Test Definition: LYWB

Lyme Disease Ab, Immunoblot, S

Overview

Useful For

Aiding in the diagnosis of systemic Lyme disease

This test **should not be used** as a screening assay.

Testing Algorithm

See Acute Tick-Borne Disease Testing Algorithm in Special Instructions.

Special Instructions

- Acute Tick-Borne Disease Testing Algorithm

Method Name

Immunoblot Microarray

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume:0.75 mL

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-General Request (T239)

-Microbiology Test Request (T244)

Specimen Minimum Volume

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)	14 days	
	Frozen	30 days	

Clinical and Interpretive

Clinical Information

Lyme disease is caused by the spirochete *Borrelia burgdorferi.* The spirochete is 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 dammini* (Northeastern and upper Midwestern US) and *Ixodes pacificus* (West Coast US). In Europe, *Ixodes ricinus* transmits the spirochete.

Lyme disease exhibits a variety of symptoms that may be confused with immune and inflammatory disorders. Inflammation around the tick bite causes skin lesions. Erythema chronicum migrans (ECM), a unique expanding skin lesion with central clearing, which results in a ring-like appearance, is the first stage of the disease. Any of the following clinical manifestations may be present in patients with Lyme disease: arthritis, neurological or cardiac disease, or skin lesions. Neurologic and cardiac symptoms may appear with stage 2 and arthritic symptoms with stage 3 of Lyme disease. In some cases, a definitive distinction between stages is not always seen. Further, secondary symptoms may occur even though the patient does not recall having a tick bite or a rash.

The Second National Conference on the Serologic Diagnosis of Lyme Disease (1994) recommended that laboratories use a 2-test approach for the serologic diagnosis of Lyme disease. Accordingly, specimens are first tested by the more sensitive enzyme immunoassay (EIA). An immunoblot assay is used to supplement positive or equivocal Lyme (EIA). An immunoblot identifies the specific proteins to which the patient's antibodies bind. Although there are no proteins that specifically diagnose *B burgdorferi* infection, the number of proteins recognized in the immunoblot assay is correlated with diagnosis.

Culture or polymerase chain reaction (PCR) of skin biopsies obtained near the margins of ECM are frequently positive. In late (chronic) stages of the disease, serology is often positive and the diagnostic method of choice. PCR testing also may be of use in these late stages if performed on synovial fluid or cerebrospinal fluid.

Diagnosis of neuroinvasive Lyme disease (ie, neuroborreliosis) can be achieved by determining the Lyme antibody index value using paired serum and cerebrospinal fluid samples (LNBAB / Lyme Central Nervous System Infection IgG with Antibody Index Reflex, Serum and Spinal Fluid).

Reference Values

IgG: Negative

IgM: Negative

Reference values apply to all ages

Interpretation

IgM:

IgM antibodies to *Borrelia burgdorferi* may be detectable within 1 to 2 weeks following the tick bite; they usually peak during the third to sixth week after disease onset, and then demonstrate a gradual decline over a period of months. IgM antibody may persist for months following completion of treatment. IgM antibody results against *B burgdorferi* should only be considered during the 30 days following exposure and symptom onset.

Negative specimens typically demonstrate antibodies to fewer than 2 of the 3 significant *B burgdorferi* proteins. Additional specimens should be submitted in 2 to 3 weeks if *B burgdorferi* exposure has not been ruled out.

IgG:

IgG antibodies to *B burgdorferi* can be detected approximately 2 weeks after onset of disease and can remain detectable for months to years following completion of therapy.

Normal specimens and false-positive enzyme immunoassay (EIA) specimens generally have antibodies to 4 or fewer proteins. Except for early patients, antibodies from patients with Lyme disease generally bind to 5 or more proteins.

Cautions

The immunoblot result may be negative in specimens that are weakly positive by enzyme immunoassay (EIA) or in patients with early Lyme disease.

Test results should be used in conjunction with clinical evaluation and information related to tick exposure.

A negative test result does not necessarily rule-out current or recent infection. The specimen may have been collected before demonstrable antibody developed. Patients with early disease often have serum antibody titers below the diagnostic threshold for several weeks following disease onset.

Test results from immunosuppressed patients and pregnant women may be difficult to interpret.

Positive test results may not be valid in persons who have received blood or blood product transfusions within the past several months.

Antibiotic therapy administered early following exposure or disease onset may suppress the antibody response to the point that diagnostic threshold levels are never attained.

Lyme disease serology should not be used for monitoring treatment response, as IgG can remain detectable for years post-resolution of infection.

False-positive reactions may occur with patients with other spirochetal diseases (syphilis, yaws, pinta, relapsing fever, or leptospirosis), recent Epstein-Barr virus infection (ie, infectious mononucleosis), influenza, autoimmune disorders (eg, present of extractable nuclear antigens: ENA), multiple sclerosis, or amyotrophic lateral sclerosis.

Clinical Reference

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

Performance

Method Description

The Viramed Biotech AG Borrelia B31 ViraChip IgM and IgG are protein microarray assays and can be considered modified solid-phase enzyme linked immunosorbent assays (ELISAs). Highly purified antigens from the *Borrelia burgdorferi* B31 strain, including the 93 kD, 66 kD, 58 kD, 45 kD, 41 kD, 39 kD, 30 kD, 28 kD, 23 kD, and 18 kD

proteins, are bound to the solid phase nitrocellulose membrane in triplicate. The positions of these antigen "spots" are well defined and are reliably identifiable using customized software. Each microarray also has "spots" for a negative control, serum controls, conjugate controls, and 6 calibrators. One microarray is fixed to the bottom of a well in a standard 96-well microtiter plate.

For each test to be performed, the diluted patient serum is added to each microarray (note: the *B burgdoreri* IgG and IgM microarrays are in separate wells). If specific antibodies recognizing a *B burgdorferi* antigen are present, they will bind to the specific antigens on the microarray. After incubation the microarray is washed to remove unbound antibodies. Alkaline-phosphatase antihuman IgG or antihuman IgM (conjugate) is then added to the well and incubated. If antibodies are present, the conjugate will bind to those respective antibodies, and after a washing step to remove unbound conjugate, substrate solution is added. If the antibody/conjugate complex is present, the substrate will undergo precipitation and color change. After an incubation period, the reaction is stopped and the presence of precipitated substrate is visualized at specific locations on the microarray. The presence of a colored precipitation at various locations on the microarray is an indirect measurement of *B burgdorferi* specific antibodies in the patient specimen. Visualized spots from the reaction are compared for intensity with the integrated calibrator controls for evaluation.(Package inserts: Borrelia B31 ViraChip IgM and Borrelia B31 ViraChip IgG. VIRAMED Biotech AG; 07/2016)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. 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

86617 x 2

LOINC® Information

Test Definition: LYWB

Lyme Disease Ab, Immunoblot, S

Test ID	Test Order Name	Order LOINC Value
LYWB	Lyme Disease Ab, Immunoblot, S	18203-0

Result ID	Test Result Name	Result LOINC Value
5744	IgG Immunoblot	6320-6
2992	IgG detected against:	13502-0
23931	IgM Immunoblot	6321-4
23932	IgM detected against:	13503-8
6241	Interpretation	12781-1