Lyme Antibody Determination
IgG and IgM Whole Cell Enzyme Immunoassay (EIA)

ANALYTES TESTED:
Borrelia burgdorferi (Lyme disease) antibodies

USE OF TEST:
Specimens which are equivocal or positive by the Zeus *Borrelia* VlsE1/pepC10 IgG/IgM enzyme immunoassay (screening assay) will receive supplemental testing by the Zeus IgM and IgG whole cell *B. burgdorferi* enzyme immunoassays (EIA) using the modified two-tier test methodology (MTTT) following national recommendations. Detection of IgG and IgM antibodies uses whole-cell *Borrelia burgdorferi* antigen by enzyme immunoassay (EIA).

SPECIMEN COLLECTION AND SUBMISSION GUIDELINES:
Test Request Form DCH-0583
Specimen Submission Guidelines
Serum Specimen Collection DCH-0811
Transport Temperature: Frozen, cold packs or ambient temperature
No special patient preparation is required.

SPECIMEN TYPE:
Specimen Required: Serum
Minimum Acceptable Volume: 1 ml
Container: 3 ml polypropylene screw capped tube
Shipping Unit: Unit 8

SPECIMEN REJECTION CRITERIA:
Specimens lacking unique patient identifiers (i.e., full name, date of birth) will not be tested.
Plasma, CSF, and contaminated or grossly hemolyzed, icteric or lipemic specimens are unacceptable for testing and will be reported as Not Tested.

TEST PERFORMED:
Methodology: Enzyme Immunoassay
Turn Around Time: One week unless repeat testing is required.
Where/When Performed: Lansing/Wednesday.

RESULT INTERPRETATION:
Reference Range: NEGATIVE

1. Negative IgG and Negative IgM antibody results indicate that no reliable serologic evidence of *B. burgdorferi* infection was present at the time of specimen collection. However, a negative result does not exclude the possibility

of infection since antibodies may not be detectable during early infection. Antibiotic therapy may also abort the antibody response. If clinical history and symptoms support a diagnosis of Lyme disease, testing a new serum collected 7-14 days after the first specimen is recommended.

2. Positive IgM and Negative IgG antibody results provide presumptive evidence of acute *B. burgdorferi* infection (within 4 weeks of disease onset) only when symptoms have been present for 30 days or less.
3. Positive IgG and Positive IgM results provide presumptive evidence of *B. burgdorferi* infection. Testing should not be used for the monitoring of treatment since antibodies may remain present for years after successful treatment. Response to therapy is confirmed through resolution of clinical symptoms.
4. Positive IgG and Negative IgM antibodies provide presumptive evidence of either a current *B. burgdorferi* infection of greater than 4 weeks duration, or a previous, inactive infection. Testing should not be used for the monitoring of treatment since antibodies may remain present for years after successful treatment. Response to therapy is confirmed through resolution of clinical symptoms.

FEES: N/A

NOTES:

1. Testing should not be used for purposes of screening the general population. Results should be used in conjunction with history of a tick bite and clinical evaluation.
2. False antibodies may be caused by other conditions (e.g., syphilis, yaws, Pinta, leptospirosis, relapsing fever, infectious mononucleosis and Rheumatoid factor).

ALIASES: Lyme disease, Lyme EIA, *Borrelia burgdorferi* antibody