

What is the advantage of the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ assay over other Lyme tests?

- Unlike other whole-cell sonicate EIA tests, the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ assay can detect infection even in an individual who has been vaccinated with the OspA Lyme vaccine. The C6 test recognizes antibodies specific to unique portions of *B. burgdorferi* which are not components of the Lyme vaccine. Other EIA antibody tests may detect antibodies produced in response to the vaccine, thereby causing false-positive test results and making serological diagnosis extremely difficult.

When would the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ test be useful?

The C6 test is useful in the following situations:

- Identifying *Borrelia burgdorferi* infection
- Differentiating infection from non-infection. For instance, in symptomatic patients having adverse reactions to the Lyme vaccine (will eliminate false-positives picked up by other less specific tests)
- Identifying infection in vaccinated patients suspected of breakthrough infection

Will the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ test pick up infection by all genospecies of *Borrelia burgdorferi*?

- Yes.

Will the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ test discriminate between *B. burgdorferi* and other tick-borne diseases?

- Yes, the C6 test is highly specific for *B. burgdorferi* and does not produce false-positive results in patients with other tick-borne diseases. The C6 test will identify *Borrelia burgdorferi* infection in those with co-transmitted tick-borne zoonoses such as Babesiosis and Ehrlichiosis.

When can the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ assay be ordered?

- The test can be ordered on patients suspected of infection with *B. burgdorferi* in early, acute, and chronic stages of disease. Because seroconversion (production of antibodies against an organism) can take several weeks from the time of exposure, the test should not be performed earlier than two weeks post-tick bite; a negative result should be repeated in two weeks. For testing in the first two weeks, a *Borrelia burgdorferi* DNA test by PCR is recommended.

When do you recommend ordering the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ assay?

- The C6 test is intended for use in the presumptive detection of IgG and IgM antibodies to *B. burgdorferi* in human serum. The assay should be used only on samples from patients with clinical history or signs or symptoms consistent with *B. burgdorferi* infection. It can be ordered on individuals who have received the OspA Lyme disease vaccine to test for breakthrough infection.

What if the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ test is positive? Does this confirm infection with *B. burgdorferi*?

- All positive or equivocal test results should be supplemented by testing with the *Borrelia burgdorferi* Immunoblot test. Positive immunoblot results provide evidence for exposure to or infection with *B. burgdorferi*.

Can the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ assay be used to help diagnose infection even if the patient has been vaccinated?

- Yes. The C6 Peptide test can detect infection in individuals who have received the OspA Lyme vaccine. Other whole-cell sonicate EIA tests cannot do this, because false positive results will be detected due to the anti-OspA antibodies produced in response to the vaccine.

What is the sensitivity of the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ assay?

- The overall sensitivity of the *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ is 97% compared to clinical diagnosis.

Relevant Test

7570 *Borrelia burgdorferi* DNA DetectR™ [PCR]—useful for the diagnosis of early disease, and identifies the presence of *B. burgdorferi* DNA in body fluids including cerebrospinal fluid, synovial fluid, blood and urine.

8944 *Borrelia burgdorferi* C6 Peptide Antibody DetectR™ EIA—useful in identifying *B. burgdorferi* infection; C6 Peptide antibody testing differentiates patients with active infection from patients who have been vaccinated with the OspA Lyme vaccine.

8954 *Borrelia burgdorferi* IgG & IgM Antibodies plus C6 Peptide Antibodies—useful in identifying exposure to *B. burgdorferi*; helpful in initial Lyme Disease assessment.

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

7721B *Borrelia burgdorferi* IgG & IgM Immunoblot: Alternate Criteria with bands — provides sensitive, specific detection of antibodies to denatured *B. burgdorferi* antigens and is useful in confirming the diagnosis. While not recommended as a primary test for Lyme Disease, immunoblot is more specific than many EIA tests.

8968 *Borrelia*, *Babesia*, *Ehrlichia*: Lyme Co-Infection (Tick-Borne Disease Antibody Panel with *Borrelia burgdorferi* (Lyme), *Ehrlichia equi* (HGE), *Ehrlichia chaffeensis* (HME) and *Babesia* IgG & IgM Antibodies [IFA])

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