

Antimicrobial Susceptibility, Mycobacterium tuberculosis Complex, First Line, Varies

Overview

Useful For

Rapid, qualitative susceptibility testing of *Mycobacterium tuberculosis* complex isolates growing in pure culture

Affirming the initial choice of chemotherapy for *M tuberculosis* complex infections

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
TB2LN	Susceptibility, Mtb	Yes	No
	Complex, 2 Line		

Additional Tests

Test Id	Reporting Name	Available Separately	Always Performed
STV1	Susceptibility, Mtb	No, (Bill Only)	Yes
	Complex, Broth		
STV2	Susceptibility, Mtb Cx, 2nd	No, (Bill Only)	Yes
	Line		

Testing Algorithm

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

If resistance to a first line antimicrobial agent is detected, reflex testing of second line agents will be performed at an additional charge.

Special Instructions

Infectious Specimen Shipping Guidelines

Method Name

Broth Dilution at Critical Drug Concentrations

NY State Available

Yes

Specimen

Specimen Type Varies



Antimicrobial Susceptibility, Mycobacterium tuberculosis Complex, First Line, Varies

Ordering Guidance

This test includes testing for the drugs isoniazid, rifampin and ethambutol. If testing for pyrazinamide is needed, order TBPZA / Susceptibility, *Mycobacterium tuberculosis* Complex, Pyrazinamide, Varies on the same order number as this test.

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 <u>Infectious Specimen Shipping Guidelines</u> 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.

Forms

If not ordering electronically, complete, print, and send a <u>Microbiology Test Request</u> (T244) with the specimen.

Reject Due To

Other Agar plate

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Primary treatment regimens for *Mycobacterium tuberculosis* complex often include isoniazid, rifampin, ethambutol, and pyrazinamide. Susceptibility testing of each *M tuberculosis* complex isolate against these first-line antimycobacterial agents is a key component of patient management.

In vitro susceptibility testing methods are available to assess the susceptibility of M tuberculosis complex isolates to



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selected antimycobacterial agents. The Clinical Laboratory Standards Institute (CLSI) provides consensus protocols for the methods, antimycobacterial agents, and critical concentrations of each agent to be tested in order to permit standardized interpretation of *M tuberculosis* complex susceptibility testing results. Current recommendations indicate that laboratories should use a rapid broth method in order to obtain *M tuberculosis* susceptibility data as quickly as possible to help guide patient management.

This test uses an FDA-cleared commercial system for rapid broth susceptibility testing of *M* tuberculosis complex and assesses resistance to the antimycobacterial drugs isoniazid, rifampin and ethambutol at the critical concentrations.

Pyrazinamide rapid broth susceptibility testing must be ordered separately (TBPZA / Susceptibility, *Mycobacterium tuberculosis* Complex, Pyrazinamide, Varies).

Reference Values

Results are reported as susceptible or resistant.

Interpretation

Mycobacterium tuberculosis complex isolates are reported as susceptible or resistant to the aforementioned drugs at the critical concentrations.

Some experts believe that patients infected with strains exhibiting resistance to low levels of isoniazid (0.1 mcg/mL) but not exhibiting resistance to high levels (0.4 mcg/mL) may benefit from continuing therapy with this agent. A specialist in the treatment of tuberculosis should be consulted concerning the appropriate therapeutic regimen and dosages.

Cautions

No significant cautionary statements

Clinical Reference

1. Blumberg HM, Burman WJ, Chaisson RE, et al: American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America: treatment of tuberculosis. Am J Respir Crit Care Med 2003;167(4):603-662

2. Inderlied CB, Pfyffer GE: Susceptibility test methods: *Mycobacteria*. <u>In</u> Manual of Clinical Microbiology. Eighth edition. Edited by PR Murray, EJ Baron, JH Jorgensen, et al. ASM Press, 2003, pp 1149-1177

3. LaBombardi VJ: Comparison of the ESP and BACTEC Systems for testing susceptibilities of *Mycobacterium tuberculosis* complex isolates to pyrazinamide. J Clin Microbiol 2002;40:2238-2239

4. CLSI. Susceptibility Testing of *Mycobacteria, Nocardia* species, and Other Aerobic Actinomycetes. Third edition. CLSI standard M24. Clinical and Laboratory Standards Institute; 2018

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

Performance

Method Description

This test method is based on presence or absence of growth of *Mycobacterium tuberculosis* complex in broth cultures



Antimicrobial Susceptibility, Mycobacterium tuberculosis Complex, First Line, Varies

with the presence of critical concentrations of the antimycobacterial drugs isoniazid, rifampin, and ethambutol. One of 2 FDA-cleared platforms (VersaTREK or BD MGIT 960) may be used.

The VersaTrek platform uses the presence or absence of a pressure increase inside broth vials containing *M tuberculosis* complex in the presence of critical concentrations of the antimycobacterial drugs isoniazid, rifampin, and ethambutol. Increasing pressure indicates the presence of actively growing *M tuberculosis* that is resistant to the critical concentration of drug contained in the broth. Low or undetectable pressure increases in the presence of critical drug concentrations suggests a lack of *M tuberculosis* complex growth and susceptibility to the drug at the tested concentration. Antimycobacterial drugs and concentrations tested are: isoniazid (0.1 mcg/mL and 0.4 mcg/mL), rifampin (1 mcg/mL), and ethambutol (5 mcg/mL and 8 mcg/mL).(Package insert: VersaTREK Mycobacteria Detection and Susceptibility Testing system, TREK Diagnostics, 10/2018)

The BACTEC MGIT 960 platform uses the production and measurement of fluorescence within a mycobacterial growth indicator tube (MGIT) in the presence of actively growing *M tuberculosis* complex isolates in the presence of critical concentrations of the antimycobacterial drugs isoniazid, rifampin, and ethambutol. Low or undetectable levels of fluorescence in the presence of critical drug concentrations suggest lack of *M tuberculosis* growth and susceptibility to the drug tested at the tested concentration. Increased fluorescence suggests active growth of *M tuberculosis* and resistance to the drug at the tested concentration. Antimycobacterial drugs and concentrations tested are: isoniazid (0.1 mcg/mL and 0.4 mcg/mL), rifampin (2 mcg/mL), and ethambutol (5 mcg/mL).(Package insert: BACTEC MGIT 960 SIRE Kit, BD Diagnostics, 10/2016)

PDF Report

No

Day(s) Performed Monday through Sunday

Report Available 10 to 21 days

Specimen Retention Time 1 year

Performing Laboratory Location Rochester

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>.



Antimicrobial Susceptibility, Mycobacterium tuberculosis Complex, First Line, Varies

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

87188 x 3-Antimicrobial Susceptibility, Mycobacterium tuberculosis Complex, Broth Method

LOINC[®] Information

Test ID	Test Order Name	Order LOINC [®] Value
TB1LN	Susceptibility, Mtb Complex, 1 Line	29579-0

Result ID	Test Result Name	Result LOINC [®] Value
TB1LN	Susceptibility, Mtb Complex, 1 Line	29579-0