

Imperfect test fuels alternative treatments for Lyme disease

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This March 2002 file photo shows a deer tick under a microscope in the entomology lab at the University of Rhode Island in South Kingstown, R.I. Far from a summertime nuisance, Lyme Disease is a potentially debilitating disease that has been subject to vigorous medical debate for more than two decades. At issue is both how to test for the tick-borne disease and how to treat it, especially in patients suffering long-term symptoms like fatigue, arthritis and cognitive problems with memory and concentration. (AP Photo/Victoria Arocho, File)

Lyme disease conjures memories of checking for ticks at camp and fretting over bug bites after hikes in the woods. But far from a summertime nuisance, Lyme is a potentially debilitating disease - and the subject of a vigorous debate in modern medicine.

Doctors not only debate how to treat the [disease](#), which starts with fever and rash but also can develop into long-term problems such as fatigue, arthritis and concentration problems. After decades, they still argue over the standard test for Lyme, which is subject to severe limitations. The conflict has given rise to a cottage industry of alternative Lyme physicians, laboratories, medical guidelines and even research centers at universities.

Here's a look at the debate surrounding Lyme disease, which infects an estimated 300,000 people in the U.S. annually.

Q: How does the blood test work?

Lyme disease is caused by a strain of bacteria carried by certain ticks, primarily found in Northeast and Midwestern U.S. and parts of Europe. But the only U.S.-recommended Lyme test doesn't detect the bacteria. Instead, it measures the immune system's response to Lyme in the form of antibodies, proteins that help fight infections. While it's the best approach available, experts acknowledge it is fraught with problems of accuracy and interpretation: The test usually comes back negative even several weeks after infection. Yet the test also can show a positive result years after infection, even after successful antibiotic treatment.

"We don't have a way of telling, once we put you on therapy, how successful that has been," says Dr. John Branda, of Harvard Medical School.

The test's inability to detect early-stage Lyme isn't a problem for patients

who display the signature bull's eye rash caused by disease-carrying ticks - guidelines instruct doctors to skip the test and treat those patients with antibiotics. But as many as 30 percent of those infected never get the rash, leaving doctors to diagnose the disease based on symptoms and patients' recollections of possible exposure.

Q: Is there really no other way to test?

A host of independent laboratories, such as Advanced Laboratory Services in Sharon Hill, Pennsylvania, sell alternative tests claiming to be able to detect the bacteria directly.

But scientists at the Centers for Disease Control and Prevention have been unable to reproduce their results. And a CDC paper published last year suggested the company's findings may have been marred by laboratory contamination.

Mainstream experts say inaccurate alternative Lyme tests lead to over diagnosis and costs hundreds of dollars, since insurance doesn't pay for them. Yet patients request them.

"Patients are so convinced they have Lyme disease that there's a demand for tests that will prove they have it," says Dr. Paul Lantos, an infectious disease specialist at Duke University Medical Center.

Laboratories that develop alternative tests for Lyme are not regulated by the Food and Drug Administration, unlike traditional [test](#) manufacturers. But last year the FDA said the growing number of so-called "home brew" tests - estimated at 11,000 for all sorts of diseases - demanded closer attention.

"We have concerns that people can be misled and act on information that may or may not have validity," says Katherine Serrano, an FDA deputy

division director.

Under a 2014 proposal, FDA would require labs to begin demonstrating the accuracy of their tests, including those for Lyme disease. The proposal has not yet been finalized. Serrano says the FDA would take a risk-based approach to reviewing tests, meaning tests for diseases like cancer would likely come before conditions like Lyme. She estimates it could be more than five years before FDA begins reviewing alternative Lyme tests.

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