

In the early 1990s, the U.S. government's Centers for Disease Control and Prevention (CDC) issued criteria for determining the spread of Lyme disease. One of the CDC's primary responsibilities is to track diseases, and to do that they must have great assurance that the patients who are counted actually have the disease. Therefore a very strict standard was adopted that required first a positive result from a screening test called ELISA (sometimes doctors call this a "Lyme titer"). If positive, then a more specific test called a Western blot is to be performed to further confirm the presence of Lyme disease.

Unfortunately, the ELISA test is positive in fewer than half of the patients who actually have Lyme

The CDC is aware of the limitations of the ELISA/Western Blot testing procedure. They state that, "This surveillance case definition was developed for

used only to support a clinical diagnosis of Lyme disease."

Lyme disease requires a clinical diagnosis

A clinical diagnosis means that your doctor will base his diagnosis on the *signs* of the disease that you show and the *symptoms* that you report. He should also take into account how likely it is that you have been exposed to the ticks that carry Lyme disease.

Signs are simply indications that the doctor can see or detect, such as a bull's eye rash. Symptoms are the complaints like fatigue, or burning/tingling sensations, etc. that you tell the doctor you are experiencing.

If your doctor orders blood tests, they should only be used to support his clinical diagnosis. The one exception is that a positive PCR test for Lyme DNA is a true positive for the disease.

Many doctors have confused the surveillance criteria with the proper approach to diagnosis

They seem to think the CDC's two-test surveillance method is OK to use to diagnose Lyme disease.

As a result, many people with Lyme disease are told they do not have it because their test was negative

Your doctor is on solid medical ground if he treats you for Lyme disease based on your symptoms alone.

Insurance companies sometimes confuse the surveillance criteria with the proper diagnostic technique and deny payment for Lyme disease treatment

This may be because they either don't understand the disease or because they want to avoid paying for your treatment.

There is no test that can reliably diagnose Lyme disease.

national reporting of Lyme disease; it is NOT appropriate for clinical diagnosis." (Emphasis is theirs.)

The Food and Drug Administration (FDA) says this about Lyme disease lab tests: "[blood tests] should be

Don't take our word for it . . .

Read what these government agencies have to say on their Web sites:

CDC: Case Definitions for Public Health Surveillance; Wharton, et al (<http://www.cdc.gov/mmwr/PDF/RR/RR4610.pdf> page 26)

FDA: Public Health Advisory: Assays for Antibodies to *Borrelia burgdorferi*; Limitations, Use, and Interpretation for Supporting a Clinical Diagnosis of Lyme Disease; issued July 7, 1997 (<http://www.fda.gov/cdrh/lyme.html>)

Learn more from our free booklet, **Lyme Disease: The Basics**, and from our Web site



Lyme Disease Association of Southeastern Pennsylvania, Inc.

The LDASEPA is an all-volunteer, 501(c)(3) non-profit corporation dedicated to education and support

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