



MAYO CLINIC
Mayo Medical Laboratories
1-800-533-1710

TEST UPDATE

REFERRAL

NOTIFICATION DATE: April 23, 2012

EFFECTIVE DATE: May 21, 2012

BORRELIA BURGDORFERI C6 PEPTIDE AB, ELISA

Test ID: FBBC6

Secondary ID: 91899

EXPLANATION OF CHANGE: Test ID FBBC6, referred to Focus Diagnostics, Inc., will reflect the following updates effective May 21, 2012.

CURRENT PUBLISHED NAME: Borrelia Burgdorferi C6 Peptide AB, ELISA

NEW PUBLISHED NAME: Lyme Disease C6 Antibody, Total

CURRENT REPORTING NAME: B. Burgdorferi C6 Peptide Ab

NEW REPORTING NAME: Lyme Disease C6 Ab, Total

CURRENT REFERENCE VALUES:

REFERENCE RANGE: < or = 0.90

INTERPRETIVE CRITERIA:

- < or = 0.90 Antibody Not Detected
- 0.91 - 1.09 Equivocal; submission of a second specimen (collected 3-4 weeks after initial specimen) suggested if clinically warranted.
- > or = 1.10 Antibody Detected

This ELISA detects both IgG and IgM antibodies against the C6 peptide derived from the V1sE protein of *Borrelia burgdorferi*, the causative agent of Lyme disease. IgM-specific titers usually peak 4 to 6 weeks after onset of infection and may persist in the presence of disease. IgG levels tend to rise above background levels about 2 to 3 weeks after infection, and may remain elevated in cases of prolonged disease. The C6 peptide antibody ELISA exhibits sensitivity and specificity values greater than 95% for Lyme disease. Further, sera from individuals vaccinated with the OspA Lyme disease vaccine do not react in this assay.

As recommended by the Food and Drug Administration (FDA) Public Health Advisory, July 7, 1997), all samples with positive or equivocal results in the *Borrelia burgdorferi* antibody EIA (Screening) should be tested by Western Blot. Positive or equivocal screening test results should not be interpreted as truly positive until verified as such using a confirmatory assay. (e.g. *B. Burgdorferi* Western Blot). The screening test and/or Western Blot for *B. burgdorferi* antibodies may be falsely negative in early stages of Lyme disease, including the period when erythema migrans is apparent.

NEW REFERENCE VALUES:

REFERENCE RANGE: < or = 0.90

INTERPRETIVE CRITERIA:

- < or = 0.90 Antibody Not Detected
- 0.91 - 1.09 Equivocal; submission of a second specimen (collected 3-4 weeks after initial specimen) suggested if clinically warranted.
- > or = 1.10 Antibody Detected

This ELISA detects both IgG and IgM antibodies against the C6 peptide derived from the V1sE protein of *Borrelia burgdorferi*, the causative agent of Lyme disease. IgM-specific titers usually peak 4 to 6 weeks after onset of infection and may persist in the presence of disease. IgG levels tend to rise above background levels about 2 to 3 weeks after infection, and may remain elevated in cases of prolonged disease. The C6 peptide antibody ELISA exhibits sensitivity and specificity values greater than 95% for Lyme disease.

As recommended by the Food and Drug Administration (FDA) Public Health Advisory, July 7, 1997), all samples with positive or equivocal results in the Lyme Disease C6 Antibody EIA (Screening) should be tested by Western Blot/Immunoblot. Positive or equivocal screening test results should not be interpreted as truly positive until verified as such using a confirmatory assay. [e.g. Lyme Disease Antibodies (IgG, IgM), IBL (serum)]. The screening test and/or immunoblot for Lyme disease antibodies may be falsely negative in early stages of Lyme disease, including the period when erythema migrans is apparent.

NOTE: Effective with this change, all orders placed for this test must be submitted in the alphanumeric character Test ID format instead of the numeric Secondary ID. Please review Test Set-Up information at <http://www.mayomedicallaboratories.com/test-notifications/index.html>

QUESTIONS: Contact Mary Erath, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710