Lyme Disease: The Pitfalls of Laboratory Testing

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Since Lyme disease is caused by a spirochete bacterium, Borrelia burgdorferi, the ideal diagnostic test would be one which could isolate the bacteria from the patient by culture or direct stain. This is rarely accomplished.

There are a few blood tests available, but they are not reliable, at this time, according to the CDC. Currently available commercial tests for Lyme disease provide indirect evidence of exposure to the Lyme bacteria. Most experts believe that the ELISA test (the typical test used by most family doctors) is only about 30-60%. When someone is infected with the Lyme bacteria, the immune system responds by making specific proteins, called antibodies, whose role is to seek out the Lyme bacteria, attach to them and initiate the process of destruction. In most patients, these antibodies are unable to destroy the Lyme bacteria, which by methods which are not completely understood, may remain alive in the human body for many years, in spite of high “titers” or concentrations of antibodies. Detectable levels of these antibodies may not be found until 3 to 8 weeks after exposure. Significant illness may be present before the test is positive.

A number of patients clearly do not develop measurable antibodies. This is usually due to antibiotics given early in the infection for Lyme or non-Lyme infections. There is significant strain variability in Lyme bacteria isolated in different geographic areas, and since commercial tests have been developed from certain particular isolates, they may be incapable of detecting antibodies to a different strain of Lyme bacteria. It is also possible that some people’s immune systems do not recognize the Lyme bacteria as an invader and do not produce specific bacteria and their fragments; they may combine with all the circulating Lyme specific antibodies. Current commercial antibody tests for Lyme can only detect free circulating antibodies, and are incapable of detecting those bound up in immune complexes. Investigational tests have been developed to free these sequestered antibodies and render them measurable by the standard tests. There is wide variability between tests of commercial laboratories, and it is not unusual to have a serum sample test positive in one lab and negative in another. The percentage of Lyme patients who test negative on the antibody tests is close to 100% if the test is performed early in the infection, to anywhere between 5% and 40% in late disease, depending on the particular published data we wish to site. It is also known that false positive tests can occur. These may be due to other previous or current spirochetal infections such as syphilis, tick-borne relapsing fever, leptospirosis, and gingivitis. Some patients who have rheumatoid arthritis, Lupus, or mononucleosis may test positive. Some people who appear to be in good health and have no Lyme related symptoms may test positive. This may indicate past exposure to the Lyme bacteria, with spontaneous recovery, or it may represent a dormant infection which may activate at some future date and cause clinical disease. This has been well documented in European literature.
The Western Blot is also available for Lyme disease. Here various sized Lyme antibodies are allowed to migrate on a strip of filter paper. They separate into distinctive bands, and serve as a fingerprint for Lyme disease. It may be useful to sort out false positive tests and in cases where the antibody titer is “borderline”. Since its results depend on the presence of Lyme specific antibodies, the same factors which can cause a negative serologic test may cause a negative Western Blot. The U.S. Center for Disease Control (CDC), unfortunately, has set criteria arbitrarily for reading a Western Blot test as a positive for Lyme disease. The criteria were set up for statistical analysis of the spread of Lyme disease and were not intended in general to guide doctors in diagnosis and treatment of the disease. The CDC surveillance criteria are very strict and miss many people with Lyme disease.

The most common errors made by physicians in interpreting these previously mentioned tests are:

1. A negative test excludes the diagnosis of Lyme disease.
2. A negative test in someone who previously tested positive and received antibiotic treatment implies “cure”.

PCR analysis is another type of test that looks for the DNA of the Lyme bacteria in the blood, urine, or tissue. To obtain a sample that contains the bacteria, multiple tests are usually required. In recent years, PCR testing has become extremely reliable when positive.

According to Medical textbooks, the FDA and the CDC, Lyme disease is a clinical diagnosis, which means that the doctor should examine the patient for typical Lyme disease signs, look at the patient’s history and description of his or her symptoms and use this information to make a diagnosis. The laboratory tests may be a useful adjunct in making diagnosis, negative results do not rule out the possibility of the disease. They should not be relied upon for diagnosis.

Testing is also available for co-infections, namely, Babesiosis, Erlichiosis, and Bartonella. Although B. burgdorferi remains the most common pathogen in tick-borne illnesses, coinfections are increasingly seen in patients with Lyme disease, particularly in those with chronic illness. Recent animal and human studies suggest that Lyme disease may be more severe and resistant to therapy in coinfected patients. Lyme disease patients should be aware that concurrent testing and treatment for coinfection should be mandatory.

*Originally written by John Drulle, M.D. in 1991 and updated by the John Drulle, M.D. Memorial Research Fund, Inc. in 2005.*