

**Overview****Useful For**

Aiding in the diagnosis of *Coxiella burnetii* infection (eg, Q fever)

**Method Name**

Real-Time Polymerase Chain Reaction (PCR)

**NY State Available**

Yes

**Specimen****Specimen Type**

Whole Blood EDTA

**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.

**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 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**

0.5 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
Whole Blood EDTA	Refrigerated (preferred)	7 days	
	Frozen	7 days	

## Clinical and Interpretive

### Clinical Information

*Coxiella burnetii*, the causative agent of Q fever, is a small obligate intracellular bacterium that is distributed ubiquitously in the environment. The agent is acquired through aerosol exposure and generally causes mild respiratory disease. A small number of these acute cases will advance to a chronic condition, which typically manifests as endocarditis. If left untreated, cases of Q fever endocarditis are fatal.

Current diagnostic methods of Q fever endocarditis include serologic studies and histopathologic examination of excised cardiac tissue. These current methods are subjective and nonspecific, limiting usefulness in patient diagnostics.

Evaluation of infected tissue, blood, or serum using PCR has been shown to be an effective tool for diagnosing *C burnetii* infection. Mayo Clinic Laboratories has developed a real-time PCR test that permits rapid identification of *C burnetii*.

The assay targets a unique sequence of the shikimate dehydrogenase gene (*aroE*) present in *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.<sup>(1)</sup> Complete concordance was noted between the 2 assays ( $P > 0.999$ ). The limit of detection (LoD) of the assay is 2.16 targets/mL for EDTA whole blood.

### Clinical Reference

1. Frangoulidis D, Meyer H, Kahlhofer C, Splettstoesser WD: 'Real-time' PCR-based detection of *Coxiella burnetii* using conventional techniques. *FEMS Immunol Med Microbiol* 2012;64:134-136
2. Marrie TJ, Raoult D: *Coxiella burnetii* (Q fever). In Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. Edited by GL Mandell, JE Bennett, R Dolin. Seventh edition. Philadelphia, Churchill Livingstone/Elsevier, 2010, pp 2511-2519

3. Maurin M, Raoult D: Q fever. Clin Microbiol Rev 1999;12:518-533
4. Fenollar F, Fournier PE, Raoult D: Molecular detection of *Coxiella burnetii* in the sera of patients with Q fever endocarditis or vascular infection. J Clin Microbiol 2004;42:4919-4924
5. Fournier PE, Raoult D: Comparison of PCR and serology assays for early diagnosis of acute Q fever. J Clin Microbiol 2003;41:5094-5098
6. Tande A, Cunningham S, Raoult D, et al: *Coxiella burnetii* prosthetic joint infection-case report and assay for detection. J Clin Microbiol 2013;51:66-69
7. CDC Releases First National Guidelines on Managing Q Fever. JAMA 2013;309(18):1887
8. Anderson A, Bijlmer H, Fournier PE, et al: Diagnosis and management of Q fever-United States, 2013: recommendations from CDC and the Q Fever Working Group. MMWR Recomm Rep 2013;62(RR-03):1-30

## 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**

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**

Test ID	Test Order Name	Order LOINC Value
CBBRP	Coxiella burnetii (Q fever) PCR, B	90443-3

Result ID	Test Result Name	Result LOINC Value
35191	Specimen Source	31208-2
35192	Coxiella burnetii PCR	90443-3