MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: September 19, 2023
Effective Date: October 31, 2023

Mycobacterium tuberculosis complex, Molecular Detection and Rifampin Resistance, PCR, Sputum

Test ID: MTBXS

Useful for:

A positive result indicates the presence of *Mycobacterium tuberculosis* complex DNA.

A negative result indicates the absence of detectable *M tuberculosis* complex DNA.

Presumptive rifampin resistance mediated through mutations within the resistance determining region of the *rpoB* gene will be reported when detected.

One to 2 negative polymerase chain reaction results in conjunction with 1 to 2 negative acid-fast smears may provide evidence supporting the removal of a patient from airborne isolation. Consult your local Infection Prevention and Control for guidance.

Additional Testing Requirements

Mycobacterial culture is required for epidemiological strain typing and growth-based phenotypic antimicrobial susceptibility testing, including definitive rifampin results as well as results for other antimicrobials. If your facility is unable to perform a mycobacterial culture, order CTB / Mycobacteria and *Nocardia* Culture, Varies concurrently with this test.

Necessary Information

Specimen source is required.

Specimen Required

Specimen Type: Sputum (undigested)
Container/Tube: Sterile container
Specimen Volume: 3 mL
Minimum Volume: 1.5 mL
Specimen Stability Information: Refrigerated (preferred) 7 days/Ambient 72 hours
Additional Information:
1. If a single specimen is being shared between mycobacterial culture, acid-fast smear, and/or *M tuberculosis* PCR, a minimum volume of 3 mL for the respiratory specimen is required. Specimen volumes less than indicated may decrease sensitivity of testing.
2. If insufficient volume is submitted, testing will be canceled.

Specimen Type: N-acetyl-L-cysteine/sodium hydroxide (NALC/NaOH)-digested sputum
Container/Tube: Sterile container
Specimen Volume: 3 mL
Minimum Volume: 1.5 mL
Collection Instructions:
1. Submit digested specimen treated with NALC/NaOH.
2. Clearly indicate on container and order form that specimen is a digested specimen.
Specimen Stability Information: Refrigerated 7 days
Additional Information:
1. If a single specimen is being shared between mycobacterial culture, acid-fast smear, and/or *M tuberculosis* PCR, a minimum volume of 3 mL for the respiratory specimen is required. Specimen volumes less than indicated may decrease sensitivity of testing.
2. If insufficient volume is submitted, testing will be canceled.

Methodology:
Real-Time Polymerase Chain Reaction (PCR)/Reverse Transcription PCR

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Refrigerated (preferred)	7 days
	Ambient	72 hours

Cautions:
Per current Centers for Disease Control and Prevention recommendations, rifampin resistance results should be considered as preliminary pending definitive confirmation with gene sequencing or growth-based phenotypic antimicrobial susceptibility testing.

This polymerase chain reaction-based molecular assay detects *Mycobacterium tuberculosis* nucleic acid and, therefore, does not distinguish between viable, disease-related organisms and nucleic acid persisting from prior infection. Test results should be correlated with patient symptoms and clinical presentation before a definitive diagnosis is made.

A negative result does not rule-out infection with *M tuberculosis* or active disease because the organism may be present at levels below the limit of detection for this assay.

CPT Code:
87556
87798

Day(s) Performed: Monday through Sunday **Report Available:** Same day/1 day

Questions
Contact Brandon DeBoom, Laboratory Resource Coordinator at 800-533-1710.