Lyme Antibody Confirmation Changes

On 7/19/2021, the UVMMC laboratory will be changing its methodology for Lyme antibody confirmation testing on serum. Currently, we use a traditional two-tier system comprised of a Lyme screen (Diasorin Liason Lyme Total Antibody Plus-IgG and IgM) and confirmation via immunoblot (Roboblot). We will be switching to a modified two-tier testing (MTTT) system comprised of our current Diasorin Lyme Screen and confirmation using Diasorin semi-quantitative direct IgG and IgM immunoassays. The FDA cleared MTTT for diagnosis of Lyme disease in July of 2019 (1). In our own validation studies and through literature studies, the MTTT system utilizing the Diasorin assays provides the same level of specificity as using our traditional two-tier system, but increases the sensitivity (by as much as two-fold) in early Lyme disease (2).

New Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Lyme Ab Confirmation (CLIA)	LAB16207	LAB16207	FAH5964	No Current LOINC
New Reportables	**Epic Code**	**Atlas Code**	**Mayo Access ID**	**LOINC Code**
Lyme IgG Ab	12301014878	12301014878	FAH5965	16480-6
Lyme IgM Ab	12301014879	12301014879	FAH5966	40612-4
Lyme Ab Confirmation Interpretation	12301014880	12301014880	FAH5967	9586-9
Current Orderable Name	**Epic Code**	**Atlas Code**	**Mayo Access ID**	**LOINC Code**
Lyme ImmunoBlot Confirmation	LAB787	LYMIB	FAH5859	34942-3

	Current	New
Test Name	Lyme ImmunoBlot Confirmation	Lyme Ab Confirmation (CLIA)
Reportable Values	Lyme IgG Immunoblot Lyme IgG Band(s) Lyme IgM Immunoblot Lyme IgM Band(s) Lyme Immunoblot Interpretation	Lyme IgG Ab Lyme IgM Ab Lyme Ab Confirmation Interpretation
Acceptable Container	SST (Stable 7 days) Markedly lipemic, icteric, or hemolyzed samples will be rejected	SST (Stable 7 days) Markedly lipemic, icteric, or hemolyzed samples will be rejected
	Temperature/Specimen/Collect/Submit	**Temperature/Specimen/Collect/Submit**
Collection Requirements	Refrigerate/Serum/4 mL/0.8 mL	Refrigerate/Serum/4 mL/0.8 mL
Reference Ranges (All Ages)		
Lyme IgG Ab	Negative	Negative
Lyme IgM Ab	Negative	Negative
Instrumentation	Gold Standard Diagnostics Roboblot	DiaSorin Liaison XL
Methodology	Line Immunoblot	Chemiluminescence Immunoassay
CPT Code(s)	86617 x 2	86617 x 2
NYS Approval	Yes	Yes

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This change will affect how Lyme confirmation testing is reported. Currently, we report the individual bands detected for the Lyme IgG and IgM immunoblot along with a positive/negative determination based on the number of bands detected for both IgG and IgM. This will be replaced by two individual results for the Lyme IgG Antibody and Lyme IgM Antibody that will be reported as either Negative, Equivocal, or Positive. There will still be a Lyme Interpretation that integrates the individual IgG and IgM results into a succinct analysis.

With this change to using the MTTT system, the Lyme Ab screen needs to be assayed using the DiaSorin method. Therefore, ***the Lyme confirmation test will not be orderable to clients as a stand-alone test but is a reflex-only test that will be for UVMMC lab Use Only***. All confirmation testing requests must begin with the Lyme Ab screening test.

If you have any questions or concerns please contact the medical director of clinical chemistry (clayton.wilburn@uvmhealth.org).

References:

1. FDA. 7/29/2019. *FDA clears new indications for existing Lyme disease tests that may help streamline diagnoses* [Press Release]. https://www.fda.gov/news-events/press-announcements/fda-clears-new-indications-existing-lyme-disease-tests-may-help-streamline-diagnoses

2. Branda JA, Strle K, Nigrovic LE, Lantos PM, Lepore TJ, Damle NS, Ferraro MJ, Steere AC. Evaluation of Modified 2-Tiered Serodiagnostic Testing Algorithms for Early Lyme Disease. Clin Infect Dis. 2017 Apr 15;64(8):1074-1080. doi: 10.1093/cid/cix043. PMID: 28329259; PMCID: PMC5399943.