

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 dire 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