MAYO CLINIC LABORATORIES

Test Definition: TB1LN

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* infections

Confirming the emergence of drug resistance

Guiding the choice of alternate agents for therapy for *M tuberculosis* infections

Reflex Tests

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

Additional Tests

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

Testing Algorithm

When this test is ordered, the additional test will always be performed and charged separately.
If resistance to a first line antimicrobial agent is detected reflex testing for confirmation of resistance and second line agents will be performed and charged.

Special Instructions

- Infectious Specimen Shipping Guidelines

Method Name

Broth Dilution at Critical Drug Concentrations

NY State Available

Yes

Specimen

Specimen Type

Varies

Additional Testing Requirements

CTB / Mycobacteria and *Nocardia* Culture or CTBID / Culture Referred for Identification, *Mycobacterium* and *Nocardia* 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.

Forms

If not ordering electronically, complete, print, and send a Microbiology Test Request (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 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 *Mm 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. Resistance, as determined by rapid testing, must be confirmed by another method or by another laboratory.

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

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

For resistant organisms, confirmatory testing is automatically performed by minimum inhibitory concentration for isoniazid, rifampin, and ethambutol.

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. CLSI: Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard. CLSI document M24-A (ISBN 1-56238-550-3). CLSI, Wayne, PA, 2003
3. Inderlied CB, Pfyffer GE: Susceptibility test methods: *Mycobacteria*. In Manual of Clinical Microbiology. Eighth edition. Edited by PR Murray, EJ Baron, JH Jorgensen, et al. Washington, DC, ASM Press, 2003, pp 1149-1177
4. 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

Performance

Method Description

This test method is based on presence or absence of growth of *Mycobacterium tuberculosis* in broth cultures with the presence of critical concentrations of the antimycobacterial drugs isoniazid, rifampin, and ethambutol. One of 2 FDA-cleared platforms may be used.

The VersaTrek platform uses the presence or absence of a pressure increase inside broth vials containing *M tuberculosis*

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* 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, Cleveland, OH 2014)

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 suggests 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, Sparks, MD 2016)

A separate test (TBPZA) is available for testing of the other first-line agent pyrazinamide.

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 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 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
87186-Susceptibility, Mtb Cx, 2nd Line (if appropriate)

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