MAYO CLINIC LABORATORIES

Test Definition: CRPCR

Carbapenem Resistance Genes, Molecular Detection, PCR, Rectal Swab

Overview

Useful For

Detecting and differentiating the *bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, and *bla*IMP 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 rectal or perirectal swabs

Method Name

Real-Time Polymerase Chain Reaction (RT-PCR)

NY State Available

Yes

Specimen

Specimen Type

Swab

Ordering Guidance

This test is performed on rectal and perirectal swab specimens from patients at risk for intestinal colonization with bacteria not susceptible to carbapenem antimicrobials.

Other mechanisms of carbapenem resistance, including carbapenemases 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.

Specimen Required

Specimen Type: Rectal/perirectal swab
Supplies: Culturette (BBL Culture Swab) (T092)
Container/Tube: Culture transport swab
Specimen Volume: Entire collection

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

Gross lipemia	Reject
Incorrect swab used	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Swab	Ambient	5 days	

Clinical & Interpretive

Clinical Information

The global spread of carbapenemase-producing *Enterobacterales*, *Pseudomonas aeruginosa*, and *Acinetobacter* species (organisms not susceptible to carbapenem antimicrobials) is a critical public health issue. These bacteria are often resistant to all beta-lactam agents and, frequently, are 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 *bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, or *bla*IMP target DNA is detected. This indicates the presence of gene sequences associated with carbapenem intermediate or resistant results.

A not detected result is when *bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, and *bla*IMP 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 *bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, and *bla*IMP from rectal and perirectal specimens 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 *bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, or *bla*IMP genes.

Imipenemase-type metallo-beta-lactamase (IMP) types detected by this assay include only IMP-1, 2, 4, 6, 10, and 11.

Rectal and perirectal specimens from pediatric patients have not been evaluated.

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 OXA-carbapenemase genes, besides *bla*OXA-48 and *bla*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 *bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, and *bla*IMP variants, resulting in a false-negative result.

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

Cocolonization with 2 or more carbapenemase-producing organisms has been reported with the Xpert Carba-R Assay, but it is rare.

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

Supportive Data

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

Clinical Reference

1. McConville TH, Sullivan SB, Gomez-Simmonds A, Whittier S, Uhlemann AC. Carbapenem-resistant Enterobacteriaceae colonization (CRE) and subsequent risk of infection and 90-day mortality in critically ill patients, an observational study. PLoS One. 2017;12(10):e0186195
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 *bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, and *bla*IMP gene sequences associated with carbapenem intermediate or resistant results in gram-negative bacteria.(Package insert: Xpert Carba-R. Cepheid; 01/2018)

PDF Report

No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 day

Specimen Retention Time
5 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
87798

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CRPCR	Carbapenem Resistance Genes, PCR	85502-3

Result ID	Test Result Name	Result LOINC® Value
IMPCR	IMP Resistance Gene	85498-4
VIMCR	VIM Resistance Gene	85501-5
NDMCR	NDM Resistance Gene	73982-1
KPPCR	KPC Resistance Gene	49617-4
OXACR	OXA-48-like Resistance Gene	85503-1