Test Definition: MTBXP

M. tuberculosis/RIF PCR GeneXpert

Overview

Useful For

Rapid detection of *Mycobacterium tuberculosis* DNA from respiratory specimens for the diagnosis of pulmonary tuberculosis

Presumptive detection of rifampin resistance based on the presence of resistance-associated mutations

Method Name

Real-Time Polymerase Chain Reaction (RT-PCR)

NY State Available

Yes

Specimen

Specimen Type

Sputum

Shipping Instructions

Specimen must arrive within 7 days of collection; specimen >7 days will be rejected.

Necessary Information

Specimen source is required.

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 *Mycobacterium tuberculosis* DNA is unlikely.

Specimen Type: Sputum (undigested)

Container/Tube: Sterile container

Specimen Volume: 3 mL

Specimen Stability Information: Refrigerated (preferred) 7 days/Ambient 72 hours

Additional Information:

1. If a single specimen is being shared between mycobacteria culture, acid-fast smear, and/or *M tuberculosis* PCR, a minimum volume of 3 mL for respiratory specimen is required. Specimen volumes less than indicated may decrease sensitivity of testing.

2. If insufficient volume is submitted, test or tests will be canceled.

Specimen Type: N-acetyl-l-cysteine/*sodium hydroxide (*NALC/NaOH)-digested sputum

Container/Tube: Sterile container

Specimen Volume: 3 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 mycobacteria culture, acid-fast smear, and/or *M tuberculosis* PCR, a minimum volume of 3 mL for respiratory specimen is required. Specimen volumes less than indicated may decrease sensitivity of testing.

2. If insufficient volume is submitted, test or tests will be canceled.

Specimen Minimum Volume

1.5 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
Sputum	Varies		

Clinical and Interpretive

Clinical Information

Mycobacterium tuberculosis is a highly transmissible bacterial pathogen and is the causative agent of tuberculosis, a disease causing significant worldwide morbidity and mortality. Each year, *M tuberculosis* accounts for nearly 1.3 million deaths and is responsible for 10 million newly diagnosed cases of tuberculosis worldwide. *M tuberculosis* is spread from person to person via respiratory transmission, and has the potential to become resistant to many of the antibiotics currently used if not treated appropriately. Therefore, rapid and accurate detection of *M tuberculosis* in patient specimens is of clinical and public health importance.

Conventional culture methods can generally detect *M tuberculosis* in 2 to 3 weeks, although up to 6 weeks of incubation may be required in some instances. This qualitative molecular assay utilizes PCR-based nucleic acid amplification for the direct detection of *M tuberculosis* DNA within respiratory specimens without relying on culture growth, leading to more rapid diagnoses and appropriate patient care. This assay also detects the presence of mutations in the *rpoB* gene that have been documented to confer more than 95% of cases of rifampin resistance.

Reference Values

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 (RIF) resistance mediated through mutations within the resistance determining region of the *rpoB* gene will be reported when detected.

One to 2 negative PCR 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.

Cautions

This test should always be performed in conjunction with mycobacterial culture, which is required for epidemiological strain typing and definitive drug susceptibility testing.

Per current CDC recommendations, rifampin resistance results should be considered as preliminary pending confirmation with gene sequencing or growth-based phenotypic drug susceptibility testing.

This PCR-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.

Clinical Reference

1. World Health Organization. Global Tuberculosis Report, 20th edition. Geneva, Switzerland. 2015 Available at www.who.int/tb/publications/global_report/gtbr15_main_text.pdf

2. Centers for Disease Control and Prevention. Availability of an assay for detecting Mycobacterium tuberculosis, including rifampin-resistant strains, and considerations for its use - United States, 2013. MMWR Morb Mortali wkly rep 2013;62:821-827

3. Boehme CC, Nabeta P, Hillemann D, et al: Rapid Molecular Detection of Tuberculosis and Rifampin Resistance. N Engl J Med 2010;9:1005-1015

4. Food and Drug Administration. New data shows test can help physicians remove patients with suspected TB from isolation earlier. Press Release. 2015 Feb 12. Available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm434226.htm

Performance

Method Description

The Cepheid Xpert MTB/RIF assay utilizes sputum or decontaminated and pelleted sputum sediment. Specimens are inoculated directly into single disposable test cartridge, which contains both DNA extraction and target amplification material. The assay amplifies a 192-bp segment of the *rpoB* gene for *Mycobacterium tuberculosis* complex identification as well as rifampin resistance profiling. The Cepheid Xpert MTB/RIF assay is a closed PCR system that greatly reduces the potential for false-positive results due to specimen cross-contamination as compared with traditional open-system PCR methods.(Package insert: Xpert MTB/RIF. Cepheid. Sunnyvale,CA. GXMTB/RIF-US-10, rev D, 03/2016)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Sunday

Analytic Time

Same day/1 day

Specimen Retention Time

7 days

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 has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

87556, 87798

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
MTBXP	M. tuberculosis/RIF PCR GeneXpert	89371-9

Result ID	Test Result Name	Result LOINC Value
SRCRF	Specimen Source	31208-2
MTBXR	MTB Complex Result	88874-3
RIFAR	MTB Rifampin Resistance Result	89372-7