Oct 22, 2020

The New Hampshire House of Representatives
Health, Human Services and Elderly Affairs
Attn: Representative Gary Woods, Chair for the HB490 Commission

Dear Representative Woods,

In following Section **141-C:6-a** of HB490 “to study the use and limitations of serological diagnostic tests”, I would like to point out that the only FDA approved laboratory tests for Lyme disease are antibody tests.

Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease
Weekly / August 16, 2019 / 68(32);703
https://www.cdc.gov/mmwr/volumes/68/wr/mm6832a4.htm?s_cid=mm6832a4_w

Indirect serologic testing as you know is looking for elevated antibodies to the pathogen in question. Since humans do not produce antibodies against Borrelia (the causative agent of Lyme disease) for **4-6 weeks** after a tick bite, relying on antibody production misses early detection.

Antibody tests cannot be used to gauge treatment failure or success.

For the record, I would like to archive this entire document for public viewing on the Study Commission website.

The following is just a short list of studies identifying treatment failure through **direct detection methods** with some of these references dating back thirty years.

Evidence of Persistent Infection After Extensive Antibiotic Treatment: (extracted from my letter to the editor published in the ***BMJ*** , June 10, 2020)

Re: Lyme borreliosis: diagnosis and management
https://www.bmj.com/content/369/bmj.m1041/rr-1

Excerpt:

I would like to call attention to the following 1995 study from Stony Brook Lyme clinic. I understand the patient received thirteen spinal taps, multiple courses of IV and oral meds, and relapsed after each one, proven by CSF antigens and/or **PCR**. The only way this patient (said to be a physician) remained in remission was to keep her on open ended clarithromycin- was on it for 22 months by the time of publication.

1. **Seronegative Chronic Relapsing Neuroborreliosis.**
2. https://www.ncbi.nlm.nih.gov/pubmed/7796837

Lawrence C.a · Lipton R.B.b · Lowy F.D.c · Coyle P.K.d

aDepartment of Medicine, bDepartment of Neurology, and cDivision of Infectious Diseases, Albert Einstein College of Medicine, and dDepartment of Neurology, State University of New York at Stony Brook, New York, NY., USA

Eur Neurol 1995; 35:113–117 (DOI:10.1159/000117104)

Abstract

We report an unusual patient with evidence of Borrelia burgdorferi infection who experienced repeated neurologic relapses despite aggressive antibiotic therapy. Each course of therapy was associated with a Jarisch-Herxheimer-like reaction. Although the patient never had detectable free antibodies to B. burgdorferi in serum or spinal fluid, the CSF was positive on multiple occasions for complexed anti-B. burgdorferi antibodies, **B. burgdorferi nucleic acids** and free antigen.

Let's review another early publication where persistent infection was recognized:

May 13, 1988

2. **Fatal Adult Respiratory Distress Syndrome in a Patient With Lyme Disease**
3. Michael Kirsch, MD; Frederick L. Ruben, MD; Allen C. Steere, MD; et al

JAMA. 1988;259(18):2737-2739. doi:10.1001/jama.1988.03720180063034

Abstract

A dry cough, fever, generalized maculopapular rash, and myositis developed in a 67-year-old woman; she also had markedly abnormal liver function test results. Serologic tests proved that she had an infection of recent onset with Borrelia burgdorferi, the agent that causes Lyme disease. During a two-month course of illness, her condition remained refractory to treatment with antibiotics, salicylates, and steroids. Ultimately, fatal adult respiratory distress syndrome developed; this was believed to be secondary to Lyme disease.

3. **Granulomatous hepatitis associated with chronic Borrelia burgdorferi infection: a case report**
4. http://www.labome.org/research/Granulomatous-hepatitis-associated-with-c...

The patient had active, systemic Borrelia burgdorferi infection and consequent Lyme hepatitis, despite antibiotic therapy. Spirochetes were identified as Borrelia burgdorferi

by molecular testing with **specific DNA probes**.

4. **Culture evidence of Lyme disease in antibiotic treated patients living in the Southeast**.
5. http://danielcameronmd.com/culture-evidence-of-lyme-disease-in-antibioti...

Rudenko and colleagues reported **culture confirmation** of chronic Lyme disease in 24 patients in North Carolina, Florida, and Georgia. All had undergone previous antibiotic treatment

5. **DNA sequencing diagnosis of off-season spirochetemia with low bacterial density in Borrelia burgdorferi and Borrelia miyamotoi infections.**

6. https://www.ncbi.nlm.nih.gov/pubmed/24968274

Faulty/misleading antibody tests landed a sixteen year old male in a psychiatric ward when his lab results did not meet the CDC's strict criteria for positive results. His Western blot had only four of the required five IgG bands. Subsequent **DNA sequencing** identified a spirochetemia in this patient's blood so his psychiatric issues were a result of neurologic Lyme disease misdiagnosed by antiquated/misleading serology. This patient was previously treated with antibiotics.

6. **The Long-Term Persistence of Borrelia burgdorferi Antigens and DNA in the Tissues of a Patient with Lyme Disease**

7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6963883/

Autopsy tissue sections of the brain, heart, kidney, and liver were analyzed by histological and immunohistochemical methods (IHC), confocal microscopy, fluorescent in situ hybridization (FISH), **polymerase chain reaction (PCR), and whole-genome sequencing (WGS)/metagenomics**. We found significant pathological changes, including borrelial spirochetal clusters, in all of the organs using IHC combined with confocal microscopy.

7. **Persistent Borrelia Infection in Patients with Ongoing Symptoms of Lyme Disease**

8. http://www.mdpi.com/2227-9032/6/2/33

"This pilot study recently identified chronic Lyme disease in twelve patients from Canada. All of these patients were **culture positive** for infection (genital secretions, skin and blood) even after multiple years on antibiotics so there was no relief from current antimicrobials. Some of these patients had taken as many as eleven different types of antibiotics."

_____

Persistent infection after extensive antibiotic treatment has been identified through the use of direct detection methods in academic centers and autopsy findings yet the average patient cannot obtain these tests to justify how sick they are with their chronic active infection.

Serology cannot be used to gauge treatment failure or success which makes it the ideal tool for concealing persistent infection.

Serology has allowed the 30-year dogma to persevere **[iii]** whereas direct detection methods are exposing the exact opposite.

We are dealing with a life-altering/life-threatening infection with faulty/misleading antibody tests, inadequate treatment, no medical training and absolutely no disease control whatsoever; a public health disaster.

Respectfully submitted,

Carl Tuttle
Hudson, NH