EV0432

Evaluation of the performance of OXA-48 *K*-SeT immunochromatographic test for rapid identification of OXA-48 carbapenemase-producing Enterobacteriaceae

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Objectives

Carbapenemase-producing *Enterobacteriaceae* pose great diagnostic challenges to microbiology laboratories. The phenotypic tests lack the required sensitivity and specificity and the molecular methods are costly and time-consuming. Among carbapenemases, OXA-48 is particularly problematic since there is currently no specific inhibitor to identify its activity in phenotypic tests. In this study we evaluated the performance of newly developed immunochromatographic test "OXA-48 K-SeT" to rapidly detect OXA-48-like carbapenemases from bacterial colonies.

Methods

A well-characterised collection of carbapenemase positive and negative clinical *Escherichia coli* and *Klebsiella pneumoniae* isolates together with reference strains was used to evaluate the performance of OXA-48 K-SeT (Coris BioConcept, Belgium) lateral flow assay (Figure 1).

For this purpose, a total of 232 isolates harboring one or two carbapenemase gene(s) were studied in this study; OXA-48 (n=194), OXA-48+NDM-1 (n=13), OXA-48+VIM (n=1), NDM-1 (n=16), KPC (n=3), IMP (n=3), VIM (n=2). In addition, 30 isolates which lack any carbapenemase activity (negative in CARBA NP test, negative in multiplex polymerase chain reaction test designed for OXA-48, IMP, VIM, NDM-1 and KPC genes) were included to assess the specificity of the test. Bacterial colonies grown on Columbia agar + 5% sheep blood plates (bioMerieux, France) were used to perform the test as per manufacturer's instructions.

Methods

The test showed excellent sensitivity (100%) and specificity (100%) for the study collection (Table 1). The performance of the test was found not to be affected by the presence of OXA-48 together with another carbapenemase gene (NDM, n=13; VIM, n=1), also none of the other carbapenemase-gene harboring isolates gave a positive result. The test provided easy-to-read results in 10 minutes with less than 15 minutes total hands-on time.

Figure 1. OXA-48 positive (below) and OXA-48 negative (above) test results

Table 1. The performance of OXA-48 K-SeT on challenge strains (n=262)

Carbapenemase gene	n	OXA-48 K-Set (n) Positive	Negative
OXA-48	194	194	0
OXA-48 + NDM-1	13	13	0
OXA-48 + VIM	1	1	0
NDM-1	16	0	16
KPC	3	0	3
IMP	3	0	3
VIM	2	0	2
Negative	30	0	30

Conclusion

- The OXA-48 K-SeT immunochromatographic test was recently developed for the detection of OXA-48 carbapenemases from colonies grown on solid media which allows rapid and easy detection of an important resistance mechanism.
- The test was found to provide excellent sensitive and specific results within minutes that may help to proper manage the treatment and initiate necessary infection control measures.
- In Turkey, OXA-48 is the most prevalent carbapenemase gene in *Enterobacteriaceae*, followed by NDM-1 and the new kit exhibited superb performance for these carbapenemases (no false positivity, no false negativity).
- This new test might be useful for institutions with limited molecular microbiology services to rapidly detect OXA-48-producing isolates.