Overview

Useful For

Detection of aerobic bacterial pathogens in specimens from patients with cystic fibrosis

Determining the in vitro antimicrobial susceptibility of potentially pathogenic aerobic bacteria, if appropriate

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
COMM	Identification Commercial Kit	No, (Bill Only)	No
RMALD	Ident by MALDI-TOF mass spec	No, (Bill Only)	No
GID	Bacteria Identification	No, (Bill Only)	No
ISAE	Aerobe Ident by Sequencing	No, (Bill Only)	No
REFID	Additional Identification Procedure	No, (Bill Only)	No
SALS	Serologic Agglut Method 1 Ident	No, (Bill Only)	No
EC	Serologic Agglut Method 2 Ident	No, (Bill Only)	No
SHIG	Serologic Agglut Method 3 Ident	No, (Bill Only)	No
STAP	Identification Staphylococcus	No, (Bill Only)	No
STRP	Identification Streptococcus	No, (Bill Only)	No
BLA	Beta Lactamase	No, (Bill Only)	No
MIC	Sensitivity, MIC	No, (Bill Only)	No
SUS	Susceptibility	No, (Bill Only)	No
SIDC	Ident Serologic Agglut Method 4	No, (Bill Only)	No
PCRID	Identification by PCR	No, (Bill Only)	No
MARP1	mecA PCR (Bill Only)	No, (Bill Only)	No

Testing Algorithm

When this test is ordered, the reflex tests may be performed at an additional charge. Antimicrobial agent appropriate to the organism and specimen source will be tested according to Mayo Clinic's practice.

The following tables provide a listing of the antimicrobials routinely tested in the laboratory as well as antimicrobials

that may be tested upon request. These tables are organized by isolate groups and are not all inclusive. Call 800-533-1710 and ask to speak to the Bacteriology Antimicrobial Susceptibility Testing Laboratory if the organism or antimicrobial of interest are not listed in these tables.

â€¢	Aerobic Gram-Negative Bacilli Antimicrobials
â€¢	Additional Gram-Negative Bacteria Antimicrobials
â€¢	Staphylococcus, Enterococcus, Bacillus, and Related Genera Antimicrobials
â€¢	Additional Gram-Positive Bacteria Antimicrobials

Special Instructions

- Aerobic Gram-Negative Bacilli Antimicrobials
- Additional Gram-Negative Bacteria Antimicrobials
- Staphylococcus, Enterococcus, Bacillus, and Related Genera Antimicrobials
- Additional Gram-Positive Bacteria Antimicrobials

Method Name

Conventional Culture Technique with Minimum Inhibitory Concentration (MIC) by Agar Dilution (if appropriate)

NY State Available

Yes

Specimen

Specimen Type

Varies

Shipping Instructions

Specimen must be received in laboratory within 48 hours of collection.

For shipping information see Infectious Specimen Shipping Guidelines in Special Instructions.

Necessary Information

Specimen source is required.

Specimen Required

Submit only 1 of the following specimens:

Preferred:

Specimen Type: Sputum, expectorated or induced

Container/Tube: Sterile container

Specimen Volume: Entire collection

Acceptable:

Specimen Type: Bronchial aspirate or washing, bronchoalveolar lavage, endotracheal, or tracheal

Container/Tube: Sterile container

Specimen Volume: Entire collection

Specimen Type: Throat swab

Supplies:

Culturette (BBL Culture Swab) (T092)

BD E-Swab (T853)

Container/Tube: Culture transport swab (Dacron or rayon swab with aluminum or plastic shaft with either Stuart or Amies liquid medium)

Specimen Volume: Entire collection

Forms

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

Specimen Minimum Volume

2 mL

Reject Due To

Dry swab	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated	48 hours	

Clinical and Interpretive

Clinical Information

Life expectancy of patients with cystic fibrosis (CF) has increased steadily over the past 50 years, in large part due to improvements in the management of lung disease in this patient population. Still, chronic lung infection is responsible for 75% to 85% of deaths in patients with CF. Appropriate treatment for the causative organism can reduce morbidity and mortality.

The number of microbial species associated with CF lung disease is relatively limited. These include *Pseudomonas aeruginosa* (mucoid and nonmucoid), *Staphylococcus aureus*, *Burkholderia cepacia* complex, *Stenotrophomonas maltophilia*, other non-fermenting Gram-negative rods, *Haemophilus influenzae,* and *Streptococcus pneumoniae*. Nontuberculous mycobacteria and *Aspergillus* species may also play a role in CF lung disease, in addition to common respiratory viruses. This culture is specifically designed and utilizes conventional and additional selective media (compared to non-CF respiratory cultures) to isolate bacteria commonly associated with pulmonary disease in

patients with CF.

In selected centers, lung transplantation is performed on patients with CF. This test is appropriate for lung transplant patients with underlying CF because they can continue to harbor the same types of organisms as they did prior to transplantation. Patients with CF may be colonized or chronically infected by these organisms over a long period of time.

Antimicrobial susceptibility testing determines the minimal inhibitory concentration (MIC) value of selected antimicrobial agents against isolated potentially pathogenic bacteria. The MIC is the lowest antimicrobial concentration (of a series of increasing concentrations) that inhibits growth of the bacterium. Agar dilution MIC testing is performed by testing for growth of bacteria on agar plates containing varying concentrations of antimicrobial agents.

For each organism-antimicrobial agent combination, the Clinical and Laboratory Standards Institute provides interpretive criteria for determining whether the MIC should be interpreted as susceptible, susceptible-dose dependent, intermediate, nonsusceptible, resistant, or epidemiological cutoff value (ECV).

Reference Values

No growth or usual flora

Identification of probable pathogens:

Results are reported as minimal inhibitory concentration (MIC) in mcg/mL. Breakpoints (also known as "clinical breakpoints") are used to categorize an organism as susceptible, susceptible-dose dependent, intermediate, resistant, nonsusceptible, or epidemiological cutoff value according to the Clinical and Laboratory Standards Institute (CLSI) guidelines.

In some instances an interpretive category cannot be provided based on available data and the following comment will be included: "There are no established interpretive guidelines for agents reported without interpretations."

Susceptible (S):

A category defined by a breakpoint that implies that isolates with an MIC at or below or a zone diameter at or above the susceptible breakpoint are inhibited by the usually achievable concentrations of antimicrobial agent when the dosage recommended to treat the site of infection is used, resulting in likely clinical efficacy.

Susceptible-Dose Dependent (SDD):

A category defined by a breakpoint that implies that susceptibility of an isolate depends on the dosing regimen that is used in the patient. In order to achieve levels that are likely to be clinically effective against isolates for which the susceptibility testing results (either MICs or zone diameters) are in the SDD category, it is necessary to use a dosing regimen (ie, higher doses, more frequent doses, or both) that results in higher drug exposure than that achieved with the dose that was used to establish the susceptible breakpoint. Consideration should be given to the maximum approved literature-supported dosage regimen, because higher exposure gives the highest probability of adequate coverage of a SDD isolate. The drug label should be consulted for recommended doses and adjustment for organ function.

Intermediate (I):

A category defined by a breakpoint that includes isolates with MICs or zone diameters within the intermediate range that approach usually attainable blood and tissue levels and for which response rates may be lower than for susceptible isolates.

Note: The intermediate category implies clinical efficacy in body sites where the drugs are physiologically concentrated or when a higher than normal dosage of a drug can be used. This category also includes a buffer zone, which should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations, especially for drugs with narrow pharmacotoxicity margins.

Resistant (R):

A category defined by a breakpoint that implies that isolates with an MIC at or above the resistant breakpoint are not inhibited by the usually achievable concentrations of the agent with normal dosage schedules and that demonstrate MICs that fall in the range in which specific microbial resistance mechanisms are likely, and clinical efficacy of the agent against the isolate has not been reliably shown in treatment studies.

Nonsusceptible (NS):

A category used for isolates for which only a susceptible breakpoint is designated because of the absence or rare occurrence of resistant strains. Isolates for which the antimicrobial agent MICs are above or the zone diameters are below the value indicated for the susceptible breakpoint should be reported as nonsusceptible.

Note: An isolate that is interpreted as nonsusceptible does not necessarily mean that the isolate has a resistance mechanism. It is possible that isolates with MICs above the susceptible breakpoint that lack resistance mechanisms may be encountered within the wild-type distribution subsequent to the time the susceptible-only breakpoint was set.

Epidemiological Cutoff Value (ECV):

The minimal inhibitory concentration (MIC) that separates microbial populations into those with and without phenotypically detectable resistance (non-wild-type or wild-type, respectively). The ECV defines the highest MIC for the wild type population of isolates. ECVs are based on in vitro data only, using MIC distributions. ECVs are **not** clinical breakpoints, and the clinical relevance of ECVs for a particular patient has not yet been identified or approved by CLSI or any regulatory agency.

When an ECV is reported, the following comment will be included: "This MIC is consistent with the Epidemiological Cutoff Value (ECV) observed in isolates (WITH / WITHOUT) acquired resistance; however, correlation with treatment outcome is unknown."

(Clinical and Laboratory Standards Institute: Performance Standards for Antimicrobial Susceptibility Testing. 30th ed. CLSI supplement M100. Clinical and Laboratory Standards Institute; 2020)

Interpretation

A negative test result is no growth of bacteria or growth of only usual flora. A negative result does not rule out all causes of infectious lung disease (see Cautions).

Organisms associated with lower respiratory tract infections are reported.

For positive test results, pathogenic bacteria are identified. Patients with cystic fibrosis (CF) may be colonized or chronically infected by some organisms over a long period of time, therefore, positive results must be interpreted in conjunction with previous findings and the clinical picture to appropriately evaluate results.

A susceptible category result and a low minimum inhibitory concentration value indicate in vitro susceptibility of the organism to the antimicrobial tested.

For interpretation of various antimicrobial susceptibility interpretive categories (ie, susceptible, susceptible-dose dependent, intermediate, nonsusceptible, resistant, or Epidemiological Cutoff Value: ECV), see Reference Values

section.

Cautions

When culture of sputum is delayed, successful isolation of bacterial pathogens is less likely, due to the overgrowth of usual oropharyngeal flora.

Some bacterial agents that cause lower respiratory infections (eg, mycobacteria, *Legionella* species, *Mycoplasma pneumoniae*) are not detected by this assay and require special procedures. If the bacterial culture is negative, clinicians should consider additional testing to detect other bacterial, viral, or fungal agents.

Results must be interpreted in conjunction with clinical findings and previous culture results.

When antimicrobial susceptibilities are performed, in vitro antimicrobial 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.

Clinical Reference

1. Miller JM, Binnicker MJ, Campbell S, et al: A guide to utilization of the microbiology laboratory for diagnosis of infectious diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. Clin Infect Dis. 2018 Aug 31;67(6):e1-e94. doi: 10.1093/cid/ciy381

2. York MK, Gilligan P, Alby K: Lower respiratory tract cultures. In: Leber AL, ed. Clinical Microbiology Procedures Handbook, Vol 1, 4th ed. ASM Press; 2016:section 3.11.2

3. LiPuma JJ, Currie BJ, Peacock SJ, VanDamme PAR: Burkholderia, Stenotrophomonas, Ralstonia, Cupriavidus, Pandoraea, Brevundimonas, Comamonas, Delftia, and Acidovorax. In: Carroll KC, Pfaller MC, eds. Manual of Clinical Microbiology. 12th ed. ASM Press; 2019:807-828

4. Clinical and Laboratory Standards Institute: Performance Standards for Antimicrobial Susceptibility Testing. 30th ed. CLSI supplement M100. CLSI; 2020: 3-5 and 254

Performance

Method Description

Standard media (5% sheep blood, chocolate, and eosin methylene blue: [EMB] agar plates) used for respiratory cultures are inoculated. In addition, 2 selective agar plates are utilized to enable isolation of slower growing pathogens that may be easily overgrown by usual flora and the longstanding colonization by *Pseudomonas aeruginosa*. *Burkholderia cepacia* Selective Agar plate is used for the isolation of *B cepacia* complex, which includes 20 distinct species. Isolates of *B cepacia* will be forwarded to the University of Michigan's CFF Research Testing and Repository for genotyping. There is no additional charge for this shipping/testing. A chromogenic *Staphylococcus aureus* agar is used to enhance the isolation of *S aureus*. Finally, a second chocolate blood agar plate is incubated in an anaerobic atmosphere. The anaerobic atmosphere allows for detection of *Haemophilus* species that may otherwise be overgrown by *P aeruginosa*. Pathogens or possible pathogens are identified using 1 or a combination of the following techniques: commercial identification strips or panels, matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry, conventional biochemical tests, carbon source utilization, real-time polymerase chain reaction (PCR), and nucleic acid sequencing of the 16S ribosomal RNA (rRNA) gene.(Gilligan P, Alby K, York MK: Respiratory cultures from cystic fibrosis patients. In: Leber AL, ed. Clinical Microbiology Procedures Handbook, Vol 1, 4th ed. ASM Press; 2016:section 3.11.3)

When antimicrobial susceptibility testing is performed, an agar dilution method is used for routine testing. The antimicrobial is added to agar in various concentrations depending upon levels attainable in serum, urine, or both. A

standardized suspension of the organism is applied to the agar plates, which are incubated for 16 to 18 hours at 35 degrees C. Complete inhibition of all but 1 colony or a very fine residual haze represents the end-point.(Clinical and Laboratory Standards Institute: Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically. 11th ed. CLSI standard M07; 2018)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Sunday

Analytic Time

5 days

Maximum Laboratory Time

12 days

Specimen Retention Time

1 day

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 has been cleared, approved or is exempt by the U.S. 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

87070-Bacteria, culture, cystic fibrosis, respiratory

87186-Antimicrobial Susceptibility, Aerobic Bacteria, MIC-per organism for routine battery (if appropriate)

87181-Susceptibility per drug and per organism for drugs not in routine battery (if appropriate)

87077-Identification commercial kit (if appropriate)

87077-Ident by MALDI-TOF mass spec (if appropriate)

87077-Bacteria Identification (if appropriate)

87077-Additional Identification procedure (if appropriate)

87077-Identification Staphylococcus (if appropriate)

87077-Identification Streptococcus (if appropriate)

87147 x 1-3-Serologic agglut method 1 ident (if appropriate)

87147-Serologic agglut method 2 ident (if appropriate)

87147 x 4-Serologic agglut method 3 ident (if appropriate)

87147 x 2-6-Serologic Agglut Method 4 Ident (if appropriate)

87153-Aerobe Ident by Sequencing (if appropriate)

87185-Beta lactamase (if appropriate)

87150-Identification by PCR (if appropriate)

87150-mecA PCR (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CFRCS	Bacterial Culture,Cystic Fib +Susc	44798-7

Result ID	Test Result Name	Result LOINC Value
CFRCS	Bacterial Culture,Cystic Fib +Susc	44798-7