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P2827 QC evaluation of the three FASTinov kits for ultra-rapid antimicrobial susceptibility evaluation directly from blood cultures

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Background: FASTinov has developed a disruptive technology able to give ultra-fast results (<2 hours) regarding antimicrobial susceptibility directly from positive blood cultures (BC). In this study we have used quality control strains to evaluate practical issues for the end-users regarding performance of FASTinov ® kits: grampos (gram positive bacteria), gramneg (gram negative bacteria) and MAR (mechanisms of resistance).

Materials/methods: Fourteen quality control strains were spiked into BC (BD) with human donor blood; after positivity, FASTinov® kits were inoculated under different experimental conditions and analyzed on the CytoFLEX (Beckam) flow cytometer: *E. coli* ATCC 35218, *E. coli* ATCC 8739, *Kl. pneumoniae* ATCC 700603, *Kl. pneumoniae* ATCC BAA 1705, *Kl. pneumoniae* ATCC 13442, *Kl. pneumoniae* NCTC 13443, *E. cloacae* CCUG 59627, *Ps. aeruginosa* ATCC 27853, *Ps. aeruginosa* BAA 2108, *A. baumanni* ATCC BAA 1709, *E. faecalis* ATCC 29212, *E. faecalis* ATCC 51299, *S. aureus* ATCC 29213, *S. epidermidis* ATCC 35984.

BC were analyzed immediately after becoming positive as well as 12, 24 and 48 h afterwards. In order to understand the impact on the workflow, the maximum period that the inoculum could wait before kit inoculation (immediately, 1, 4 and 6 h at 4ºC) was also investigated. Additionally, we checked the operator-to-operator and the lot-to-lot variability. The possibility of carry-over and its impact was investigated. In order to study reproducibility, the kits were inoculated in triplicate, in different days. Statistical analysis was performed.

Results: No significant differences were found up to 24h after a BC flagged positive. After that period, minor and several major errors (36%) were found. High concordance in FASTinov® kits results was registered up to 4h of inoculation (k =0.77). No significant differences were detected between operator-to-operator or between results from different lots (k = 1.00). No carry-over was detected. Statistical analysis showed no significant differences between FASTinov® panel results performed on 3 distinct days, supporting the reproducibility of the technology.

Conclusions: FASTinov® kits performance was evaluated and exhibited high reproducibility. Several characteristics will be included in the Instructions for Use. A promising AST tool is under external validation under H2020 program and the CE/IVD mark will be obtained.