Lab Dept:	**Microbiolgy/Virology**
Test Name:	**LYME DISEASE PCR, SPINAL/SYNOVIAL FLUID OR FRESH TISSUE**

General Information

Lab Order Codes:	LYPCR
Synonyms:	*Borrelia burgdorferi* PCR; Lyme Disease PCR; Lyme Disease by Polymerase Chain Reaction
CPT Codes:	87476 – *Borrelia burgdorferi*, amplified probe technique 87798 x2 – Infectious agent, amp probe technique, each organism
Test Includes:	A positive or negative result indicating the presence or absence of *Borrelia burgdorferi* DNA, *Borrelia mayonii* DNA and *Borrelia afzelii/garinii* DNA in the specimen submitted.

Logistics

Test Indications:	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.
Lab Testing Sections:	Microbiology/Virology – Sendouts
Referred to:	Mayo Clinic Laboratories (MML Test: LYMPV)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1 – 4 days; Performed Monday-Saturday (June through November) and Monday-Friday (December through May)
Special Instructions:	Testing of CSF by PCR in patients with suspected Lyme neuroborreliosis should be requested only on patients with positive *Borrelia burgdorferi* antibody in serum confirmed by Western blot assay and with abnormal CSF findings (elevated protein and WBC >10 cells/high power field).

Specimen

Specimen Type:	Spinal (CSF) fluid or Synovial fluid Fresh tissue: Skin or synovial biopsy
Container:	CSF/Synovial fluid: Screw-capped sterile vial Fresh tissue: Sterile container with normal saline
Draw Volume:	CSF: 1 mL (Minimum: 0.3 mL) Synovial fluid: 1 mL (Minimum: 0.5 mL) Fresh tissue: Approximately 4 mm (Minimum: 3 mm)
Processed Volume:	Same as Draw Volume
Collection:	CSF/Synovial: Fluid collection (label specimen as spinal fluid or synovial fluid). Tissue: 4 mm (Minimum: 3 mm) Skin or Synovial Biopsy in Sterile container with normal saline. 1. Submit only fresh tissue 2. Skin biopsies: a. Wash biopsy site with 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
Special Processing:	Lab Staff: Fluid specimen should be in a sterile, screw-capped plastic vial. Maintain sterility. Store at ship at refrigerated temperatures. Specimen stable refrigerated (preferred) or frozen for 7 days.
Patient Preparation:	None
Sample Rejection:	Mislabeled or unlabeled specimens

Interpretive

Reference Range:	Negative (reported as positive or negative) A positive result indicates the presence of DNA from *Borrelia burgdorferi*, *Borrelia mayonii*, *Borrelia afzelii* or *Borrelia garinii*, the agents of Lyme disease. A negative result indicates the absence of detectable target DNA in the specimen. Due to the clinical sensitivity limitations of the PCR assay, a negative result does not preclude the presence of the organism or active Lyme disease.

Critical Values: N/A

Limitations: Serologic tests are recommended for diagnosis of Lyme disease. PCR may play an adjunctive role, but nay not detect *Borrelia burgdorferi* DNA from 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.

Concurrent infections with multiple tick-borne pathogens, including *Erhlichia chaffeensis/Anaplasma phagocytophilum* and/or *Babesia microti*, and Borrelia miyanotoi (a relapsing fever of Borrelia) have been reported in the 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 (BbsI) complex, including Borrelia andersoni, 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.

Methodology: Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

References: Mayo Clinic Laboratories November 2023

Update: 12/20/2022: Testing transitions to a new performing laboratory within Mayo Clinic to streamline processes of molecular microbiology.

11/9/2023: Update to minimum volume for CSF and added specimen stability.