CPAL
Central **P**ennsylvania **A**lliance **L**aboratory

Technical Bulletin
No. 77

November 10, 2009

Lyme Assay

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Effective Date:
July, 20 2009

Mnemonics:
LYME AB (Test # 3003080)
Positive specimens are held for 14 days to allow Lyme IgG/IgM Western blot to be ordered

.LYME PG (Test # 3003082)
Group reflexively orders a Lyme IgG/IgM western blot if Lyme IgG/IgM Ab screen is positive. Lyme IgG/IgM western blot is referred to Quest Diagnostics Nichols Institute, Chantilly, VA. Positive results are reported to the PA State Department of Health.

Performed:
Daily (Monday-Friday)

Specimen:
1.0 mL Serum; Store at 2-8C up to 7 days.

Reference Range:
Negative

Summary:
Currently CPAL perform testing for antibodies to Borrelia burgdorferi utilizing the Diasorin Liaison platform. The detection of antibodies to B. burgdorferi is suggestive of infection and is used in support of a clinical diagnosis of Lyme disease. Differential diagnosis of Lyme disease is difficult as clinical manifestations associated with different stages of the disease are variable. Diagnosis of Lyme disease is based upon a physician's review of clinical symptoms, patient's exposure to an endemic area, and laboratory test results. In ambiguous cases, there may be a greater reliance on laboratory data to confirm the diagnosis.

The Liaison *Borrelia burgdorferi* assay uses chemiluminescent immunoassay (CLIA) technology on the Liaison for the qualitative presumptive detection of IgG and IgM

antibodies to VlsE (variable major protein-like sequence, expressed) protein antigen of *Borrelia burgdorferi* in human serum. This assay should be used only on samples from patients with signs and symptoms that are consistent with Lyme disease. Positive or equivocal results should be supplemented by testing with a standardized Western blot procedure. Positive supplemental results provide evidence of exposure to *Borrelia burgdorferi* and can be used to support a clinical diagnosis of Lyme disease. Negative results by Liaison *Borrelia burgdorferi* assay should not be used to exclude Lyme disease.

Lyme disease is caused by the tickborne spirochete *Borrelia burgdorferi* and is the most common vectorborne disease in the United States. The CDC initiated surveillance for Lyme disease in 1982, and since 1991 Lyme disease has been a nationally reportable disease. In the United States, the disease is primarily localized to states in the northeast, mid-Atlantic, upper north-central regions, and northwestern California. The bacterium, *Borrelia burgdorferi,* is the etiologic agent of Lyme borreliosis, a disease which is transmitted by different tick species of the genus *Ixodes.* Lyme borreliosis is a multisystemic disorder that can affect several organs, such as skin, nervous system, large joints, and cardiovascular system. Even though Lyme disease spirochetes elicit a vigorous immune response, *Borrelia* bacteria survive and persist in the circulation of infected patients. Lyme borreliosis generally progresses through several different stages from early to late infection:

Stage 1-Localized infection: After an incubation period a slowly expanding skin lesion, erythema migrans (EM), forms at the site of the tick bite in 70-80% of the cases. General flu-like symptoms including malaise, fatigue, headache, arthralgias, myalgias, and fever accompany the skin lesion.

Stage 2-Disseminated infection: *B. burgdorferi* often disseminates within days to weeks after disease onset. Possible clinical manifestations include secondary skin lesions, acute lymphocytic meningitis and musculoskeletal pain in joints, tendon, muscle, or bone.

Stage 3- Persistent infection: After weeks of disseminated infection, the Lyme disease agents may still survive in localized niches and may persist up to several years. Months after onset of illness, about 60% of untreated patients with this infection experience intermittent attacks of arthritis.

Testing on the Diasorin Liaison platform has been ongoing since July 20, 2009. Preliminary results indicate that since implementation of this platform the number of false positive Lyme antibody test results has decreased, as compared to the previous methodology (Wampole *Borrelia burgdorferi* ELISA test system). Prior to the implementation of the Diasorin Liaison assay, about half (49.8%) of all screen positive Lyme assay results were confirmed positive by western blot analysis. Since the implementation of the Diasorin Liaison Lyme assay, 82.1% of the screen positive Lyme test results are confirmed by western blot analysis.