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Evaluation of a new triplex immunochromatographic assay Trio (OXA-48, KPC, NDM) K-SeT for the rapid detection of carbapenemases from cultured bacteria

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Background: There is an urgent need for accurate and fast diagnostic tests to identify multidrug resistant bacteria for both therapeutic management and infection control purposes. We assessed the performance of a new multiplex immunochromatographic assay (RESIST-3 O.K.N *K*-SeT) for the detection of OXA-48, KPC and NDM carbapenemase-producing Enterobacteriaceae from culture colonies.

Material/methods: A collection of 200 characterized bacterial isolates from the French National Reference Center including 140 carbapenemase-producing Enterobacteriaceae (CPE) and 60 non CPE with various resistance mechanisms to carbapenems (ESBL and/or acquired AmpC cephalosporinases +/- impermeability) was challenged with the test. Then, 173 consecutive, non duplicated putative CPE isolates (decreased susceptibility to carbapenem drugs according to EUCAST or CLSI guidelines) referred to the Belgian reference laboratory from July to September 2016 were analyzed prospectively in parallel to the phenotypic tests and to multiplex PCR used as gold standard.

Results: The RESIST-3 O.K.N *K*-SeT assay yielded 100% sensitivity and 100% specificity for the detection of OXA-48 like, KPC and NDM enzymes at 15 minutes. In the collection panel**,** the triplex assay correctly detected all 42 OXA-48-like variants including (including OXA-48, OXA-162, OXA-181, OXA-204, OXA-232 and OXA-244), 30 NDM (including NDM-1, NDM-4, NDM-5, NDM-6, NDM-7 and NDM-9) and 27 KPC-producing isolates (KPC-2, KPC-3) whatever the species and their association with other β-lactamases. The assay also correctly identified NDM and OXA-48-like in 6 Enterobacteriaceae isolates expressing both NDM and OXA-48-like (OXA-181). No cross reactivity were observed with other carbapenemase producers non targeted by the assay (n=41) and non carbapenemase-producing isolates. In the prospective study, all OXA-48-like (n=68), NDM (n=18), KPC (n=9) and NDM+OXA-48 variant (OXA-181) (n=1) –producing Enterobacteriaceae isolates were correctly detected while no false positive results was observed. In countries like Belgium and France, the RESIST-3 O.K.N *K*-SeT covers 90% of all CPE types and allows confirmation of these carbapenemases on the same day as the antibiogram result.

Conclusions: The Trio *K*-SeT assay allows rapid and reliable direct detection of OXA-48, KPC and NDM carbapenemases from culture colonies and is very easy to implement in the routine workflow of a clinical microbiology laboratory. Confirmation of CPE by immunochromatographic tests further represents acost-effective alternative to difficult to operate and more costly characterization by molecular amplification methods.