



Xpert® Carba-R QC Panel M219

INTENDED USE:

The Xpert Carba-R QC Panel M219 is intended for *in vitro* use as a quality control to monitor the detection and differentiation of 5 beta-lactamase gene sequences (*bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, and *bla*IMP-1) when tested by the Cepheid Xpert Carba-R Assay on the GeneXpert® instrument.

The gene sequences are associated with carbapenem-non-susceptibility in gram-negative bacteria. The global spread of carbapenem non-susceptible bacteria is a critical public health issue.^{1,2} These bacteria are often resistant to all beta-lactam agents and frequently are co-resistant to multiple classes of other antimicrobial agents, leaving very few treatment options.³

PRODUCT SUMMARY and PRINCIPLE:

Xpert Carba-R QC Panel M219 contains Xpert Carba-R Positive Control and Xpert Carba-R Negative Control. Xpert Carba-R Positive Control carries all 5 beta-lactamase gene sequences detected by Xpert Carba-R Assay. Xpert Carba-R Negative Control does not carry any beta-lactamase gene sequences.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Routine use of quality controls assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents or malfunctioning equipment. Early investigation can prevent failed assay runs.

COMPOSITION:

The Xpert Carba-R QC Panel M219 is comprised of 12 tubes, 50µL each of synthetic DNA encapsulated in chemically killed and fixed, non-pathogenic bacterial cells, suspended in buffer and preservative. Six (6) of the tubes are Xpert Carba-R Positive Control, which carries all 5 beta-lactamase gene sequences. The other 6 tubes are Xpert Carba-R Negative Control which does not carry any beta-lactamase gene sequences. Table 1 lists the beta-lactamase gene sequences that are monitored by the Xpert Carba-R QC Panel M219 when tested by the Cepheid Xpert Carba-R Assay on the GeneXpert instrument.

STORAGE:

Xpert Carba-R QC Panel M219 should be stored at 2° – 8°C. Unopened Xpert Carba-R QC Panel M219 is stable through the expiration date printed on each tube when stored refrigerated (2° – 8°C). Xpert Carba-R Positive Control and Xpert Carba-R Negative Control are for single use. Discard after use according to your local and federal regulations.

ORDERING INFORMATION:

Xpert Carba-R QC Panel M219

Part Number: M219

Kit Contains: 12 tubes x 50µL

6 Positive controls and 6 Negative controls

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Do not dilute. Use the control as provided.
- This product is provided for *in vitro* analytical testing and is provided for Research Use only, not for use in diagnostic procedures.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Appearance: Clear liquid.
- The Xpert Carba-R QC Panel M219 cannot be cloned, sold or transferred without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

1. Allow the control to come to room temperature.
2. Use the control as provided. **DO NOT DILUTE.**
3. **MIXING IS CRITICAL. Immediately before use, mix the control by vortexing at highest speed for 10 - 15 seconds and then shake the tube down firmly to remove any droplets caught in the cap.**
4. Transfer 50µL of control to a Sample Reagent vial using a quantitative pipette.
5. Close the Sample Reagent cap and **vortex at high speed for 10 seconds.**
6. Analyze the control as you would a patient sample.
7. Discard after use according to your local and federal regulations.

EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for Xpert Carba-R QC Panel M219 in demonstrating adequate system performance. Recoveries may vary depending on instrumentation, reagents and systematic or random errors. The expected results when the controls are analyzed are listed in Table 1.

Table 1: Xpert Carba-R Assay Results

Assay	Xpert Carba-R Positive Control	Xpert Carba-R Negative Control
IMP	Detected	Not Detected
VIM	Detected	Not Detected
NDM	Detected	Not Detected
KPC	Detected	Not Detected
OXA	Detected	Not Detected

References:

1. Kallen, A. J. & A. Srinivasan. 2010. Current epidemiology of multidrug-resistant gram-negative bacilli in the United States. *Infect Control Hosp Epidemiol.* 31 Suppl 1: S51-54.
2. Nordmann, P. & G. Cornaglia. 2012. Carbapenemase-producing Enterobacteriaceae: a call for action! *Clin Microbiol Infect.* 18: 411-412.
3. Cornaglia, G., H. Giamarellou & G. M. Rossolini. 2011. Metallo-beta-lactamases: a last frontier for beta-lactams? *Lancet Infect Dis.* 11: 381-393.
4. ISO 15189: Medical laboratories – Particular requirements for quality and competence.
5. CAP Molecular Pathology Checklist; Commission on Laboratory Accreditation, Laboratory Accreditation Program, Mol.20000