

## Additional information about Rapid Diagnostic Tests:

- The FilmArray BCID is a sample-to-result assay for the analysis of positive blood culture broths. BCID relies on two-stage nested-PCR for identification of 8 Gram-positive, 11 Gramnegative, and 5 yeast targets in addition to the mecA, vanA/B, and blaKPC resistance determinants on a single panel. Clinical evaluations of BCID have demonstrated an overall sensitivity of >97% for targets present on the panel and a specificity of 97% to 100% for individual targets.
- In contrast, the Verigene BC-GP and BC-GN assays are nonamplified tests that rely on nucleic acid extraction from positive blood cultures, followed by microarray-based detection using capture and detection probes. The BC-GP assay is specific for 12 Grampositive bacterial identification targets and 3 associated resistance markers (mecA, vanA, and vanB), while the BC-GN assay is specific for 8 Gram-negative bacterial identification targets and 6 key resistance markers (blaCTX-M, blaKPC, blaNDM, blaVIM, blaIMP, and blaOXA).
- The FDA-cleared BC-GN does not contain a target for S. marcescens. The BCID panel detects only the KPC resistance gene, while the BC-GN-RUO test identifies the KPC gene plus the CTX-M, IMP, NDM, OXA, and VIM genes. https://www.ncbi.nlm.nih.gov/pmc/ articles/PMC4313169/
- A recent assessment of the BC-GN-RUO test also reported an inability to detect resistance genes in P. aeruginosa with a carbapenem resistance phenotype. The mechanisms of antibiotic resistance in Gram-negative bacteria are complex, particular P. aeruginosa, which can harbor mutations resulting in reduced outer membrane permeability, express multidrug efflux systems, and/or possess beta-lactamases outside those detected by the BC-GN-RUO test.
- Therefore, the absence of known resistance genes does not equate to a susceptible organism, particularly for P. aeruginosa. Thus, the clinical utility of genotypic assays, such as the BC-GN-RUO test, to detect several resistance genes depends on local susceptibility patterns and prevalent mechanisms of resistance. https://www.ncbi.nlm.nih.gov/ pubmed/24478405/

