

Notification Date: November 15, 2022 Effective Date: December 20, 2022

# Lyme Disease, Molecular Detection, PCR, Varies

Test ID: LYMPV

#### **Useful for:**

Supporting the diagnosis of Lyme disease in conjunction with serologic testing.

Specific indications including testing skin biopsies when a rash lesion is not characteristic of erythema migrans and testing synovial fluid or synovium to support the diagnosis of Lyme arthritis.

This test should **not** be used to screen asymptomatic patients.

#### Methods:

Real-Time Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

#### **Reference Values:**

Negative (Reference values apply to all ages)

### **Specimen Requirements:**

Submit only 1 of the following specimens:

Specimen Type: Spinal fluid

Container/Tube: Sterile vial

Specimen Volume: 1 mL

Collection Instructions: Label specimen as spinal fluid.

Specimen Type: Synovial fluid

Container/Tube: Sterile vial

Specimen Volume: 1 mL

**Collection Instructions:** Label specimen as synovial fluid.

**Specimen Type:** Tissue (fresh only)

**Sources:** Skin or synovial biopsy

**Container/Tube:** Sterile container with normal saline

**Specimen Volume:** Approximately 4 mm(3)

**Collection instructions:** 1. Submit only fresh tissue.

2. Skin biopsies:

a. Wash biopsy site with an antiseptic soap. Thoroughly rinse area with sterile water. Do not use alcohol or iodine preparations. A local anesthetic may be used.

b. Biopsy specimens are best taken by punch biopsy to include full thickness of dermis.

3. Label specimen with source of tissue.

## **Specimen Stability Information:**

Specimen Type	Temperature	Time
Varies	Refrigerated (preferred)	7 days
	Frozen	7 days

## **Necessary Information:**

Specimen source is required.

#### **Cautions:**

Serologic tests are recommended for diagnosis of Lyme disease. Polymerase chain reaction (PCR) may play an adjunctive role but may not detect *Borrelia burgdorferi* DNA from cerebrospinal fluid (CSF) in cases of active or chronic disease. The presence of inhibitory substances may also cause a false-negative result. If clinical features of illness are highly indicative of Lyme neuroborreliosis, serologic testing on CSF is warranted. PCR test results should be used as an aid in diagnosis and not considered diagnostic by themselves. These results should be correlated with serologic and epidemiologic data and clinical presentation of the patient.

Testing of CSF by PCR in patients with suspected Lyme neuroborreliosis should be requested only on patients with positive *B burgdorferi* antibody in serum confirmed by Western blot assay (LYWB / Lyme Disease Antibody, Immunoblot, Serum) and with abnormal CSF findings (elevated protein and WBC >10 cells/high-power field).

Concurrent infections with multiple tick-borne pathogens, including *Ehrlichia muris eauclairensis*, *Anaplasma phagocytophilum*, *Babesia microti*, and *Borrelia miyamotoi* (a relapsing fever *Borrelia*) have been reported in United States, and consideration should be given to testing for other pathogens, if clinically indicated.

This assay detects most members of the *Borrelia burgdorferi* sensu lato (Bbsl) complex, including *Borrelia andersonii*, *Borrelia americana*, and *Borrelia bissettii*, which have been rarely detected in humans. Detection of DNA from these organisms would be reported as an atypical result and prompt additional laboratory testing to further identify the DNA present. The sensitivity of this assay for detecting these organisms has not been determined.

This assay also detects some members of the Bbsl complex that are not considered to be human pathogens but may be found in ticks and other animals. Therefore, this assay should not be used to test nonhuman specimens.

## **CPT Code:**

87476 87798 x 2 87999 (if appropriate for government payers)

Day(s) Performed: Report Available: 1 to 4 days

June through November: Monday through Saturday

December through May: Monday through Friday

## **Questions**

Contact James Conn, Laboratory Technologist Resource Coordinator at 800-533-1710.