Overview

Useful For
Aids in the diagnosis of neuroinvasive Lyme disease or neuroborreliosis due to *Borrelia* species associated with Lyme disease (e.g., *B. burgdorferi*, *B. garinii*, *B. afzelii*)

Testing Algorithm
Only orderable as a reflex. For more information see LNBAB / Lyme CNS Infection IgG with Antibody Index Reflex. If LNBAB / Lyme CNS Infection IgG w/ Antibody Index Reflex is reactive, then this test is performed at an additional charge.

Method Name
Only orderable as a reflex. For more information see LNBAB / Lyme CNS Infection IgG with Antibody Index Reflex.

NY State Available
Yes

Specimen

Specimen Type
CSF

Specimen Required
Only orderable as part of a profile. For more information see LNBAB / Lyme CNS Infection IgG with Antibody Index Reflex.

Specimen Minimum Volume
Only orderable as part of a profile. For more information see LNBAB / Lyme CNS Infection IgG with Antibody Index Reflex.

Reject Due To

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Gross hemolysis</td>
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<tr>
<td>Gross lipemia</td>
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Specimen Stability Information

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<th>Specimen Type</th>
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Clinical and Interpretive

Clinical Information
Lyme disease is a multisystem and multistage tick-transmitted infection caused by spirochetal bacteria in the *Borrelia* species.
burdorferisensu lato (Bbsl) complex. Nearly all human infections are caused by 3 Bbsl species; *B burgdorferisensu stricto* (hereafter referred to as *B burgdorferi*) is the primary cause of Lyme disease in North America, while *B afzelii* and *B garinii* are the primary causes of Lyme disease in Europe and parts of Asia.

Lyme disease is the most commonly reported tick-borne infection in North America and Europe, causing an estimated 300,000 cases in the United States each year and 85,000 cases in Europe. The clinical features of Lyme disease are broad and may be confused with various immune and inflammatory disorders. The classic presenting sign of early localized Lyme disease caused by *B burgdorferi* is erythema migrans (EM), which occurs in approximately 80% of individuals. Other early signs and symptoms include malaise, headache, fever, lymphadenopathy, and myalgia. Arthritis, cardiac disease, and neurological disease may be later stage manifestations.

Neuroinvasive Lyme disease (NLD) can affect either the peripheral or central nervous system, with patients classically presenting with the triad of lymphocytic meningitis, cranial neuropathy (especially facial nerve palsy) and radiculoneuritis, which can affect the motor or sensory nerves, or both. These symptoms can occur in any combination or alone. Some patients may present with Bannwarth syndrome, which includes painful radiculoneuritis with variable motor weakness.

NLD should be considered in individuals presenting with appropriate symptoms who have had exposure to ticks in a Lyme endemic region of the United States, Europe or Asia. Patients meeting these criteria should be evaluated for the presence of anti-Bbsl antibodies in serum using the standard 2-tiered testing algorithm as recommended by the Centers for Disease Control and Prevention (CDC). Briefly, the STTTA includes testing of serum specimens by an anti-Bbsl antibody ELISA, followed by supplemental testing of all reactive samples using an immunoblot or western blot for detection of IgM- and IgG-class antibodies to Bbsl. Notably, the majority of patients with NLD, more than 99%, will be seropositive in serum. This alongside appropriate exposure history and clinical presentation may be used to establish a diagnosis of NLD.

Cerebrospinal fluid (CSF) may also be tested for the presence of antibodies to Bbsl using the current 2-tiered testing algorithm as defined for serum samples. However, there are currently no interpretive criteria for assessment of anti-Bbsl IgM and IgG immunoblot banding patterns in CSF. Additionally, while the presence of antibodies to Bbsl in CSF may be due to true intrathecal antibody synthesis, thus indicating CNS infection, antibodies may alternatively be present as a result of passive diffusion through the blood-brain barrier or due to blood contamination of CSF during a traumatic lumbar puncture.

The Lyme CNS Antibody Index (AI) quantitatively measures the level of anti-Bbsl antibodies in CSF and serum, ideally collected within 24 hours of each other, and normalizes those levels to total IgG and albumin in both specimen sources. A positive Lyme CNS AI indicates true intrathecal antibody synthesis to Bbsl, which alongside clinical and exposure history can be used to establish a diagnosis of NLD.

**Reference Values**

Only orderable as a reflex. For more information see LNBAB / Lyme CNS Infection IgG with Antibody Index Reflex.

**Interpretation**

Negative (Lyme CNS AI 0.6 to <1.3): Results indicate lack of intrathecal antibody synthesis to Lyme disease associated *Borrelia* species. This suggests the absence of neuroinvasive Lyme disease. The initial screen reactive result may be due to anti-*Borrelia* species antibodies present in the CSF due to increased permeability of the blood-brain barrier or transient introduction during lumbar puncture.

Equivocal (Lyme CNS AI 1.3 to 1.5): Low level of intrathecal antibody synthesis to Lyme disease associated *Borrelia* species detected. Results should be correlated with exposure history and clinical presentation to establish a diagnosis of neuroinvasive Lyme disease.
Positive (Lyme CNS AI >1.5): Results indicate the presence of intrathecal antibody synthesis to Lyme disease associated *Borrelia* species, suggesting neuroinvasive Lyme disease. Results should be correlated with exposure history and clinical presentation to establish the diagnosis.

Invalid (Lyme CNS AI <0.6): Result is due to abnormally elevated total IgG levels in CSF. This may be due to passive diffusion through the blood-brain barrier or contamination of the cerebrospinal fluid with blood during a traumatic lumbar puncture. Repeat testing may be considered.

**Cautions**

A single negative result should not be used to exclude the diagnosis of neuroinvasive Lyme disease in a patient with appropriate exposure history and symptoms suggestive of infection. Testing of serum samples using the CDC recommended Standard Two Tiered Testing Algorithm should be performed.

False-negative results may be acquired in patients tested soon after infection, prior to the development of a detectable level of antibodies in the CSF.

Falsely reactive results may occur in patients with syphilis or *Leptospira* infections. Patient management decisions should not be made on a single reactive result.

**Clinical Reference**


**Performance**

**Method Description**

The test kit contains microwell strips with break-off reagent wells coated with a mix of *Bb* sp antigens (whole antigen extracts of *Borrelia burgdorferi* sensu stricto, *B afzelii, B garinii* and recombinant VlsE of *B burgdorferi* sensu stricto). In the first reaction step, diluted patient samples are incubated in the wells. In the case of positive samples, *Borrelia*-specific IgG antibodies will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using an enzyme-labelled antihuman IgG (enzyme conjugate), followed by a third incubation using chromogen/substrate (TMB/H2O2), which catalyzes a color reaction that is then measured for optical density (OD) using spectrophotometry. The obtained OD values of the paired patient serum and cerebrospinal fluid (CSF) samples are compared against a 6-level calibration curve to quantitatively determine the relative anti-*Borrelia* IgG antibody titers. (Package insert: Antibodies of the IgG class against *Borrelia* in cerebrospinal fluid, Euroimmun Ag, Seekamp 31, 23560 Luebeck, Germany)

The quantitative test results obtained on paired serum and CSF specimens using the *Borrelia* IgG ELISA are expressed as relative units (U/mL) and must be used along with the total IgG and albumin levels in the patient’s paired serum and CSF samples to calculate the anti-*Borrelia* antibody index (AI), which determines the absence or presence of intrathecal anti-*Borrelia* IgG antibody synthesis. Total IgG and albumin testing on serum and CSF is performed using the Siemens BN II nephelometric testing system (Siemens Healthcare GmbH; Erlangen, Germany).

To detect an infection of the CNS it is necessary to differentiate between intrathecally produced antibodies and antibodies passed from blood into the CSF. The AI is the value of intrathecal pathogen-specific antibody production. This AI value represents the portion of pathogen-specific antibodies in total IgG of CSF and the portion of pathogen-specific antibodies in total IgG of serum. The patient’s AI is calculated using the Reiber and Lange method. (Reiber H, Lange P: Quantification of virus-specific antibodies in cerebrospinal fluid and serum: sensitive and specific detection of antibody synthesis in brain. Clin Chem 1991;37(7):1153-1160)
Test Definition: LNBAI
Lyme CNS Infection IgG, Ab Index

PDF Report
No

Day(s) and Time(s) Test Performed
Monday, Wednesday, Friday 8 a.m.

Analytic Time
Same day/1 day

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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
86618 x 2
82040
82042
82784 x 2

LOINC® Information

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