Test Definition: LYME

Lyme Disease Serology, Serum

Overview

Useful For

Diagnosing Lyme disease

This test **should not be used** as a screening procedure for the general population.

This test **should not be used** for treatment monitoring.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
LYWB	Lyme Disease Ab, Immunoblot, S	Yes	No

Testing Algorithm

If Lyme disease serology is positive or equivocal, then Lyme disease antibody confirmation (by Western blot) will be performed at an additional charge.

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Supplies: Sarstedt Aliquot Tube 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Information: Centrifuge and aliquot serum into plastic vial.

Forms

If not ordering electronically, complete, print, and send Infectious Disease Serology Test Request (T916) with the

specimen.

Specimen Minimum Volume

0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Heat inactivated	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	10 days	
	Frozen	30 days	

Clinical & Interpretive

Clinical Information

Lyme disease (LD) is caused by infection with a member of the *Borrelia burgdorferi* sensu lato complex, which includes *B burgdorferi* sensu stricto (herein referred to as *B burgdorferi*), *Borrelia afzelii,* and *Borrelia garinii.* Among these species, *B burgdorferi* is the most frequent cause of LD in North America. These tick-borne spirochetes are transmitted to humans through the bite of *Ixodes* species ticks. Endemic areas for Lyme disease in the United States correspond with the distribution of 2 tick species, *Ixodes scapularis* (Northeastern and upper Midwestern US) and *Ixodes pacificus* (West Coast US).

Transmission of LD-associated *Borrelia* requires at least 36 hours of tick attachment. Approximately 80% of infected individuals will develop a unique expanding skin lesion with a central zone of clearing, referred to as erythema migrans (EM; stage 1). In the absence of treatment, patients may progress to early disseminated disease (stage 2), which is characterized by neurologic manifestations (eg, meningitis, cranial neuropathy, radiculoneuropathy) and is often associated with *B garinii* infection. Patients with late LD often present with intermittent or persistent arthralgia, most often associated with *B burgdorferi* infection, or with acrodermatitis chronica atrophicans, typically due to infection with *B afzelii*.

Diagnosis of LD is currently based on a 2-tiered serologic testing algorithm, as recommended by the Centers for Disease Control and Prevention, and involves an initial screening assay for detection of antibodies to LD-causing *Borrelia* species. Samples that are screen positive or equivocal are subsequently reflexed for supplemental assessment using a *B burgdorferi* immunoblot for detection of IgM- and IgG-class antibodies to specific *B burgdorferi* antigens.

Importantly, while serologic assessment for LD may be negative in the early weeks following infection, over 90% of patients with later stages of infection are seropositive by serology, which remains the diagnostic method of choice for

this disease.

Reference Values

Negative
Reference values apply to all ages.

Interpretation

Negative:
No evidence of antibodies to *Borrelia burgdorferi* detected. False-negative results may occur in recently infected patients (< or =2 weeks) due to low or undetectable antibody levels to *B burgdorferi*. If recent exposure is suspected, a second specimen should be collected and tested in 2 to 4 weeks.

Equivocal:
Not diagnostic. Supplemental testing by immunoblot has been ordered by reflex.

Positive:
Not diagnostic. Supplemental testing by immunoblot has been ordered by reflex.

Cautions

A negative result does not exclude the possibility of infection with *Borrelia burgdorferi.* Patients in the early stages of Lyme disease and those who have been treated with antibiotics may not exhibit detectable antibody titers. Patients with clinical history, signs, or symptoms suggestive of Lyme disease should be retested in 2 to 4 weeks if the initial test result is negative.

A positive result is not definitive evidence of infection with *B burgdorferi*. It is possible that other disease conditions may produce artifactual reactivity in the assay (eg, infectious mononucleosis, syphilis). All equivocal or positive results should be supplemented immunoblot testing for IgM- and IgG-class antibodies in accordance with Centers for Disease Control and Prevention, the Association of State and Territorial Public Health Laboratory and directors (CDC/ASTPHLD) recommendations.

Patients infected with other members of the *B burgdorferi* sensu lato complex, including *Borrelia garinii*, *Borrelia afzelii*, and *Borrelia mayonii* will be detected by this assay; however, they cannot be differentiated.

This test should not be performed as a screening procedure for the general population. The predictive value of a positive or negative result depends on the prevalence of analyte (antibodies present to VlsE1 and pepC10 antigens) in a given population. Testing should only be performed when clinical evidence suggests the diagnosis of *Borrelia* infection or related etiological conditions observed by the physician.

This test will not distinguish results that are both IgG and IgM positive from results that are either IgG or IgM positive.

Lyme serology should not be used for treatment monitoring as IgG can remain for years post-resolution of infection. Instead, monitoring resolution of symptoms in response to treatment is recommended.

Clinical Reference

1. Theel ES. The past, present and (possible) future of serologic testing for Lyme disease. J Clin Microbiol. 2016;54(5):1191-1196. doi:10.1128/JCM.03394-15

2. Dattwyler RJ. Lyme borreliosis: an overview of clinical manifestations. Lab Med. 1990;21:290-292
3. Schwan TG, Burgdorfer W, Rosa PA. *Borrelia*. In: Murray PR, eds. Manual of Clinical Microbiology. 7th ed. ASM Press; 1999:746-758
4. Center for Disease Control and Prevention: Recommendation for test performance and interpretation from second national conference on serological diagnosis of Lyme disease. MMWR Morb Mortal Wkly Rep. 1996;45:481-484

Performance

Method Description

The first-tier Lyme disease screening enzyme-linked immunosorbent assay (ELISA) is the Zeus ELISA *Borrelia* VlsE1/pepC10 IgG/IgM test system. The Zeus ELISA *Borrelia* VlsE1/pepC10 IgG/IgM test system is designed to detect IgG- and IgM-class antibodies (not differentiated by the assay in the final result) in human sera to VlsE1 and pepC10 antigens. Diluted test sera are incubated in antigen coated microwells. Any antigen-specific antibody in the sample will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components. Peroxidase conjugated goat antihuman IgG and IgM are added to the wells and the plate incubated. The conjugate will react with IgG and IgM antibodies immobilized on the plate. The wells are washed to remove unreacted conjugate. The microwells containing immobilized peroxidase conjugate are incubated with peroxidase substrate solution. Hydrolysis of the substrate by peroxidase produces a color change. After a period of time the reaction is stopped and the color intensity of the solution is measured photometrically.(Package insert: *Borrelia* VlsE1/pepC10 IgG/IgM Test System. Zeus Scientific, Inc; Rev. date 05/2021)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 4 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Definition: LYME

Lyme Disease Serology, Serum

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86618
86617 x 2-Lyme disease confirmation (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
LYME	Lyme Disease Serology, S	20449-5

Result ID	Test Result Name	Result LOINC® Value
LYME	Lyme Disease Serology, S	20449-5