INFECTIOUS DISEASE

Labcorp's Lyme disease testing is guideline-driven

Labcorp offers the new **Lyme Antibodies, Modified 2-Tier Testing Profile, Serum/Plasma [164226]** to aid in the diagnosis of Lyme disease.

Labcorp made this transition following FDA approval of enzyme immunoassays (EIAs) for use as the second step in the Lyme disease testing algorithm in place of the traditional immunoblot (e.g., western blot).[1] Current guidelines and recommendations support the use of the Modified Two Tier Testing (MTTT) algorithm.[2-4] Internal studies and studies published in peer-reviewed literature demonstrate that relative to the traditional testing algorithm, which includes line blot/western blot,[5-6] the MTTT:

- has higher sensitivity in detecting early disease
- offers objective values that lead to less variability in interpretation of results

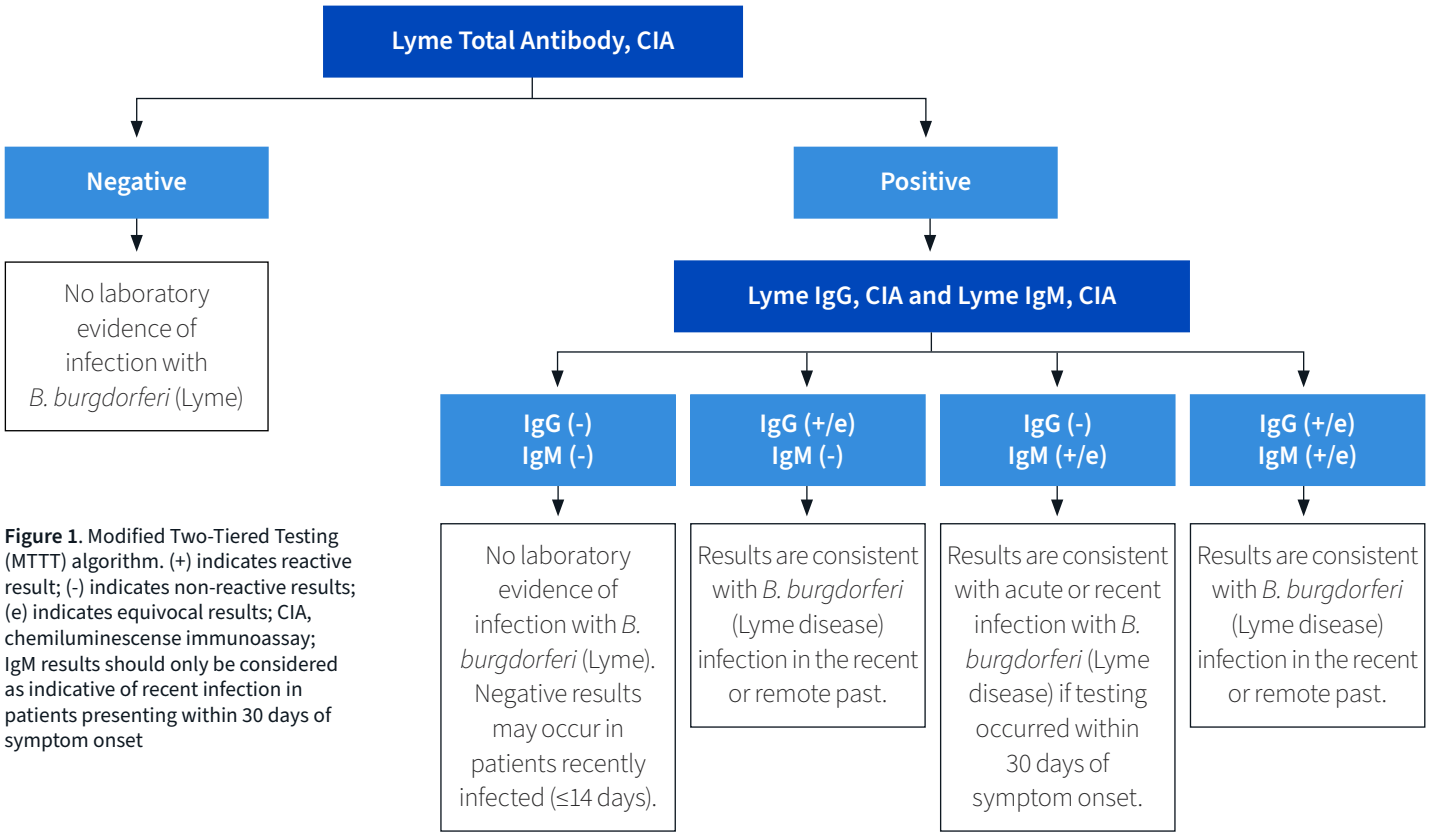

Figure 1. Modified Two-Tiered Testing (MTTT) algorithm. (+) indicates reactive result; (-) indicates non-reactive results; (e) indicates equivocal results; CIA, chemiluminescense immunoassay; IgM results should only be considered as indicative of recent infection in patients presenting within 30 days of symptom onset

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Test no.	Test name	Intended use
164226	Lyme Antibodies, Modified 2-Tier Testing Profile, Serum/Plasma	Aid in the diagnosis of Lyme disease in individuals with clinical signs and symptoms consistent with Lyme disease. Lyme disease should be considered based on the presence of typical signs and symptoms of infection in patients with a history of possible exposure to infected ticks.
138685	Lyme Disease, *Borrelia burgdorferi*, Real-time PCR	Aid in the diagnosis of infections caused by *Borrelia burgdorferi* sensu stricto. Can be performed on synovial fluid to support treatment decisions for Lyme arthritis.
163600	Lyme Disease, Line Blot	Detect antibodies specific for *B. burgdorferi*. This test is intended as the second step in testing serum samples found to have been equivocal or positive using an ELISA or IFA test as the first step to provide supportive evidence of infection with *B. burgdorferi*.

About Lyme disease

Lyme disease, or Lyme borreliosis, is the most prevalent tick-borne infection in the United States with greater than 30,000 confirmed or probable Lyme disease cases reported to the CDC annually and an estimated 476,000 people infected each year.[7]

Lyme disease is a bacterial infection caused by spirochetes of the *Borrelia burgdorferi* sensu lato complex, which are transmitted to humans by the bite of certain species of Ixodes (hard) ticks. Reported cases of Lyme disease are highest in the Northeastern U.S. (Virginia to Maine) and the upper Midwest (Minnesota and Wisconsin); however, infections have been identified in almost every state associated with travel and expansion of the range of the Ixodes tick. The incidence of Lyme disease matches the seasonality of the tick with the rate of cases rising in early spring, peaking in the summer months and decreasing during the fall and winter months.

Serologic (Antibody) testing for Lyme disease

In 1994, the scientific and clinical community recommended the use of a standard two-tier testing (STTT) algorithm to maximize the clinical utility of serological testing. Sequential testing of specimens using different assays provides improved sensitivity and specificity over a single assay alone. The STTT algorithm includes a screening immunoassay for total antibody against *B. burgdorferi*, with reflex of positive specimen to immunoblot (e.g., Western blot or line blot) for IgG and IgM. In 2019, the FDA cleared the first Lyme disease serologic assays with new indications for use, allowing for an enzyme immunoassay rather than immunoblot assay as the second test in a Lyme disease testing algorithm, known as a modified two-tiered testing (MTTT) algorithm (Figure 1).[1] Current guidelines and recommendations including those developed by the Centers for Disease Control and Prevention (CDC), the Infectious Diseases Society of America (IDSA), the American Academy of Neurology and the American College of Rheumatology support the use of either the STTT or MTTT algorithms to aid in the diagnosis of Lyme disease.[2-4]

References

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2. Mead P, Petersen J, Hinckley A. Updated CDC recommendation for serologic diagnosis of Lyme disease. *MMWR Morb Mortal Wkly Rep*. 2019 Aug 16;68(32):703.
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Visit the online test menu at **Labcorp.com** for additional test options and full test information, including CPT codes and specimen collection instructions.

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