



Change in Instrumentation: Lyme Disease (*Borrelia burgdorferi*)

Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.

Effective March 16, 2020, Clinical Pathology Laboratories will implement a new DiaSorin LIAISON® Chemiluminescent immunoassay for *Borrelia burgdorferi* (Lyme Disease) to replace the Immunitics ELISA method. The LIAISON® assay format includes the entire VlsE (the variable major protein-like sequence surface protein) antigen complex in a reagent format that provides greater specificity for Lyme Disease. The prior assay utilized the C6 antigen, a portion of the VlsE antigen. In laboratory validation studies, manufacturer instruction for use and literature review, the Diasorin LIAISON® assay shows lower false positive rate and decrease in overall positivity rates relative to prior methods.

Background information:

- The LIAISON® assay provides presumptive qualitative detection of IgG and IgM antibodies to VlsE 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 Immunoblot confirmatory testing.
- Positive Immunoblot confirmatory testing provides 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 do not completely exclude Lyme disease as early stages of infection or treatment for Lyme disease may be associated with low or undetectable antibody levels. If clinical suspicion remains high, repeat serologies or other testing should be considered.

Additional Test Information:

Specimen Requirements:	0.5 mL serum from SST
Transport Temperature:	Refrigerated
Stability (collection to initiation of testing):	7 Days Refrigerated; 1 Month Frozen
Performed:	Monday through Friday
Analytic Time:	1 Day
Specimen Retention:	1 Week
CPT Codes:	86618

Please contact your Account Representative should you have any questions.

Thank you for supporting Clinical Pathology Laboratories