

COUNTY OF SAN LUIS OBISPO PUBLIC HEALTH LABORATORY

Phone: (805) 781-5507 | Fax: (805) 781-1023 www.sloPublicHealth.org/Lab

LABORATORY TEST FACT SHEET

TEST: Xpert Carba-R Assay

ORDER CODE: 2350

TEST DESCRIPTION

The development of antibiotic resistance by bacteria is of public health concern because it means that fewer effective treatment options are available and can contribute to the spread of disease in healthcare settings. Beta-lactams, including penicillin, are the most frequently used antibiotics to treat bacterial infections. Among the beta-lactams, carbapenems have the broadest antibacterial activity. When organisms no longer respond to carbapenems, they are called CROs (carbapenem-resistant organisms). Knowing whether a patient has a CRO can both inform treatment choice and improve infection prevention and control. The Xpert Carba-R Assay (Cepheid) detects the five most common genes associated with carbapenem-non-susceptibility. These genes are:

- IMP: Imipenemase
- VIM: Verona integron-mediated metallo-beta-lactamase
- NDM: New Delhi metallo-beta-lactamase
- KPC: Klebsiella pneumonia carbapenemase
- OXA-48: Oxacillinase (class D)

The test is performed on rectal and perirectal swabs from patients at risk for intestinal colonization with carbapenem-non-susceptible bacteria. In addition, testing may also be performed on pure bacterial colonies to both confirm the mechanism of resistance and help guide treatment strategies.

SENSITIVITY AND SPECIFICITY

For bacterial isolates, the overall sensitivity has been shown to be 100%, with the specificity ranging from 97.1% to 98.1% depending on the culture medium. For rectal and perirectal swabs, the limit of detection has been estimated to be between 54 and 1303 colony forming units/swab.

LIMITATIONS

- Detection of a carbapenem resistance gene sequence does not indicate the presence of viable bacteria.
- A negative test result does not preclude the possibility of other resistance mechanisms to carbapenems because certain bacterial species can show intrinsic resistance.
- Not all variants of the IMP, VIM, NDM, KPC, and OXA-48 genes are detected by the assay. For example, IMP-7, IMP-13, and IMP-14 are not detected with the IMP target.

SPECIMENS ACCEPTED FOR TESTING

- 1. Two types of specimens are acceptable:
 - a. Paired rectal or perirectal swabs collected in liquid Stuart medium (to determine colonization)
 - i. Patients must have had exposure to a known case or be living in a skilled-nursing or long-term acute care facility.
 - b. Bacterial isolates that show resistance to a carbapenem during susceptibility testing

LABORATORY TEST FACT SHEET

Xpert Carba-R Assay

- i. Antibiotic susceptibility testing (AST) must be submitted with the specimen.
- ii. Appropriate bacteria are Enterobacterales, *Acinetobacter baumannii*, or *Pseudomonas aeruginosa*.

STORAGE AND TRANSPORT TEMPERATURE

- 1. Rectal or perirectal swabs in the transport tube are stored at 15–28 °C for up to five days.
- 2. Isolates can be submitted at ambient or refrigerated temperature but must be viable for subculturing.

CPT CODE: 87150