

## Overview

### Useful For

Rapid detection of *Coccidioides* DNA

Aiding in the diagnosis of coccidioidomycosis

### Method Name

Real-Time Polymerase Chain Reaction (PCR)

### NY State Available

Yes

## Specimen

### Specimen Type

Tissue, Paraffin

### Necessary Information

Specimen source is required.

### Specimen Required

**Preferred Paraffin-embedded tissue block:**

**Supplies:** Tissue Block Container (T553)

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

**Sources:** Body tissue

**Container/Tube:** Tissue block

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

**Acceptable Paraffin-embedded tissue block:**

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

**Sources:** Body tissue

**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 Minimum Volume

See Specimen Required.

### Reject Due To

Any non-FFPE tissue blocks FFPE bone marrow FFPE slides body fluids	Reject
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### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Tissue, Paraffin	Ambient (preferred)		
	Refrigerated		

### Clinical & Interpretive

#### Clinical Information

Coccidioidomycosis is caused by the dimorphic fungi, *Coccidioides immitis* and *Coccidioides posadasii*. These organisms are endemic to the southwestern regions of the United States, northern Mexico, and areas of Central and South America. The illness commonly manifests as a self-limited upper respiratory tract infection, but can also result in disseminated disease that may be refractory to treatment.(1) Clinical onset generally occurs 10 to 16 days following inhalation of coccidioidal spores (arthroconidia).(2) Disease progression may be rapid in previously healthy or immunosuppressed individuals.

At present, the gold standard for the diagnosis of coccidioidomycosis is culture of the organism from clinical specimens. Culture is highly sensitive and, with the implementation of DNA probe assays for confirmatory testing of culture isolates, yields excellent specificity.(3) However, growth in culture may take up to several weeks. This often delays the diagnosis and treatment of infected individuals. Serological tests including immunodiffusion and complement fixation are widely used for the detection of antibody against *Coccidioides*. Serology for *Coccidioides* can be limited by delays in antibody development or nonspecificity due to cross-reactions with other fungi. In addition, immunodiffusion and complement fixation tests are highly labor intensive and are generally limited to reference laboratories.

Molecular methods can identify *Coccidioides* species directly from clinical specimens and should be used in conjunction with culture. For specimen types such as formalin-fixed, paraffin-embedded tissue, culture is not possible, but the molecular test may provide useful information.

#### Reference Values

Not applicable

#### Interpretation

A positive result indicates presence of *Coccidioides* DNA.

A negative result indicates absence of detectable *Coccidioides* DNA.

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An inhibition result indicates that the detection of *Coccidioides* DNA is inhibited in this specimen. A new specimen can be resubmitted under a new order, if desired.

**Cautions**

This rapid PCR assay detects *Coccidioides* nucleic acid and, therefore, does not distinguish between viable, disease-related organisms or nucleic acid persisting from old disease. Test results should be correlated with patient symptoms and clinical presentation before a definitive diagnosis is made.

A negative result does not rule out the presence of *Coccidioides* or active disease because the organism may be present at levels below the limit of detection for this assay.

This test does not distinguish between *Coccidioides immitis* and *Coccidioides posadasii*.

Formalin fixation has been demonstrated to decrease the sensitivity of PCR.(4) Therefore, a negative PCR result from fixed tissue should be interpreted with caution if the clinical presentation is suggestive of coccidioidomycosis.

**Supportive Data**

The sensitivity and specificity of the assay testing 148 formalin-fixed, paraffin-embedded tissue specimens was 73.4% and 100% respectively.

The limit of detection of the assay was determined to be between 1 and 10 copies of target/microliter (<50 copies of target/reaction). The analytic specificity of the assay was determined by performing a Basic Local Alignment Search Tool (BLAST) search of the primer and probe sequences on the National Center for Biotechnology Information website (<http://www.ncbi.nlm.nih.gov>). In addition, an extensive panel of nucleic acid extracted from 114 potentially cross-reacting organisms including fungi, bacteria, mycobacteria, viruses, and human DNA was tested. The assay did not demonstrate cross-reactivity with any of the organisms included in the specificity panel.

**Clinical Reference**

1. Vucicevic D, Blair JE, Binnicker MJ: The utility of *Coccidioides* polymerase chain reaction testing in the clinical setting. *Mycopathologia*, 2010; 170:345-351
2. Hartmann CA, Aye WT, Blair JE: Treatment considerations in pulmonary coccidioidomycosis. 2016; 10:1079-1091

**Performance****Method Description**

Following specimen processing, nucleic acids are extracted and the extract is then transferred to individual self-contained cuvettes for amplification using the LightCycler real-time PCR platform (Roche Applied Sciences). The LightCycler is an automated instrument that amplifies and monitors the development of target nucleic acid (amplicon) after each cycle of PCR. The detection of amplicon is based on fluorescence resonance energy transfer, which utilizes hybridization probes. The presence of the specific organism nucleic acid is confirmed by performing a melting curve analysis of the amplicon.(Binnicker MJ, Buckwalter SP, Eisberner JJ, et al: Detection of *Coccidioides* species in clinical specimens by real-time PCR. *J Clin Microbiol* 2007;45:173-178)

**PDF Report**

No

**Day(s) Performed**

Monday through Friday

**Report Available**

5 to 7 days

**Specimen Retention Time**

7 days; after which time the block will be returned to the client

**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**

87798

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
CIMT	Coccidioides PCR, FFPE	95913-0

Result ID	Test Result Name	Result LOINC® Value
SRCCI	Coccidioides PCR, FFPE, Source	31208-2
CIRR	Coccidioides PCR, FFPE, Result	95913-0