NEWS RELEASE

A New Test That Could Change Lyme Disease Testing

Single-tier test showed >90% sensitivity in early Lyme disease patients

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A new serologic test for Lyme disease shows promise to streamline the testing protocol and to enable the diagnosis of patients in very early stages of the disease, as described in a study published online today in the Journal of Clinical Microbiology, a publication of the American Society for Microbiology[1].

Dr. Gary P. Wormser, a co-author of the study at New York Medical College, said “this test could potentially change the standard of clinical practice, allowing clinicians to diagnose all manifestations of Lyme disease with a time-saving one-step antibody test.”

Lyme disease, a tick-transmitted infection that is principally caused by the spirochete *Borrelia burgdorferi* in the United States and closely related species in Europe, has become the most common vector-borne disease in the United States, with almost half a million cases diagnosed each year according to the U.S. Centers for Disease Control and Prevention (CDC)[2]. The earliest and most common clinical manifestation of infection is a skin rash at the tick bite site referred to as erythema migrans. If patients with erythema migrans are untreated, Lyme disease can progress to a systemic infection with a variety of neurologic, joint and cardiac manifestations. Early diagnosis and appropriate antibiotic treatment, however, can halt progression of the infection. Once past the erythema migrans stage, laboratory testing for Lyme disease has relied on a standard two-step approach recommended by the CDC since 1995. In this approach, blood samples are initially screened for antibodies to *B. burgdorferi*, typically by an enzyme-linked immunosorbent assay (ELISA), and those found positive are confirmed by a second antibody test[3]. While the original protocol used a labor-intensive method called the Western Blot as the confirmatory antibody test, the CDC updated the recommendations in 2019 to allow substitution of the Western Blot by a second ELISA, which yielded equivalent results with less time and labor[4]. With either approach, however, the sequential testing required will result in a delay in obtaining the final test result. Moreover, testing of patients with erythema migrans is still not recommended due to the low sensitivity of both of these current two-step testing methods.

The single-tier test described in the newly published study, which was developed by Kephera Diagnostics (Framingham, MA) and is called “Hybrid Lyme ELISA”, uses a novel immunoassay principle based on the finding that antibody molecules in human serum that are elicited by infection with the bacteria that cause Lyme disease can simultaneously bind to two related but not identical antigens. This approach, which has not been used in any previous diagnostic assay for any other infectious disease, makes possible for the first time a combination of

sensitivity and specificity in a single test that rivals that of currently approved protocols that require two sequential tests. Furthermore, the sensitivity of this new single-tier test in patients with erythema migrans was found to be over 90%, significantly higher than the sensitivity of either of the currently FDA-approved two-tier testing methods. If these results are confirmed by further clinical evaluations, this new single-tier test would become the first Lyme disease serologic test that is sensitive enough to diagnose patients with erythema migrans, the earliest clinical manifestation of Lyme disease, as well as patients with later stages of Lyme disease. As an ELISA, this new test will be compatible with manual as well as high throughput automated testing procedures, enabling efficient performance in testing laboratories.

"Current two-tiered serology tests are insensitive in early Lyme disease, missing up to 70% of patients presenting with erythema migrans," said Liz Horn, PhD, MBI, a coauthor of the study and Principal Investigator of Lyme Disease Biobank, a Bay Area Lyme Foundation program that provides much-needed samples to approved researchers working to better understand tick-borne diseases and develop improved diagnostic tests and therapeutics. "More accurate tests are urgently needed, and the Hybrid ELISA results are very promising."

“The publication of this study is an important milestone in our efforts to bring about meaningful improvements in the diagnosis of Lyme disease that will benefit both patients and clinicians” said Andrew Levin, Kephera’s Chief Executive and Scientific Officer. “We are very excited by the results that were achieved by the Hybrid Lyme ELISA in this initial study. Naturally, these findings will have to be corroborated in larger-scale trials, which are currently underway.” Kephera Diagnostics is seeking regulatory approval for the Hybrid Lyme ELISA, and plans to offer it concurrently through its CLIA laboratory.

The Hybrid Lyme ELISA was developed by Kephera Diagnostics with collaborators at New York Medical College and the Lyme Disease Biobank. The work was supported by an SBIR grant from the National Institute of Allergy and Infectious Diseases, an agency of the National Institutes of Health, to Kephera Diagnostics.

About Kephera Diagnostics

Kephera Diagnostics is a young and growing company that is addressing the public health challenges of global infectious diseases using new assay technologies. We also operate a CLIA-certified and CAP-accredited diagnostic laboratory delivering excellence in specialized diagnostics. We focus on diagnostic solutions for diseases where there are significant gaps in addressing patient needs, particularly in underserved areas of healthcare including infectious diseases and women’s health. Our mission is to promote more effective and affordable medical treatment through faster diagnosis. We collaborate with a global community of researchers and clinicians to develop and translate new technologies into accessible products for clinical diagnostics and research applications.

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Sources

[1]Journal of Clinical Microbiology (2025) https://doi.org/10.1128/jcm.00483-25
A novel single tier serologic test to diagnose all stages of Lyme disease
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[2]Kugeler KJ, Schwartz AM, Delorey MJ, Mead PS, Hinckley AF. Estimating the Frequency of Lyme Disease Diagnoses, United States, 2010-2018. Emerg Infect Dis. 2021 Feb;27(2):616-619. doi: 10.3201/eid2702.202731. PMID: 33496229; PMCID: PMC7853543.

[3]Centers for Disease Control and Prevention (CDC). Recommendations for test performance and interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease. MMWR Morb Mortal Wkly Rep. 1995 Aug 11;44(31):590-1. PMID: 7623762.

[4]Mead P, Petersen J, Hinckley A. Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease. MMWR Morb Mortal Wkly Rep 2019;68:703. DOI: http://dx.doi.org/10.15585/mmwr.mm6832a4