

**P2763 Prospective clinical evaluation of the BL-Detectool: an innovative tool for rapid detection of broad-spectrum beta-lactamases directly from clinical samples**

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**Background:** Lateral Flow immunoassays (LFIA) have shown their usefulness to detect ESBL- and carbapenemase-producing Enterobacteriaceae from bacterial cultures. Here, we have validated a novel, rapid and easy-to-use diagnostic tool, the BL-Detectool to detect CTX-M-ESBLs- and carbapenemases directly in clinical samples.

**Materials/methods:** The BL-Detectool corresponds to a LFIA that is embedded in a plastic device, which carries out easy sample preparation (filtration, concentration, extraction, incubation and loading). The clinical added value of the BL-Detectool was evaluated in a multicentric prospective study (three university hospitals in Paris, Barcelona and Budapest) on urine, blood and rectal swab specimens. Detection of ESBL-producers was performed directly on clinical samples from patients, while for CPEs, given their low prevalence, spiked samples of urine and blood cultures were also evaluated. For rectal swabs direct testing and after a 24h enrichment culture (ertapenem 0.5 mg/L) were evaluated.

**Results:** Among the 29 rectal swabs from high risk patients tested for CPEs and for ESBLs after a 24h enrichment culture, 5 were positive (pos) for CPE and 14 for CTX-Ms like ESBLs. 90-positive blood cultures from patients revealed 27 pos for ESBL-producers and 1 for CPE (VIM). In addition, 26 blood cultures spiked with 22 CPEs and 4 non-CPEs were also correctly identified. 92 urine samples from patients revealed 17 pos for ESBL-producers and no CPE. Except for one urine sample, weakly CTX-M pos but culture negative, there was a good match between the LFIA-detected  $\beta$ -lactamases and the corresponding genotype. Overall, B-Detectool gave 1 false positive and no false negative results (considering mandatory the enrichment step for rectal swab testing).

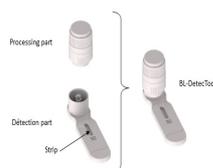


Figure 1: The BL-Detectool

**Conclusions:** BL-Detectool is a novel device integrating rapid pre-treatment of clinical samples that allows direct detection of  $\beta$ -lactamases in less than 30 min. For positive blood cultures and urines, it was able to detect all targeted CTX-M-ESBLs and carbapenemases. For rectal swabs, direct reading is possible, but for obtaining strong

signals, a 24h enrichment is recommended. This preliminary study showed excellent biological performances close to 100% in sensitivity and specificity. This test is sensitive, specific, easy to use, cost-effective and could be implemented in any microbiology laboratory around the world.

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