Test Definition: CDIFS

Clostridioides difficile Culture with Antimicrobial Susceptibilities, Varies

Reporting Title: C. difficile Culture + Susc
Performing Location: Rochester

Ordering Guidance:

Culture is not the preferred diagnostic test for Clostridioides difficile. For routine diagnostic testing, order CDPCR / Clostridioides difficile Toxin, PCR, Feces

Necessary Information:

Specimen source is required.

Specimen Requirements:

Submit only 1 of the following specimens:

Patient Preparation: Patient should not use antacids, barium, bismuth, antidiarrheal medication, zinc oxide paste, Vagisil cream or oily laxatives prior to specimen collection.

Preferred:
Specimen Type: Preserved feces
Supplies: Culture and Sensitivity Stool Transport Vial (T058); Stool Collection Kit, Random (T635)
Container/Tube: Commercially available transport system specific for recovery of enteric pathogens from fecal specimens (15 mL of non-nutritive transport medium containing phenol red as a pH indicator, either Cary-Blair or Para-Pak C and S [T058])
Specimen Volume: Representative portion of feces; 5 mL
Collection Instructions:
1. Collect 1 gram or 5 mL fresh fecal specimen and submit in container with transport medium.
2. Place feces in preservative within 2 hours of collection.
Additional Information: Only diarrheal (ie., unformed) feces should be tested. Testing formed feces for C difficile is not clinically indicated.
Specimen Stability Information: Ambient (preferred) 96 hours/Refrigerated 96 hours/Frozen 7 days

Acceptable:
Specimen Type: Unpreserved feces
Supplies: Stool container, Small (Random), 4 oz (T288); Stool Collection Kit, Random (T635)
Specimen Volume: Representative portion of stool
Collection Instructions: Collect fresh stool and submit representative sample in stool container.
Specimen Stability Information: Ambient (preferred) 72 hours/Frozen 7 days
Additional Information: Only diarrheal (i.e., unformed) stool should be tested. Testing formed stool for C difficile is not clinically indicated.
Specimen Stability Information: Ambient (preferred) 72 hours/Frozen 7 days

Specimen Type: Fresh tissue or biopsy
Sources: Colon
Supplies: Anaerobe Transport Tube (T588)
Specimen Volume: Entire collection, 1-2 cm(3)
Collection Instructions: Aseptically collect a 1-2 cm(3) piece of tissue whenever possible. In general, a larger piece of

tissue is preferred. Submit in an anaerobic transport tube.
Specimen Stability Information: Ambient 72 hours

Specimen Minimum Volume:

Stool: 1 gram or 5 mL
Tissue: 5 mm(3)

Specimen Type	Temperature	Time	Special Container
Varies	Varies		

Ask at Order Entry (AOE) Questions:

Test ID	Question ID	Description	Type	Reportable
CDIFS	Q00M0077	Specimen Source	Plain Text	No

Result Codes:

Result ID	Reporting Name	Type	Unit	LOINC®
CDIFS	C. difficile Culture + Susc	Alphanumeric		563-7

LOINC and CPT codes are provided by the performing laboratory.

Supplemental Report:

No

CPT Code Information:

87081-C. difficile Culture
87076-Anaerobe Ident (if appropriate)
87076-Id MALDI-TOF Mass Spec Anaerobe (if appropriate)
87153-Anaerobe Ident by Sequencing (if appropriate)
87181-Anaerobe Susceptibility per agent (if appropriate)
87181 x 3-Antimicrobial Susceptibility, Anaerobic Bacteria, MIC (if appropriate)

Reflex Tests:

Test ID	Reporting Name	CPT Units	CPT Code	Always Performed	Orderable Separately
ANAID	Anaerobe Ident			No	No (Bill Only)
RMALA	Id MALDI-TOF Mass Spec Anaerobe			No	No (Bill Only)
ISAN	Anaerobe Ident by Sequencing			No	No (Bill Only)
SANA	Anaerobe Suscep per agent			No	No (Bill Only)
BATTA	Anaerobe Suscep Battery			No	No (Bill Only)

Reference Values:

No growth of Clostridioides difficile.
Susceptibility 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, intermediate, or resistant according to the Clinical and Laboratory Standards Institute (CLSI) guidelines.(3)

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 susceptibility of an isolate depends on the dosing regimen that is used in the patient. 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 susceptible-dose dependent (SDD) category, it is necessary to use a dosing regimen (ie, higher doses, more frequent doses, or both, or extended infusion) 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, literature-supported dosage regimen, because higher exposure gives the highest probability of adequate coverage of an 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/or for which response rates may be lower than for susceptible isolates.
Note: The intermediate category also includes a buffer zone for inherent variability in test methods, 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 or a zone diameter at or below the resistant breakpoint are not inhibited by the usually achievable concentrations of the agent with normal dosage

schedules and/or that demonstrate MICs or zone diameters 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.

Epidemiological Cutoff Value (ECV):
The 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 or without] acquired resistance; however, correlation with treatment outcome is unknown."(CLSI: Performance Standards for Antimicrobial Susceptibility Testing. 32nd. CLSI Supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2023)

European Committee on Antimicrobial Susceptibility Testing (EUCAST) Interpretive Category Definitions:

S - Susceptible, standard dosing regimen: A microorganism is categorized as "Susceptible, standard dosing regimen", when there is a high likelihood of therapeutic success using a standard dosing regimen of the agent.

I - Susceptible, increased exposure*: A microorganism is categorized as "Susceptible, Increased exposure*" when there is a high likelihood of therapeutic success because exposure to the agent is increased by adjusting the dosing regimen or by its concentration at the site of infection.

R - Resistant: A microorganism is categorized as "Resistant" when there is a high likelihood of therapeutic failure even when there is increased exposure*.

*Exposure is a function of how the mode of administration, dose, dosing interval, infusion time, as well as distribution and excretion of the antimicrobial agent will influence the infecting organism at the site of infection.

(The European Committee on Antimicrobial Susceptibility Testing. Available at www.eucast.org.)