Lab Dept:	**Microbiology/Virology**
Test Name:	**MYCOBACTERIUM TUBERCULOSIS COMPLEX, MOLECULAR DETECTION & RIFAMPIN RESISTANCE, PCR, SPUTUM**

General Information

Lab Order Codes:	MTBXS
Synonyms:	*M tuberculosis*/ RIF PCR GeneXpert; MTB and Rif resistance detection; TB and Rifampin resistance PCR
CPT Codes:	87556 – *Mycobacterium tuberculosis*, complex, molecular detection, PCR 87798 – Infectious agent detection by nucleic acid, not otherwise specified, amplified probe technique, each organism
Test Includes:	Qualitative result indicating the presence or absence of *M. tuberculosis* complex DNA and the presence or absence of presumptive rifampin resistance mutations.

Logistics

Test indications:	Useful for the rapid detection of *Mycobacterium tuberculosis* DNA from respiratory specimens for the diagnosis of pulmonary tuberculosis. Presumptive detection of rifampin resistance is based on the presence of resistance-associated mutations. This test should always be performed in conjunction with mycobacterial culture, which is required for epidemiological strain typing and growth-based phenotypic antimicrobial susceptibility testing, including definitive rifampin results as well as results for other antimicrobials.
Lab Testing Sections:	Microbiology - Sendouts
Referred to:	Mayo Clinic Laboratories (MML Test: MTBXS)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily
Turnaround Time:	1 day

Special Instructions:	This test should always be performed in conjunction with mycobacterial culture, which is required for epidemiological strain typing and growth-based phenotypic antimicrobial susceptibility testing, including definitive rifampin results as well as results for other antimicrobials.

Specimen

Specimen Type:	Sputum Undigested specimens or specimens digested with N-acetyl-L-cysteine/sodium hydroxide (NALC/NaOH) are acceptable.
Container:	Sterile container
Collection Volume:	3 mL sputum (minimum 1.5 mL) NOTE: If a single specimen is being shared between mycobacterial culture, acid-fast smear, and/or *M. tuberculosis* PCR, a **minimum** volume of 3 mL is required.
Processed Volume:	See Collection Volume
Collection:	Sputum collection in sterile container
Special Processing:	Lab Staff: Store and transport specimen at refrigerated temperature. Forward promptly. If specimen has been treated with NALC/NaOH, clearly indicate on the label that it is a Digested specimen. The high sensitivity of amplification by polymerase chain reaction requires the specimen to be processed in an environment in which contamination of the specimen by *Mycobacterium tuberculosis* DNA is unlikely. Specimen stable for 7 days refrigerated (preferred) or ambient for 72 hours.
Patient Preparation:	N/A
Sample Rejection:	Specimen other than sputum, insufficient volume, mislabeled or unlabeled specimen, specimens past the required stability from date of collection.

Interpretive

Reference Range: Negative

Interpretation:
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 two negative polymerase chain reaction results in conjunction with one to two negative acid-fast smears may provide evidence supporting the removal of a patient from airborne isolation. Consult Infection Prevention and Control for guidance.

Critical Values: Positive

Limitations: This test should always be performed in conjunction with mycobacterial culture, which is required for epidemiological strain typing and growth-based phenotypic antimicrobial susceptibility testing, including definitive rifampin results as well as results for other antimicrobials.

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.

Methodology: Real-Time Polymerase Chain Reaction (PCR)

References: Mayo Clinic Laboratories August 2024

Updates: 8/27/2024: Initial entry