

# Mycobacterium tuberculosis Complex Species Identification, PCR, Varies

### Overview

#### Useful For

Determining the species of a Mycobacterium tuberculosis complex culture isolate

#### Additional Tests

Test Id	Reporting Name	Available Separately	Always Performed
RTBSP	Id, Mtb Speciation, PCR	No, (Bill Only)	Yes

#### **Testing Algorithm**

When this test is ordered, species identification will always be performed at an additional charge.

#### **Special Instructions**

• Infectious Specimen Shipping Guidelines

#### Method Name

Real-Time Polymerase Chain Reaction (PCR)

#### NY State Available

Yes

# Specimen

### **Specimen Type**

Varies

#### **Ordering Guidance**

This test should be used to identify the species within the *Mycobacterium tuberculosis* complex from a known *M tuberculosis* complex isolate.

For identification of *M* tuberculosis complex from isolate growth, order CTBID / Culture Referred for Identification, *Mycobacterium* and *Nocardia*, Varies.

For rapid identification of *M tuberculosis* complex directly from a specimen, order MTBRP / *Mycobacterium tuberculosis* Complex, Molecular Detection, PCR, Varies or MTBXS / *Mycobacterium tuberculosis* Complex, Molecular Detection and Rifampin Resistance, PCR, Sputum.

#### **Shipping Instructions**

1. For shipping information see <u>Infectious Specimen Shipping Guidelines</u>.



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2. Place specimen in a large infectious container and label as an etiologic agent/infectious substance.

#### Necessary Information

Specimen source and suspected organism identification are required.

#### Specimen Required

**Specimen Type:** *Mycobacterium tuberculosis* complex isolate growing in pure culture **Supplies:** Infectious Container, Large (T146)

**Container/Tube:** Growth on solid slant media, eg, Middlebrook 7H10, 7H11 and Lowenstein Jensen; growth in broth medium, eg, Mycobacteria Growth Indicator Tube, 7H9 broth BACT/ALERT MP or VersaTREK

**Specimen Volume:** Isolate with visible growth on solid media; if broth is sent, 3 mL or more of broth culture **Collection Instructions:** 

1. Bacterial organism must be submitted in pure culture, actively growing. Do not submit mixed cultures.

2. Place specimen in a large infectious container and label as an etiologic agent/infectious substance.

Additional Information: If subculture to Middlebrook agar medium is needed to ensure purity, turnaround time for results may be delayed.

#### Reject Due To

Agar plate	Reject
Mixed culture	

#### **Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)		
	Refrigerated		

#### Clinical & Interpretive

#### **Clinical Information**

This assay provides a species-level identification of microbiologic culture isolates previously identified to be a member of the *Mycobacterium tuberculosis* complex. Species level identification can be important for patient care or for epidemiologic investigations. For example, the species-level identification of *Mycobacterium bovis* bacillus Calmette-Guerin (BCG) can assist with identification of disseminated infections following use of the vaccine as an adjuvant during chemotherapy.

#### **Reference Values**

Not applicable

#### Interpretation

This assay can differentiate the most common species within the *Mycobacterium tuberculosis* complex, which are, *M tuberculosis*, *Mycobacterium bovis*, *Mycobacterium bovis* bacillus Calmette-Guerin (BCG; the vaccine strain),



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*Mycobacterium canettii, Mycobacterium caprae, Mycobacterium microti,* and *Mycobacterium pinnepedii.* This assay cannot distinguish *Mycobacterium africanum* from *Mycobacterium mungi* so if that result is obtained, the organism will be reported as *M africanum/M mungi*.

#### Cautions

Only isolates of *Mycobacterium tuberculosis* complex should be submitted and they must be in pure culture. Nontuberculous mycobacteria should not be submitted. Mixed cultures will result in a delay because the *M tuberculosis* complex organism must be isolated prior to performing the polymerase chain reaction assay.

This assay has not been verified for the direct detection of *M* tuberculosis complex from clinical specimens. It is intended for use on microbiologic culture isolates already identified as *M* tuberculosis complex.

### Supportive Data

Type strains of *Mycobacterium tuberculosis* complex members were tested using the species identification polymerase chain reaction (PCR) assay and all were identified correctly. Type strains tested were *M tuberculosis* ATCC 27294, *Mycobacterium bovis* ATCC 19210, *M bovis* BCG ATCC 101472, *Mycobacterium africanum* ATCC 25240, *Mycobacterium microti* ATCC 19422, *Mycobacterium caprae* ATCC BAA 824, *Mycobacterium pinnipedii* ATCC BAA 688.

In addition, a clinical isolate of *Mycobacterium canettii*, identified by whole genome sequencing at the New York State Department of Health Wadsworth Center, was tested and confirmed to be *M canettii* by the *M tuberculosis* complex species identification PCR assay.

As part of the verification of this assay, 78 *M tuberculosis* complex isolates with the species identified at a reference laboratory were tested using the species identification PCR assay. All 78 isolates were correctly identified to the species level.

LC 480 PCR results		M tuberculosis	M bovis	M bovis BCG	M africanium
	M tuberculosis	53			
	M bovis		4		
	M bovis BCG			14	
	M africanium				7

Table. Species reported by reference laboratory

Although the species identification test can be used only for mycobacterial isolates already identified as *M tuberculosis* complex, 159 other *Mycobacterium* species isolates were tested to determine whether any nontuberculous mycobacteria would be positive in the test. No nontuberculous mycobacteria were positive in the *M tuberculosis* complex species identification PCR assay.

#### **Clinical Reference**

Fitzgerald DW, Sterling TR, Haas DW. Mycobacterium tuberculosis. In: Mandell GL, Bennett JE, Dolin R, eds. Mandell, Douglas and Bennett's Principles and Practice of Infectious Diseases. 9th ed. Elsevier; 2020:2985-3021

# Performance



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### **Method Description**

The method uses real-time polymerase chain reaction on the LightCycler 480 platform with *Mycobacterium tuberculosis* complex-specific primers coupled with fluorescence resonance energy transfer probes to differentiate the members of the complex to the species level. The probes target specific regions of difference (RD) within the *M tuberculosis* complex genome. Detection of the presence or absence of these RD allows for differentiation of the species within the *M tuberculosis* complex. (Halse TA, Escuyer VE, Musser KA. Evaluation of a single tube multiplex real-time PCR for differentiation of members of the *Mycobacterium tuberculosis* complex in clinical specimens. J Clin Microbiol. 2011;49:2562-2567; Warshauer DM, Salfinger M, Desmond E, and Lin S-Y G. *Mycobacterium tuberculosis* complex. In: Carroll KC, Pfaller MA, Landry ML, et al, eds. Manual of Clinical Microbiology. 12th edition, ASM Press; 2019:576-594)

The RD's expected for each species within the *M* tuberculosis complex are shown in the table below. "+" indicates the region is present and "-" indicates the region is absent.

Expected RD					
signature					
patterns	RD1	RD4	RD9	RD12	RD9-2
Mycobacterium	+	+	+	+	+
tuberculosis					
Mycobacterium	+	-	-	-	+
bovis					
Mycobacterium	-	-	-	-	+
bovis BCG					
Mycobacterium	+	+	-	+	+
africanum					
Mycobacterium	+	+	+	-	+
canettii					
Mycobacterium	+	+	-	-	+
caprae					
Mycobacterium	-	+	-	+	+
microti					
Mycobacterium	+	+	-	+	+
mungi					
Mycobacterium	+	+	-	-	+
pinnepedii					

#### PDF Report

No

# Day(s) Performed

Monday through Friday

# **Report Available**



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7 to 14 days

#### **Specimen Retention Time**

Subculture: 1 year

### **Performing Laboratory Location**

Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

#### Fees

- Authorized users can sign in to <u>Test Prices</u> for detailed fee information.
- Clients without access to Test Prices can contact <u>Customer Service</u> 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact <u>Customer Service</u>.

#### **Test Classification**

This test has been cleared, approved, or is exempt by the US 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**

87150

#### LOINC<sup>®</sup> Information

Test ID	Test Order Name	Order LOINC <sup>®</sup> Value
TBSP	M tuberculosis species ID, PCR	94576-6

Result ID	Test Result Name	Result LOINC <sup>®</sup> Value
TBSP	M tuberculosis species ID, PCR	94576-6