

Overview

Useful For

Rapid identification to the species level and susceptibility testing for *Mycobacterium* species, *Nocardia* species, and other aerobic actinomycete genera and species from pure culture isolates

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
RMALM	Id MALDI-TOF Mass Spec AFB	No, (Bill Only)	No
RTBSP	Id, Mtb Speciation, PCR	No, (Bill Only)	No
TBMP	Mycobacteria Probe Ident	No, (Bill Only)	No
TBPB	Mycobacteria Probe Ident Broth	No, (Bill Only)	No
ISMY	ID by 16S Sequencing	No, (Bill Only)	No
SRG	Susceptibility Rapid Grower	No, (Bill Only)	No
RSLG	Susceptibility Slow Grower	No, (Bill Only)	No
SSNS	Susceptibility Nocardia species	No, (Bill Only)	No
STV1	Susceptibility, Mtb Complex, Broth	No, (Bill Only)	No
STV2	Susceptibility, Mtb Cx, 2nd Line	No, (Bill Only)	No
STVP	Susceptibility, Mtb Complex, PZA	No, (Bill Only)	No
MTBVP	Mtb PZA Confirmation, pnc A Sequence	No, (Bill Only)	No
MIC	Sensitivity, MIC	No, (Bill Only)	No

Testing Algorithm

When this test is ordered, the reflex antimicrobial susceptibility test will be performed at an additional charge. All mycobacteria and *Nocardia* (including aerobic actinomycetes) submitted will be identified and billed as appropriate.

Nucleic acid probes used for identification, when applicable, include those for *Mycobacterium avium*-intracellulare complex, *M. goodii*, and *M. tuberculosis* complex. Matrix-assisted laser desorption ionization time-of-flight mass spectrometry (MALDI TOF MS) and/or 16S rDNA sequencing is used for identification, when applicable, for slowly and rapidly growing *Mycobacterium* species and aerobic actinomycetes (including *Nocardia* species and *Streptomyces* species). The *M. tuberculosis* complex can be further identified to the species level upon request, using a separate rapid PCR test. Minimum inhibitory concentration (MIC) determination by either the microtiter broth dilution method or critical concentration testing by broth dilution will be automatically performed as appropriate after species identification.

See [Culture Referred for Identification and Susceptibility for *Mycobacterium* and *Nocardia* Algorithm](#) in Special

Instructions.

Special Instructions

- [Infectious Specimen Shipping Guidelines](#)
- [Culture Referred for Identification and Susceptibility for Mycobacterium and Nocardia](#)

Method Name

Nucleic Acid Probe/16S rDNA Sequencing/Matrix-Assisted Laser Desorption Ionization Time-of-Flight Mass Spectrometry (MALDI TOF MS) /Rapid Polymerase Chain Reaction (PCR)

NY State Available

Yes

Specimen

Specimen Type

Varies

Shipping Instructions

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

Necessary Information

1. Specimen source is required.
2. Isolate description is required: Gram stain reaction, morphology, tests performed.

Specimen Required

Specimen Type: Organism in pure culture

Supplies: Infectious Container, Large (T146)

Container/Tube: Middlebrook (7H10 or 7H11) or Lowenstein-Jensen medium slant or in broth (eg, Mycobacteria Growth Indicator Tube [7H9] broth)

Specimen Volume: Isolate

Collection Instructions: Organism must be in pure culture, actively growing. **Do not submit mixed cultures.**

Forms

If not ordering electronically, complete, print, and send a [Microbiology Test Request](#) (T244) with the specimen.

Reject Due To

Other	Agar plate
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Specimen Stability Information

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

Clinical and Interpretive

Clinical Information

There are nearly 200 recognized species of mycobacteria and more than 100 *Nocardia* species. Many are human pathogens and, therefore, identification to the species level is important to help guide patient care. In addition, there are other aerobic actinomycete genera that can be human pathogens including, but not limited to, *Tsukamurella*, *Rhodococcus*, and *Gordonia* species.

Nucleic acid hybridization probes are utilized that identify specific ribosomal RNA sequences of *Mycobacterium tuberculosis* complex, *M avium* complex, and *M gordonae*. Other *Mycobacteria* species, *Nocardia* species, and other aerobic actinomycete genera are identified using matrix-assisted laser desorption ionization time-of-flight mass spectrometry (MALDI TOF MS) or nucleic acid sequencing of a 500-base pair region of the 16S ribosomal RNA gene.

After identification, antimicrobial susceptibility testing is performed following Clinical and Laboratory Standards Institute (CLSI) M24 guidelines using either broth dilution or critical concentration methods as appropriate for the species.

Reference Values

Not applicable

Interpretation

Organisms growing in pure culture are identified to the species level whenever possible.

Cautions

If the organism is received in mixed culture or contaminated, the report may be delayed or identification may not be possible.

Clinical Reference

1. Pfyffer GE: *Mycobacterium*: general characteristics; laboratory detection, and staining procedures. In Manual of Clinical Microbiology. 11th edition, Vol 1. Edited by JH Jorgensen, MA Pfaller. Washington DC, ASM Press. 2015, pp 536-569
2. Clinical and Laboratory Standards Institute: Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard. Second edition. CLSI document M24-A2 (ISBN 1-56238-746-4), Clinical and Laboratory Standards Institute, 950 West Valley road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011

Performance

Method Description

The Gen-Probe AccuProbe system uses an acridinium-labeled, single-stranded DNA probe that is complementary to the ribosomal RNA of the target organism. After the ribosomal RNA is released from the organism, the labeled DNA probe combines with the target organism's ribosomal RNA to form a stable DNA:RNA hybrid. Chemiluminescence is

used as an indicator to detect specific hybrids.(Musial CE, Tice LS, Stockman L, Roberts GE: Identification of *Mycobacterium* from culture by using Gen-Probe rapid diagnosis system for *M avium* complex and *M tuberculosis* complex. J Clin Microbiol 1988;26:2120-2123)

The DNA sequence analysis utilizes a 500-base pair region of the 16S rRNA gene as the target for identification of mycobacteria and is performed using the MicroSeq kit from Applied Biosystems. Sequence data generated is compared to several different databases of known mycobacterial and aerobic actinomycete sequences to obtain organism identification. These include MicroSeq, NCBI GenBank, and Mayo Clinic Mycobacteria database. A 100% or greater agreement with a database strain is needed for an acceptable identification to the species level.(Hall L, Doerr KA, Wohlfiel SL, Roberts GD: Evaluation of the MicroSeq system for identification of mycobacteria by 16S ribosomal DNA sequencing and its integration into a routine clinical mycobacteriology laboratory. J Clin Microbiol 2003;41[4]:1447-1453)

Matrix-assisted laser desorption ionization time-of-flight mass spectrometry (MALDI TOF MS) Å analysis is done using the Bruker BioTyper platform and the Bruker BDAL library, Bruker Mycobacterial Library, and the Mayo Clinic Library. A spectral score of 2.0 or greater is required for identification to the species level.

The method employed in this assay is broth microtiter dilution using a commercially available plate from Trek Diagnostics, Inc. Antimicrobials included in the assay are tested according to the Clinical and Laboratory Standards Institute (CLSI) guidelines.(CLSI. Susceptibility Testing of *Mycobacteria*, *Nocardiae*, and Other *Actinomycetes*; Approved Standard. CLSI document M24-A2. CLSI, Wayne, PA, 2011; Woods GL, Lin SYG, Desmond EP: Susceptibility test methods: *Mycobacteria*, *Nocardia*, and Other Actinomycetes. In Manual of Clinical Microbiology. Vol 1. 11th edition. Edited by JH Jorgensen, MA Pfaller, KC Carroll, et al. Washington, DC, ASM Press, 2015, pp 1356-1378)

M tuberculosis first line susceptibilities are tested with the presence of critical concentrations of the antimycobacterial drugs isoniazid, rifampin, and ethambutol. One of 2 FDA-cleared platforms may be used. Second-line susceptibilities utilizes the MycoTB broth microtiter dilution plate (Trek Diagnostic Systems Inc, Cleveland, OH). 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 *M tuberculosis* isolate is added to the plate wells and the plate is incubated at 36 degrees C in 5% to 10% CO2 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. CLSI document M24-A2. CLSI, Wayne, PA, 2011; 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)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

60 to 70 days

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. 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 U.S. Food and Drug Administration.

CPT Code Information

Culture Referred for Identification, *Mycobacterium*

87118-Identificaiton of mycobacteria

87158-Identification of mycobacteria by other methods (if appropriate)

87118 -Id MALDI-TOF Mass Spec AFB (if appropriate)

87153-Mycobacteria Identification by Sequencing (if appropriate)

87150-Mycobacteria Probe Ident, Solid (if appropriate)

87150-Mycobacteria Probe Ident, Broth (if appropriate)

87150-Id, Mtb Speciation, PCR (if appropriate)

87186-Susceptibility Rapid Grower (if appropriate)

87186-Susceptibility Slow Grower (if appropriate)

87186-Susceptibility Nocardia species (if appropriate)

87188 x 3-Antimicrobial Susceptibility, Mycobacterium tuberculosis Complex, Broth Method (if appropriate)

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

87188-Susceptibility, Mycobacterium tuberculosis Complex, Pyrazinamide (if appropriate)

87153-Mtb PZA Confirmation, pncA Sequencing (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
TBIDS	Mycobacteria Culture Refer ID+Susc	543-9

Result ID	Test Result Name	Result LOINC Value
TBIDS	Mycobacteria Culture Refer ID+Susc	543-9