MAYO CLINIC LABORATORIES

Test Definition: BMIPB

Borrelia miyamotoi Detection, PCR, Blood

Overview

Useful For

Aiding in the diagnosis of *Borrelia miyamotoi* infection in conjunction with clinical findings

Preferred method for detection of *B miyamotoi* using blood specimens

Testing Algorithm

For information see Acute Tickborne Disease Testing Algorithm.

Special Instructions

- Acute Tickborne Disease Testing Algorithm

Method Name

Real-Time Polymerase Chain Reaction (PCR)

NY State Available

Yes

Specimen

Specimen Type

Whole Blood EDTA

Ordering Guidance

This assay does not detect the *Borrelia* species that cause Lyme disease. If Lyme disease is suspected, order SLYME / Lyme Antibody Modified 2-Tier with Reflex, Serum.

Specimen Required

Container/Tube:

Preferred: Lavender top (EDTA)

Acceptable: Royal blue top (EDTA), pink top (EDTA), or sterile vial containing EDTA-derived aliquot

Specimen Volume: 1 mL

Collection Instructions: Send whole blood specimen in original tube (preferred).

Forms

If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume

0.3 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Whole Blood EDTA	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information

Borrelia miyamotoi is a spirochetal bacterium, closely related to the *Borrelia* species that causes tick-borne relapsing fever (TBRF), and it is more distantly related to the *Borrelia* species that cause Lyme disease. This organism causes a febrile illness like TBRF, with body and join pain, fatigue, and, rarely, rash. *B miyamotoi* has been detected in *Ixodes scapularis* and *Ixodes pacificus* ticks. These ticks are also the vectors for Lyme disease, anaplasmosis, and babesiosis.

The preferred method for detecting *B miyamotoi* is real-time polymerase chain reaction. Less sensitive and specific methods for detecting *B miyamotoi* and agents of TBRF include serologic testing and identification of spirochetes in peripheral blood films or spinal fluid preparations. This assay does not detect the *Borrelia* species that cause Lyme disease.

Reference Values

Negative
Reference values apply to all ages.

Interpretation

A positive result indicates the presence of *Borrelia miyamotoi* DNA and is consistent with active or recent infection. While positive results are highly specific indicators of disease, they should be correlated with symptoms and clinical findings of tick-borne relapsing fever.

Cautions

Inadequate specimen collection or improper storage may invalidate test results.

After adequate treatment, *Borrelia miyamotoi* DNA may remain detectable for an unknown period of time.

Supportive Data

The following assay verification data supports the use of this assay for clinical testing.

Accuracy/Diagnostic Sensitivity and Specificity:
Clinical Samples:
Sixty-two clinical EDTA blood specimens received in the clinical laboratory for *Ehrlichia*/*Anaplasma* polymerase chain

reaction (PCR) were tested using the *Borrelia miyamotoi* PCR assay. Results were compared to the Minnesota Department of Health 16S rRNA TaqMan assay. In addition, 2 retrospectively identified *B miyamotoi*-positive specimens were confirmed by the *B miyamotoi* PCR assay and the MDH TaqMan assay.

Spiking studies:
To supplement the clinical specimens, negative whole blood and spinal fluid (CSF) specimens were spiked with genomic or plasmid DNA of *B miyamotoi* near the limit of detection and tested in a blinded fashion. The sensitivity of the PCR assay was 100% and the specificity with spiked specimens was 100%. The samples were extracted and tested in a blinded fashion.

Analytical Sensitivity/Limit of Detection:
The limit of detection is 2800 target copies/mL (5.6 target copies/mcL) of whole blood or CSF.

Analytical Specificity:
No PCR signal was obtained from the extracts of 31 bacterial, viral, parasitic, and fungal isolates from similar organisms or from organisms commonly found in the specimens tested.

Precision:
Interassay and intra-assay precision were 100%.

Reference Range:
The reference range of this assay is negative. This assay is designed to detect only species of clinical significance and is to be used for patients with a clinical history and symptoms consistent with tickborne relapsing fever. It should not be used to screen healthy patients.

Reportable Range:
This is a qualitative assay, and the results are reported as negative or positive for *B miyamotoi* DNA.

Clinical Reference

1. Hoornstra D, Azagi T, van Eck JA, et al. Prevalence and clinical manifestation of Borrelia miyamotoi in Ixodes ticks and humans in the northern hemisphere: a systematic review and meta-analysis. Lancet Microbe. 2022;3(10):e772-e786
2. McCormick DW, Brown CM, Bjork J, et al. Characteristics of hard tick relapsing fever caused by borrelia miyamotoi, United States, 2013-2019. Emerg Infect Dis. 2023;29(9):1719-1729
3. Xu G, Luo CY, Ribbe F, et al. Borrelia miyamotoi in human-biting ticks, United States, 2013-2019. Emerg Infect Dis. 2021;27(12):3193-3195
4. Kingry LC, Anacker M, Pritt B, et al. Surveillance for and discovery of borrelia species in US patients suspected of tickborne illness. Clin Infect Dis. 2018;66(12):1864-1871
5. Wormser GP, Shapiro ED, Fish D. Borrelia miyamotoi: an emerging tick-borne pathogen. Am J Med. 2019;132(2):136-137
6. Telford SR, Goethert HK, Molloy PJ, Berardi V. Blood smears have poor sensitivity for confirming borrelia miyamotoi disease. J Clin Microbiol. 2019;57(3):e01468-18. Published 2019 Feb 27. doi:10.1128/JCM.01468-18

Performance

Method Description

The assay is performed on the Roche LightCycler (LC) 480 instrument, following DNA extraction on the Roche MagNA Pure. The LC 480 instrument amplifies and monitors the development of target nucleic acid (amplicon) after each cycle of polymerase chain reaction (PCR).

The DNA target for this PCR assay is a gene encoding the glycerophosphodiester phosphodiesterase (*glpQ*) gene specific to *Borrelia* species in the relapsing fever group. This gene is not found in *Borrelia* species that cause Lyme disease.

The specific base pair DNA target sequence is amplified by PCR. The detection of amplicon is based on fluorescence resonance energy transfer, which utilizes 1 hybridization probe with a donor fluorophore, fluorescein, at the 3' end, and a second hybridization probe with an acceptor fluorophore, LC-Red 640, at the 5' end. When the target amplicon is present, the LC-Red 640 emits a measurable and quantifiable light signal at a specific wavelength. Presence of the specific organism nucleic acid is confirmed by performing a melting temperature analysis of the amplicon; the presence or absence of a melting peak in the appropriate temperature range is used to determine if a specimen is positive or negative.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 to 4 days

Specimen Retention Time

1 week

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

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

CPT Code Information

87478

Test Definition: BMIPB

Borrelia miyamotoi Detection, PCR, Blood

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BMIPB	Borrelia miyamotoi Detection, PCR, B	82475-5

Result ID	Test Result Name	Result LOINC® Value
618298	B. miyamotoi PCR, B	82475-5