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Evaluation of a MALDI Biotyper and Rapidec Carba NP-based alghoritm for direct identification of carbapenemase-producing Klebsiella pneumoniae from positive blood cultures

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Background: Bactaeremia caused by carbapenemase-producing *Klebsiella pneumoniae* can cause devastating complications and markedly increase the costs of hospital care. Mortality remains high, especially when effective antimicrobial therapy is not promptly administered. Consequently, rapid and accurate detection of these organisms is critical for early initiation of adequate treatment. We evaluated the reliability of a MALDI BioTyper and Rapidec® Carba NP-based algorithm in the identification of carbapenemase-producing *K. pneumoniae* directly on positive blood culture (BC) bottles.

Material/methods: The study was performed in two phases. First, we evaluated the Rapidec® Carba NP test with BCs spiked with well-characterized gram-negative strains. This strain collection included 22 non-carbapenemase producers, 20 KPC producers, 10 VIM producers, 4 OXA-48 producers, 3 NDM producers, 1 NMC-A producer and 1 OXA-372 producer. The clinical study was then conducted on BCs submitted as part of routine care for patients who were hospitalized from September 2015 through September 2016 at the Catholic University of the Sacred Heart Medical Center, which is a large tertiary-care hospital in Rome. Broth aliquots from each positive BC bottle were collected for standard method (Gram staining, and culture-based method) and direct species identification of the infecting pathogens using the MALDI BioTyper system. The Rapidec® Carba NP assay was performed on BC broths immediately after *K. pneumoniae* was identified by direct MALDI BioTyper analysis.

Results: In preliminary testing conducted on spiked samples, the Rapidec® Carba NP assay correctly discriminated between carbapenemase-producers and non-carbapenemase producers. During the study period, 192 BCs yielded *K. pneumoniae* isolates and all organisms were correctly identified by direct MALDI BioTyper analysis performed on BC broths. These included 108 non-carbapenemase producers, 82 KPC producers, 1 VIM producer, and 1 OXA-48 producer. The

Rapidec® Carba NP assay correctly detected all isolates producing carbapenemases, with no false positives, and results were available in 60 min (median).

Conclusions: Our MALDI BioTyper and Rapidec® Carba NP -based algorithm appears to be a reliable, timesaving tool for routine identification of carbapenemase-producing *K. pneumoniae* causing bacteraemia in the population we studied, although further studies are needed to evaluate its performance in other settings.