

MTTT Lyme Diagnostics

B. burgdorferi IgG/IgM VIsE-OspC EIA

Gold Standard Diagnostics new diagnostic solution for the Modified Two-Tiered Testing (MTTT) algorithm complements our existing market leading Lyme test portfolio. With this new assay, laboratories can choose which tests and algorithms best meet their needs.

- Superior sensitivity: includes antigens from *B. burgdorferi* strains B31 and 2591
- Optimal specificity: contains VIsE immunogenic lipoprotein
- Convenient: kit includes ready to use controls for ease of use
- Automatable: simple procedure is easy to automate
- FDA cleared



SDM-0337

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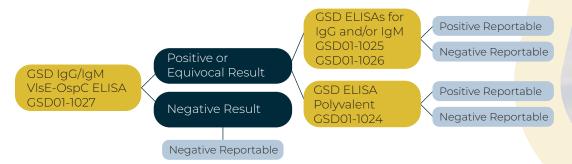
Modified Two-Tiered Algorithm

In 2014, the CDC published an article¹ describing a new two-tiered testing algorithm based on use of two ELISA tests. This modified algorithm would serve as an alternate to the standard two-tiered ELISA + Immunoblot testing (STTT) algorithm. Following this CDC discussion, the US FDA accepted the proposed testing option and published guidelines² for this modified two-tiered testing (MTTT) algorithm.

Example of the MTTT workflow using GSD EIA:

Full Lyme Test Portfolio

GSD offers four Lyme ELISA kits that can work with laboratory preferences to determine the best workflow. A separate B. burgdorferi IgG/IgM VIsE-OspC recombinant ELISA is available to be used with any of the ELISA assays listed below. All GSD Lyme ELISA assays are FDA cleared and easily automatable on any open EIA/ELISA processors.



ORDERING INFORMATION - ELISA & INMMUNOBLOT ASSAYS

Product	Order No.	Format
GSD Borrelia burgdorferi IgG/IgM VIsE -OspC ELISA	GSD01-1027	96 tests
GSD Borrelia burgdorferi lgG/lgM ELISA	GSD01-1024	96 tests
GSD Borrelia burgdorferi IgG ELISA	GSD01-1025	96 tests
GSD Borrelia burgdorferi IgM ELISA	GSD01-1026	96 tests
GSD B. burgdorferi 831 IgG Immunoblot	GSD01-1022	50 tests
GSD B. burgdorferi 831 IgM Immunoblot	GSD01-1023	50 tests

- 1. Molins CR, et al. Collection and characterization of samples for establishment of a serum repository for Lyme disease diagnostic test development and evaluation. J Clin Microbiol. 2014 Oct; 52(10): 3755–3762. doi: 10.1128/JCM.01409-14
- 2. Mead P, et al. Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease. MMWR Morb Mortal Wkly Rep 2019;68:703. doi: http://dx.doi.org/10.15585/mmwr.mm6832a4



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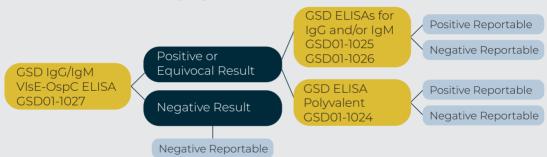
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Modified Two-Tiered Testing Algorithm



(MTTT first and second tiers can be run in reverse)