Overview

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

Method Name
Real-Time Polymerase Chain Reaction (PCR)

NY State Available
Yes

Specimen

Specimen Type
Serum

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.

Collection Container/Tube:

Preferred: 5-mL red top

Acceptable: Serum gel

Submission Container/Tube: Sterile vial

Specimen Volume: 1 mL

Collection Instructions:
All tubes should be centrifuged and the serum aliquoted into a sterile vial within 2 hours of collection.

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

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>Serum</td>
<td>Frozen (preferred)</td>
<td>7 days</td>
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Clinical and Interpretive

Clinical Information

*Coxiella burnetii*, the causative agent of Q fever, is a small obligately 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 *Coxiella burnetii* infection. Mayo Clinic Laboratories has developed a real-time PCR test that rapidly detects *Coxiella burnetii* DNA in clinical specimens by targeting a sequence of the shikimate dehydrogenase gene (*aroE*) unique to *Coxiella 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 was determined to contain PCR inhibitors and 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. Complete concordance was noted between the 2 assays (P >0.999). The limit of detection (LoD) of the assay is 21.6 targets/mcL for serum.

Clinical Reference


### 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 *Coxiella 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)

### 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
Test Definition: CBSRP
Coxiella burnetii (Q fever) PCR, S

- 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 U.S. Food and Drug Administration.

CPT Code Information
87798

LOINC® Information

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