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Evaluation of the ability of the Gene Xpert Carba-R system to detect KPC and IMP carbapenemases variants

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The accurate differentiation among carbapenemases is vital for effective antimicrobial therapy and infection prevention and control (IPC). Novel combinations of ß-lactam and ß-lactamase inhibitors, such as ceftazidime/avibactam (CZA), have received approval against Class A, C, and some D (OXA-48 like) carbapenemase producing organisms (CPO). However, the emergence of CZA-resistant KPC variants and the increase of metallo- ß-carbapenemases in the region, such IMP, has introduced a new hurdle in accurately identifying these enzymes. Aim: to assess the performance of RT-PCR GeneXpert Carba-R for the rapid detection of CPO.

A total of 30 clinical CPO isolates from the National Reference Laboratory repository were included: 18 KPC, 8 IMP and 4 KPC+IMP: i) KPC-producing isolates were 17 *Klebsiella pneumoniae (*KPN) and 1 *K. aerogenes* that collectively carried the following alleles: KPC-14, KPC-25, KPC-31, KPC-33, KPC-44, KPC-57, KPC-73, KPC-80, KPC-81, KPC-96, KPC-97, KPC-161, KPC-162, KPC-163, KPC-164, KPC-165, KPC-168 and KPC-193; ii) IMP-producing isolates were 3 KPN, 4 *Pseudomonas aeruginosa*, and 1 *Acinetobacter baumannii* that carried 1 IMP-1, 2 IMP-8, 1 IMP-4, 1 IMP-13, 1 IMP-16, 1 IMP-18, and 1 IMP-26; iii) 3 KPN and 1 *K. oxytoca* dual producers of IMP-8+KPC-2. GeneXpert Carba-R was conducted using a pure culture, in accordance with the manufacturer's instructions. Results with sensitivity (SE), specificity (SP), and accuracy (AC) >=95% were considered satisfactory.

GeneXpert Carba-R was able to detect all 19 KPC variants, with 100% SE/SP. In contrast, GeneXpert Carba-R identified IMP-1, IMP-4 and IMP-26 but not IMP-8, IMP-13, IMP-16 and IMP-18 variants, with a final SE 25% and SP 100%.

The performance GeneXpert Carba-R for IMP variants detection was suboptimal. It is advisable that when dealing with CPO exhibiting a phenotypic suspicion of carbapenemase production and yielding negative results with GeneXpert Carba-R, further identification of carbapenemases should be conducted using alternative methods. Conversely, GeneXpert Carba-R demonstrated reliable performance in KPC variant detection. Accurate identification of KPC mutants, in combination with phenotypic analysis, are indispensable to inform antimicrobial therapy and more intense IPC measures.