immunoblot for Lyme Disease: Determination of Sensitivity, Specificity, and Interpretative Criteria with Use of Commerically Available Performance Panels. Clin. Infect. Dis. 25: S31-S34). Reprints are available upon request.

The major differences between the interpretive criteria are:
(1) The Alternative IgM Criteria is similar to the CDC Criteria except that the 83/93kD band has been included as a significant IgM band specific to B. burgdorferi.
Criteria, there is significant immunologic activity that may be related to B. burgdorferi infection.
Criteria, there is significant immunologic activity that may be related to B. burgdorferi infection.

Patient

MACDONALD, AMY

Ver. 14.10

View:	M		Lyme
Mail:	Yes	USPS	Fax: Yes Manual
	One	Yes	One No

Medical Director, Mats Sanden, M.D.

MDL#: 9499744 30783
10/10/2019
PATH Final

Sept. 2019

MEDICAL DIAGNOSTIC LABORATORIES L.L.C.

2439 KUSER ROAD

HAMILTON, NJ 08690-3303

TL: 609-570-1000 FX: 609-570-1050 TF: 877-269-0090

www.mdlab.com

Final

MDL#: 9499744

* Test Results

Patient Information	Ordering Physician/Lab:
SSN: N/A DOB: [redacted] (Age:43)	NPI: 1720490022
MACDONALD, AMY	MAINE COMPREHENSIVE HEALTH
[redacted]	KATHRYN SAWAI, ND
[redacted]	143 SILVER STREET
	SUITE 1
	WATERVILLE, ME 04901
	Tel: (207) 395-6101
	Fax: (207) 692-1090

Patient ID: Date Received: 9/28/2019 Date Reported: 10/10/2019

Test	Specimen	Date Collected / Comment	Results: Normal	Results: Abnormal	Reference/Units/Comments
Lyme disease Western blot (IgM / IgG)	313 Verified 10/10/2019	9/25/2019 Serum - 1	IgMCDC Neg IgMAlt Neg IgGCDC Neg IgGAlt Equiv.		IgM: No bands present. IgG: 93/83, 41, 28 See attached report.
Bartonella henselae IgG/IgM by ELISA	355 Verified 10/3/2019	9/25/2019 Serum - 1	IgM Neg (Index=0.02)	IgG Pos (Index=1.55)	* IgM Index range: Neg: <= 0.89, Equivocal: 0.90 - 1.10, Pos: >= 1.11 * IgG Index range: Neg: <= 0.89, Equivocal: 0.90 - 1.10, Pos: >= 1.11
Lyme disease C6 Peptide by ELISA	417 Verified 10/5/2019	9/25/2019 Serum - 1	Neg (Index=0.14)		* Index range: Neg: <= 0.90, Equivocal: 0.91 - 1.09, Pos: >= 1.10
Lyme disease IgG / IgM by ELISA	427 Verified 10/9/2019	9/25/2019 Serum - 1	Neg (Index=0.11)		* Index range: Neg: <= 0.79, Equivocal: 0.80 - 1.09, Pos: >= 1.10
Anaplasma phagocytophilum IgG/IgM by IFA	439 Verified 10/4/2019	9/25/2019 Serum - 1	Negative (IgM, IgG)		IgM:Negative; No significant level of detectable IgM antibodies (1:16 dilution negative). IgG:Negative; No significant level of detectable IgG antibodies (1:80 dilution negative).
Babesia microti IgG/IgM by IFA	440 Verified 10/2/2019	9/25/2019 Serum - 1	Negative (IgM, IgG)		IgM:Negative; No significant level of detectable IgM antibodies (1:16 dilution negative). IgG:Negative; No significant level of detectable IgG antibodies (1:64 dilution negative).
Lyme disease (B. burgdorferi) DNA by Real-Time PCR	305 Verified 10/1/2019	9/25/2019 Blood - 2	Negative		

View:	M		Lyme
Mail:	Yes	USPS	Fax: Yes Manual
	One	Yes	One No

Medical Director, Mats Sanden, M.D.

MDL#: 9499744 30783
10/10/2019
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TL: 609-570-1000 FX: 609-570-1050 TF: 877-269-0090

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Final

MDL#: 9499744

* Test Results

Patient Information	SSN: N/A	DOB: 6/18/1976 (Age:43)	Ordering Physician/Lab:	NPI: 1720490022
MACDONALD, AMY [redacted]			MAINE COMPREHENSIVE HEALTH KATHRYN SAWAI, ND 143 SILVER STREET SUITE 1 WATERVILLE, ME 04901 Tel: (207) 395-6101 Fax: (207) 692-1090	

Patient ID:

Date Received: 9/28/2019

Date Reported: 10/10/2019

Test / Specimen / Comment	Date Collected	Results: Normal	Results: Abnormal	Reference/Units/Comments
Bartonella henselae by Real-Time PCR * 317 Verified 10/1/2019 Blood - 2	9/25/2019	Negative		
Babesia microti by Real-Time PCR * 410 Verified 10/1/2019 Blood - 2	9/25/2019	Negative		
Ehrlichia chaffeensis (HME) & Anaplasma phagocytophila (HGE) by Real-Time PCR * 411 Verified 10/5/2019 Blood - 2	9/25/2019	Negative (HGE,HME)		HGE:Negative; HME:Negative.
Babesia duncani (WA-1) by Real-Time PCR * 431 Verified 10/1/2019 Blood - 2	9/25/2019	Negative		
Rickettsia rickettsii by Real-Time PCR * 447 Verified 9/30/2019 Blood - 2	9/25/2019	Negative		
Borrelia mayonii by Real-Time PCR * 449 Verified 9/29/2019 Blood - 2	9/25/2019	Negative		
Ehrlichia ewingii by Real-Time PCR * 456 Verified 9/29/2019 Blood - 2	9/25/2019	Negative		

*This test was developed and its performance characteristics determined by Medical Diagnostic Laboratories, L.L.C. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

Blood-2;410:Babesia microti by Real-Time PCR

A positive result is provided for bacteria, virus, parasites, and/or fungal species when PCR amplification (real-time PCR), sequence information (Pyrosequencing), and/or signal detection (Bio-Plex Analysis) occurs above cut-off levels established by the laboratory. Pertinent reference intervals for the tests reported above are available from the laboratory upon request.

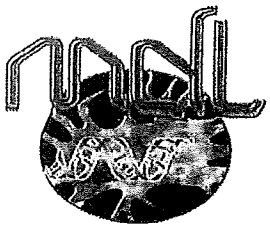
View:	M		Lyme		
Mail:	Yes	USPS	Fax:	Yes	Manual
	One	Yes		One	No

Medical Director, Mats Sanden, M.D.

MDL#: 9499744 30783

10/10/2019

PATH Final



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TL: 609-570-1000 FX: 609-570-1050 TF: 877-269-0090

www.mdlab.com

Final

MDL#: 9499744

* Test Results

Patient Information	SSN: N/A	DOB: 6/18/1976 (Age:43)	Ordering Physician/Lab:	NPI: 1720490022
MACDONALD, AMY [redacted]			MAINE COMPREHENSIVE HEALTH KATHRYN SAWAI, ND 143 SILVER STREET SUITE 1 WATERVILLE, ME 04901 Tel: (207) 395-6101 Fax: (207) 692-1090	

Patient ID:

Date Received: 9/28/2019

Date Reported: 10/10/2019

A positive result is provided for bacteria, virus, parasites, and/or fungal species when PCR amplification (real-time PCR), sequence information (Pyrosequencing), and/or sequencing analysis occurs above cut-off levels established by the laboratory. Pertinent reference intervals for the tests reported above are available from the laboratory upon request.

end of report

View:	M		Lyme		
Mail:	Yes	USPS	Fax:	Yes	Manual
	One	Yes		One	No

Medical Director, Mats Sanden, M.D.

MDL#: 9499744 30783

10/10/2019

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MEDICAL DIAGNOSTIC LABORATORIES, L.L.C.

INTERPRETATION GUIDELINES

WESTERN BLOTS, C6 ELISAS, LYME IgG / IgM ELISAS

Lyme IgG and IgM Western blot Kits - This kit is a membrane immunoassay based on the Western blot method. As recommended by the CDC, all samples which test positive or indeterminate on a serological screening test should be re-tested on a *B. burgdorferi* Western blot test. *B. burgdorferi* Western blot IgG and IgM assays are recommended for the evaluation of sera from patients believed to be in the first four weeks of infection, while an IgG assay alone is recommended for evaluation of sera from patients with symptoms of late Lyme disease.

Report Key - The Alternative Interpretive Criteria is based upon a study published by MDL's Clinical Director, Dr. Richard Tilton (Tilton RC, Sand MN, Manak M. (1997). The Western Immunoblot for Lyme Disease: Determination of Sensitivity, Specificity, and Interpretive Criteria with Use of Commercially Available Performance Panels. Clinical Infectious Disease. 25:S31-4). Reprints are available upon request.

**Effective for results verified on or after 10/17/2013.* To be considered positive, bands must have a value of 60 or greater.

	Result	CDC Criteria (Antibody.CDC)	Alternative Criteria (Antibody.Alt)
IgM	Negative (Non-reactive)	Fewer than 2 bands: 23, 39, 41	No Lyme specific bands
	Negative (Equivocal)	--	One band must be present: 23, 31, 34, 39, 41
	Positive (Reactive)	Two or more bands must be present: 23, 39, 41	Two or more bands must be present: 23, 31, 34, 39, 41
IgG	Negative (Non-reactive)	Fewer than 5 bands: 18, 23, 28, 30, 39, 41, 45, 58, 66, 93	No Lyme specific bands
	Negative (Equivocal)	--	One or two bands must be present: 23, 31, 34, 39, 93
	Positive (Reactive)	Five or more bands must be present: 18, 23, 28, 30, 39, 41, 45, 58, 66, 93	Three or more bands must be present: 23, 31, 34, 39, 93

Negative Results: Additional specimens should be submitted in 2-4 weeks if *B. burgdorferi* exposure has not been ruled out.

Positive Results: The corresponding antibodies (IgG or IgM) to significant *B. burgdorferi* proteins detected; presumptive evidence of probable exposure.

The use of the Lyme Western blot on Cerebrospinal fluid is an off-label application and is for investigational use only. This test kit was designed for human serum specimens. There is no validation data available for the use of this test on human Cerebrospinal fluid (CSF) specimens.

The major differences between the interpretative criteria are:

1. IgM – The Alternative Criteria is similar to the CDC except that the 93 band has been included as a significant IgM band specific to *B. burgdorferi*.
2. IgG – The Alternative Criteria is based on both the number of bands and the significance of the antibodies detected. For example, Osp A (31) and Osp B (34) are important bands seen often in late stages of Lyme disease.
3. There is an "equivocal" category for both IgG and IgM blots which indicates that although there are not sufficient antibody bands present for the blot to be reactive, there is significant immunologic activity that may be related to Lyme disease.

Toll Free: (877) 269-0090 • Fax: (609) 570-1050 • www.mdlab.com
A MEMBER OF GENESIS BIOTECHNOLOGY GROUP

View: M

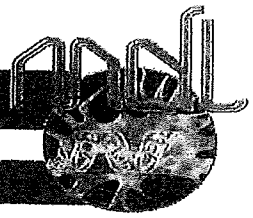
Mail:	Yes	USPS
	One	Yes

Lyme

Fax:	Yes	Manual
	One	No

Medical Director, Mats Sanden, M.D.

MDL#: 9499744 30783
10/10/2019
PATH Final



WESTERN BLOTS, C6 ELISAS, LYME IgG / IgM ELISAS CONTINUED...

C6 Lyme ELISA Diagnostic Kit - Immunetics reports that their FDA approved diagnostic kit is 98% specific and 97% sensitive in comprehensive clinical trials of Lyme patients at every stage of the disease - from early onset to late stage disseminated infection. The C6 Lyme ELISA can also distinguish between true infections and vaccination responses.

Lyme Index	Interpretation
≤ 0.90	**Negative result.** No antibody to *B. burgdorferi* detected in the present assay. This result does not exclude the possibility of *B. burgdorferi* infection, and where early Lyme disease is suspected, a second sample should be drawn 2-4 weeks later and re-tested.
0.91 – 1.09	**Equivocal result.** The imprecision inherent to any method implies a lower degree of confidence in the interpretation of samples with A450 values very close to the calculated cut off value. For this reason, an equivocal result has been designated. Equivocal samples should be tested with a supplemental assay such as a standardized Western blot test in accordance with CDC/ ASTPHLD recommendations.
≥ 1.10	**Positive result.** Antibody to *B. burgdorferi* detected in the present assay. All positive results should be supplemented by re-testing the corresponding serum samples on a standardized Western blot test in accordance with CDC/ASTPHLD recommendations.

Lyme IgG / IgM ELISA - This test is an enzyme-linked immunosorbent assay (ELISA) designed for the qualitative presumptive detection of total (IgG and IgM) antibodies to *B. burgdorferi* in human serum. The test system should only be used for patients with signs and symptoms that are consistent with Lyme disease. Equivocal or positive results must be supplemented with testing with a standardized Western blot procedure. Positive supplemental results are supportive evidence of exposure to *B. burgdorferi* and can be used to support a clinical diagnosis of Lyme disease.

Effective for results verified on or after 7/21/2006

ISR Value	Interpretation
≤ 0.90*	**Negative result.** No detectable antibody; result does not exclude B. burgdorferi infection. An additional sample should be tested within 4-6 weeks if early infection is suspected.
0.91 – 1.09*	**Equivocal result.** Current recommendations state that equivocal results should be followed by supplemental Western blot. (Western blot assays for *B. burgdorferi* are supplemental rather than confirmatory because their specificity is less than optimal, particularly for detecting IgM.) This equivocal result should be reported with results from Western blot testing. Results should not be reported until the supplemental testing is completed.
≥ 1.10*	**Positive result.** Antibody to *B. burgdorferi* presumptively detected. Per current recommendations, the result cannot be further interpreted without supplemental Western blot testing. (Western blot assays for *B. burgdorferi* are supplemental rather than confirmatory because their specificity is less than optimal, particularly for detecting IgM.) This equivocal result should be reported with results from Western blot testing. Results should not be reported until the supplemental testing is completed.

View:	M		Lyme		
Mail:	Yes	USPS	Fax:	Yes	Manual
	One	Yes		One	No

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MDL#: 9499744 30783
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