

A RAPID METHOD FOR ANTIMICROBIAL SUSCEPTIBILITY EVALUATION DIRECTLY FROM BLOOD CULTURES

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Bloodstream infections represent a critical healthcare condition associated to high mortality and morbidity. The increasing rates of antimicrobial resistance and the late laboratorial answer regarding the antibiotic drug susceptibility (AST) turn urgent the need of rapid diagnostic tests. FASTinov developed a breakthrough method to rapidly determine AST, improving patients' treatment of serious bacterial infections. The current gold standard methodology in AST has a turnaround time of 48 hours in case of positive blood cultures and automated systems. This novel flow cytometry-based test delivers results within two hours. This will enable clinicians to start sooner optimal antibiotic treatment with major impacts on health and quality of life of patients, healthcare costs and combating earlier AMR. The performance of FASTinov[®] gramneg, FASTinov[®] grampos and FASTinov[®] MAR kits for the detection of the main mechanisms of resistance (MAR) directly on positive blood cultures will be presented. The product is a microplate, containing panels of antibiotics and probes to determine the effect of the antibiotics on bacteria isolated from the patients' blood; the analysis is performed on a flow cytometer and a software package will provide a report (according to both EUCAST and CLSI protocols). The technical file for regulatory proceedings has been finalized and large-scale production of the panels is done in collaboration with an industrial partner. The overall CA between FASTinov[®] gramneg kit and broth microdilution was 0.93 and 0.9 for FASTinov[®] grampos kit for both EUCAST and CLSI. The rate for minor discrepancies was 3.7%, major discrepancies 3.2% and very major discrepancies 2.9%. Regarding resistance mechanisms, the CA between FASTinov[®] MAR kit and EUCAST protocol was 96%. ESBL, carbapenemases and AmpC positive strains, were detected with a sensitivity of 100%. The specificity of FASTinov MAR kit was 92% for detection of ESBL, 95% for carbapenemases, and 95% for AmpC.

Biography

Cidalia Pina Vaz, has long experience in Clinical Microbiology in Porto Medical School. She is a Co-author of more than 100 scientific papers and chapters of books. She is Co-author of an international patent regarding a new method for susceptibility evaluation. In order to transfer that technology to the market, she is a Co-founder of FASTinov, a spin-off of Porto University and has been dedicated the last years on the validation of this product.

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