**Prospective evaluation of the OXA-48 K-SeT for the detection of OXA-48-type carbapenemase producing Enterobacteriaceae**

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### Background

Carbapenemase-producing Enterobacteriaceae represent a major health concern and a great challenge for clinical diagnostic laboratories. In France, OXA-48-like producing Enterobacteriaceae represent 86% of the CPE. In the current context of growing multidrug resistance, there is an urgent need for accurate and fast diagnostic tests to track antimicrobial resistance patterns in diagnostic laboratories.

### Objectives

We evaluated an immunochromatographic assay (OXA-48 K-SeT) aiming to detect OXA-48-like-producing Enterobacteriaceae from culture colonies.

### Methods

**Strain collection**

The OXA-48 K-SeT was evaluated on 175 well-characterized Enterobacteriaceae including 55 non-carbapenemase- and 120 carbapenemase-producers, among which 40 expressed OXA-48-variants displaying carbapenemase activity (21 OXA-48, 1 OXA-162, 9 OXA-181, 5 OXA-204, 2 OXA-232 and 2 OXA-244) and 2 (OXA-405 and OXA-163) that were lacking carbapenemase activity.

**Prospective evaluation**

Two hundred consecutive Enterobacteriaceae with decreased susceptibility to carbapenems sent to the French NRC for Antibiotic Resistance from February to March 2015 were prospectively studied using the Carba NP test, PCR and OXA-48 K-SeT.

### Results

<table>
<thead>
<tr>
<th>Carbapenemases</th>
<th>Non Carbapenemases</th>
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<tbody>
<tr>
<td>OXA-48</td>
<td>OXA-162 OXA-181 OXA-204 OXA-232 OXA-244 OXA-163 OXA-405</td>
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<td>Case ESBL</td>
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<tr>
<td>ESBL + Case</td>
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<tr>
<td>KPC NDM VIM IMP OXA-48</td>
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The OXA-48 K-SeT assay detected all the 40 well-characterized OXA-48-like producers displaying carbapenemase activity but not those lacking this activity (OXA-405 and OXA-163).

No false positive result was observed. Among the 200 isolates received, 89 were carbapenemase-producers as revealed by Carba NP test and PCR. The OXA-48 K-SeT assay perfectly identify the 23 OXA-48, the 10 OXA-181 and the 11 co-producing OXA-48 and NDM-1 isolates. The 25 isolates that produced a different carbapenemase (1 KPC-2, 20 NDM-1, 2 NDM-7 and 2 VIM-1) and the 111 non-carbapenemase-producing Enterobacteriaceae were negative.