Lyme VlsE1/pepC10 IgG/IgM Immunoassay (EIA)

ANALYTES TESTED: *Borrelia burgdorferi* (Lyme disease) antibodies

USE OF TEST: Screening test used for the detection of IgM and IgG antibody to Borrelia VlsE1/pepC10 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: 1ml
Container: 3 ml polypropylene screw capped tube
Shipping Unit: Unit 8

SPECIMEN REJECTION CRITERIA:

Specimens lacking two 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: EIA
Turn Around Time: One week, unless repeat testing is required.
Where/When Performed: Lansing/Tuesday

RESULT INTERPRETATION:

Reference Range: NEGATIVE (no antibody detected)

1. Negative Result:
   Negative 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 very 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 or Equivocal Result:
   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.

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. This assay detects both IgM and IgG antibody and does not differentiate between the two immunoglobulins.

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