



NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy
and Infectious Diseases

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To: Editors, Reporters and Producers

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Subject: NIAID Collaboration Yields New Test for Lyme Disease

A new test developed with funding from the National Institute of Allergy and Infectious Diseases (NIAID) has been shown to be highly accurate and sensitive for detecting antibodies to Lyme disease. Produced by Immunetics, Inc. of Cambridge, Massachusetts, the new assay recently won approval from the Food and Drug Administration (FDA) for use as a diagnostic test for Lyme disease.

It is the first diagnostic tool to use a synthetic product called C6, a hybrid chemical marker based on components derived from the surface of *Borrelia burgdorferi*, the tick-borne bacterium that causes Lyme disease. The C6 test is sensitive only to antibodies generated during an active infection.

Lyme disease can be difficult to diagnose, especially in later stages of infection when an individual's antibodies can fall to very low levels. Laboratory testing showed the C6 approach resulted in a high rate of sensitivity to antibodies from both the early and late stages of Lyme disease. The kit also resulted in fewer false positive readings when compared with current screening methods. Significantly, no false positive readings were obtained when the kit was used to test people who had previously received Lymerix®, the Lyme disease vaccine. Another advantage is the test's ability to detect antibodies specific to both U.S. and European strains of *Borrelia*.

"The C6 test is the result of years of collaboration in an ongoing effort to improve our ability to diagnose Lyme disease," explains microbiologist Phillip Baker, Ph.D., NIAID's Lyme disease program officer. "This new approach is an important first step in that direction."

NIAID is a component of the National Institutes of Health (NIH). NIAID supports basic and applied research to prevent, diagnose, and treat infectious and immune-mediated illnesses, including HIV/AIDS and other sexually transmitted diseases, tuberculosis, malaria, autoimmune disorders, asthma and allergies.

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