05084

Preliminary evaluation of KarbaDiag, a new rapid test for the detection of carbapenemase in bacterial colonies

04. Diagnostic microbiology

4a. Diagnostic bacteriology – culture based and general microbiology

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Background

KarbaDiag is a new rapid test based on lateral flow assay technology for the detection of five carbapenemase types including KPC-, NDM, IMP, VIM and OXA-48). The present investigation reports performance evaluation of KarbaDiag on carbapenem resistant clinical isolates.

Methods

A total of 212 clinical isolates were collected from European hospitals (81%) and American hospitals (15%) in 2019 and 2020, including 19 carbapenemase- negative isolates (9%) and 193 (91%) carbapenem-resistant Enterobacterales (CRE) with various carbapenemase types. These were collected from various infection sources including respiratory, urinary tract, intra-abdominal and chorionic villus sampling. Molecular analysis was performed on all isolates and MIC determination on discordant results. The isolates were cultivated on blood agar for 24h at 37°C and analysed with KarbaDiag rapid test.

Results

Performance of KarbaDiag rapid test on the 5 different carbapenemase types, compared to reference methods genetic analysis and MIC determination, are shown in the Table

Conclusions

KarbaDiag exhibited high diagnostic performance for KPC, OXA, NDM and VIM type carbapenemase with sensitivity and specificity greater than 95%. For NDM and OXA types, 2 isolates for both types showed positive genetic analysis but the MIC determinations were negative, indicating that the carbapenemase was not expressed in these conditions. Regarding the IMP type carbapenemase, the sensitivity was relatively low. This was due to the undetectability of the IMP-8 variant with the test. When excluding all IMP-8 variants, the sensitivity for all other IMP variants is 93% (CI95%: 66-100%). These preliminary data are encouraging and suggest that of the

KarbaDiag rapid test may prove useful in the detection of the majority of carbapenemase variants

Table

KarbaDiag Rapid test performance compared to genetic and MIC reference analysis for each carbapenemase types					
KPC	+	-	**Se**	**100%**	(CI95%: 87-100%)
+	32	0	**SP**	**100%**	(CI95%: 97-100%)
-	0	180	**PPV**	**100%**	(CI95%: 87-100%)
			NPV	**100%**	(CI95%: 97-100%)
OXA	+	-	**Se**	**98%**	(CI95%: 90-100%)
+	58	2	**SP**	**99%**	(CI95%: 95-100%)
-	1	149	**PPV**	**97%**	(CI95%: 87-99%)
			NPV	**99%**	(CI95%: 96-100%)
NDM	+	-	**Se**	**97%**	(CI95%: 89-99%)
+	65	1	**SP**	**99%**	(CI95%: 95-100%)
-	2	139	**PPV**	**98%**	(CI95%: 91-100%)
			NPV	**99%**	(CI95%: 94-100%)
IMP	+	-	**Se**	**64%**	(CI95%: 41-82%)
+	14	0	**SP**	**100%**	(CI95%: 98-100%)
-	8	190	**PPV**	**100%**	(CI95%: 73-100%)
			NPV	**96%**	(CI95%: 92-98%)
VIM	+	-	**Se**	**100%**	(CI95%: 85-100%)
+	29	0	**SP**	**100%**	(CI95%: 97-100%)
-	0	183	**PPV**	**100%**	(CI95%: 85-100%)
			NPV	**100%**	(CI95%: 97-100%)

Keyword 1
carbapenemase
Keyword 2
KarbaDiag
Keyword 3
diagnostics

Conflicts of interest

Do you have any conflicts of interest to declare?
I have the following potential conflict(s) of interest to report
Institutional grants/research supports