MAYO CLINIC LABORATORIES

# Test Definition: SLYME

Lyme Antibody Modified 2-Tier with Reflex, Serum

## Overview

### Useful For

Diagnosis of Lyme disease

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

### Reflex Tests

| Test Id | Reporting Name | Available Separately | Always Performed |
|---|---|---|---|
| TLYME | Lyme IgM/IgG, WCS, EIA, S | Yes | No |

### Testing Algorithm

If the Lyme antibody result is positive or equivocal, then confirmation by whole cell sonicate will be performed at an additional charge.

For more information see Acute Tick-Borne Disease Testing Algorithm.

### Special Instructions

- Acute Tick-borne Disease Testing Algorithm

### Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

### NY State Available

No

## 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:** 0.6 mL Serum

**Collection Instructions:** Centrifuge and aliquot serum into a plastic vial.

### Forms

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

### Specimen Minimum Volume

Serum: 0.5 mL

### Reject Due To

| | |
|---|---|
| Gross hemolysis | Reject |
| Gross lipemia | Reject |
| Gross icterus | Reject |
| Heat-inactivated specimen | 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 *Ixodes* species tick bite. Endemic areas for LD 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 (ACA), typically due to infection with *B afzelii*.

Diagnosis of LD is currently based on either the standard or modified 2-tiered serologic testing algorithm (STTTA or MTTTA, respectively). For the STTTA, see LYME / Lyme Disease Serology, Serum.

The MTTTA starts with an initial enzyme immunoassay (EIA) screen for detection of total antibodies against the *Borrelia* Vlse/pepC10 proteins. Samples that are screen positive or equivocal by this first tier EIA are subsequently reflexed for supplemental assessment using 2 separate EIAs for detection of IgM and IgG antibodies against *B burgdorferi* whole cell sonicate material.

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 sample should be collected and tested in 2 to 4 weeks.

Equivocal:
Not diagnostic. Supplemental testing in accordance with the modified 2-tiered testing algorithm for Lyme disease has been ordered by reflex.

Positive:
Not diagnostic. Supplemental testing in accordance with the modified 2-tiered testing algorithm for Lyme disease has been ordered by reflex.

## Cautions

A negative result does not exclude the possibility of infection with Lyme disease causing *Borrelia* species. 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 *Borrelia burgdorferi*. It is possible that other disease conditions may produce artifactual reactivity in the assay (eg, infectious mononucleosis, syphilis). All samples with equivocal or positive results should be tested using a second-tier method, including either immunoblot testing or enzyme immunoassay (EIA) methods for IgM- and IgG-class antibodies in accordance with Centers for Disease Control and Prevention and the Association of State and Territorial Public Health Laboratory 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 specific population. Testing should only be performed when clinical evidence suggests the diagnosis of *Borrelia* infection or related etiological conditions observed by the healthcare professional.

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.

Specimens with abnormal IgG and rheumatoid factor (RF) antibody concentrations may interfere with this assay.

Interpret test results of specimens from immunosuppressed patients with caution.

Performance characteristics of the device have not been established for matrices other than serum or with specimens containing heterophile antibodies (known to cause false positive immunoassay results).

False-positive results may occur in patients with syphilis infection (current or past) or infectious mononucleosis.

False-negative results may occur in patients tested too soon following infection, in immunosuppressed patients or in patients treated for Lyme disease immediately following exposure/infection.

Specimens known to contain potentially cross-reactive antibodies to *B burgdorferi* due to infections with tick-borne relapsing fever, rickettsial diseases, ehrlichiosis, babesiosis and leptospirosis have not been tested. The performance of this device is unknown if there are any cross-reactive antibodies present.

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

The MTTT study was conducted using the Anti-Borrelia VlsE1/pepC10 IgG/IgM as the first-tier assay and the Anti-B burgdorferi IgG/IgM Test System; the Anti-B burgdorferi IgM Test System; or the Anti-B burgdorferi IgG Test System as the second-tier assay with testing performed in that order. The performance characteristics of the device have not been established for the alternate order of testing or for the use of other enzyme immunoassay (EIA) assays in the MTTT (2-EIA) procedure.

Hemolytic, icteric, or lipemic samples and specimens with abnormal IgG and RF antibody concentrations may interfere with the outcome of this assay. Avoid the use of these types of specimens.

### Clinical Reference

1. Association of Public Health Laboratories (APHL). Suggested reporting language, interpretation and guidance for Lyme disease serologic test results. Association of Public Health Laboratories. Updated April 2024. Accessed June 8, 2026. Available at https://aphl.org/docs/default-source/technical/ID-2024-Lyme-Disease-Serologic-Testing-Reporting.pdf
2. Branda JA, Steere AC. Laboratory diagnosis of Lyme Borreliosis. Clin Microbiol Rev. 2021;34(2):e00018-19. Published 2021 Jan 27. doi:10.1128/CMR.00018-19

## Performance

### Method Description

The first tier Lyme disease screening enzyme-linked immunosorbent assay (ELISA) is the Zeus Anti-Borrelia VlsE1/pepC10 IgG/IgM. The Anti-Borrelia VlsE1/pepC10 IgG/IgM is designed to detect IgG and IgM class antibodies in human sera to VlsE1 and pepC10 antigens. Properly 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 anti-human IgG and IgM are added to the wells and the plate is incubated. The conjugate will react with IgG and/or IgM antibodies immobilized on the solid phase. 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. The color intensity of the solution depends upon the antibody concentration in the original test sample.(Package insert: Anti-Borrelia VlsE1/pepC10 IgG/IgM. Zeus Scientific; Rev 02/18/2026)

### PDF Report

No

### Day(s) Performed

Monday through Saturday

### Report Available

Same day/1 to 4 days

### Specimen Retention Time

14 days

### Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

## 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 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 x2 (if appropriate)

## LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| SLYME | Lyme Ab Modified 2-Tier w/Reflex, S | 83081-0 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| SLYME | Lyme Ab Modified 2-Tier w/Reflex, S | 83081-0 |