MAYO CLINIC LABORATORIES

Test Definition: TB2LN

Susceptibility, Mycobacterium tuberculosis Complex, Second Line, Varies

Overview

Useful For

Determination of *Mycobacterium tuberculosis* complex minimal inhibitory concentrations to second-line antimicrobial agents

Additional Tests

Test Id	Reporting Name	Available Separately	Always Performed
STV2	Susceptibility, Mtb Cx, 2nd Line	No, (Bill Only)	Yes

Testing Algorithm

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

Special Instructions

- Infectious Specimen Shipping Guidelines

Method Name

Minimum Inhibitory Concentration (MIC) by Microtiter Broth Dilution Method

NY State Available

Yes

Specimen

Specimen Type

Varies

Additional Testing Requirements

CTB / Mycobacteria and Nocardia Culture, Varies or CTBID / Culture Referred for Identification, *Mycobacterium* and *Nocardia*, Varies must also be ordered and will be charged separately **unless identification of organism is provided.**

Shipping Instructions

1. See Infectious Specimen Shipping Guidelines in Special Instructions.
2. Place specimen in a large infectious container (T146) and label as an etiologic agent/infectious substance.

Necessary Information

Specimen source and suspected organism identification are required.

Specimen Required

Specimen Type: Organism
Supplies: Infectious Container, Large (T146)
Container/Tube: Middlebrook 7H10 agar slant
Specimen Volume: Isolate
Collection Instructions: Organism must be in pure culture, actively growing.

Reject Due To

Other	Agar plate

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

The Clinical and Laboratory Standards Institute (CLSI) provides a consensus protocol for the methods, antimycobacterial agents, and critical concentrations of each agent to be tested in order to permit standardized interpretation of *Mycobacterium tuberculosis* complex susceptibility testing results. CLSI guidelines suggest that second-line agents should be tested when an isolate of *M tuberculosis* complex is resistant to rifampin, is monoresistant to the critical concentration of isoniazid and the physician intends to use a fluoroquinolone for therapy, or is resistant to any combination of 2 first-line agents.

This test uses a broth microdilution method for susceptibility testing of *M tuberculosis* complex against second-line agents. Agents tested are amikacin, ethionamide, kanamycin, moxifloxacin, ofloxacin, p-aminosalicylic acid, rifabutin, and streptomycin. In contrast to other *M tuberculosis* complex susceptibility methods which test 1 or 2 critical concentrations of a drug, this method examines a range of drug concentrations and produces a minimal inhibitory concentration result.

Reference Values

Results are reported as minimal inhibitory concentration (MIC) values with units of mcg/mL and tentative interpretations of susceptible or resistant are provided.

Interpretation

Results are reported as minimal inhibitory concentrations (MIC) in mcg/mL and tentative interpretations of susceptible or resistant are provided.

Agent	MIC range tested	MIC tentative interpretations (mcg/mL)*

	(mcg/mL)	Susceptible	Resistant
Amikacin	0.12-16	< or =4.0	>4.0
Cycloserine	2-256	< or =32.0	>32.0
Ethionamide	0.3-40	< or =5.0	>5 .0
Kanamycin	0.6-40	< or =5.0	>5.0
Moxifloxacin	0.06-8	< or =2.0	>2.0
Ofloxacin	0.25-32	< or =2.0	>2.0
Para-aminosalicylic acid	0.5-64	< or =2.0	>2.0
Rifabutin	0.12-16	< or =0.5	>0.5
Streptomycin	0.25-32	< or =2.0	>2.0
Isoniazid**	0.03-4	< or =0.12	>0.12
Ethambutol**	0.5-32	< or=42	>48
Rifampin**	0.12-16	< or=1	>1

*Laboratory-derived tentative interpretations based on MIC breakpoints established relative to the indirect agar proportion method; consensus breakpoint interpretations are not available at this time.(1)

**This test is used as an alternative to TB1LN / Antimicrobial Susceptibility, *Mycobacterium tuberculosis* Complex, First Line, Varies when reagents are not available to perform the TB1LN test. These agents are not routinely reported with this test.

Cautions

Consensus guidelines for interpretive criteria using this method are not available at this time. Breakpoints were established by Mayo Clinic by comparison to the critical concentration for each drug and are considered tentative until consensus guidelines are established.

In vitro susceptibility does not guarantee clinical response. Therefore, the decision to treat with a particular agent should not be based solely on the antimicrobial susceptibility testing result.

Drug susceptibility testing should be performed on pure culture isolates of *Mycobacterium tuberculosis* complex.

Clinical Reference

1. Hall L, Jude KP, Clark SL, et al: Evaluation of the Sensititre MycoTB plate for susceptibility testing of the *Mycobacterium tuberculosis* complex against first- and second-line agents. J Clin Microbiol 2012;50:3732-3734

2. Centers for Disease Control and Prevention. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Diseases Society of America. MMWR 2003;52(No. RR-11):1-79

3. Woods GL, Lin S-Y G, Desmond EP: Susceptibility test methods: *Mycobacteria, Nocardia* and other Actinomycetes. In Manual of Clinical Microbiology. 10th edition. Edited by J Versalovic, KC Carroll, G Funke, et al: Washington, DC, ASM Press, 2011, pp 1215-1238

4. CLSI. Performance Standards for Susceptibility Testing of *Mycobacteria*, *Nocardia* species, and Other Aerobic Actinomycetes.First editionCLSI supplement M62. Clinical and Laboratory Standards Institute; 2018

Performance

Method Description

This test utilizes the MycoTB broth microtiter dilution plate (Trek Diagnostic Systems, Inc.). Antimicrobials included in the assay are tested according to the Clinical and Laboratory Standards Institute (CLSI) guidelines. The plate contains lyophilized antimicrobials which are rehydrated prior to testing. A standardized suspension of the *Mycobacterium tuberculosis* isolate is added to the plate wells and the plate is incubated at 36 degrees C in 5% to 10% carbon dioxide for up to 14 days. The first drug-containing well with no visible growth is determined to be the endpoint.(CLSI. Susceptibility Testing of *Mycobacteria*, *Nocardiae*, and Other *Actinomycetes*; Approved Standard. Third edition. CLSI standard M24.CLSI, 2018; Hall L, Jude KP, Clark SL, et al: Evaluation of the Sensititre MycoTB plate for susceptibility testing of the *Mycobacterium tuberculosis* complex against first- and second-line agents. J Clin Microbiol 2012;50:3732-3734; Thermo Scientific Sensititre MIC Susceptibility Plates for *Mycobacterium tuberculosis*. Product Insert. 011 - MYCOTB - CID9502. Revision Date: 09/07/2016)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

21 to 30 days

Specimen Retention Time

1 year

Performing Laboratory Location

Rochester

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. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87186-Susceptibility, Mtb Cx, 2nd Line

Test Definition: TB2LN

Susceptibility, Mycobacterium tuberculosis Complex, Second Line, Varies

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
TB2LN	Susceptibility, Mtb Complex, 2 Line	29579-0

Result ID	Test Result Name	Result LOINC® Value
TB2LN	Susceptibility, Mtb Complex, 2 Line	29579-0