Overview

Useful For
Aiding in the diagnosis of *Coxiella burnetii* infection (eg, Q fever) using tissue specimens

Testing Algorithm
See *Infective Endocarditis: Diagnostic Testing for Identification of Microbiological Etiology* in Special Instructions.

Special Instructions
- *Infective Endocarditis: Diagnostic Testing for Identification of Microbiological Etiology*

Method Name
*Real-Time Polymerase Chain Reaction (PCR)*

NY State Available
Yes

Specimen

Specimen Type
Varies

Necessary Information
Specimen source is required.

Specimen Required
The high sensitivity of amplification by PCR requires the specimen to be processed in an environment in which contamination of the specimen by *Coxiella burnetii* DNA is unlikely.

Submit only 1 of the following specimens:

**Specimen Type:** Fresh tissue or biopsy

**Sources:** Lung, bone, liver, heart valve, aorta, or endocardium

**Container/Tube:** Sterile container

**Specimen Volume:** Entire collection or 5 mm(3) - approximately the size of a pencil eraser

**Collection Instructions:**
1. Collect fresh tissue specimen.
2. Submit tissue only, do not add fluid to tissue
3. Refrigerate or freeze specimen.
Specimen Stability Information: Refrigerated (preferred) <7 days/ Frozen <7 days

Preferred Paraffin-embedded tissue block:

Supplies: Tissue Block Container (T553)

Specimen Type: Formalin-fixed, paraffin-embedded tissue block (FFPE)

Sources: Lung, bone, liver, heart valve, aorta, or endocardium

Container/Tube: Tissue block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded tissue block to be cut and returned.

Specimen Stability Information: Ambient (preferred)/Refrigerated

Acceptable Paraffin-embedded tissue block:

Specimen Type: Formalin-fixed, paraffin-embedded tissue block (FFPE)

Sources: Lung, bone, liver, heart valve, aorta, or endocardium

Container/Tube: Sterile container for each individual cut section (scroll). Collection Instructions: Perform microtomy and prepare five separate 10-micron sections. Each section (scroll) must be placed in a separate sterile container for submission.

Specimen Stability Information: Ambient (preferred)/Refrigerated

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

Specimen Minimum Volume
Fresh tissue or biopsy: 5 mm(3)
Paraffin-embedded tissue block: two 10-micron sections

Reject Due To

<table>
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<tr>
<th>Other</th>
<th>Tissue in formalin, formaldehyde, or acetone; bone marrow; decalcified bone; bone marrow; slides</th>
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Specimen Stability Information

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Clinical and Interpretive

Clinical Information

*Coxiella burnetii*, the causative agent of Q fever, is a small obligate intracellular bacterium, which is associated with animals. It is acquired through aerosol exposure and generally causes mild respiratory disease. A small number of acute cases advance to a chronic infection, which typically manifests as endocarditis. Left untreated, Q fever endocarditis may be fatal. Serologic and histopathologic studies may be nonspecific and subjective, respectively, limiting usefulness for patient diagnosis.

Evaluation of infected tissue, blood, or serum using PCR may be a useful tool for diagnosing some cases of *C. burnetii* infection. Mayo Clinic Laboratories has developed a real-time PCR test that rapidly detects *C. burnetii* DNA in clinical specimens by targeting a sequence of the shikimate dehydrogenase gene (*aroE*) unique to *C. burnetii*.

Reference Values

Not applicable

Interpretation

A positive result indicates the presence of *Coxiella burnetii* DNA.

A negative result indicates the absence of detectable *C. burnetii* DNA, but does not negate the presence of the organism and may occur due to inhibition of PCR, sequence variability underlying primers or probes, or the presence of *C. burnetii* DNA in quantities less than the limit of detection of the assay.

Cautions

Test results should be used as an aid in diagnosis and not be considered diagnostic in themselves. The single assay should not be used as the only criteria to form a clinical conclusion, but results should be correlated with patient symptoms and clinical presentation. A negative result does not negate the presence of the organism or active disease.

Supportive Data

This assay was clinically validated in a blinded manner using 52 archived, formalin-fixed, paraffin-embedded heart valve specimens from patients with endocarditis. A single sample within this set determined to contain PCR inhibitors was omitted from the final analysis set. Compared with existing diagnostic data, PCR had a sensitivity of 100% (8/8) and specificity of 100% (43/43). All samples were assayed with a second PCR assay targeting the IS1111 element.(1) Complete concordance was noted between the 2 assays (P > 0.999). The limit of detection (LoD) of the assay is 216 targets/mcL for fresh tissue and estimated (by Probit analysis) to be 9.7 targets/mcL in formalin-fixed paraffin-embedded tissue.

Clinical Reference


Test Definition: CBRP
Coxiella burnetii (Q fever) PCR


Performance

Method Description
Bacterial nucleic acid is extracted from the specimen using the automated MagNA Pure instrument. The purified DNA is placed on the LightCycler instrument, which amplifies and monitors by fluorescence the development of target nucleic sequences after each PCR cycle. A specific target sequence from Coxiella burnetii is amplified and the resulting segment is detected using specific hybridization probes. Detection of the C burnetii target is performed through melting curve analysis using the LightCycler software. (Cockerill FR, Uhl JR: Applications and challenges of real-time PCR for the clinical microbiology laboratory. In Rapid Cycle Real-Time PCR Methods and Applications. Edited by U Reischl, C Wittwer, F Cockerill. Berlin, Germany, Springer-Verlag, 2002, pp 3-27; Kersh G, Bleeker-Rovers C: Coxiella, In Manual of Clinical Microbiology. 12th edition. Edited by K Carroll, M Pfaller. Washington DC, ASM Press, 2019, pp 1180-1188)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday, Wednesday, Friday

Analytic Time
2 days

Maximum Laboratory Time
7 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
Test Definition: CBRP
Coxiella burnetii (Q fever) PCR

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 U.S. Food and Drug Administration.

CPT Code Information
87798

LOINC® Information

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