MAYO CLINIC LABORATORIES

Test Definition: CIMT

Coccidioides immitis/posadasii, Molecular Detection, PCR, Paraffin, Tissue

Overview

Useful For

Rapid detection of *Coccidioides* DNA

Aiding in the diagnosis of coccidioidomycosis using paraffin-embedded tissue specimens

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 FFPE body fluids	Reject

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, with recent literature suggests the geographic area of endemicity may be expanding over time.

The gold standard for the diagnosis of coccidioidomycosis is culture of the organism from clinical specimens due to its high sensitivity. However, growth in culture may take up to several weeks, which can delay diagnosis and treatment. In addition, the propagation of *Coccidioides* species in the clinical laboratory is a significant safety hazard to laboratory personnel.

This polymerase chain reaction method can identify *Coccidioides* species directly from clinical specimens, allowing for a rapid diagnosis, 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.

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 polymerase chain reaction (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. 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.nml.nig.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, et al: The utility of Coccidioides polymerase chain reaction testing in the clinical setting. Mycopathologia. 2010 Nov;170(5):345-351
2. Hartmann CA, Aye WT, Blair JE: Treatment considerations in pulmonary coccidioidomycosis. 2016 Oct;10(10):1079-1091

Performance

Method Description

Following specimen processing, nucleic acids are extracted, and the extract transferred to individual self-contained cuvettes for amplification using the LightCycler real-time polymerase chain reaction (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 Sunday

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. It 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