Cepheid
A better way.

Xpert® Carba-R

Detection and differentiation of KPC, NDM, VIM, IMP, and OXA-48 in 50 minutes

The Need

- The emergence and **global spread of carbapenemase producing *Enterobacterales* (CPE)** is of great concern to health services worldwide[1]
- Carbapenem resistance results in **increased mortality** in hospitalized patients and is associated with **higher total hospital costs**[2]
- CPE are multi-drug resistant organisms that can cause **serious infections** and require interventions in healthcare settings to prevent spread[3]
- ECDC and CDC recommend comprehensive infection control measures for patients who are **colonized or infected** with carbapenemase-producing organisms[3,4]

The Solution

- **Detection and differentiation** of patients with the Xpert Carba-R test can quickly alert clinicians and infection preventionists to the presence of gene sequences associated with carbapenem non-susceptibility
- Rapid detection and differentiation of the KPC, NDM, VIM, IMP, and OXA-48 gene sequences from pure colonies helps clinicians **optimize patient management** and **direct therapeutic strategy**
- Rectal and perirectal swabs assist with **infection control measures**
- On-demand identification of the most prevalent carbapenemase gene families enables healthcare systems to **prevent onward transmission** throughout the patient pathway and facilitates more efficient bed management for improved hospital flow[5]

The Impact

- Reduced turnaround time enables rapid infection control measure to **reduce transmission**[6,7]
- **Significant reduction** the number of bed-days lost due to CPE compared to culture[5]
- Significant decrease in CPE colonization and infection rates with **fast PCR results**[8]

1 Bonomo RA, Burd EM, Conly J, Limbago BM, Poirel L, Segre JA, Westblade LF. Carbapenemase-Producing Organisms: A Global Scourge. Clin Infect Dis. 2018 Apr 3;66(8):1290-1297. doi: 10.1093/cid/cix893. PMID: 29165604; PMCID: PMC5884739.

2 Judd WR, et al. Clinical and economic impact of meropenem resistance in Pseudomonas aeruginosa–infected patients. American Journal of Infection Control. June 2016. http://www.sciencedirect.com/science/article/pii/S0196655316303431

3 CDC Healthcare Facilities: Information about CRE https://www.cdc.gov/hai/organisms/cre/cre-facilities.html

4 ECDC RAPID RISK ASSESSMENT. Carbapenem-resistant Enterobacteriaceae–second update. 26 Sept. 2019. Accessed June 2020 https://www.ecdc.europa.eu/sites/portal/files/documents/carbapenem-resistant-enterobacteriaceae-risk-assessment-rev-2.pdf

5 Corless C. et al. Impact of different carbapenemase-producing Enterobacterales screening strategies in a hospital setting. IPIP. 2020 May;3(2):100011.

6 Jin S, Lee JY, Park JY, Jeon MJ. Xpert Carba-R assay for detection of carbapenemase-producing organisms in patients admitted to emergency rooms. Medicine (Baltimore). 2020 Dec 11;99(50):e23410.

7 Ambretti S et al. Total integration of cultural and molecular testing for CPE screening with liquid based microbiology (LBM). Poster presented at ECCMID. 2018 21-24 April. Madrid, Spain.

8 Zhou M, Kudinha T, Du B, Peng J, Ma X, Yang Y, Zhang G, Zhang J, Yang Q, Xu YC. Active Surveillance of Carbapenemase-Producing Organisms (CPO) Colonization With Xpert Carba-R Assay Plus Positive Patient Isolation Proves to Be Effective in CPO Containment. Front Cell Infect Microbiol. 2019 May 14;9:162. doi: 10.3389/fcimb.2019.00162. PMID: 31157176; PMCID: PMC6528581.

Xpert® Carba-R

Product Reference Sheet — IVD

Test Reagent Kit	Xpert Carba-R	
Catalog Number	**US-IVD** GXCARBAR-10	**CE-IVD** GXCARBARP-CE-10 GXCARBARP-CE-120
Technology	Real-time PCR	
Targets	KPC. NDM. VIM. OXA-48. IMP^	
Batch or On-Demand	On-Demand	
Minimum Batch Size	1	
Sample Extraction	Automated/Integrated	
Precision Pipetting	Not Required	
Turnaround Time	50 minutes	
Workflow	Sample in, answer out in 3 easy steps	
Controls: Probe Function/Detection	Probe Check Control (PCC)	
Controls: Process	Sample Processing Control (SPC)	

	Bacterial Isolate	**Perirectal or Rectal Specimen**
Sample Types	Pure culture of carbapenem-non-susceptible organism	Perirectal or Rectal Swab

Performance

Sensitivity*					**Positive Percent Agreement***				
KPC	**NDM**	**VIM**	**OXA-48**	**IMP**	**KPC**	**NDM**	**VIM**	**OXA-48**	**IMP**
100%	100%	100%	100%	100%	100%	100%	99.4%	99.4%	97.5%
Specificity*					**Negative Percent Value***				
KPC	**NDM**	**VIM**	**OXA-48**	**IMP**	**KPC**	**NDM**	**VIM**	**OXA-48**	**IMP**
100%	99.7%	99.7%	100%	99.8%	100%	100%	100%	100%	100%

Sample Storage	Colonies in sample reagent 2–28 °C for 5 days	Swabs in transport tube 15–28 °C for 5 days
Kit Storage	2–28 °C	
Commercial Controls	Refer to Package Insert or Contact Cepheid Technical Support	

* Xpert Carba-R vs. Reference Culture + Sequencing. Combined perirectal and rectal swab data from contrived specimens.

^ Not all blaIMP subtypes are detected.

Xpert® Carba-R Package Insert: 301-9242, Rev. D March 2023. CE-IVD

Xpert® Carba-R Package Insert: 301-2438, Rev. G July 2020. US-IVD.

IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries.

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