

Lyme Disease Testing: Why it Continues to Fail to Properly Identify Lyme Disease

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Dr. Ingels spoke at a past Restorative Medicine Conference and is on the Scientific Advisory Board of the Restorative Medicine Herbal Certification program.

When I was working as a microbiologist in the early 1990's, Lyme testing was still pretty new and we didn't know much about Lyme disease and all of the nuances of testing that would soon follow. Now that it is 25 years later, we have learned a great deal about Lyme disease and the pitfalls of Lyme testing have been revealed. Here is a brief excerpt from my upcoming book on Lyme disease, *"The Lyme Solution: A 5-part Plan to Fight the Inflammatory Auto-Immune Response and Beat Lyme Disease"*.



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The current recommendation by the CDC for someone who is suspicious of having Lyme disease is to run a two-step process. The first step is to run a Lyme antibody blood test, which measure two types of antibodies against Lyme disease (immunoglobulin G or IgG and immunoglobulin M or IgM). If this test is positive, then a second test called a Lyme Western Blot should be run to confirm the results of the first test. The Lyme Western Blot looks at a series of specific antibodies against the Lyme organism for both IgG and IgM. If someone has at least 5 out of 10 antibodies for IgG or 2 out of 3 antibodies for IgM, then the Lyme Western Blot is considered positive. The CDC does not recommend doing a Lyme Western Blot IgM test on anyone whose illness occurred within the past month.

Conventional immunology teaches that the immune system will undergo a predictable immune response after exposure to a microbe, with IgM being the first antibody to respond to an infection, followed by the production of IgG in later stages of the illness. By that logic then, someone who has an IgM positive test would suggest his or her exposure to the Lyme organism was recent and someone with an IgG positive test would indicate a past infection. But in Lyme disease, this does not necessarily hold true. One study found that in 55 people with known Lyme disease, less than 46% of them had either IgG or IgM antibodies on their initial Lyme screen test. I

have seen patients with IgM antibodies that we suspect their exposure was from many years prior and others with IgG positive antibodies that was a recent exposure. So the current testing does not distinguish between active and past infection and is an unreliable marker for when someone may have been exposed to an infected tick.

I should point out that the criteria for determining if a Lyme Western Blot test is positive is based on a CDC-led scientific group that included the FDA and State laboratory directors back in the early 1990's. This group held several meetings and their conclusions were published in 1995. So in more than 20 years of studying Lyme disease, these outdated criteria are still used today. We have since learned that some of the antibodies that we test for are specific to Lyme disease and other antibodies are not specific to Lyme, but may reflect exposure to some other type of microbe. To complicate this further, there are now over 100 known strains of *Borrellia* in the United States and over 300 species worldwide and the Lyme testing is primarily looking for only one type (*Borrellia burgdorferi*). For example, we now know that many cases of Lyme disease on the West Coast of the United States is caused by *Borrellia miyamotoi*, which does not get picked up on the Lyme Western Blot. So it is possible that some patients who experience Lyme disease symptoms and have a negative test, may actually have a different strain of Lyme disease that the tests do not detect. It is surprising that with everything we know about Lyme disease and the antibodies associated with it, that the CDC has yet to alter its criteria to reflect the current research.

There are several inherent problems with Lyme disease testing that often lead to misdiagnosis or lack of diagnosis. Perhaps the most troubling problem with the Lyme screen test is that it is not a very sensitive test and can miss someone who has Lyme disease. The College of American Pathologists, who develop guidelines for screening blood tests, state that a good screening test will pick up at least 95% of the people who have the condition for which the test is being used. However, one study found that the currently used Lyme screening test does not meet these criteria and can therefore fail to identify if someone has had exposure to Lyme disease. To make matters even worse, since the CDC guidelines do not recommend doing a Lyme Western Blot if the Lyme screen is negative, your doctor may easily skip over the more sensitive and specific test that might help show if you have been exposed to Lyme disease.

There are also no official guidelines for tests that may be considered borderline or equivocal. I have seen many Lyme Western Blot tests where patients only have 4 out of 10 IgG antibodies instead of 5 required to call the test positive. Or they only have 1 out of 3 antibodies for IgM, but the one antibody they have is a Lyme-specific band. Since the tests are actually measuring the amount of antibodies, the cut-off for these tests assumes each patient exposed to *Borrellia* has the same exact immune response. It seems the stringent criteria established by the CDC have failed to recognize the diversity of the human population and immune responses. If someone has several Lyme-specific antibodies, even if they do not meet the CDC criteria for calling the test positive, isn't that important? Isn't that kind of like being a little pregnant? I have seen enough of these tests to realize that patients with Lyme disease symptoms who have borderline tests, especially when they have Lyme-specific antibodies, usually respond well to treatment.

The other major problem with Lyme disease testing is that it is only measuring antibodies and does not directly measure the bacteria itself. Like all antibody tests, it is dependent on the person's ability to have a strong immune response when they have exposure to a virus, bacteria or other microbe that can cause infection. The assumption is always that if a tick that carries Lyme disease has bitten someone, the person will have a significant antibody response. While in theory that sounds good, the reality is that many people who end with chronic Lyme disease may not have a healthy immune system to start with and therefore, do not produce antibodies in the amount needed to get rid of the infection or be picked up on a blood test. To complicate this further, antibody levels can fluctuate as time goes on. I have seen hundreds of patients who get Lyme Western Blots done at regular intervals and the antibody levels can change from test to test. It can be maddening, as a patient as you would expect that antibody levels would go down once treatment had begun. However, this does

not usually occur and each antibody can increase, decrease or go away completely with each test for reasons that are not well understood. This observation speaks to the complexity of the immune system and that antibody levels do not necessarily drop at a continuous rate.

The methodology behind Lyme disease testing has long been a point of controversy among treating practitioners and part of this is due to differences in the laboratories themselves. The test kits that each lab uses vary and this may alter the sensitivity of the testing itself. The major reference labs around the United States tend to have similar testing methods, but some specialty labs use a different methodology, which seems to have improved the sensitivity of the testing. The strain of *Borrellia* used to perform the test makes a significant difference in the outcome and not all labs use the same strain. I only use labs that use the strains that yield the best results, such as Medical Diagnostic Laboratories or IGeneX.

The bottom line is that Lyme disease is ultimately a clinical diagnosis, which is based on your symptoms and ruling out other causes of your illness. False positive Lyme tests are rare where false negative tests are common. Make sure to work with a Lyme-literate doctor to ensure you get good testing, a proper diagnosis and treatment.

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