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Evaluation of the AusDiagnostics Easy-PlexTM assay for detection of carbapenemases and colistin resistance genes mcr-1/-2 in multidrug-resistant Gram-negative bacteria

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Background: The dissemination of KPC, OXA-48-like, NDM, VIM and IMP carbapenemase genes is of public health concern. As such these genes are the focus of most commercial detection assays meaning that the rapid detection of rarer carbapenemases is challenging.

We evaluated a commercial assay (AusDiagnostics *Easy-Plex*™ assay) for the detection of carbapenemases and acquired colistin resistance genes *mcr-1/-2*.

Material/methods: The 16-plex tandem PCR assay allows detection of bla_{KPC}, $bla_{OXA\text{-}48\text{-}like}$, bla_{NDM}, bla_{VIM}, bla_{IMP}, bla_{SIM}, bla_{GIM}, bla_{SPM}, $bla_{FRI\text{-}1\text{-}like}$, bla_{IMI}, bla_{GES} (differentiating ESBL and carbapenemase GES variants), bla_{SME} and *mcr-1/-2*.

It was evaluated against Enterobacteriaceae, *Pseudomonas* and *Acinetobacter* isolates, tested retrospectively (n=211 with previously characterised resistance mechanisms) and prospectively (n=182 sent for investigation of carbapenem or colistin resistance mechanisms). Two isolates co-produced a carbapenemase and a GES ESBL.

The assay was performed on 2-3 colonies from overnight growth.

The AusDiagnostics *Easy-Plex*™ assay was performed on an Easy-Plex 384 (High Plex) System according to the AusDiagnostics *Easy-Plex*™ assay protocol.

Results were automatically interpreted using the *Easy-Plex*™ software and compared with in-house PCR results and whole-genome sequencing data.

Results: The AusDiagnostics *Easy-Plex*™ was easy to use and was performed in less than 4h from colony to result output.

When combining the data from the first runs of both retrospective and prospective evaluations, the AusDiagnostics *Easy-Plex*™ detected 268/270 carbapenemase genes, including bla_{KPC} (n=48), $bla_{OXA\text{-}48\text{-}like}$ (n=79), bla_{NDM} (n=62), bla_{VIM} (n=26), bla_{IMP} (n=24), bla_{SPM} (n=1), $bla_{FRI\text{-}1\text{-}like}$ (n=1), bla_{IMI} (n=7), bla_{GES} (n=18) and bla_{SME} (n=2). One $bla_{GES\text{-}5}$ and one $bla_{OXA\text{-}48\text{-}like}$ were not initially detected.

The detection of bla_{SIM} and bla_{GIM} by the assay was assessed by testing in each run a positive control combining the thirteen targeted genes.

Seventeen out of 21 *mcr-1*-producing isolates were correctly identified, as were two GES ESBL producers.

The overall sensitivity and specificity of the assay were initially 97.9% and 99.6%, respectively.

Repeat testing of the false-positive and false-negative results resulted in detection of all carbapenemase producers and reduced the number of false-positive results from 26 to zero. The overall specificity of the assay was 100% and the sensitivity was 98.6% as 4/21 *mcr-1* producers were still negative due to the instability of the *mcr-1* plasmid in these isolates.

The positive and negative predictive values *for this isolate panel* were 91.7% and 99.9%, respectively and were improved to 100% and 99.9%, respectively upon repeat testing.

Conclusions: The AusDiagnostics *Easy-Plex*™ assay allowed detection of the carbapenemase families and carbapenemase gene variants detected in the UK in Enterobacteriaceae, *Pseudomonas* and *Acinetobacter* spp. Its coverage is greater than other products marketed for detecting carbapenemases, thereby offering increased confidence that isolates negative in the assay are unlikely to be carbapenemase producers. It also allowed the concomitant detection of *mcr-1/-2* genes in colistin-resistant isolates.