

Laboratory News

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Changes to Lyme Disease Serologic Testing

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Effective March 6th 2023, Marshfield Labs will transition from the standard two-tier test (STTT) algorithm to the modified two-tier test (MTTT) algorithm for Lyme disease (LD) serological testing.

Inside this Issue

| | |
|--------------------------------|---|
| Lyme Disease Serologic Testing | |
| MTTT Testing | 1 |
| MTTT Cont. | 2 |
| Table | |
| Guidance for Interpretation... | 2 |
| References..... | 3 |

Modified Two-Tier Testing

When Marshfield Labs transitions to the modified two-tier test (MTTT) algorithm for Lyme disease (LD) serological testing, confirmatory immunoblots will not be performed, nor bands data reported; instead, final results will consist of a negative or positive report together with an interpretive comment.

The test code "LYMPAN" will remain but reflex confirmatory testing will be done by the EIA method. The test code "LYIBMG" (Lyme Immunoblot, IgM, IgG) will be retired and replaced with "LYMG" (Lyme Immunoassay, IgM, IgG)

| | | |
|---------------|---------------|--|
| Orderable: | LYMPAN | Lyme Disease Serology, Serum |
| Retire: | LYIBMG | Lyme Immunoblot, IgM, IgG |
| Replace with: | LYMG | Lyme Immunoassay, IgM, IgG CPT code 86617 x 2 |

Further Details

Our current LD antibody test follows the longstanding STTT algorithm that uses a screening enzyme immunoassay (EIA) and a confirmatory immunoblot (aka Western blot) for all samples that screen as Positive or Equivocal.

In the past decade studies have demonstrated that using a second, immunologically different, EIA to confirm screen EIA Positive or Equivocal results gives increased sensitivity for early LD with no loss in sensitivity in more advanced cases nor in specificity overall^{1, 2, 3, 4}.

In this so-called MTTT algorithm, immunoblots are not used, thus positive bands cannot be reported. Instead, a report of Negative, Positive for IgM, Positive for IgG, or Positive for IgM & IgG anti-*B. burgdorferi* antibodies together with an interpretive comment will be made.

Please see the Table below for reporting and interpretation examples. Note that the MTTT still suggests that IgM results in patients with ≥ 30 days of the infection be disregarded, since a detectable IgM titer after that time may be due to non-specific cross-reactions.

For any technical questions, please contact: Immunodiagnostics lab at 715-221-6290.
For any clinical consultations, please contact: Dr. Thomas Novicki at 715-221-6132.

Guidance for the Interpretation of LD MTTT Results

| Test Sequence | | | Interpretation for Laboratories | Interpretation for Providers |
|--|---|---|--|--|
| Tier 1 | Tier 2a | Tier 2b | | |
| <i>VlsE/pepC10</i> IgM/IgG Total Immunoassay | <i>Whole Cell</i> Antigen IgM Immunoassay | <i>Whole Cell</i> Antigen IgG Immunoassay | | |
| Negative | Testing Not Indicated | Testing Not Indicated | Negative for antibodies to <i>B. burgdorferi</i> (Lyme disease). | No laboratory evidence of infection with <i>B. burgdorferi</i> (Lyme disease). |
| Positive/ Equivocal | Negative | Negative | Antibodies to <i>B. burgdorferi</i> (Lyme disease) not confirmed. | No laboratory evidence of infection with <i>B. burgdorferi</i> (Lyme disease). |
| Positive/ Equivocal | Positive | Negative | IgM-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with acute or recent infection with <i>B. burgdorferi</i> (Lyme disease). |
| Positive/ Equivocal | Negative | Positive | IgG-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with <i>B. burgdorferi</i> (Lyme disease) infection in the recent or remote past. IgG-class antibodies may remain detectable for months to years following resolution of infection. |
| Positive/ Equivocal | Positive | Positive | IgM and IgG-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with <i>B. burgdorferi</i> infection (Lyme disease) in the recent or remote past. Antibodies may remain detectable for months to years following resolution of infection. |

(Excerpted from APHL [Suggested Reporting Language, Interpretation and Guidance Regarding Lyme disease Serologic Test Results.](https://www.aphl.org/aboutAPHL/publications/Documents/ID-2021-Lyme-Disease-Serologic-Testing-Reporting.pdf) <https://www.aphl.org/aboutAPHL/publications/Documents/ID-2021-Lyme-Disease-Serologic-Testing-Reporting.pdf>. Accessed 12/10/2022

References

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3. Branda JA, Body BA, Boyle J *et al.* Advances in Serodiagnostic Testing for Lyme disease Are at Hand. *Clin Infect Dis* 2018 Mar 19; 66(7):1133-1139.
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