

TECHNICAL BULLETIN

☒ TEST CHANGE ☒ NEW TEST

NOTIFICATION DATE: 08/31/2021

EFFECTIVE DATE: 08/31/2021

Lyme Disease Testing Update - Modified Two-Tier Testing (MTTT) Algorithm

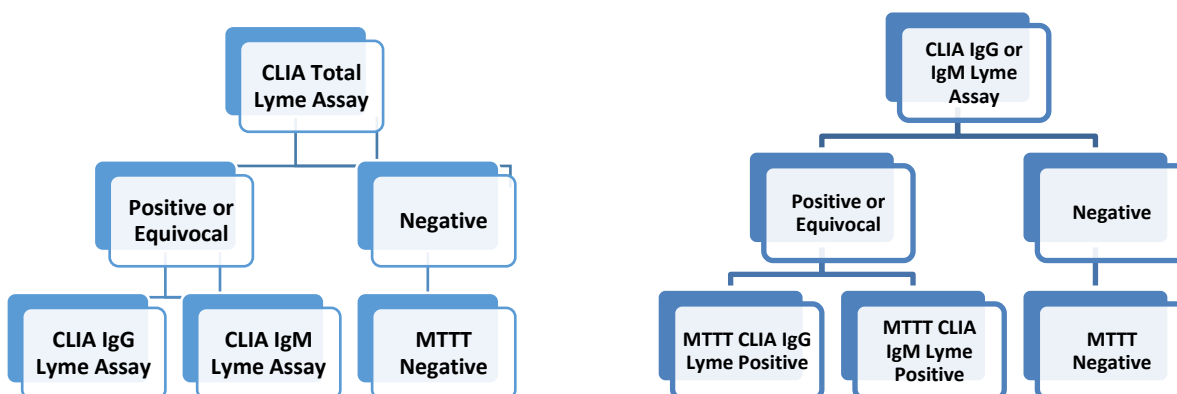
On the effective date, Northwell Health Laboratories, as a part of our continued quality improvement will implement the Modified Two-Tier Testing (MTTT) Algorithm for Lyme disease testing. The Modified Two-Tiered Testing Algorithm (MTTT) for Lyme disease diagnosis is based on two Enzyme Immunoassay (EIA) tests. This is an alternate option to the Standard Two-Tiered Testing algorithm (STTT) in which a positive screen result is confirmed with an Immunoblot. Modified Two-Tier Testing (MTTT) for Lyme borreliosis (i.e., confirmation with an EIA instead of an immunoblot) has been shown to have improved sensitivity compared with standard two-tier testing.

Lyme disease is a growing health issue; in fact, according to the Centers of Disease Control and Prevention (CDC), recent estimates suggest that approximately 300,000 people may get Lyme disease each year in the United States. Treatment is more effective if begun early, and an updated recommendation from the CDC paves the way for earlier detection and diagnosis of the disease using Modified Two-Tier testing (MTTT) which utilizes immunoassays rather than immunoblots in the second tier of the algorithm.

Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease: 2-step Testing Process:

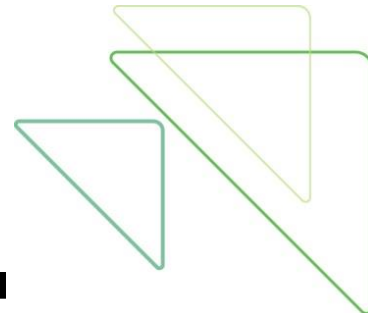
1. Test serum in an immunoassay measuring combined IgG and IgM antibodies to specific borrelial proteins.
2. Verify the results using a second FDA-cleared IgG and IgM immunoassays in place of a Western blot (Immunoblot) test. This is an acceptable alternative for the serologic diagnosis of Lyme disease.

Modified Two-Tier Testing (MTTT) Algorithm for Lyme Disease ¹



- By using two Chemiluminescence Immunoassay (CLIA) tests in the MTTT algorithm, it enables improved sensitivity yet comparable specificity to the Standard Two-Tier Test Western Blot algorithm. This is because samples that contribute to specificity issues on any one CLIA test rarely cause a specificity issue on both CLIA tests.
- All CLIA Total Lyme positive results will automatically reflex to Lyme IgG and Lyme IgM testing.
- Following NYSDOH recommendation, Lyme Western Blot testing will gradually be phased out for serum/plasma.

If you have any questions, please contact Client Services at (516) 719-1100.



TECHNICAL BULLETIN

Test Requirement/Parameters	New Requirement	Previous Requirement
Tests	Lyme Vise Total antibody IgG and IgM Serum, Lyme Vise IgG/IgM AB Reflex MTTT	Lyme Vise Total antibody IgG and IgM Serum, Lyme Vise IgG/IgM AB Reflex WB
Reflex to	Lyme IgM and Lyme IgG	Lyme Western Blot Pan IgG, IgM
Method:	Chemiluminescence Immunoassay (CLIA) Reflex-Enzyme Immunoassay	Chemiluminescence Immunoassay (CLIA) Reflex-Immunoblot
Reflex Test Turn Around Time	Same day	1 week
Computer Interface Code	5700530, 5304324	5700530, 5304324
Test Order	LYME, LYMEX	LYME, LYMEX

References

1. Diasorin Pocket Reference Guide, APM-1330-ENG—v2 06/21

If you have any questions, please contact Client Services at (516) 719-1100.