MAYO CLINIC LABORATORIES

Test Definition: DMTBR

Mycobacterium tuberculosis Complex, Molecular Detection of Drug Resistance Markers, Next-Generation Sequencing

Overview

Useful For

Molecular detection of drug resistance variants in culture isolates of the *Mycobacterium tuberculosis* complex

May provide a more rapid detection of drug resistance than phenotypic, broth-based testing for selected gene targets

Aiding in the resolution of discrepant results obtained using phenotypic methods

Testing for *M tuberculosis* complex isolates that are not sufficiently viable to allow for culture-based testing

Testing Algorithm

Next-Generation sequencing (NGS) of *Mycobacterium tuberculosis* complex isolates is performed followed by evaluation of selected genes of interest for the presence of well-characterized, drug resistance-conferring variants.

Special Instructions

- Infectious Specimen Shipping Guidelines

Method Name

Next-Generation Sequencing (NGS)

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

This test is used to identify the drug resistance variants in an *M tuberculosis* complex culture isolate.

Shipping Instructions

1. For shipping information see Infectious Specimen Shipping Guidelines
2. Place specimen in a large infectious container (T146) and label as an etiologic agent/infectious substance.

Necessary Information

Specimen source and organism identification are required.

Specimen Required

Supplies: Infectious Container, Large (T146)
Specimen Type: *Mycobacterium tuberculosis* complex isolate growing in pure culture
Container/Tube:
Preferred: Solid slant medium (eg. Middlebrook 7H10, 7H11 or Lowenstein Jensen agar)
Acceptable: Broth medium (eg. Mycobacteria Growth Indicator Tube, 7H9 broth, BACT/ALERT MP or VersaTREK bottle).
Note: Broth specimens will require subculture which will delay results.
Specimen Volume:
Solid slant medium: Isolate with visible growth
Broth medium: Greater than or equal to 3 mL of broth culture
Collection Instructions:
1. Organism must be 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.
3. Turnaround time for results may be delayed if subculture is needed to ensure purity.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Agar plate	Reject
Mixed culture	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

An important component of disease management for patients with tuberculosis is testing of *Mycobacterium tuberculosis* complex isolates for resistance to antituberculous medications. Phenotypic culture-based drug resistance testing is often performed using broth methods since they are more rapid than the agar proportion method. However, even the rapid broth methods require approximately 14 to 21 days.

This targeted next-generation sequencing testing provides molecular detection of well-characterized drug-resistance variants in *M tuberculosis* complex by sequencing selected genes of interest:

Drug Name	Genomic Targets
Rifampin	*rpoB*
Isoniazid	*katG, ahpC, inhA, fabG1*

Pyrazinamide	*pncA*
Ethambutol	*embB*
Streptomycin	*gidB, rrs, rpsL*
Fluoroquinolones	*gyrA, gyrB*
Kanamycin	*eis, rrs*
Amikacin	*rrs*
Capreomycin	*rrs, tlyA*
Ethionamide	*ethA, inhA, fabG1*
Linezolid	*rplC, rrl*
Bedaquiline, Clofazimine	*rv0678*

Reference Values

Not applicable

Interpretation

Variants detected in *Mycobacterium tuberculosis* complex that are associated with drug resistance according to the World Health Organization (WHO) "Catalogue of mutations in *Mycobacterium tuberculosis* and their association with drug resistance" are reported.(1)

If no variants associated with drug resistance are detected in the *M tuberculosis* complex isolate, a "no mutation detected" result is reported.

Genetic variants of unknown significance according to the WHO catalog are also noted.(1)

Cautions

The absence of a genetic variant in this assay does not indicate that the isolate is susceptible to an antimicrobial agent since not all genes in the *M tuberculosis* complex are queried. Phenotypic susceptibility testing is required.

Clinical Reference

1. Catalogue of mutations in Mycobacterium tuberculosis complex and their association with drug resistance. 2nd ed. World Health Organization; 2023. Accessed December 4, 2025. Available at https://www.who.int/publications/i/item/9789240082410

2. Mansoor H, Hirani N, Chavan V, et al. Clinical utility of target-based next-generation sequencing for drug-resistant TB. Int J Tuberc Lung Dis. 2023;27(1):41-48. doi:10.5588/ijtld.22.0138.

3. Jouet A, Gaudin C, Badalato N, et al. Deep amplicon sequencing for culture-free prediction of susceptibility or resistance to 13 anti-tuberculous drugs. Eur Respir J. 2021;57(3):2002338. Published 2021 Mar 18. doi:10.1183/13993003.02338-2020

Performance

Method Description

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Targeted next-generation sequencing is used to detect variants in selected genes of *M tuberculosis* complex.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
7 to 14 days

Specimen Retention Time
1 year

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
87153 - *M tuberculosis* drug resistance, NGS

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
DMTBR	M tuberculosis drug resistance, NGS	94053-6

Result ID	Test Result Name	Result LOINC® Value
TBSS	Isolate from Specimen Source	31208-2
TBDI	Organism Identification	42803-7
623238	inhA	94055-1
623237	rpoB	94065-0

623239	fabG1	94056-9
623240	katG	94054-4
623241	ahpC	94057-7
623242	ethA	72866-7
623243	pncA	94059-3
623244	embB	94058-5
623245	gidB	94061-9
623246	rpsL	94063-5
623247	rrs	94062-7
623248	eis	94064-3
623249	tlyA	In Process
623250	gyrA	94060-1
623251	gyrB	101576-7
623252	rrl	In Process
623253	rplC	In Process
623254	rv0678	In Process
623255	rifampin (RIF) Interpretation	46244-0
623256	isoniazid (INH) Interpretation	In Process
623257	pyrazinamide (PZA) Interpretation	46245-7
623258	ethambutol (EMB) Interpretation	46247-3
623259	streptomycin (SM) Interpretation	In Process
623260	amikacin (AMI) Interpretation	In Process
623261	kanamycin (KAN) Interpretation	In Process
623262	capreomycin (CAP) Interpretation	In Process
623263	fluoroquinolones (FQ) Interpretation	In Process
623264	ethionamide (ETH) Interpretation	72866-7
623265	linezolid (LIN) Interpretation	In Process
623266	bedaquiline (BDQ) Interpretation	In Process
623267	clofazimine (CFZ) Interpretation	In Process
623508	Footnotes	48767-8