Overview

Useful For
An initial screening or confirmatory testing method for suspected babesiosis during the acute febrile stage of infection in patients from endemic areas, especially when Giemsa-stained peripheral blood smears do not reveal any organisms or the organism morphology is inconclusive.

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

NY State Available
Yes

Specimen

Specimen Type
Whole Blood EDTA

Ordering Guidance
This is a qualitative assay and the results are reported either as negative or positive for targeted Babesia species DNA.

Specimen Required
Container/Tube: Lavender top (EDTA)

Specimen Volume: 1 mL

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

Specimen Minimum Volume
0.5 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acceptance</th>
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<tbody>
<tr>
<td>Hemolysis</td>
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<tr>
<td>Lipemia</td>
<td>Mild OK; Gross reject</td>
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<tr>
<td>Icterus</td>
<td>NA</td>
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<tr>
<td>Other</td>
<td>Green-top (heparin) tube</td>
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Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Whole Blood EDTA</td>
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Clinical and Interpretive

Clinical Information

Babesiosis is a tick-transmitted zoonosis caused by intraerythrocytic protozoa in the genus *Babesia*. *Babesia microti* is responsible for the vast majority of human cases in the United States, with most cases occurring along the Northeast Coast and the upper Midwestern states. A small number of cases of *B duncanihuman infection have also been reported along Pacific Coast states from Washington to northern California, and *B divergens/B divergens*-like strains have been detected in humans in Missouri (MO-1 strain), Kentucky, and Washington. In Europe, *B divergens and B venatorum* are the primary causes of human babesiosis.

Humans most commonly acquire infection through the bite of an infected tick. The most common tick vectors in the United States are *Ixodes scapularis and Ixodes pacificus*, while *Ixodes ricinus* and other ticks transmit the parasite in Europe and Asia. Less commonly, babesiosis may be acquired through blood transfusion and across the placenta from the mother to the fetus.

Most patients with babesiosis are asymptomatic or have only a self-limited mild flu-like illness, but some develop a severe illness that may result in death. Patient symptoms may include fever, chills, extreme fatigue, and severe anemia. The most severe cases occur in asplenic individuals and those over 50 years of age. Rare cases of chronic parasitemia, usually in immunocompromised patients, have been described.

Babesiosis is conventionally diagnosed through microscopic examination of Giemsa-stained thick and thin peripheral blood films looking for characteristic intraerythrocytic *Babesia* parasites. This method is relatively rapid, widely available, and capable of detecting (but not differentiating) human-infective *Babesia* species. It is also necessary for calculating the percentage of parasitemia which is used to predict prognosis, guide patient management, and monitor response to treatment. However, microscopic examination requires skilled microscopists and may be challenging in the setting of low parasitemia or prior drug therapy. Also, *Babesia* species may closely resemble those of *Plasmodium falciparum*.

The Mayo Clinic real-time PCR assay provides a rapid and more sensitive alternative to blood film examination for detection and differentiation of *B microti, B duncanii*, and *B divergens/B divergens*-like parasites. It does not cross-react with malaria parasites.

Reference Values

Negative

Interpretation

A positive result indicates the presence of *Babesia* species DNA and is consistent with active or recent infection. While positive results are highly specific indicators of disease, they should be correlated with blood smear microscopy, serological results and clinical findings.

A negative result indicates absence of detectable DNA from *Babesia* species in the specimen, but does not always rule out ongoing babesiosis in a seropositive person, since the parasitemia may be present at a very low level or may be sporadic.

Other tests to consider in the evaluation of a patient presenting with an acute febrile illness following tick exposure include serologic tests for Lyme disease (*Borrelia burgdorferi*), and molecular detection (PCR) for ehrlichiosis/anaplasmosis. For patients who are past the acute stage of infection, serologic tests for these organisms should be ordered prior to PCR testing.

Cautions
While this assay is designed to detect symptomatic infection with Babesia microti, B duncani, and B divergens/MO-1, it may detect low-grade asymptomatic parasitemia in individuals in babesiosis-endemic areas. Thus, it should only be used for testing patients with a clinical history and symptoms consistent with babesiosis.

Inhibitory substances may cause false-negative results.

Inadequate specimen collection or improper storage may invalidate test results.

**Supportive Data**

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

**Accuracy/Diagnostic Sensitivity and Specificity:**

Ninety-six whole blood specimens were tested by this real-time PCR assay and another real-time PCR assay. Concordance was 99%.

Analytical Sensitivity/Limit of Detection (LoD). The LoD established using whole organism spiked into specimen matrix (whole blood) is as follows:

- *Babesia microti*, ATCC PRA 99 - 2,670 target copies/mL
- *B duncani* ATCC PRA 302 - 1,540 target copies/mL
- *B MO-1* positive patient DNA - 10,700 target copies/mL
- *B divergens* positive patient DNA - 5,270 target copies/mL

Serial 10-fold dilutions of microscopy-positive specimens were also tested in a blinded fashion using conventional thick and thin blood films and the Mayo *Babesia* species PCR. The PCR was able to consistently detect 2 10-fold dilutions lower than using microscopy.

**Analytical Specificity:**

No cross-reactivity was noted using a panel of 34 bacteria, viruses, parasites and fungi were detected by the *Babesia* species PCR.

**Precision:**

Interassay and intra-assay precision was 100% precision.

**Reference Range:**

The reference range is negative. This was confirmed by testing 93 blood specimens from asymptomatic individuals for the presence of *Babesia* species by the *Babesia* species PCR assay. All 93 specimens were negative.

**Reportable Range:**

This test is a qualitative assay, and results are reported as positive or negative for *Babesia* species (*B microti, B duncani, B divergens, and Babesia MO-1*).

**Clinical Reference**


**Performance**

**Method Description**

Nucleic acid is extracted from EDTA whole blood using the automated MagNA Pure bead-based system (Roche Molecular Systems). The extract is then transferred to individual self-contained capillary cuvettes for amplification. The LightCycler is an automated instrument that amplifies and monitors the development of target nucleic acid (amplicon) after each cycle of PCR.

The DNA target for PCR assay is a gene encoding the nuclear small subunit ribosomal RNA (SS-rDNA). This assay consists of 2 forward primers, 1 reverse primer, and 2 probes, which are specific for the Babesia species target DNA. The specific base pair DNA target sequence is first amplified by PCR using the target-specific primers. Amplicon is then detected during melting curve analysis using fluorescence resonance energy transfer (FRET) probes, which utilizes one 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. Fluorescence is produced when the 2 probes anneal to the target sequence in close proximity to one another. The LC-Red 640 then emits a measurable and quantifiable light signal at a specific wavelength.(Burgess MJ, Rosenbaum ER, Pritt BS, et al. Possible Transfusion-Transmitted Babesia divergens-like/MO-1 in an Arkansas Patient. Clin Infect Dis 2017; Supplemental Data)

**PDF Report**

No

**Day(s) Performed**

Monday through Saturday; Varies

**Report Available**

Same day/1 day - 4 days

**Specimen Retention Time**

1 week

**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 US Food and Drug Administration.

CPT Code Information
87798 x 3

LOINC® Information

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