SPECIALTY LABORATORIES
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Borrelia burgdorferi C6 Peptide Antibody DetectR™

Overview

Lyme disease, caused by the spirochete *Borrelia burgdorferi,* is the most frequently reported arthropod-borne disease in the United States.[1] The bite of an infected *Ixodes* species tick transmits the spirochete. In December 1998, a Lyme disease vaccine was approved by the FDA to inoculate adults (over age 15) against infection. The vaccine's efficacy is dependent on the vaccinated patient's OspA antibodies (generated in response to the vaccine) inactivating *B. burgdorferi* at the time of a tick bite.

The vaccine is about 75% effective so cases of breakthrough infection do occur. On the other hand, a subset of vaccinated patients may develop vaccine-related symptoms unrelated to infection with *B. burgdorferi*. Unfortunately, OspA antibodies in vaccine recipients generate false-positive results on conventional Lyme screening tests, making it impossible to distinguish between these possibilities. Thus, the need exists to accurately detect the immune response in vaccinated individuals and differentiate true infection from false-positive reactions.

A new test, the *Borrelia burgdorferi* C6 Peptide Antibody DetectR,™ is highly sensitive and specific for *B. burgdorferi* infection, including in those patients who have been vaccinated with the OspA Lyme disease vaccine. This unique test identifies antibodies to a newly discovered conserved peptide called C6, which is a component of the variable surface antigen, VlsE[1,2] . The test detects both IgG and IgM antibodies in patients with early, chronic or late Lyme disease as well as in infected patients who have received the Lyme vaccine. OspA antibodies generated in response to the Lyme vaccine do not cross-react with C6, so Lyme vaccine recipients will not test positive unless they are actually infected. While the C6 test is important in vaccinated patients, it should also be considered as a front line test for Lyme disease as it is highly sensitive and specific and detects antibodies to all genospecies of *B. burgdorferi*.

Clinical Utility

- Identifies *Borrelia burgdorferi* infection, even in patients who have received the Lyme vaccine.
- Differentiates infection from non-infection, vaccine-related symptoms in patients having adverse reactions to the Lyme vaccine.
- Differentiates infection from false-positives (detected by whole-cell sonicate EIA tests) in vaccinated patients suspected of breakthrough infection.
- Identifies *Borrelia burgdorferi* infection in those with co-transmitted tick-borne zoonoses such as babesiosis and ehrlichiosis.

Relevant Tests

8944	***Borrelia burgdorferi* C6 Peptide Antibody DetectR,™ EIA**
8954	***Borrelia burgdorferi* IgG/IgM by EIA plus C6 Peptide Antibody**
8956B	***Borrelia burgdorferi* IgG/IgM by EIA plus C6 Peptide Antibody; reflex to IgG/IgM by IB (with bands)**

Related Tests

7570 ***Borrelia burgdorferi*** **DNA DetectR;™ PCR**

7970 ***Borrelia burgdorferi*** **IgG & IgM Antibody Index (CSF and serum)**

8941 ***Borrelia burgdorferi*** **IgG & IgM Abs [EIA]**

7711B ***Borrelia burgdorferi*** **IgG & IgM Immunoblot: CDC Criteria with bands**

7721B ***Borrelia burgdorferi*** **IgG & IgM Immunoblot: Alternate Criteria with bands**

References

1. Liang FT, Steere AC, Marques AR, Johnson BJB, Miller JN, Philipp MT. Sensitive and specific serodiagnosis of Lyme disease by enzyme-linked immunosorbent assay with a peptide based on an immunodominant conserved region of *Borrelia burgdorferi* VlsE. J Clin Micro 1999;37:3390-6.
2. Lawrenz MB, Hardam JM, Ownes RT, et al. Human antibody responses to VlsE antigenic variation protein in *Borrelia burgdorferi*. J Clin Micro 1999;37:3997-4004.

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