Test Definition: ESBLS

Extended-Spectrum Beta-Lactamase-Producing Gram-Negative Bacteria Surveillance Culture, Feces

Overview

Useful For

Screening for colonization of extended-spectrum beta-lactamase (ESBL)-producing organisms in stool

Screening fecal microbiota transplant donor feces for ESBL-producing organisms.

This test is **not intended for** medicolegal use.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
RMALD	Ident by MALDI-TOF mass spec	No, (Bill Only)	No
CHESB	ESBL SUS Test Charge	No, (Bill Only)	No

Testing Algorithm

When this test is ordered, the reflex tests may be performed at an additional charge. All bacterial isolates tested, to rule in or out as a potential extended-spectrum beta-lactamase (ESBL)-producing pathogen, will be billed for work performed and resources consumed. The following Enterobacterales will be tested for ESBL production: *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca,* and *Proteus mirabilis.*

Highlights

This test screens fecal microbiota transplant donor stool for extended-spectrum beta-lactamase-producing organisms.

Method Name

Conventional Culture Technique

NY State Available

Yes

Specimen

Specimen Type

Fecal

Shipping Instructions

Specimen must arrive within 96 hours of collection.

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Specimen Required

Patient Preparation: Do not use barium or bismuth before specimen collection.
Supplies: Culture and Sensitivity Stool Transport Vial (T058)
Specimen Type: Preserved feces
Container/Tube: Cary-Blair or modified Cary-Blair transport system is required.
Commercially available transport system specific for recovery of enteric pathogens from fecal specimens (15 mL of nonnutritive transport medium containing phenol red as a pH indicator. Submit sample in original Cary Blair medium container (not an aliquot of Cary Blair medium).
Specimen Volume: Representative portion of feces; 1 gram or 5 mL
Collection Instructions:
1. Collect fresh fecal specimen and place 1 gram or 5 mL in container with transport medium.
2. Place feces in preservative within 2 hours of collection.
3. Place vial in a sealed plastic bag.

Forms

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

Specimen Minimum Volume

See Specimen Required

Reject Due To

Products containing formalin SAF fixative PVA fixative EcoFix preservative Endoscopy specimen Processed stool	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fecal	Ambient (preferred)	4 days	
	Refrigerated	4 days	

Clinical & Interpretive

Clinical Information

In June 2019, the US Food and Drug Administration recommended stool testing of fecal microbiota transplant (FMT) donors to assess for the presence of certain infectious agents.(1) FMT donor feces should be screened for extended-spectrum beta-lactamase (ESBL)-producing organisms. ESBLs are enzymes that confer variable resistance to third- and fourth-generation cephalosporins as well as aztreonam. Because these resistance genes are encoded on plasmids, which are easily transmissible, ESBL-producing organisms raise important infection control issues.

FMT donor feces may be screened on a regularly scheduled basis for ESBL-producers. Screening will be performed via culture of stool samples using vancomycin, amphotericin B, ceftazidime, and clindamycin (VACC) agar. Remel VACC agar is a primary selective medium for the isolation of ESBL-producing Enterobacterales. In addition to multiple substrates necessary for bacterial growth, this medium also contains multiple antimicrobials which inhibit normal intestinal microbiota. Possible ESBL-producers isolated on VACC agar will be confirmed by the Clinical and Laboratory Standards Institute ESBL disk diffusion test.(2)

Reference Values

Negative for extended-spectrum beta-lactamase-producing organisms

Positive for extended-spectrum beta-lactamase-producing organisms

Interpretation

Exclusion of feces from use in fecal microbiota transplantation is recommended if extended-spectrum beta-lactamase -producing bacteria are detected. Refer to US Food and Drug Administration guidance for details.(3)

Cautions

Not all extended-spectrum beta-lactamase-producing organisms may be detected by this method.

Supportive Data

Thiry-two gram-negative bacilli (22 confirmed extended-spectrum beta-lactamase [ESBL]-producing isolates and 10 non ESBL-producing isolates with resistance to either ceftriaxone or ceftazidime) were evaluated. Recovery of ESBL-producing isolates with vancomycin, amphotericin B, ceftazidime, and clindamycin (VACC) media was 100%. Of the non ESBL-producing isolates, 70% (7/10) were inhibited while 30% grew on VACC but tested negative with ESBL confirmatory disk testing. This finding aligns with the package insert information for VACC media.

Clinical Reference

1. Food and Drug Administration (FDA) Safety and Availability (Biologics) Communication. Information Pertaining to Additional Safety Protections Regarding Use of Fecal Microbiota for Transplantation - Screening and Testing of Stool Donors for Multi-drug Resistant Organisms. FDA; June 18, 2019. Accessed November 17, 2023. Available at www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/information-pertaining-additional-safety-protections-regarding-use-fecal-microbiota-transplantation
2. Clinical and Laboratory Standards Institute [CLSI]. Performance Standards for Antimicrobial Susceptibility Testing. 31st ed. CLSI supplement M100. CLSI; 2021.
3. Food and Drug Administration (FDA) Safety and Availability (Biologics) Communication. Important Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Risk of Serious Adverse Reactions Due to Transmission of Multi-Drug Resistant Organisms. FDA; June 13, 2019. Updated December 04, 2020. Accessed November 17, 2023.

Available at www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-safety-alert-regarding-use-fecal-microbiota-transplantation-and-risk-serious-adverse

Performance

Method Description

Remel vancomycin, amphotericin B, ceftazidime, and clindamycin (VACC) primary selective media is used to isolate extended-spectrum beta-lactamase (ESBL)-producing Enterobacterales from stool. This media contains antimicrobials which inhibit normal intestinal microbiota. Colonial morphologies consistent with Gram-negative bacilli are screened with oxidase reagent and matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) is utilized to identify oxidase negative gram-negative bacilli. ESBL confirmatory disk testing is performed on any isolate identified as *Escherichia coli*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, or *Proteus mirabilis.* Confirmatory disk diffusion testing is performed using cefotaxime and ceftazidime with and without the addition of clavulanic acid. ESBLs show an increased zone of inhibition in the presence of clavulanate.(Clinical and Laboratory Standards Institute [CLSI]. Performance Standards for Antimicrobial Susceptibility Testing. 31st ed. CLSI supplement M100.CLSI; 2021)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

4 to 6 days

Specimen Retention Time

7 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

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

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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

87081-ESBL GNB surveillance culture
87077-Ident by MALDI-TOF mass spec (if appropriate)
87184-ESBL SUS test charge (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
ESBLS	ESBL GNB Surveillance Culture, F	102121-1

Result ID	Test Result Name	Result LOINC® Value
ESBLS	ESBL GNB Surveillance Culture, F	102121-1