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**Lab Dept:** Microbiology/Virology

**Test Name:** MYCOBACTERIUM TUBERCULOSIS COMPLEX,  
MOLECULAR DETECTION PCR

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**General Information**

**Lab Order Codes:** MTBRP

**Synonyms:** MTB Complex PCR, TB PCR, AFB PCR

**CPT Codes:** 87556 – *Mycobacterium tuberculosis*, complex, molecular detection, PCR  
87015 – Mycobacteria culture, concentration (if appropriate)

**Test Includes:** Rapid detection of *Mycobacterium tuberculosis* complex DNA, preferred method. When this test is ordered, the reflex test may be performed and charged.

Detection of *Mycobacterium tuberculosis*, when used in conjunction with mycobacterial culture.

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**Logistics**

**Lab Testing Sections:** Microbiology

**Referred to:** Mayo Medical Laboratories (MML: MTBRP)

**Phone Numbers:** MIN Lab: 612-813-5866

STP Lab: 651-220-6555

**Test Availability:** Daily, 24 hours

**Turnaround Time:** 3 – 7 days

**Special Instructions:** **Specific site and date/time of collection** are required for specimen processing. Do not submit specimens on swabs if other sample types are possible. Negative results from swab specimens are unreliable. **Specimens must arrive within 7 days of collection.**

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**Specimen**

**Specimen Type:** Preferred specimens: Body fluid, cerebrospinal fluid (CSF), ocular fluid, respiratory (eg, bronchoalveolar lavage [BAL], bronchial washing, sputum), stool, fresh tissue, bone, bone marrow, or urine.

Acceptable specimens: If no fresh specimen is available, digested respiratory specimens treated with N-acetyl-L-cysteine (NALC/NaOH) are

acceptable (eg, BAL, bronchial washing, respiratory fluid, sputum, or tracheal secretion), as are NALC/NaOH-treated gastric washings.

**Container:** Sterile container

**Volume:** See Collection

**Collection:**

<b>Specimen Type</b>	
<b>Quantity</b>	<b>Special Instructions</b>
<b>Body Fluids (Body, bone marrow aspirate, ocular or CSF)</b>	
1 mL (Min: 0.5 mL)	Collect aseptically, using SPS (yellow top) tubes for bloody specimens. Only fresh specimens accepted.
<b>Gastric wash</b>	
2 mL (Min: 1 mL)	Neutralize specimen within 4 hours of collection with 20 mg of sodium carbonate per 2 mL of gastric washing.
<b>Respiratory (BAL, bronchial washing, or sputum)</b>	
3 mL (Min: 1 mL if done without smear and culture)	<p>Collect from an early morning, deep cough on at least 3 consecutive days. For follow-up of patients on therapy, collect at weekly intervals beginning 3 weeks after initiation of therapy. Do not pool specimens. Optimal specimens have a PMN to squamous epithelial cell ratio of &gt;2:1.</p> <ol style="list-style-type: none"> <li>1. Have patient rinse or gargle with water.</li> <li>2. Instruct patient to cough deeply to produce a lower respiratory tract specimen. Collect in sterile container.</li> <li>3. For pediatric patients unable to produce sputum, respiratory therapist should collect via suction.</li> </ol>
<b>Stool</b>	
5 - 10 gm	Collect specimen directly into a leakproof container not contaminated with urine, residual soap, or disinfectants. Only fresh specimens will be accepted.
<b>Tissue (Fresh tissue, bone or bone marrow biopsy)</b>	
5 – 10 mm	<p>Aseptic collection.</p> <p>Keep moist with sterile water or sterile saline. Only fresh specimens will be accepted.</p>
<b>Urine</b>	

<p>1 mL (Min: 0.5 mL)</p>	<p>Collect first morning specimen. 24-hour pooled specimens are not acceptable.</p> <p><b>Catheterized specimen: Straight Catheter</b></p> <ol style="list-style-type: none"> <li>1. Thoroughly cleanse the urethral area with povidone - iodine and water.</li> <li>2. Aseptically insert catheter into the bladder.</li> <li>3. Allow ~10 mL to pass, then collect 1 - 10 mL into a sterile tube.</li> <li>4. After urine is collected, pull catheter out of the cap of the tube, tighten cap, and depress spout.</li> <li>5. Transport to the lab.</li> </ol> <p><b>Clean-catch, Mid-stream specimen:</b></p> <p><b>Males:</b></p> <ol style="list-style-type: none"> <li>1. Clean glans with soap and water.</li> <li>2. Rinse area with wet gauze pads.</li> <li>3. While holding foreskin retracted, begin voiding.</li> <li>4. After several mL have passed, collect midstream portion without stopping flow of urine.</li> <li>5. Transfer specimen to a leak-proof sterile container.</li> </ol> <p><b>Females:</b></p> <ol style="list-style-type: none"> <li>1. Thoroughly clean urethral area with soap and water.</li> <li>2. Rinse area with wet gauze pads.</li> <li>3. While holding labia apart, begin voiding.</li> <li>4. After several mL have passed, collect midstream portion without stopping flow of urine.</li> <li>5. Transfer specimen to a sterile leak-proof container.</li> </ol>
<p><b>Acceptable specimens: NALC/NaOH-digested respiratory specimens (Lavage fluid, bronchial washing, gastric washing, respiratory fluid, sputum or tracheal secretion)</b></p>	
<p>NALC/NaOH – digested respiratory specimens</p> <p>2 mL (Min: 1 mL)</p>	<p>Sterile container</p> <ol style="list-style-type: none"> <li>1. Submit digested specimen treated with NALC/NaOH.</li> <li>2. Clearly label as digested specimen</li> </ol>

**Special Processing:**

- Refrigerate all specimens for mycobacteria.
- Lab will neutralize gastric fluid specimens within four hours of collection.

**Transport/Storage:** **Onsite collections:** Transport to the Laboratory immediately.

**Offsite collections:** Specimens must be promptly transported to the laboratory, with the next available courier, not to exceed 24 hours from the time of collection or 4 hours for gastric specimens requiring neutralization.

**Sample Rejection:** Improperly labeled specimen; specimens with prolonged transit time (see [Transport/Storage](#)) specimen not submitted in appropriate transport container; insufficient volume; external contamination; 24-hour urine collections; 24-hour sputum collections; insufficient volume; specimens submitted in viral transport medium (ie, M4, M5 or thioglycolate broth); fixed tissue; swab sources of nasal, sinus, ear, mouth, throat, or scalp. If an unacceptable specimen is received, the physician or nursing station will be notified and another specimen requested before the specimen is discarded. Specimens >7 days old.

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### ***Interpretive***

**Reference Range:** Negative

**Critical Values:** Positive AFB PCR results will be called to the physician or patient's nurse.

**Limitations:** This test should always be performed in conjunction with mycobacterial culture.

This rapid PCR assay detects Mycobacterium tuberculosis complex 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 the presence of Mycobacterium tuberculosis complex or active disease because the organism may be present at levels below the limit of detection for this assay.

This test has not been studied for use with specimens from patients being treated with antituberculosis agents and, therefore, should not be used to determine bacteriologic cure or to monitor response to therapy. It is not known how long the PCR assay can remain positive following treatment for Mycobacterium tuberculosis.

The sensitivity of this test with stool specimens is 80% and testing of additional stool specimens should be considered if the result from the first specimen is negative.

**Methodology:** Real-Time Polymerase Chain Reaction (PCR)

**References:** [Mayo Medical Laboratories](#) October 2016