

### ***TEST UPDATE: LYME ANTIBODY (BORRELIA BURGORTEN)***

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#### **ASSAY INFORMATION:**

As of November 3, 2009, the Chemistry Laboratory will begin using a new method for the Lyme Antibody assay. The new method is an indirect chemiluminescence immunoassay performed on the DiaSorin Liaison. This replaces the current method, which is an Immunetics C6 *Borrelia burgdorferi* ELISA assay. If you have any questions concerning this change, please contact Dr. Greg Sharp in the laboratory (847-5115) or by email ([greg.sharp@vtmednet.org](mailto:greg.sharp@vtmednet.org)).

#### **METHOD:**

The DiaSorin Liaison Lyme Antibody (*Borrelia burgdorferi*) assay is an indirect chemiluminescence immunoassay. In the first step of the reaction, anti-*Borrelia burgdorferi* antibodies present in the patient serum bind to magnetic particles coated with VlsE antigen. During the second step of the reaction, the conjugate (mouse monoclonal antibodies to human IgG and human IgM conjugated to isoluminol) reacts with patient anti-*Borrelia burgdorferi* IgG and IgM antibodies that have bound to the VlsE antigen coated magnetic particles. Starter reagents are then added to induce a chemiluminescent reaction. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units and is indicative of the concentration of *Borrelia burgdorferi* antibodies present in the patient serum.

#### **CLINICAL APPLICATION:**

Lyme disease is caused by the tickborne spirochete *Borrelia burgdorferi*. Lyme borreliosis is a multisystemic disorder that can affect several organs, such as large joints, cardiovascular system, skin and nervous system. Despite the fact that the *Borrelia* spirochetes elicit a strong immune response, the bacteria survive and persist in the circulation of infected patients. Lyme borreliosis generally progresses through several different stages, from early to late infection.

The DiaSorin Liaison assay features a solid phase coated with VlsE (variable major protein-like sequence, expressed) antigen from two different strains of the *Borrelia burgdorferi* sensu lato complex (*Borrelia burgdorferi* and *Borrelia garinii*). VlsE is an outer surface lipoprotein that is believed to play a major role in the immune response to Lyme disease. Lyme disease patients consistently produce a strong antibody response against VlsE, in all stages of the disease, including the early stages.

#### **ASSAY LIMITATIONS:**

- Grossly hemolyzed, icteric or lipemic samples are not acceptable for testing.
- Some patient samples may be reactive with the DiaSorin Liaison *Borrelia burgdorferi* assay but not reactive with the Western Blot test due to the use of different antigens in the Western Blot.
- Testing should be performed on patients with clinical symptoms of Lyme disease or when exposure is suspected.
- Potential assay interference due to circulating antibodies against Human Ehrlichiosis (HGE) and Tick Borne Relapsing Fever (TBRF) has been observed. Interpret results from these patients with caution.
- Samples from individuals vaccinated with a licensed OspA vaccine (LYMERix) have been assayed using the Liaison *Borrelia burgdorferi* assay and were found to be negative. The assay performance has not been determined on samples from recipients of other Lyme vaccines.
- Potential assay interference due to HAMA (human anti-mouse antibodies) exists.

# FLETCHER ALLEN HEALTH CARE

## PATHOLOGY & LABORATORY MEDICINE

### ***TEST UPDATE: LYME ANTIBODY (BORRELIA BURGORTEN)***

#### **ORDERING INFORMATION:**

**Test Name:** Lyme Antibody

**Test Code:** LYMAB

**CPT Code:** 86618

**Sample Requirements:** Collect 2.5 mL of blood in either a SST or Red Top Tube.  
Submit 0.8 mL of serum refrigerated. The minimum volume is 0.5 mL.

**Test Note:** Samples with results of Positive or Equivocal will reflex Lyme Disease Antibody Western Blot analysis (CPT 86617 x 2) to be sent to Mayo Medical Laboratories. You have the option to decline reflex testing if you believe it is not medically necessary.

**Expected value:** Negative

**Test Schedule:** Monday-Friday

**Analytical Time:** Same Day

**Price:** Contact Laboratory Customer Service for pricing information (847-5121 or 1-800-991-2799).

**Effective Date:** November 3, 2009

#### ***References:***

Liaison *Borrelia burgdorferi* Assay product insert, DiaSorin Inc., September, 2008.