Test Definition: CARBI

Carbapenem Resistance Genes, Molecular Detection, PCR, Varies

Overview

Useful For

Detecting and differentiating *blaKPC, blaNDM, blaVIM, blaOXA-48,* and *blaIMP* gene sequences associated with carbapenem intermediate or resistant results

Aiding in infection control in the detection of gastrointestinal colonization of patients in healthcare settings with bacteria not susceptible to carbapenems using bacterial isolates from rectal or perirectal swabs

Method Name

Real-Time Polymerase Chain Reaction (PCR)/Reverse Transcription (RT-PCR)

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

This assay should be used for testing of isolates of Enterobacterales, *Pseudomonas aeruginosa* and *Acinetobacter baumannii.* If testing directly from rectal swabs is desired, order CRPCR / Carbapenem Resistance Genes, Molecular Detection, PCR, Rectal Swab.

Other mechanisms of carbapenem resistance, including other carbapenemase not targeted by this assay, porin mutations, and hyperexpression of drug efflux pumps, may result in carbapenem resistance. These mechanisms are not detected by this assay.

Additional Testing Requirements

1. Organism identification must be provided. If organism identification is unknown, concomitantly order IDENT / Organism Referred for Identification, Aerobic Bacteria.
2. If susceptibility testing is needed, also order ZMMLS / Antimicrobial Susceptibility, Aerobic Bacteria, Varies.

Shipping Instructions

1. For shipping information, see Infectious Specimen Shipping Guidelines.
2. Place specimen in a large infectious container and label as an etiologic agent/infectious substance if appropriate.

Necessary Information

Organism identification and specimen source are required.

Specimen Required

The high sensitivity of amplification by polymerase chain reaction requires the specimen to be processed in an environment in which contamination of the specimen by *Klebsiella pneumoniae* carbapenemase (KPC), New Delhi metallo-beta-lactamase (NDM), Verona integron-encoded metallo-beta-lactamase (VIM), oxacillin-hydrolyzing beta-lactamase (OXA-48), and imipenemase-type metallo-beta-lactamase (IMP) DNA is not likely.

Supplies: Infectious Container, Large (T146)
Container/Tube: Slant
Specimen Volume: Isolate
Collection Instructions:
1. Perform isolation of infecting bacteria.
2. Bacterial organism must be submitted 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

Agar plate Mixed culture	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

The global spread of carbapenemase-producing *Enterobacterales*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* (organisms not-susceptible to carbapenem antimicrobials) is a critical public health issue. These bacteria are often resistant to all beta-lactam agents and frequently also resistant to multiple classes of other antimicrobial agents, leaving very few treatment options. Tracing the spread of organisms not-susceptible to carbapenems is complicated by the diversity of carbapenem-hydrolyzing enzymes that have emerged and the ability of the genes to spread among multiple bacterial species.

Reference Values

Not Detected

Interpretation

A detected result is when *blaKPC, blaNDM, blaVIM*, *blaOXA-48*, or *blaIMP* target DNA is detected. This indicates the

presence of gene sequences associated with carbapenem intermediate or resistant results.

A not detected result is when *blaKPC, blaNDM, blaVIM, blaOXA-48,* and *blaIMP* target DNA is not detected.

A not detected Xpert Carba-R Assay result does not preclude the presence of other carbapenem-resistance mechanisms.

Cautions

The Xpert Carba-R Assay detects *blaKPC, blaNDM, blaVIM, blaOXA-48,* and *blaIMP* from pure colonies and is not for bacterial identification. Detection of these gene sequences does not indicate the presence of viable organisms.

The Xpert Carba-R Assay is not a genetic relatedness subtyping tool and does not report variants of the *blaKPC, blaNDM, blaVIM, blaOXA-48,* or *blaIMP* genes.

IMP types detected by this assay include only IMP-1, 2, 4, 6, 10 and 11.

Certain bacterial species, such as *Pseudomonas aeruginosa* and *Acinetobacter baumannii* have been shown to exhibit resistance to the carbapenem antimicrobial ertapenem due to intrinsic resistance mechanisms.

The detection of other OXA-carbapenemase genes besides $bla_{\text{OXA-48}}$ and $bla_{\text{OXA-181}}$ has not been evaluated with this assay.

Variants or alterations in primer or probe binding regions may affect detection of current, new, or *unknown blaKPC, blaNDM, blaVIM, blaOXA-48,* and *blaIMP* variants, resulting in a false-negative result.

Testing with the Xpert Carba-R Assay should be used as an adjunct to other available methods.

Carbapenem-resistant anaerobes potentially present in fecal specimens have not been evaluated by the Xpert Carba-R Assay.

Erroneous test results might occur from improper culture techniques, failure to follow recommended procedure to prepare the 0.5 McFarland suspension, handling and storage procedures, technical error, sample mix-up, or because the number of organisms in the specimen is too low to be detected by the test. Careful compliance with the instructions in the test instructions for use is necessary to avoid erroneous results.

Supportive Data

The Xpert Carba-R Assay is an FDA-cleared test. The Xpert Carba-R was further verified for use with a Zeptometrix verification panel and organisms (*Enterobacterales, Pseudomonas, and Acinetobacter* bacteria) with known carbapenem antimicrobial susceptibility test results. The verification passed and is acceptable for use with patient testing.

Clinical Reference

1. Bush K, Bradford PA. Epidemiology of beta-lactamase-producing pathogens. Clin Microbiol Rev. 2020;33(2): e00047-19
2. Tenover FC, Nicolau DP, Gill CM. Carbapenemase-producing Pseudomonas aeruginosa - an emerging challenge. Emerg Microbes Infect. 2022;11(1):811-814
3. Clinical and Laboratory Standards Institute (CLSI). Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically. 11th ed. CLSI standard M07. CLSI; 2018

Performance

Method Description

The GeneXpert Dx System automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in simple or complex specimens using a real-time polymerase chain reaction (PCR) assay. The system requires the use of single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is eliminated. The primers and probes in the Xpert Carba-R Assay detect proprietary sequences for the *blaKPC, blaNDM, blaVIM, blaOXA-48,* and *blaIMP* gene sequences associated with carbapenem intermediate or resistant results in gram-negative bacteria.(Package insert: Xpert Carba-R. Cepheid; 301-2438, Rev. G, 7/2020)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

2 to 4 days

Specimen Retention Time

30 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

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

87183

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CARBI	Carbapenem Resistance Genes, Varies	85502-3

Result ID	Test Result Name	Result LOINC® Value
IMPCB	IMP Resistance Gene	85498-4
VIMCB	VIM Resistance Gene	85501-5
NDMCB	NDM Resistance Gene	73982-1
KPPCB	KPC Resistance Gene	49617-4
OXACB	OXA-48-like Resistance Gene	85503-1
CRORG	Organism Identified by Client	In Process
CRSRC	Specimen Source	31208-2