Test Order
Carbapenemase Gene PCR
(\textit{blaKPC}, \textit{blaNDM}, \textit{blaVIM}, \textit{blaOXA-28}, \textit{blaIMP} gene detection)

**Synonym(s)**
\textit{Klebsiella pneumoniae} carbapenemase (KPC) gene detection; New Delhi metallo-β-lactamase 1 (NDM-1) gene detection; Verona integron-mediated metallo-beta-lactamase (VIM) gene detection; imipenemase (IMP) class gene detection, Class D oxacillinase (OXA-48) gene detection

**Methodology**
Real time PCR for the carbapenemase genes \textit{blaKPC} (KPC), \textit{blaNDM} (NDM), \textit{blaVIM} (VIM), \textit{blaOXA-48} (OXA-48), and \textit{blaIMP} (IMP).

**Acceptable Specimen Type(s) for Testing**
Pure bacterial isolates of \textit{Enterobacteriaceae}, \textit{Acinetobacter baumannii}, or \textit{Pseudomonas aeruginosa}. Rectal swabs (see “Transport / Collection Medium” below).

**Transport / Collection Medium**
Bacterial isolates: transport on nutrient agar slant, packaged and sealed according to regulations. Rectal swabs: using the Cepheid Collection Devices (manufacturer catalog #900-0370) (also known as Copan Transystem Culture Swab Transport System).

**Storage and Preservation of Specimen**
Refrigerate bacterial isolates until transported to the laboratory; transport at room temperature. Rectal swabs in the transport tube can be stored at 15–28°C, and must be transported to the laboratory and tested within five days.

**Minimum Volume Required**
N/A

**Additional Collection Instructions**
Rectal Swab Specimen Collection Instructions:
• Collection of a paired rectal swab: Carefully insert both swab tips approximately 1 cm beyond the anal sphincter and rotate gently. See Figure 1 and Figure 2 below for examples of acceptable and unacceptable swabs.
• Place swab pair back into the original transport tube. Label the tube with the patient’s first and last name.
• Swabs in the transport tube can be stored at 15–28 °C for up to five days. See Figure 1 below for examples of acceptable swab specimens to be used. See Figure 2 for examples of highly soiled swab specimens that should not be used.

Figure 1: Examples of Acceptable Swab Specimens for Xpert Carba-R Testing:

![Figure 1](image1)

Figure 2. Examples of Unacceptable Swab Specimens for Xpert Carba-R Assay Testing:

![Figure 2](image2)
Include identification and phenotypic drug sensitivity results with bacterial isolate submissions.

Testing Restrictions
- The performance of this assay has not been evaluated with rectal swab specimens from pediatric patients.
- Interference with this assay may be observed with barium sulfate at > 0.1% w/v, and Pepto-Bismol at > 0.01% w/v in tests with rectal swab matrix samples.

Limitations / Notes / Disclaimers
Xpert Carba-R Assay detects sequences for the \textit{bla}KPC (KPC), \textit{bla}NDM (NDM), \textit{bla}VIM (VIM), \textit{bla}OXA-48 (OXA-48), and \textit{bla}IMP (IMP) gene sequences associated with carbapenem-non-susceptibility in gram negative bacteria. Include identification and phenotypic drug sensitivity results with bacterial isolate submissions.

Disclaimer: This PCR assay is not intended to guide or monitor treatment for carbapenem non-susceptible bacterial infections. A negative result does not preclude the presence of other resistance mechanisms, and these results should be used in conjunction with other laboratory tests including phenotypic antimicrobial susceptibility testing. Certain bacterial species, such as \textit{Pseudomonas aeruginosa} and \textit{Acinetobacter baumannii} have been shown to exhibit resistance to carbapenems due to intrinsic resistance mechanisms.

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