LABORATORY ALLIANCE of Central New York, LLC

Lyme Disease Serological Testing

Background: Lyme disease, or Lyme borreliosis, is a bacterial infection caused by *Borrelia burgdorferi.* The infectious spirochete is transmitted via the bite of an infected tick. Initial symptoms may include a distinctive bull's-eye rash at the site of the bite or expanding skin lesion termed erythema migrans. Untreated patients may go on to develop a wide range of symptoms including neurological, cardiac and arthritic conditions. Direct detection of the causative agent is often not practical, so serological testing remains important in support of the diagnosis of Lyme disease.[1]

Screening Assays: Serological testing requires a two-tiered approach beginning with an immunoassay followed by confirmatory testing. Currently, Laboratory Alliance of CNY offers a screening test for Lyme total antibodies that detects both IgG and IgM. This first tier assay, DiaSorin Lyme Total Antibody Plus, incorporates antigens VlsE and OspC. These outer surface proteins are thought to play major roles in the immune response with OspC serving as the immunodominant antigen of the IgM response during early stage infection and VlsE producing strong antibody response at all stages of disease, including the early stage.[2]

OspC vs pepC10 Antigens: Although not offered by Laboratory Alliance of CNY, some Lyme assays incorporate antigen pepC10 as alternative antigen to OspC. Both pepC10 and OspC antigens are included in their respective immunoassays to improve the detection of Lyme IgM antibodies. The combination of VlsE and either pepC10 or OspC improves the sensitivity of immunoassay in early Lyme disease.[1] DiaSorin received FDA Substantial Equivalence approval in 2021 as compared to the Zeus ELISA Borrelia VlsE-1/pepc10 IgG/IgM Test System.[3] Given the equivalence of the two assays, the advantage of utilizing the DiaSorin Lyme Total Antibody Plus assay offered by Laboratory Alliance is turn-around time for negative screens. This testing is performed Monday through Saturday at our Operations Center, with negative results being reported on same day as request. Positive or equivocal results are held and reported upon the receipt of confirmatory testing results.

Confirmatory Testing: The confirmatory processes for Lyme serology are designated as the Standard Two-Tiered Testing (STTT) strategy or the Modified Two-Tiered Testing (MTTT) strategy. Our current process uses the STTT with confirmation via immunoblot performed by Quest Diagnostics. The MTTT strategy confirms the initial combined IgM/IgG screen result with separate immunoassays for Lyme IgG and Lyme IgM antibodies. We intend to migrate to the MTTT later this year with all testing performed at Laboratory Alliance Operations Center and all testing reported on the same day as request.

Test Name	Test Code	CPT Code	Schedule of Testing	Specimen Requirements
Lyme Disease IgM / IgG Antibodies	LYME	86618	Mon - Sat	1 gold top, 2 mL serum Stable 7 days at 2 - 8°C
All positive or equivocal results will reflexively order Lyme IgM/IgG Immunoblot confirmatory testing (STTT)				

Questions regarding Lyme testing may be directed to Cheryl M. Haskins, MS, MT(ASCP)SC, Chemistry Special Projects Coordinator, at 315-410-7014 or cherylhaskins@lacny.com.

References:

1. Laboratory Diagnosis of Lyme Borreliosis. Clinical Microbiology Reviews, April 2021, Volume 34, Issue 2. cmr.asm.org
2. Liaison Lyme Total Antibody Plus Instructions for Use. DiaSorin Inc., 1951 Northwestern Avenue Stillwater, MN 55082-0285, 1-800-328-1482. Ref 318330, US – 54547 – 2021-04
3. FDA Substantial Equivalence Document K193051, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002, www.fda.gov

Questions regarding this issue may be directed to Cheryl Haskins, MS, MT(ASCP)SC, Chemistry Special Projects Coordinator at 315-410-7014 or cherylhaskins@lacny.com.

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