

New York Times Dan Hurley ANTI-IGENEX Article OUT!!!!

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Unproved Lyme Disease Tests Prompt Warnings

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By DAN HURLEY and MARC SANTORA

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Steve Courcier just wanted to know: did he have Lyme disease or didn't he?

Doctors who tested Mr. Courcier in March at the Mayo Clinic in Scottsdale, Ariz., ruled out Lyme, a tick-borne illness, as an explanation for the disabling pain and exhaustion he was suffering. Then a Texas doctor sent his blood sample to a California laboratory that indicated he did have Lyme disease. But a New York specialist who tested his blood a third time, in June, said emphatically that he did not.

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Allison V. Smith for The New York Times

After several rounds of testing, Steve Courcier, a 38-year-old executive from Dallas, was told both that he had Lyme disease and that he didn't. A regimen of antibiotics, he said, was only making him feel worse.

"It's amazing to me that you could have this much disparity in medical test results and not have the government do something," said Mr. Courcier, 38-year-old executive with a consulting firm who lives with his wife and two young children in a Dallas suburb.

Now the New York State Department of Health has opened an investigation of the California laboratory, IGeneX Inc., that issued Mr. Courcier's positive result, after receiving eight complaints from doctors and patients who said its Lyme tests also gave them positive results not confirmed by other labs' results.

Concern about Lyme testing goes beyond New York State. This year the

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Food and Drug Administration and the Centers for Disease Control and Prevention released a warning about Lyme tests "whose accuracy and clinical usefulness have not been adequately established."

The warning did not mention IGeneX or any other lab by name. But Dr. Paul Mead, a C.D.C. scientist who helped write it, said in a telephone interview, "Quite simply, we're concerned that patients are being misdiagnosed through the use of inaccurate laboratory tests." He added that some of the tests and techniques used by IGeneX were among those the agencies were concerned about.

Nick Harris, the founder and chief executive of IGeneX, defended his company's testing, saying that the federal guidelines miss many patients who have Lyme disease.

Guidelines from the disease control agency recommend Lyme testing only when patients have symptoms and live in an area of the United States where ticks are known to be infected with *Borrelia burgdorferi*, the organism that causes the disease. Under the guidelines, laboratories should first conduct a test called Elisa. But the Elisa test often gives a false positive result, so the agency also calls for a second, more sensitive test, the Western blot.

The recent warning by the two federal agencies named some tests they said had not proved useful or accurate. They noted, for instance, that some laboratories performed a test called polymerase chain reaction "on inappropriate specimens such as blood and urine." IGeneX offers such tests on both blood and urine. The alert also warned against methods of interpreting Western blots "that have not been validated and published in peer-reviewed scientific literature."

Nationally, reported cases of Lyme disease have more than doubled in a decade, to at least 23,963 in 2003 (the most recent year for which statistics are available) from fewer than 9,000 in 1993. Infectious disease experts agree that infections have been on the rise, but they worry that part the increase may be due to overdiagnosis.

A misdiagnosis can have serious consequences. In some cases, Dr. Mead said, Lou Gehrig's disease was misdiagnosed as Lyme by unproved tests. The patients in those cases, he said, wasted thousands of dollars on ineffective treatment. The antibiotics used to treat Lyme disease can also cause complications, including severe allergic reactions.

Some doctors and patients, however, have a different concern. They believe Lyme is often missed by the traditional tests recommended in C.D.C. guidelines.

Dr. Harris, of IGeneX, estimated that his laboratory tested 50,000 to 75,000 patients each year. (Prices go up to \$390 for a battery of tests it recommends.) "These are patients who have been bounced around," he said. "A lot of them were undertreated at some time, and their disease

came back."

Still, he went on, IGeneX runs the traditional tests accurately and gives doctors guidelines for interpreting them both by the C.D.C.'s conservative standard and by IGeneX's more liberal standard – even though he asserted that the conservative standard would miss many cases of chronic Lyme infection.

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He provided a reporter with a document showing that in each year since 2000, IGeneX had achieved scores of at least 97 percent accuracy on the Western blot and Elisa tests, well above the minimum 80 percent required by the state.

But Robert Kenny, a spokesman for the State Department of Health, said the agency was not convinced that IGeneX was performing the recommended tests for the public in the same manner as it has been performing them to pass the state's proficiency review.

Moreover, Mr. Kenny said IGeneX had not supplied requested proof that its urine antigen test can be used to accurately diagnose Lyme disease.

Dr. Harris says IGeneX has been working for more than two years to supply New York State with the proof it wants. "It's been an exceedingly long process that's nearing completion," he said. Dr. Mead at the C.D.C. also confirmed that another laboratory, Bowen Research and Training Institute Inc. of Tarpon Springs, Fla., went beyond the agency's recommended tests.

The State of Florida denied its application last year for a license to perform tests meant to diagnose Lyme, but its founder and president, Dr. JoAnne Whitaker, asserts that the tests it continues to perform are for research purposes only.

Some patients insist that IGeneX's tests have been instrumental in detecting the Lyme disease that other laboratories missed. One such patient is Ronald Hamlen, 64, a plant biologist from Maryland who worked at DuPont for 22 years before retiring recently. Tests run by IGeneX, he said, detected Lyme disease that was missed by other

laboratories.

"If I had not had the positive result at IGeneX, I seriously question whether I would have been alive at this point," he said in a telephone interview. Before getting tested by IGeneX and going on intravenous antibiotics for 10 weeks, he said, "all I could do at that point was lie on the couch."

In contrast, Mr. Courcier's odyssey into the Lyme testing labyrinth began last year on the Sunday after Thanksgiving, when a severe pain in his leg led him to seek care at a walk-in clinic. Preliminary diagnoses of phlebitis and muscle strain proved inaccurate, and as the pain increased and spread, he finally went to the Mayo Clinic.

Doctors there told him that an initial test for Lyme disease came back negative, but they could offer no other clear diagnosis for what was ailing him.

Back home in Texas, Mr. Courcier was referred to a neurologist specializing in Lyme disease. The neurologist sent samples of his blood to IGeneX, as well as to Quest Diagnostics, one of the country's largest medical testing companies. Each lab followed the two-step process recommended by the C.D.C.

IGeneX and Quest Diagnostics performed the Elisa and the Western blot tests on Mr. Courcier's samples. The Elisa came back positive from both labs, suggesting that Mr. Courcier might have antibodies to *B. burgdorferi*.

On the Western blot tests, however, IGeneX sent back positive results, while the Quest testing came back negative.

Although his doctor started him on antibiotics to treat the possible infection, Mr. Courcier was encouraged by a colleague to visit Dr. Gary Wormser, chief of the division of infectious diseases at New York Medical College in Valhalla, for another opinion. Dr. Wormser repeated the Western blot test and told him in June that he did not have Lyme disease.

At first, Mr. Courcier did not know whom to trust, and he remained on the antibiotics therapy prescribed by his doctor in Texas. But by July he concluded that he did not have Lyme disease and stopped taking the antibiotics, which he said were only making him feel worse.

"It's been a hell of an emotional roller coaster," said Mr. Courcier, who conceded that it was a comfort for a while to have a definite explanation for the pain and exhaustion that continue to plague him.

Dr. Mead of the C.D.C. said he sympathized with Mr. Courcier's plight. But for now, he said, patients and physicians should rely on the recommended two-step process. The tests, he said, are accurate in more

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than 90 percent of cases of long-term Lyme infection.

But he added that he was still troubled by the dispute. "We don't want to be absolutely dogmatic that it's our way or the highway," he said. "At the same time, it's clear there are tests out there for which there is really precious little to support their accuracy."

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