

# Evaluation of Amplidiag CarbaR kit for the accurate detection of carbapenemase-producing bacteria

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## OBJECTIVES

The Amplidiag® CarbaR+VRE has been tested on a collection of **100 well-characterized isolates** with a reduced susceptibility to carbapenems, and **200 isolates** collected at the **French National Reference Center for Antibiotic Resistance** between January and February 2016.

## INTRODUCTION

Carbapenemase-producing *Enterobacteriaceae* (CPE) and carbapenemase-producing non-fermenters (CPNF; *Pseudomonadaceae* and *Acinetobacter* sp.) have been increasingly reported worldwide. Therefore, reliable detection of carbapenemase production is essential for the prompt implementation of infection control measures able to prevent clonal expansion or transfer of carbapenemase genes.

We evaluated the performance of the Amplidiag® CarbaR+VRE (Mobidiag Ltd, Espoo, Finland), a qualitative multiplexed nucleic acid-based in vitro diagnostic test.

## METHODS

Qualitative multiplexed nucleic acid-based diagnostic test intended for the detection of carbapenemase was performed on pure DNA. Targeted genes are *bla*<sub>KPC</sub>, *bla*<sub>NDM</sub>, *bla*<sub>VIM</sub>, *bla*<sub>IMP</sub>, *bla*<sub>OXA-48-like</sub>, *Acinetobacter* OXA genes including *bla*<sub>OXA-23</sub>, *bla*<sub>OXA-24</sub>, *bla*<sub>OXA-58</sub>, and *bla*<sub>OXA-51</sub> with upstream promoter *ISAbal*. (*vanA* and *vanB* genes were not evaluated)

## RESULTS

### Results of the 100 well-characterized isolates

	Enterobacteriaceae	Pseudomonadaceae	<i>Acinetobacter</i> sp.
Class_A Carbapenemases	KPC Type: n=9 (KPC-2, KPC-3)	KPC-2: n=2 GES Type n=2 (GES-2, GES-5)	GES-12: n=1
Class_D Carbapenemases	OXA-48 Type: n=15 (OXA-48, 162, 181, 204, 232, 244)	OXA-198: n=1	OXA Ac : n=13 (OXA-51, 23, 24/40, 72, 58, 143 and 253)
Class_B Carbapenemases	NDM, VIM and IMP Type: n=12 (NDM-1,4,5,6 and 7; VIM-1,2,4 and 19; IMP-1,8 and 11)	VIM and IMP Type: n=11 (VIM-1,2 and 4; IMP-1,2 and 13) Others : n=4 (GIM, AIM, SPM, DIM)	NDM, VIM and IMP Type: n=3 (NDM-1; VIM-4; IMP1)
Multiple carbapenemases	n=5		n=1 (NDM-1 + OXA-23)
Non carbapenemase	Overexpressed AmpC/ ESBL/ impermeability Extended spectrum oxacillinase (OXA-163, OXA-405) n=9	Efflux/ OprD deficiency AmpC + other β-lactamases (GES-9, OXA-32) n=11	n=2 (OXA-21, PER-1)

**Table.** Results of the Amplidiag Carba-R+VRE on a collection of carbapenemase and non-carbapenemase producing organisms.

100% sensitivity  
and  
99% specificity

100% detected  
Not detected

### Results of the prospective study on 200 isolates collected at the F-NRC for Antibiotic Resistance

101 non-CPO ( 8 false positives with Ct > 30) and 99 CPOs: NDM (n=11), VIM (n=2), IMP (n=1), OXA-48 (n=83), OXA-48+NDM (n=2)

### Results for PCR directly on colonies grown on MH medium

100% sensitivity and specificity

100% sensitivity  
and 96% specificity

## CONCLUSIONS

The Amplidiag® CarbaR+VRE was able to detect all targeted genes including their variants. The **main advantage** of this test is that it contains a **large panel of targeted resistance determinants**. Requires DNA extraction, but works on colonies directly (4h/2h)

As claimed by the manufacturer, other carbapenemases such as GES-like carbapenemases (GES-2, GES-5 in *P. aeruginosa*, GES-14 in *A. baumannii*), GIM-1, AIM-1, SPM-1, DIM-1 or OXA-198 in *P. aeruginosa*, or OXA-143-like in *A. baumannii* were not detected.

The Amplidiag® CarbaR+VRE assay is **well adapted to the French epidemiology** with a **good sensitivity and specificity**. Interestingly this assay could detect also *A. baumannii* carbapenemases producing *Enterobacteriaceae*, as recently described in a OXA-58-producing *P. mirabilis* isolate.