SEARCH FOR NEW LYME DISEASE TEST

Researchers look to improve faulty clinical method

ONLY IN NEWSDAY

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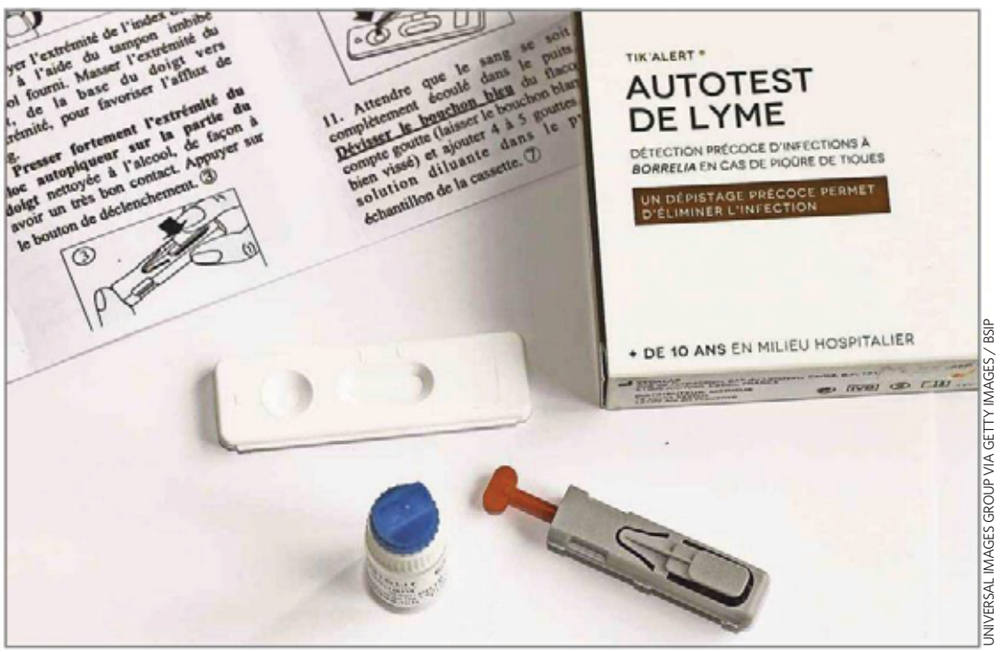

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Above, a self-test kit for Lyme disease. Tests are less than 30% effective in the first several weeks.

WHAT NEWSDAY FOUND

- **Current Lyme disease tests** are often ineffective early on, leading to false negatives.
- **Diagnosis is often based on clinical symptoms**, such as a bull's-eye rash, especially in high-risk areas like Long Island.
- **Researchers are working on new testing methods**, including a urine-based test to directly detect the bacteria that causes Lyme.

You just pulled a deer tick off your body — now what?

For Long Islanders, who live in one of the nation's Lyme disease hot spots, the first thought may be to rush to the doctor's office or clinic for a blood test.

But experts say it would be a waste of time, at least in this scenario. Current federally approved tests for Lyme disease take weeks or months to detect the body's response to the bacteria that causes the illness. Testing too early could give false negative results.

"In the first four to six weeks of Lyme disease, the tests are less than 30% effective," said Holly Ahern, a microbiologist developing a new, more sensitive test to detect Lyme disease. That time period "also happens to be the stage when antibiotic treatment is most effective."

New Lyme disease tests are being developed that scientists hope will be more accurate. That could lead to earlier treatment of the most common tick-born disease in the United States, the U.S. Centers for Disease Control and Prevention estimates it affects 476,000 people a year.

Early diagnosis and the proper use of antibiotics can help prevent more serious Lyme disease symptoms such as neck stiffness, facial palsy and arthritis with severe joint pain and swelling, according to the agency.

Current tests track the development of antibodies, which can often be misleading. Besides early false negatives, positive results can show up months or years after the infection is gone.

"A lot of people will have a positive antibody test, but that doesn't mean they have the disease," said Dr. John Aucott, director of the Johns Hopkins Lyme Disease Research Center. "They may have had it five years before and been treated, or had it and their immune system defeated the infection . . . that's a huge limitation."

Instead of measuring the body's immune response, scientists are hoping to find a way to find the bacteria that causes Lyme disease. "Nobody's really got the 'Holy Grail' of a sensitive test for early Lyme disease that directly detects or measures the bacteria itself," Aucott said.

Diagnosing Lyme

Since tests can take weeks to show an infection, doctors often diagnose Lyme disease based on clinical symptoms, such as a rash that looks like a bull's-eye or a reddish, swollen area on the skin. They also consider whether it is spring, summer or early fall, when ticks are most active, and their location before developing the rash, said Dr. Sandeep Gandhi, an infectious disease consultant at Stony Brook Southampton Hospital.

The size of the red area is also a factor, he said. Anything less than 5 centimeters in size is probably just an allergic reaction to the tick. Even if they are not aware they were bit, being in an area where Lyme disease is prevalent can help make a determination.

"If you have a bull's-eye rash on Long Island, it's Lyme disease until proven otherwise," Gandhi said.

If Lyme is diagnosed through clinical symptoms, the patient can be given antibiotics immediately.

Gandhi and Dr. Andrew Handel, a pediatric infectious disease expert at Stony Brook Children's Hospital, also see patients at the health system's Regional Tick-Borne Disease Resource Center in Hampton Bays.

It's a busy place where patients sometimes ask for Lyme disease tests even if they have no symptoms.

"The recommendation is typically not to do any blood work unless they develop symptoms, but families are often not comfortable with that," said Handel. "In those circumstances, I say we should wait for a month. Typically that's the time it takes to show a positive test."

Handel also said children can develop swollen joints three to six months after they are infected if not treated.

"That's a common issue that we see," he said. "A child who has arthritis where they have one large swollen knee."

The blood tests currently approved by the U.S. Food and Drug Administration to help detect Lyme disease measure different antibodies in a person's body. Some of those antibodies may be reacting to other bacteria. And some are more specific to the Lyme bacteria but may take longer to appear. There is also a complex timeline of when the tests should be done.

"It's so complicated, most providers can never figure out how to use the test correctly," said Aucott, adding that tests should be used along with a review of clinical symptoms.

The current Lyme disease tests and how results are interpreted "have remained largely the same for over 40 years," according to Ahern, who is chief scientific officer at ACES Diagnostics.

"Several studies now show that people respond differently in terms of which antibodies they produce, and that the antibodies a single person may produce can vary over the course of the infection," she said.

Ahern is part of a group at ACES Diagnostic that helped develop LymeSeek, a test she said can more accurately diagnose all phases of Lyme disease at about 90% — including the first two weeks. They are set to apply for FDA approval and hopeful the test will be available to the public by late 2026.

In search of 'Holy Grail'

At George Mason University in Fairfax, Virginia, researchers are going for the "Holy Grail" of tests that will directly identify Borrelia burgdorferi, the bacteria that causes Lyme disease.

Instead of blood, the test will examine a person's urine for the bacteria.

Alessandra Luchini, systems biology professor at the university's College of Science and principal investigator, said urine works well as a way to search for the bacteria, which spends little time in the bloodstream.

"Tiny amounts of proteins and other molecules are concentrated in the urine," Luchini said. "This natural 'concentration step' makes it easier to detect very small amounts of disease markers."

The test looks for proteins from the bacteria and then with the help of a computer makes sure it matches Borrelia burgdorferi.

Luchini said different versions of the test have been developed and are currently being used in research studies and under clinical lab regulations.

"These could allow earlier and more reliable detection than antibody tests," she said. "We're now collecting data and preparing for FDA discussions."