MAYO CLINIC
Mayo Medical Laboratories

1-800-533-1710

TEST UPDATE
REFERRAL
NOTIFICATION DATE: April 24, 2012
EFFECTIVE DATE: May 21, 2012

BORRELIA BURGDORFERI IGG AND IGM ANTIBODY PANEL
Test ID: FBORR
Secondary ID: 91679

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

CURRENT PUBLISHED NAME: Borrelia burgdorferi IgG and IgM Antibody Panel

NEW PUBLISHED NAME: Lyme Disease Antibodies (IgG, IgM), IFA (Serum)

CURRENT REPORTING NAME: Borrelia burgdorferi IgG/IgM Panel

NEW REPORTING NAME: Lyme Disease (IgG, IgM) Panel

CURRENT REFERENCE VALUES:
Reference Range: <1:80

Interpretive criteria: <1:80 Antibody Not Detected
> or = 1:80 Antibody Detected

Borrelia burgdorferi is the causative agent of Lyme disease. Specific antibody titers are measured using an indirect immunofluorescence assay (IFA). IgM-specific titers usually peak 4 to 6 weeks after onset of infection and may persist in the presence of disease. IgG levels begin to rise above background levels about 2 to 3 weeks after infection, and may stay elevated in cases of prolonged disease. Seronegative cases of Lyme disease have been reported and alternate laboratory tests may be necessary to make a diagnosis, e.g., cultivation, Western blot. Crossreactivity is shown with other Borrelia and Treponema species.

As recommended by the Food and Drug Administration (FDA Public Health Advisory, July 7, 1997), all samples with positive or equivocal results in a screening test for Borrelia burgdorferi antibodies should be tested by Western Blot. The screening test and/or Western blot 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: <1:80
IgM <1:10

Borrelia burgdorferi is the causative agent of Lyme disease. Specific antibody titers are measured using an indirect immunofluorescence assay (IFA). IgM-specific titers usually peak 4 to 6 weeks after onset of infection and may persist in the presence of disease. IgG levels begin to rise above background levels about 2 to 3 weeks after infection, and may stay elevated in cases of prolonged disease. Seronegative cases of Lyme disease have been reported and alternate laboratory tests may be necessary to make a diagnosis, (e.g., culture, PCR). Crossreactivity is shown with other Borrelia and Treponema species.

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 alpha-numeric 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
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