Allina Health LABORATORY

TEST CHANGE
NOTIFICATION DATE: June 27, 2022
EFFECTIVE DATE: July 19, 2022

LYME DISEASE SEROLOGY, POLYVALENT WITH REFLEX

659/86618.2

QUICK REFERENCE

Effective July 19, 2022, the Lyme Disease serology, polyvalent with reflex assay (659/86612.2) will undergo a change to the methodology used to confirm positive screening results.

DETAILS

On July 19, 2022, Allina Health Laboratory will begin using the modified two-tier testing (MTTT) algorithm for Lyme screening and confirmation. The assay will continue to be the first line of testing used to screen for Lyme disease, however, with the MTTT, positive screening test will reflex to a Lyme Confirmatory Panel which consist of Lyme IgG and Lyme IgM by chemiluminescent immunoassay for confirmation rather than the Lyme Western Blot currently used.

Traditionally the CDC recommended a standard two-tier testing (STTT) algorithm for Lyme's disease, consisting of a first-tier chemiluminescent assay screen which, if positive or equivocal, was followed by a second-tier Western Blot confirmatory assay that tested for the presence of IgM and IgG antibodies associated with Lyme disease. Recently, a modified two-tier testing (MTTT) recommendation was introduced that replaces the second-tier western blot with distinct chemiluminescent assays for IgG and IgM antibodies. The MTTT assay screen and confirmation has specificity that is equivalent to STTT and most importantly has been shown to have increased sensitivity in early infection. Note that if a patient has a negative result on the Lyme disease screen there is NO indication to perform further testing and confirmatory testing will not be performed.

The results of Modified Two Tier Testing for Lyme Disease will be released with interpretative comments according to American Public Health Laboratories (APHL) guidelines which will give clinicians information regarding the results and any further recommended actions.

The new Lyme Confirmation panel which is part of MTTT will not be orderable as an independent test as it can only be used to confirm positive screening test performed using our current chemiluminescent assay.

Lyme Western Blot testing will no longer be performed within Allina Health Laboratories. Request for LWB will be referred to LabCorp for testing and will be available only to reference lab clients who perform their own version of a Lyme screen in their laboratory.

The following page includes example of reports for both negative and positive results for the new Modified Two-Tier Testing for Lyme Disease.

QUESTIONS: Contact your Allina Health Laboratory account representative, or our Client Services department

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EXAMPLE REPORTS:

Negative

Lyme Screen w/Reflex (Final result)

ID:	22CL-172L0003	Collected:	6/21/2022 1238
Source:	Blood	Verified On:	6/21/2022 1244
Resulting Lab:	ANWLCR	Received:	6/21/2022 1242

Component	Value	Ref. Interval
LYME SCREEN W/REFLEX	Positive (A)	Negative

Reflexed to Lyme Serology Confirmatory Panel. See Lyme Serology Confirmatory Panel results.

Lyme Screen w/Reflex (Final result)

ID:	22CL-172L0004	Collected:	6/21/2022 1238
Source:	Blood	Verified On:	6/21/2022 1249
Resulting Lab:	ANWLCR	Received:	6/21/2022 1249

Component	Value	Ref. Interval
LYME SCREEN W/REFLEX	Negative	Negative

No laboratory evidence of infection with B. burgdorferi (Lyme disease).

Negative results may occur in patients recently infected (less than or equal to 14 days) with B. burgdorferi. If recent infection is suspected, repeat testing on a new sample collected in 7-14 days is recommended.

Lyme Serology Confirmatory Panel (Final result)

ID:	22CL-172L0003	Collected:	6/21/2022 1238
Source:	Blood	Verified On:	6/21/2022 1244
Resulting Lab:	ANWLCR	Received:	6/21/2022 1242

Component	Value	Ref. Interval
Lyme IgG Confirmation Interpretation	Negative	Negative
Lyme IgM Confirmation Interpretation	Negative	Negative

Comments:
No laboratory evidence of infection with B. burgdorferi (Lyme disease).

Negative results may occur in patients recently infected (less than or equal to 14 days) with B. burgdorferi. If recent infection is suspected, repeat testing on a new sample collected in 7-14 days is recommended.

Legend

Positive

Lyme Screen w/Reflex (Final result)

ID:	22CL-178L0001	Collected:	6/27/2022 0948
Source:	Blood	Verified On:	6/27/2022 0949
Resulting Lab:	ANWLCR	Received:	6/27/2022 0949

Component	Value	Ref. Interval
LYME SCREEN W/REFLEX	Positive (A)	Negative

Reflexed to Lyme Serology Confirmatory Panel. See Lyme Serology Confirmatory Panel results.

Lyme Serology Confirmatory Panel (Final result)

ID:	22CL-178L0001	Collected:	6/27/2022 0948
Source:	Blood	Verified On:	6/27/2022 0949
Resulting Lab:	ANWLCR	Received:	6/27/2022 0949

Component	Value	Ref. Interval
Lyme IgG Confirmation Interpretation	Positive (A)	Negative
Lyme IgM Confirmation Interpretation	Positive (A)	Negative

Comments:
Results are consistent with B. burgdorferi infection (Lyme disease) in the recent or remote past. Antibodies may remain detectable for months to years following resolution of infection.

Results should not be used to monitor or establish adequate response to therapy. Response to therapy is confirmed through resolution of clinical symptoms; additional laboratory testing should not be performed. If both tests are equivocal consider repeat testing in 7-14 days if clinically warranted.

Legend

A - Abnormal

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