Evaluation of five commercial confirmation tests for Carbapenemase-Producing Enterobacteriaceae in an OXA-48 endemic geographic region.

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Background

The world widely increasing prevalence of carbapenemase producing enterobacteriaceae (CPE) poses a significant threat to public health, as infections caused by CPE result in higher rates of morbidity and mortality. Rapid and accurate detection of these organisms have become top priorities in clinical laboratories. Considering laboratory detection of carbapenemase production, a continuously increasing number of tests have been described and recommended including commercially available or laboratory-developed tests based on phenotypic or genotypic characteristics. Phenotypic tests are mostly based on the use of specific inhibitors, on the detection of carbapenem-hydrolysing activity by monitoring the color change of a pH indicator or by following enzymatic degradation products by MALDI-TOF products. The objective of this study was the evaluation of the performance of five commercial phenotypic CPE confirmation assays including the KPC, MBL and OXA-48 confirm kit (Rosco diagnostics), Rapidec Carba NP (Biomérieux), Neo-Rapid Carb (Rosco diagnostics), Rapid CARB Blue (Rosco diagnostics) and OXA-48 K-Set (Coris).

Material/Methods

In total 142 non-duplicate enterobacteriaceae with elevated MIC values for meropenem (≥ 0.125μg/mL), ertapenem (≥ 0.125μg/mL) and/or temocillin (≥ 32μg/mL) were included. All test isolates were subsampled twice on Mueller Hinton agar (Becton Dickinson, New York NY, USA) before performing the confirmation tests. The KPC, MBL and OXA-48 confirm kit, Rapidec Carba NP, Neo-Rapid Carb, Rapid CARB Blue and OXA-48 K-Set were evaluated by performers and interpreters blinded to the properties of the analysed isolates. Molecular detection of CPE by the Carba-R assay GeneXpert (Cepheid) was considered as gold standard. In the case of discrepant results, the tests were repeated and the isolate was eventually sent to the Belgian national reference laboratory for confirmation.

Results

Seventy-four of the 142 (62.6%) isolates were molecularly confirmed CPE. Most CPE were OXA-48 (47/75), followed by KPC (10/75), VIM (12/75), NDM (4/75) and IMP (2/75). The KPC, MBL and OXA-48 confirm kit showed the best performance for phenotypic CPE detection (100% sensitivity and 95.6% specificity). The sensitivities of the Rapidec Carba NP and Rapid CARB Blue test were excellent, both of them exceeding 98%. Specificity of the Rapidec Carba NP test however was disappointing (64.7%), also yielding interpretative difficulties when performed following manufacturer’s recommendations. The sensitivity of the Neo-Rapid Carb test was surprisingly low (40.5%). The OXA-48 K-Set showed excellent performance for the rapid and easy-to-perform detection of OXA-48 CPE.

In an OXA-48 predominant testing area (in our study 62.7% of the total CPE were OXA-48) the KPC, MBL and OXA-48 confirm kit, the Rapidec NP test, the Rapid CARB Blue and the OXA-48 K Set test are reliable tests for the detection of CPE.