

Lyme Disease Discussion Aug 18, 2011 Time: 1:00PM

Division of Public Health Services
Department of Health and Human Services
29 Hazen Drive
Concord, NH 03301
(603) 271-4612

Director Dr Jose T. Montero (not in attendance) Chief Christine Adamski,
State Epidemiologist Dr Sharon Alroy-Preis, Chief Elizabeth Daly,
State Deputy Epidemiologist Dr Jodie Dionne-Odom

Thank you for allowing us this opportunity to meet with the New Hampshire Department of Health in order to share information between clinicians in the field representing the late stage Lyme patient and our public health officials.

Meeting Agenda

- I. State of affairs; Lyme disease in New England (Page 2)
- II. Two tier testing with Elisa (Page 4) and Western blot (Page 6)
- III. Diagnosis; Lyme Disease (Page 9)

Attendees/speakers:

- 1) Dr Emory Kaplan and wife Sue McNamee Pediatrics, Nashua
- 2) Dr Kevin Young Plymouth Family Practice, Plymouth
- 3) Gail Vanark ARNP Center for Preventive Medicine, Amherst
- 4) Dr Richard Shulik Jacobs Associates, Londonderry
- 5) Dr Lynn Durand Family Tree Health Care, Concord
- 6) Dr Julia Greenspan Greenhouse Naturopathic Medicine, Hollis
- 7) State Representative Gary Daniels
- 8) State Representative John Cebrowski
- 9) Carl Tuttle Hudson

- IV. Proposed resolution (Page 11)

Attachments:

- 1) Elisa laboratory results Dartmouth Hitchcock
- 2) Western blot laboratory results Quest Diagnostics
- 3) Dr Sam Donta's clinical notes
- 4) Letter to Quest Diagnostics
- 5) Letter to the Department of Health and Human Services
- 6) Letter to U.S. Attorney John Kacavas

We are experiencing a health crisis here in New Hampshire and around the country with the growing epidemic of Lyme disease. A number of legislators have personally been affected and have introduced legislation to address this problem.

Here are just a few recent examples.

Massachusetts

Representative David Linsky of Massachusetts whose son was severely affected by Lyme disease presented his report "Lyme Disease in Massachusetts: A Public Health Crisis"

<http://www.malegislature.gov/Content/Documents/Committees/H46/LymeDiseaseReport.pdf>

Rep Linsky's summary:

"The state's official response to Lyme disease can be characterized as haphazard at best."

"The occurrence of Lyme disease has reached near epidemic proportions in Massachusetts. Virtually every family in Massachusetts has been affected by Lyme disease in some way. Lyme disease is a public health crisis in the Commonwealth."

"As a result, millions of dollars are lost in employee absences due to Lyme disease. Each year, hundreds of school children miss school. Millions of dollars are spent in medical care."

"At present, no one has a clear plan or recommendation for treatment, prevention or education. Some medical professionals question whether "chronic Lyme disease" even exists. Yet, it is clear that hundreds of Massachusetts residents are afflicted by its debilitating symptoms. Few people can effectively access treatment due to a lack of providers and problems with insurance coverage."

Connecticut, Rhode Island, New York

Blumenthal takes Lyme disease fight to the Senate

<http://ctmirror.com/story/13311/blumenthal-takes-lyme-disease-fight-senate>

"Today for me culminates more than a decade of work and probably a decade more, because I've seen firsthand the devastating, absolutely unacceptable damage done by Lyme disease to individual human beings, Connecticut children and residents whose lives have been changed forever as a result of Lyme disease," Blumenthal said.

The bill is being co-sponsored by Rhode Island senators Jack Reed and Sheldon Whitehouse, and by New York Senator Kirsten Gillibrand.

New Jersey, Pennsylvania

Cong. Smith Unveils Lyme Disease Bill

<http://chrissmith.house.gov/News/DocumentSingle.aspx?DocumentID=252549>

"It seems everywhere I go, someone comes up to me to talk about how Lyme disease has severely impacted their lives or someone they know," said Smith. "Lyme is a very prevalent disease in the U.S. today. This legislation provides a comprehensive, nationwide effort to step up the fight against this disease. My state of New Jersey is particularly hard hit."

Smith is the sponsor of the measure, H.R. 2557, which would support federal efforts concerning Lyme and other tick-borne diseases through the establishment of a Tick-Borne Diseases Advisory Committee. Smith co-chairs the House Lyme Disease Caucus, along with Frank Wolf (R-VA) and Tim Holden (D-PA), who are both cosponsors of the bill.

Virginia

Virginia Governor's Task Force Chair Michael P Farris, Esq. (Chancellor of Patrick Henry College Licensed in the District of Columbia and Washington) has eight of his ten family members have been diagnosed with Lyme disease.

Quoting the Chair of the Virginia Lyme Disease Task Force Michael P Farris:

"Doctors here in Virginia are committing malpractice by saying the ELISA test is sufficient."

<http://www.nbcwashington.com/news/health/Task-Force-Takes-Lyme-Disease-Fight-to-Loudoun-County-124824524.html>

If the IDSA and CDC got it right with their "one size fits all" treatment approach for all stages of Lyme disease and two tier test method why then do we have this much legislation involving Lyme disease?

Elisa Test Results

The attached NEGATIVE Elisa results from Dartmouth Hitchcock are typical.

Patient: Janet Tuttle

At the time of the test my wife's symptoms included:

Fatigue, tinnitus, neck pain/stiffness, dyspnea and palpitations, migrating arthralgias of the hips, knees and ankles, low back pain and migrating myalgias, lightning like pain in her ankles and fingers, occasional tremors and parasthesias of the right side of her lip, shoulders and back. Cognitive issues included short-term memory loss, problems with word-finding along with depression and mood swings.

Our "perspective" on Lyme disease comes from first hand experience as all family members have been afflicted with this disease. What we find most disturbing is the fact that our family practitioners knew absolutely nothing about Lyme disease, had a universal misunderstanding of lab results and a universal dismissal of Lyme symptoms.

None of our family members presented with a bulls-eye rash and only our daughter recalled a recent tick bite. In the absence of the bulls-eye rash, the likelihood of obtaining a timely diagnosis in a state with the highest reported number of Lyme disease cases is virtually nonexistent.

Carl W Tuttle

Inaccurate tests have consequences for people that can be major for their health and lives.

The College of American Pathologists found that the ELISA tests do not have adequate sensitivity to be used as a screening test for Lyme disease. In two blinded studies that tested laboratories accuracy, the ELISA failed miserably. In the latest study by the College of American Pathologists, 516 labs were tested. The overall result: 55% inaccurate! (Bakken 1997).

Lyme disease researcher and physician, Dr. Sam Donta of Boston University Medical Center reported that 52% of patients are negative by the ELISA, but positive through the Western Blot. (Donta, 2002). Because of this, the best antibody test to use for diagnosis is the Western Blot

A two year study out of Johns Hopkins concluded these tests were less than 50% accurate. A screening test by definition should be 95% reliable and we're not even close to that number. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1248466/>

* * * * *
ELECTRONIC REPRODUCTION FOR:
Erica Raffa Dept: Nashfp 03/17/2009 8:20:35 AM
* * * * *

DARTMOUTH-HITCHCOCK RESULTS NOTIFICATION
ENCOUNTER DATE: 03/17/2009 TUTTLE, JANET
8214586

**Dartmouth-Hitchcock
321 Derry Road
Hudson, New Hampshire 03051
603-577-3410**

Janet Tuttle
33 David Dr
Hudson, NH 03051-3102

Dear Janet

This letter is to inform you that per Dr. Patel, your Lyme titers are negative! Please follow up in our office with the provider who manages your care. If you have any questions or concerns, please feel free to call our office at 577-3410 or email us at Patient Online. Thank you.

Sincerely,

Erica Raffa, LPN
for Dr. Sanjay Patel

Electronically signed by: RAFFA LPN, ERICA 03/17/2009 08:20

Western blot Test Results

The attached NEGATIVE Western blot results from Quest Diagnostics are typical.

Patient: Janet Tuttle

Interpretation of the Western blot is another area of significant confusion. Strict criteria were created in 1994 for surveillance of Lyme disease and only those patients who met the strict case definition were reported to the CDC. So if you did not meet those criteria your Western blot stated NEGATIVE.

The CDC case definition was developed for national reporting of Lyme disease and it is not intended to be used in clinical diagnosis.

Lyme knowledgeable Infectious Disease Specialists recognize that it is not necessary to meet the case definition in order to diagnose Lyme disease.

Not a single physician we have met affiliated with Dartmouth Hitchcock has any knowledge of these significant facts.

Copied from the CDC's Lyme Case Definition website:

“Health-care providers are reminded that a diagnosis of Lyme disease should be made after evaluation of a patient's clinical presentation and risk for exposure to infected ticks, and, if indicated, after the use of validated laboratory tests.”

Note:

Commercial laboratory tests have excluded bands 31 and 34 which are highly specific to *Borrelia burgdorferi* and were originally chosen for vaccine development.



QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 1-866-697-8378

SPECIMEN INFORMATION
SPECIMEN: WC922124A
REQUISITION: 2312687

COLLECTED: NOT GIVEN
RECEIVED: 04/09/2009 01:45 ET
REPORTED: 04/16/2009 08:12 ET

PATIENT INFORMATION
TUTTLE, JANET
DOB: 12/10/1956 AGE: 52
GENDER: F ASTING: U
ID:
PHONE: 603.886.6462

REPORT STATUS FINAL REPRINT

ORDERING PHYSICIAN
DONTA, SAMUEL

CLIENT INFORMATION
NE66007401 CA000159
DONTA INFECTIOUS DISEASES

PO BOX 944
FALMOUTH, MA 02541-0944

Test Name	In Range	Out of Range	Reference Range	Lab
LYME DISEASE ANTIBODIES				
(IGG, IGM) WESTERN BLOT				
LYME DISEASE AB (IGG) WB	NEGATIVE		NEGATIVE	QCA
18 KD (IGG) BAND	NON-REACTIVE			
23 KD (IGG) BAND	NON-REACTIVE			
28 KD (IGG) BAND	NON-REACTIVE			
30 KD (IGG) BAND	NON-REACTIVE			
39 KD (IGG) BAND	NON-REACTIVE			
* 41 KD (IGG) BAND	REACTIVE		* 1 single band	
45 KD (IGG) BAND	NON-REACTIVE			
58 KD (IGG) BAND	NON-REACTIVE			
66 KD (IGG) BAND	NON-REACTIVE			
93 KD (IGG) BAND	NON-REACTIVE			

IGG WESTERN BLOTS WHICH HAVE 5 (OR MORE) OF THE 10 SIGNIFICANT BANDS ARE CONSIDERED POSITIVE FOR SPECIFIC ANTIBODY TO B. BURGDORFERI. (PROCEEDINGS OF THE 2ND CONF. ON LYME DISEASE, DEARBORN, MI, 1994.)

LYME DISEASE AB (IGM) WB
* 23 KD (IGM) BAND
39 KD (IGM) BAND
41 KD (IGM) BAND

NEGATIVE
REACTIVE
NON-REACTIVE
NON-REACTIVE

IGM WESTERN BLOTS WHICH HAVE 2 (OR MORE) OF THE 3 SIGNIFICANT BANDS ARE CONSIDERED POSITIVE FOR SPECIFIC ANTIBODY TO B. BURGDORFERI. (PROCEEDINGS OF THE 2ND CONF. ON LYME DISEASE, DEARBORN, MI, 1994.)

HARD COPY TO FOLLOW

Fifteen year old conference

NEGATIVE
For
Surveillance
Purposes
only!

TUTTLE, JANET - WC922124A

Page 1 - Continued on Page 2!

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04/20/09 13:25 4291289 1/1

No disclaimer reminding the physician that a diagnosis of Lyme should be made after evaluation of the patients clinical presentation.



QUEST DIAGNOSTICS INCORPORATED

COLLECTED: NOT GIVEN
REPORTED: 04/16/2009 08:12 ET

PATIENT INFORMATION
TUTTLE, JANET

DOB: 12/10/1956 AGE: 52
GENDER: FASTING: U

REPORT STATUS FINAL REPRINT

ORDERING PHYSICIAN
DONTA, SAMUEL

PERFORMING LABORATORY INFORMATION

QCA QUEST DIAGNOSTICS-CAMBRIDGE, 415 MASSACHUSETTS AVENUE, CAMBRIDGE, MA 02139
Laboratory Director: SALIM E KABAWAT, CLIA: 22D0660288

NO COLLECTION DATE RECEIVED. WE HAVE USED
THE DATE THE SPECIMEN WAS RECEIVED BY THIS
LABORATORY AS THE COLLECTION DATE. IF THIS
IS INCORRECT, PLEASE CONTACT CLIENT SERVICES.
PHONE NUMBER: 1-866-697-8378

TUTTLE, JANET - WC922124A

Page 2 - End of Report||

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Diagnosis; Lyme Disease

The attached clinical notes from Dr Sam Donta indicate Lyme disease.

Patient: Janet Tuttle

We are fortunate to have found Dr Sam Donta, who recognized the clinical symptoms of Lyme disease, no longer uses the Elisa and could interpret the Western blot.

I am happy to report that my wife is now doing excellent.

Carl W. Tuttle

The German Borreliosis Society has recognized that the two tier system we are currently using to test for Lyme disease is inadequate.

From the German Lyme Disease Guidelines:

“If a Borrelia infection is suspected, an IgG and IgM immunoblot for Borrelia should be carried out in all cases.”

The procedure recommended by the Robert Koch Institute (RKI) and prescribed by the Association of Health Insurance Funds [Kassenärztliche Vereinigung (KV)], to conduct immunoblotting as well as a confirmatory test only if the ELISA is abnormal (or other so-called exploratory tests) (a process known as stepwise diagnostics), must be rejected because this leads to serologically false-negative results in up to a further 15% of patients.”

<http://www.borreliose-gesellschaft.de/Texte/guidelines.pdf>

DONTA INFECTIOUS DISEASES

PHONE: 508-539-6666
FAX: 508-540-0133

Sam T. Donta, MD
Professor of Medicine (ret)
Maureen T. McKay, RN, ANP

Mailing Address:
P.O. Box 944
Falmouth, MA 02541

Boston Office
5 Whittier Place, Ste 102
Boston, MA 02114

Falmouth Office
314 Gifford Street
Falmouth, MA, 02540

Tuttle, Janet
DOB: 12-10-56 Telephone: (603) 548-9523
Date: 5-6-09

Ms. Tuttle is a 52-year-old female who presents to the office today for evaluation for chronic Lyme disease. She denies any known tick bite or rash.

The onset of Ms. Tuttle's symptoms began at least four years ago with treatment for fibromyalgia, for which she was treated with noni juice. Her husband states that rheumatologic testing has been negative.

Testing available to us today includes the following: on 11-25-08, Lyme Western blot through IGeneX showed an IgG reaction to the 41 KD protein and IgM reactions to the 30, 41 and 45 KD proteins. On 4-9-09, Lyme Western blot through Quest Diagnostics showed an IgG reaction to the 41 KD protein and IgM reaction to the 23 KD protein.

Ms. Tuttle denies any known drug allergies. Past medical history is non-contributory. Past surgical history includes tonsillectomy. Current medications include calcium, vitamin E and vitamin D.

Review of systems: Ms. Tuttle reports cycles of fatigue, one episode of tinnitus, neck pain/stiffness, dyspnea and palpitations. She reports migrating arthralgias of her wrists, elbows, hips, knees and ankles; she also has low back pain and migrating myalgias. She experiences lightning-like pain in her ankles and fingers, occasional tremors and paresthesias of the right side of her lip, shoulders and back. Cognitive issues include short-term memory loss, problems with word-finding as well as depression and mood swings, both of which occur when she is tired.

Physical exam shows an alert and oriented female in no acute distress. PERRLA, fundi are pale and discs are sharp. Mucus membranes of the mouth are moist and without lesions. Thyroid is normal size without nodules. There is no adenopathy in the neck. There are no carotid bruits. Lungs are free of rhonchi, crackles or wheezes. Cardiac rate is 64 bpm with regular rhythm, normal S1 S2, no S3 S4 and no murmurs. Abdomen is soft, non-tender, bowel sounds are present and there is no HSM. Strengths are 5/5 and she has FROM. DTRs are 1+ and symmetric at all sites. Romberg is normal. Toes are down-going to plantar stimulation. CN II-XII are intact. On mini mental exam, she was able to spell the word "world" backwards, accurately repeat the phrase "no ifs, ands or buts" and able to recall two of three objects after one minute.

In consultation with Dr. Donta, it is agreed that Ms. Tuttle does fit the multi-symptom complex of chronic Lyme disease. In addition, her Lyme Western blot showed a specific reaction to the 23 KD protein, denoting exposure to the Lyme bacteria. A plan of treatment was discussed and Ms. Tuttle will start clarithromycin 500mg bid plus hydroxychloroquine 200mg bid, with the hydroxychloroquine being required to act as a lysomotropic agent to assist the clarithromycin. She will discontinue vitamin E supplementation to avoid interfering with the body's attempt to oxidize the bacteria to rid it from the system. She will return to the office on 8-26-09 at 3:30pm.

Dr. Donta is happy to consult with Dr. Patel at any time regarding this patient.

Maureen T. McKay, R.N., C.S., A.N.P.
Nurse Practitioner for Sam T. Donta, MD
MM/vw

cc: Sanjay Patel, MD, 321 Derry Road, Hudson, NH, 03051

Proposed Resolution

- 1) Lyme testing should include both Elisa and Western blot to rule out false Negative Elisa results.
- 2) “Informed Consent” Patients should be made aware of the unreliability of existing Lyme diagnostic tests.
- 3) Health insurance companies doing business here in New Hampshire should be required to pay for both Lyme diagnostic tests. As it stands now insurance will not cover the Western blot. Is this as an intentional move to limit the number of Lyme cases?
- 4) It is the responsibility of the Department of Health to educate the medical community regarding the low reliability of the Elisa. A two year Johns Hopkins study concluded these tests were less than 50% reliable. Inaccurate tests have consequences for people that can be major for their health and lives.
- 5) Interpretation of the diagnostic tests results is of utmost importance. CDC surveillance criteria for positive Western blot should not be misused as diagnostic criteria. Provider training for proper lab interpretation should be provided by the Department of Health.
- 6) A task force should be appointed by the Governor to investigate the rampant misdiagnosis of Lyme disease in an attempt to identify faulty diagnostic testing through patient and Lyme treating physician interviews. Those who treat Lyme exclusively are flooded with late stage Lyme cases like the testimonies heard at public hearings for New Hampshire’s Lyme Bill. The panel should include at least one Lyme exclusive physician along with patient advocates familiar with the crisis. As it stands now most physicians associated with Dartmouth Hitchcock feel that this is little more than a “nuisance disease” and that viewpoint has to change in order to protect New Hampshire citizens.

The misinterpretation of laboratory results is the reason why PCP's are so dismissive of Lyme patients and their symptoms.

Those of us who have lost jobs, savings, 401k's and homes to this devastating disease were all misdiagnosed missing the narrow window of opportunity for successful short term treatment. We want to see an end to this needless suffering.

The Lyme community and treating physicians are all in agreement with this message.

June 17, 2009

Quest Diagnostics-New England
415 Massachusetts Ave.
Cambridge, MA 02139
Attn: Salim E. Kabawat, M.D. Medical Director

Dear Dr Kabawat,

Each week for the past month I submitted the following question through your online patient inquiry portal:

Could you please tell me why Quest Labs' Western blot Lyme test doesn't include band 31 and 34? Is it possible that your exclusion of these bands is missing many Lyme cases since band 31 and 34 are highly specific to Borrelia burgdorferi and were originally chosen for vaccine development?

On June 9, 2009 you responded to my inquiry referring to a thirteen year old CDC guideline for Lyme disease reporting dated August 11, 1995 (**MMWR 44(31):590-591**). You then cut and pasted the following information from that guideline:

*"It was recommended that an IgM immunoblot be considered positive if **two** of the following three bands are present: 24 kDa (OspC) *, 39 kDa (BmpA), and 41 kDa (Fla) (1). It was further recommended that an that IgG immunoblot be considered positive if **five** of the following 10 bands are present: 18 kDa, 21 kDa (OspC) *, 28 kDa, 30 kDa, 39 kDa (BmpA), 41 kDa (Fla), 45 kDa, 58 kDa (not GroEL), 66 kDa, and 93 kDa (2)."*

On February 11, 2005 the Centers for Disease Control and Prevention issued the following caution (**MMWR Morb Mortal Wkly Rep 2005; 54:125-6**) regarding testing for Lyme disease:

Health-care providers are reminded that a diagnosis of Lyme disease should be made after evaluation of a patient's clinical presentation and risk for exposure to infected ticks, and, if indicated, after the use of validated laboratory tests.

As I review my wife and daughter's Western blot lab results which were ordered through Quest laboratory Apr 16, 2009 and May 7, 2009 respectively, I cannot locate the disclaimer reminding the physician that a diagnosis of Lyme disease should be made after evaluation of the patient's clinical presentation or risk for exposure to infected ticks. In fact, my daughter's primary care physician called to inform her that she didn't have Lyme disease based on your lab results alone without considering clinical symptoms whatsoever.

The attached CDC deer tick/Lyme study concludes that we are living in an area with one of the highest rates in the state. Residents in our area have a 77% chance of contracting Lyme through a deer tick bite. Physicians in this "endemic area" as we have experienced are not familiar with the clinical manifestations of Lyme especially when the patient does not present with the typical bulls eye rash or recall experiencing a tick bite as is the case 50% of the time.

Your lab tests are contributing to the problem as all the physician sees is the word NEGATIVE on the results.

Under the Infectious Conditions for Public Health Surveillance page, the Centers for Disease Control updated its **Lyme Case Definition** in 2008 stating the following:

“This surveillance case definition was developed for national reporting of Lyme disease; it is not intended to be used in clinical diagnosis”

This includes the thirteen year old 1995 CDC guideline for reporting purposes that you referred to in your original response.

Lyme literate Infectious Disease Specialists recognize that it is not necessary to have five positive Western blot IgG bands or two IgM bands in order to diagnose Lyme disease. Those guidelines were strictly developed for surveillance purposes only.

Your lab results neglect to mention any of this so Quest Labs along with other commercial labs is misleading the physician. I don't believe this is intentional but more on the lines of complacency.

I have first hand experience after chasing an unresolved fatigue for twelve years as my Western blot results show only two positive bands. I would like to mention that private Lyme testing labs (i.e. IGeneX Labs) are informing the patient with disclaimers stating that diagnosis should not be based on laboratory tests alone and results should be interpreted in conjunction with clinical symptoms and patient history.

There is a moral responsibility to provide accurate information as I have identified in this letter. I would like to remind you of the following statement found on your **Company Info** page: *“Quest Diagnostics is People. Dedicated people who understand that behind every specimen and result there is a human life”*

Our Vision, Mission & Values

Accountability

As a company and as individuals, we accept full responsibility for our performance and acknowledge our accountability for the ultimate outcome of all that we do. We strive for continuous improvement, believing that competence, reliability, and rigorous adherence to process discipline are the keys to excellence

How many Lyme patients have been misdiagnosed and told they do not have Lyme disease due to your “NEGATIVE” lab results and missing disclaimers? There is a dyer need to change your methods and educate the physician to avoid patient suffering by missing the window of opportunity for treatment.

Sincerely,

Carl Tuttle
33 David Dr
Hudson, NH 03051
(603) 479-4927

July 7, 2010

New Hampshire Department of Health and Human Services
29 Hazen Drive
Concord, NH 03301-4604
Attn: Jose T. Montero, MD, Director

Dr Montero,

This certified letter serves as legal notice that you as New Hampshire's chief epidemiologist are being notified of ongoing health risks in the State of New Hampshire. First, there appears to be an alarming number of Lyme cases within a 500 yard radius of our home located on David Dr in the town of Hudson. We know of nine individuals who have been treated for Lyme disease with two additional cases suspected.

The second serious health risk which I will identify below is a plague of ignorance within the medical community as it relates to Lyme diagnosis. The following case studies collected from a Lyme literate practice point out that misdiagnosis is rampant with lab interpretation as the number one area of significant confusion.

Case# 1

Male age 27 with no known tick bite but many mosquito bites. FIVE previous ELISA tests were all NEGATIVE. The patient was sick with fatigue, headaches and cognitive issues for 1.5 years and missed a year of school before seeing a Lyme literate practice and given the more sensitive Western blot test. Western blot was CDC POSITIVE for Lyme disease.

Note: The ELISA test is unreliable as proven in this case but patients are routinely refused the more specific Western blot when the ELISA is negative. We have first hand experience as my wife was denied a Western blot through her primary care physician, Dr Sanjay Patel affiliated with Dartmouth Hitchcock Hospital.

Case# 2

Female age 60 diagnosed with ALS in 2008. ELISA test was NEGATIVE. When given the Western blot test last month the patient tested CDC POSITIVE for Lyme disease.

Case# 3

Male age 8 with knee pain and swelling. Underwent four knee surgeries. Seen by rheumatology and diagnosed with idiopathic knee pain "growing pains". ELISA test results were NEGATIVE through the patient's primary care office. A recent Western blot was positive for Lyme disease.

Case# 4

Female age 18 was told she had an infected bug bite and was prescribed Keflex through the patient's primary care office. ELISA test was done weeks later and results were NEGATIVE. Patient missed thirty six days of school. A Western blot which was not provided by the PCP was positive for Lyme disease. Improvement started two weeks into treatment with proper antibiotics.

Note: This patient stored a picture of the bug bite on her cell phone which was clearly a bull's-eye rash but unrecognized by the PCP.

Case# 5

Male age 39 with fatigue and swelling joints for 1.5 years. ELISA test results were NEGATIVE through the patient's primary care office. A recent Western blot was CDC POSITIVE for Lyme disease.

Many of these patients presented with the most obvious of Lyme symptoms, i.e. joint pain/swelling and fatigue yet proper diagnosis and treatment was missed by a medical community misinformed through unreliable diagnostic testing and restrictions against the use of the more sensitive Western blot.

Interpretation of the Western blot is another area of significant confusion. Strict criteria were created in 1994 for surveillance of Lyme disease and only those patients who met the strict case definition were reported to the CDC. So if you did not meet those criteria your Western blot stated NEGATIVE. (See my wife's attached Western blot results attachment # 1) In February of 2005 the CDC issued a caution regarding testing for Lyme disease:

Health-care providers are reminded that a diagnosis of Lyme disease should be made after evaluation of a patient's clinical presentation and risk for exposure to infected ticks, and, if indicated, after the use of validated laboratory tests.

In 2008 the CDC updated its Lyme Case Definition stating the following:

“This surveillance case definition was developed for national reporting of Lyme disease; it is not intended to be used in clinical diagnosis”

Dr Montero, you were recently interviewed on New Hampshire Public Radio where you made reference to the CDC's “updated Case Definition” (9 minutes into the archived program) You believed that one reason New Hampshire has the highest rate of Lyme in the country might be due to a change in case definition. So you obviously are aware that the case definition is not intended to be used in clinical diagnosis. For some reason Dr Montero your colleagues did not get that memo.

Case in point: My daughter's primary care physician (Dr Barbara Brundage, Derry Pediatrics) called to inform her she did not have Lyme disease based on the results from Quest Diagnostics NEGATIVE Western blot. (See attachment # 2) Dr Brundage did not see my daughter nor did she discuss symptoms prior to informing her she did not have Lyme disease. This story is not unique and has been repeated over and over as we hear the same scenario at the monthly Greater Manchester Lyme Support Group meetings. Lyme literate Infectious Disease Specialists recognize that it is not necessary to meet the case definition in order to diagnose Lyme disease.

I would like to point out that your department sent a health alert to doctors across the state on June 21st (Attachment# 3) SUBJECT: "Tick-borne Disease in New Hampshire – Update." Why is there no mention within that health alert that the CDC case definition was developed for national reporting of Lyme disease and it is not intended to be used in clinical diagnosis? Wouldn't it make sense to pass along this important fact?

Imagine designing a screening test where negative results are seen 95% of the time? This is happening in your state under your watch Dr Montero. If you are finding this difficult to believe I urge you to attend one of the monthly Lyme Support Group meetings and learn first hand how misinformed your medical community is as it relates to the diagnosis of Lyme disease. Let me remind you of the following statement found within your web site: "The Department of Health and Human Services' Mission is to join communities and families in providing opportunities for citizens to achieve health and independence."

The fact that each Lyme case (suspected or confirmed) has to be reported to the Department of Health and Human Services should leave a paper trail worthy of investigation. All of Quest Diagnostic's NEGATIVE Western blot results should lead directly to those cases that have been misdiagnosed. We know of cases where physicians are telling patients that their POSITIVE IGeneX lab reports are unreliable. IGeneX Laboratory is the foremost authority for Lyme disease testing in the country and CLIA-certified and inspected by the Department of Health and Human Services for Medicare testing. IGeneX lab's Western blot includes bands 31 and 34 which are highly specific to Lyme (*Borrelia burgdorferi*) and were originally chosen for vaccine development. Quest diagnostics and other commercial testing labs exclude these two critical bands.

Misdiagnosis has created a backlog of late stage Lyme patients with a waiting list to see a Lyme literate doctor in some cases approaching six months. Misdiagnosed patients are missing the narrow window of opportunity for successful short term treatment.

I have serious reservations as to whether or not the medical community could self-police itself in light of a possible professional embarrassment and that's why I have sent additional registered letters to the Attorney General and Governor's office. A study of the lab results in your department and follow-up phone calls directly to the patient should reveal what is taking place. This is a serious issue that affects all New Hampshire citizens and should not be taken lightly.

For public review, a web site has been constructed with this letter as its home page as a record of the complaint. In addition, an effort to identify those physicians who misdiagnose Lyme disease and publicly post their names along with scanned lab test results is currently being considered.

The misdiagnosis of Lyme disease has to stop Dr Montero. You and others reading this letter are just a tick bite away from Lyme disease in this state as things stand now. The Lyme community is requesting that you take an active role in preventing this ongoing tragedy. When are we going to restructure testing and training of the uninformed providers? We have presented the facts without exaggeration and would like to know how you intend to address this serious issue.

New Hampshire Lyme Community

Carl Tuttle
33 David Dr
Hudson, NH 03051
(603) 479-4927

p.s. I visited the Hudson Animal Hospital today to ask a few questions about Lyme tests for pets. As it turns out they now include Heartworm, **Lyme** and **Ehrlichia** (tick transmitted disease) as **routine tests** with annual physicals. The receptionist reported that there is a serious problem with Lyme in the Robinson Pond area.

We do not receive routine Lyme tests. You could argue that our pets are receiving better healthcare than we are.

Health Threat to New Hampshire Citizens

June 30, 2011

The United States Attorney's Office
District of New Hampshire
53 Pleasant Street, 4th Floor
Concord, NH 03301

Dear U.S. Attorney Kacavas,

We have a serious problem here in New Hampshire in getting the Department of Health to recognize that our citizens are being harmed by the faulty Lyme Elisa test. The State Deputy Epidemiologist has never treated the late stage Lyme patient and refuses to listen to anything outside of CDC recommendations.

Preliminary discussions are underway to establish a class action against the State of New Hampshire to compensate those who were misdiagnosed due to the faulty laboratory tests. We brought this problem to the attention of the Director of Health and Human Services, the Governor and Attorney General a year ago and posted these complaints (certified letters) to the [New Hampshire Lyme Misdiagnosis](#) website as a permanent record of our attempts. It is a record of who knew what and when but did absolutely nothing about it.

I receive phone calls on weekly bases from patients who found the website and had similar stories of misdiagnosis. We need to realign the faulty two tier system of diagnostics and include the Western blot as a way to rule out the false negative Elisa. Primary care physicians are not allowed to run a Western blot when the Elisa is negative and have absolutely no idea just how unreliable the Elisa test really is. A two year study out of Johns Hopkins concluded these tests were less than 50% accurate. A screening test by definition should be 95% reliable and we're not even close to that number.

The Department of Health and Human Services has turned their backs on the citizens of New Hampshire refusing to recognize our complaints as serious. We believe this response is negligent. The State Deputy Epidemiologist does not work for the CDC and is employed by the tax payers of this state.

We have a backlog of late stage Lyme patients as a result who have lost careers, savings, homes, and 401k's while trying to treat this devastating illness.

Carl Tuttle
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