MAYO CLINIC LABORATORIES

Test Definition: BMIYC

Borrelia miyamotoi Detection PCR, Spinal Fluid

Overview

Useful For

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

This test is **not useful for** detecting the *Borrelia* species that cause Lyme disease.

Testing Algorithm

For more information see Acute Tick-Borne Disease Testing Algorithm

Special Instructions

- Acute Tick-Borne Disease Testing Algorithm

Highlights

This test is intended as an aid in the diagnosis of *Borrelia miyamotoi* infection in conjunction with clinical findings.

The preferred method for detecting *B miyamotoi* is polymerase chain reaction.

Method Name

Real-Time Polymerase Chain Reaction (PCR)

NY State Available

Yes

Specimen

Specimen Type

CSF

Specimen Required

Container/Tube: Sterile vial

Specimen Volume: 1 mL

Collection Instructions: Submit aliquot from collection vial 2.

Forms

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

Specimen Minimum Volume

0.3 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
CSF	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information

Borrelia miyamotoi is a spirochetal bacterium. It is closely related to the *Borrelia* species that cause tick-borne relapsing fever (TBRF) and 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, and 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 identification of spirochetes in peripheral blood films, cerebrospinal fluid preparations, and serologic testing. This assay does not detect the *Borrelia* species that cause Lyme disease.

Reference Values

Negative

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.

Borrelia miyamotoi DNA may be detectable for an unknown period of time after adequate treatment.

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) analysis were tested using the *Borrelia miyamotoi* PCR assay. Results were compared to the MDH 16S ribosomal RNA 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%.

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 precision was 100% and intra-assay precision was 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 tick-borne 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. Gugliotta JL, Goethert HK, Berardi VP, Telford SR III: Meningoencephalitis from Borrelia miyamotoi in an immunocompromised patient. N Engl J Med. 2013 Jan 17;368(3):240-245
2. Fomenko NV, Borgoiakov VL, Panov VV: Genetic features of Borrelia miyamotoi transmitted by Ixodes persulcatus. Mol Gen Mikrobiol Virusol. 2011;(2)12-17
3. Platonov AE, Karan LS, Kolyasnikova NM, et al: Humans infected with relapsing fever spirochete Borrelia miyamotoi, Russia. Emerg Infect Dis. 2011 Oct;17(10):1816-1823

Performance

Method Description

The assay is performed on the Roche LightCycler (LC) 2.0 instrument, following DNA extraction on the Roche MagNA Pure. The LC 2.0 instrument amplifies and monitors the development of target nucleic acid (amplicon) after each polymerase chain reaction (PCR) cycle.

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 (FRET), 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 Saturday

Report Available
Same day/1 to 4 days

Specimen Retention Time
1 week

Performing Laboratory Location
Rochester

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. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
87478

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BMIYC	Borrelia miyamotoi Detection PCR, C	82476-3

Result ID	Test Result Name	Result LOINC® Value
64969	B. miyamotoi PCR, C	82476-3