

## #06948 Performance of a new Lateral Flow Assay for Detection of KPC, OXA-48-like, NDM, IMP and VIM Carbapenemases in Enterobacterales and *Pseudomonas aeruginosa* clinical Isolates

04. Diagnostic microbiology

04a. Diagnostic bacteriology (incl culture based, traditional and general microbiology, serology, excl AST methods)

J.M. De Mendieta<sup>1</sup>, M.A. Menocal<sup>1</sup>, P. Marchetti<sup>1</sup>, A. López González-Salido<sup>2</sup>, M.A. Sempere-Alcocer<sup>2</sup>, M. Rapoport<sup>1</sup>, P. Ceriana<sup>1</sup>, C. Lucero<sup>1</sup>, E. Albornoz<sup>1</sup>, F. Pasteran<sup>1</sup>, A. Corso<sup>1</sup>.

<sup>1</sup>Servicio Antimicrobianos. Laboratorio Nacional de Referencia en Resistencia a los Antimicrobianos. INEI – ANLIS “Dr. Carlos G. Malbrán” - Buenos Aires(Argentina), <sup>2</sup>Servicio de Microbiología Clínica. Hospital Universitario Virgen de la Victoria de Málaga - Málaga (Spain)

### Background

Accurate detection of carbapenemase-mediated resistance is crucial for guiding antibiotic therapy and effective infection control measures. Certest® Resist CARBAS is a rapid, multiplex, lateral immunochromatographic assay designed to identify the five most common carbapenemases KPC/OXA-48-like/VIM/IMP/NDM (CPO-5) in Enterobacterales (ETB) and *Pseudomonas aeruginosa*(PAE), within 15 minutes from bacterial colonies.

This study aimed to verify the diagnostic performance for detecting a diversity of CPO-5 in clinical isolates of ETB and PAE.

### Methods

We evaluated a collection of 72 strains, 55 ETB and 17 PAE, from the repository of INEI-ANLIS-Malbrán and CDC-AR-BANK, containing 66 strains positive for at least one CPO-5 enzymes, including 82 CPO-5 targets representing 37 allelic variants, and 6 negative strains for CPO-5. ETB species included: 29 *K. pneumoniae*, 2 *K. aerogenes*, 1 *K. oxytoca*, 8 *E. coli*, 7 *E. cloacae* complex, 3 *P. rettgeri*, 1 *P. mirabilis*, 1 *M. morgani*, 2 *C. freundii* and 1 *S. marcescens*. Allelic variants were characterized by PCR+Sanger sequencing and/or WGS. Resist CARBAS underwent evaluation in accordance with the manufacturer's instructions. False negative results were retested in triplicates. Acceptability criteria was: sensitivity (SE), specificity (SP), positive predictive value (PPV), negative predictive value (NPV) and precision (PR)  $\geq 90\%$ .

### Results

The performance of Resist CARBAS is shown in Figure 1. Resist CARBAS detected 74/82 targets CPO-5 targets with no false positive results, rendering 90% SE, 100% SP, 100% PPV, 97% NPV and 98% PR. Miss-detection (8/82 targets) were linked to: 2 NDM-1, 2 rare

IMP variants (IMP-27 and IMP-67) targets in Proteaeae and 4 KPC variants associated with resistance to ceftazidime-avibactam, KPC-14, -31, -33 and -57. False negative results persisted upon retesting. 31/37 CPO-5 allelic variants were detected.

## Conclusions

Resist CARBAS exhibited a high-level of performance, with  $\geq 90\%$  in the defined acceptability criteria. The assay effectively detects the most globally widespread variants and represents a promising option for routine laboratories, improving time to results and workflow while supporting early, guideline-based selection of appropriate therapy.

Figure 1. Performance of Resist CARBAS among Enterobacterales and *P. aeruginosa* isolates

Carbapenemase	Nro. Strains	Nro. allelic variants	Allelic variants included (n)	Nro. of CPO-5 detected	Allelic variants detected (n)	Allelic variants miss-detected (n), bacterial specie
KPC	12	9	KPC-2 (3), KPC-3 (2), KPC-4 (1), KPC-5 (1), KPC-14 (1), KPC-31 (1), KPC-33 (1), KPC-44 (1), KPC-57 (1)	5	KPC-2 (3), KPC-3 (2), KPC-4 (1), KPC-5 (1), KPC-44 (1)	KPC-14 (1), KPC-31 (1), KPC-33 (1), KPC-57 (1) <i>K. pneumoniae</i> (4)
NDM	10	4	NDM-1 (7), NDM-5 (1), NDM-7 (1), NDM-9 (1)	4	NDM-1 (6), NDM-5 (1), NDM-7 (1), NDM-9 (1)	NDM-1 (1) <i>M. morganii</i> (1)
OXA-48	8	6	OXA-48 (3), OXA-163 (1), OXA-181 (1), OXA-232 (1), OXA-370 (1), OXA-517 (1)	6	OXA-48 (3), OXA-163 (1), OXA-181 (1), OXA-232 (1), OXA-370 (1), OXA-517 (1)	-
VIM	7	5	VIM-1 (1), VIM-2 (3), VIM-27 (1), VIM-4 (1), VIM-11 (1)	5	VIM-1 (1), VIM-2 (3), VIM-27 (1), VIM-4 (1), VIM-11 (1)	-
IMP	15	12	IMP-1 (1), IMP-13 (1), IMP-16 (1), IMP-18 (1), IMP-26 (1), IMP-14 (1), IMP-15 (1), IMP-4 (2), IMP-8 (3), IMP-13 (1), IMP-27 (1), IMP-67 (1)	10	IMP-1 (1), IMP-13 (1), IMP-16 (1), IMP-18 (1), IMP-26 (1), IMP-14 (1), IMP-15 (1), IMP-4 (2), IMP-8 (3), IMP-13 (1)	IMP-27, IMP-67 <i>P. rettgeri</i> (2)
Dual or triple CPO-5 producers	14	Total 9: 2 KPC, 2 NDM, 2 VIM, 1 IMP, 2 OXA-48L	KPC-2 + NDM-1 (4), KPC-2 + NDM-5 (1), KPC-3 + NDM-1 (1), KPC-2 + VIM-2 (1), KPC-2 + IMP-8 (3), NDM-1 + OXA-232 (1), NDM-1 + OXA-163 (1), NDM-1 + VIM-36 + OXA-163 (1), KPC-2 + NDM-5 + OXA-163 (1)	9	KPC-2 + NDM-1 (4), KPC-2 + NDM-5 (1), KPC-3 + NDM-1 (1), KPC-2 + VIM-2 (1), KPC-2 + IMP-8 (3), NDM-1 + OXA-232 (1), NDM-1 + OXA-163 (1), VIM-36 + OXA-163 (1), KPC-2 + NDM-5 + OXA-163 (1)	NDM-1 <i>P. rettgeri</i> (1 triple producer of NDM-1 + VIM-36 + OXA-163)
Negative for CPO-5	6	1 TEM, 2 SHV, 1 DHA, 4 OXA, 2 CTXM, 1 PER, 1 SPM, 1 PAO, 1 Sme	TEM-18 + CTX-M-14 + SHV-11 (1), TEM-18 + CMY-2 (1), TEM-18 + CTX-M-15 + SHV-1 + OXA-10 + OXA-1 (1), Sme (1), CTXM-2 + PER-2 (1), SPM-1 + OXA-50 + PAO + OXA-56 (1)	0	-	-

### Keyword 1

Diagnostic microbiology

### Keyword 2

Antimicrobial susceptibility testing (AST)

### Conflicts of interest