PCR (comp-PCR) assays were used to confirm 41/49 additional detections, including 6 positives.

Presentation:

was concurrently tested on the BioFire BCID Panel. Frozen PBC aliquots and isolates were used to verify AMR gene detection and prototypes of the BioFire BCID2 Panel were used to prospectively SoC tests enrolled at 1 European and 4 US pilot sites; a subset

Antimicrobial stewardship. The BioFire® FilmArray® Blood Culture Identification 2 Panel (BioFire Diagnostics, LLC) expands use-only (RUO) prototypes of BioFire BCID Panel from positive blood cultures (PBC) were compared to standard of care (SoC) and independent PCR results.

Methods

Prototypes of the BioFire BCID2 Panel were used to prospectively evaluate 649 de-identified residual PBCs with clinician-ordered SoC tests enrolled at 1 European and 4 US pilot sites; a subset was concurrently tested on the BioFire BCID Panel. Frozen PBC aliquots and isolates were used to verify AMR gene detection and discrepancies by independent PCR by or the BioFire BCID Panel.

Background

Rapid identification of polymicrobial bloodstream infections (pBSI) and timely intervention with targeted antibiotic therapy can positively impact patient outcomes and improve antimicrobial stewardship. The BioFire® FilmArray® Blood Culture Identification 2 (BCID2) Panel (BioFire Diagnostics, LLC) expands the pBSI and antimicrobial resistance (AMR) gene detection capabilities of the BioFire® FilmArray® Blood Culture Identification (BCID) Panel by addition of 14 novel assays targeting 6 bacterial, 2 fungal, and 6 AMR genes. The expanded AMR menu provides accurate methillin-resistant Staphylococcus aureus (MRSA) results plus detection of mcr-1, blacTX-M, blaNDM, blaOXA-48-like, and bladOXA genes. pBSI and AMR gene detections by research-use-only (RUO) prototypes of BioFire BCID2 Panel from positive blood cultures (PBC) were compared to standard of care (SoC) and independent PCR results.

The BioFire BCID2 Panel Antimicrobial Resistance (AMR) Gene Detections and Concordance to SoC Antimicrobial Susceptibility Test (AST) Results

The BioFire BCID2 Panel detected a corresponding AMR gene in 88% (99/112) of cases with antimicrobial resistance by AST. Alternate PCR (comp-PCR) assays were used to confirm 41/49 additional detections, including 6 false negatives. Vancomycin resistance in E. faecium and E. faecalis:

1. All 11 PBC with vancomycin resistant PBC were detected by the Panel. Meticillin resistance:

1. MRSA accurately detected in all 31 cases where AST yielded a result; 4/11 additional detection remain unverified. In 54/56 (98%) of methicillin susceptible cases, the Panel algorithm accurately identified absence of MRSA. AST was not performed in 17/41 (41.5%) of detections of non-MRSA mecA gene (all detections in S. epidermidis). blacTX-M identification in extended spectrum beta-lactamase (ESBL) producers:

1. 23/26 ESBL producers identified by the panel had blacTX-M gene - 3 were confirmed to be negative for blacTX-M gene by comp-PCR assay.

Carbapenemase gene detections:

- 12 carbapenemase genes (5 bladOXA, 5 bladOXA, and 2 bladOXA) were detected in 11/16 PBC containing carbapenemase resistant isolates and verified by comp-PCR.
- Comp-PCR did not detect any on-panel carbapenemase genes in the 5 remaining PBC.
- K. pneumoniae isolates yielded all bladOXA and bladOXA detections
- bladOXA and bladOXA as well as the mobile colistin resistance gene, mcr-1, were not detected during this study by both the BioFire BCID2 Panel as well as alternate PCR assays.

Regional differences in prevalence of AMR genes detected by the BioFire BCID2 Panel:

- Higher prevalence of carbapenem resistant Staphylococci in the US.
- Although majority of bladOXA were detected in the US (78% detections), the relative prevalence was greater in Greece.
- Substantially higher prevalence (15%) was noted in samples from Greece for carbapenemase genes.
- PBC samples from Greece yielded both bladOXA detections.

Carbapenemase gene detections:

- 12 carbapenemase genes (5 bladOXA, 5 bladOXA, and 2 bladOXA) were detected in 11/16 PBC containing carbapenemase resistant isolates and verified by comp-PCR.
- Comp-PCR did not detect any on-panel carbapenemase genes in the 5 remaining PBC.
- K. pneumoniae isolates yielded all bladOXA and bladOXA detections
- bladOXA and bladOXA as well as the mobile colistin resistance gene, mcr-1, were not detected during this study by both the BioFire BCID2 Panel as well as alternate PCR assays.

Carbapenemase gene detections:

- 12 carbapenemase genes (5 bladOXA, 5 bladOXA, and 2 bladOXA) were detected in 11/16 PBC containing carbapenemase resistant isolates and verified by comp-PCR.
- Comp-PCR did not detect any on-panel carbapenemase genes in the 5 remaining PBC.
- K. pneumoniae isolates yielded all bladOXA and bladOXA detections
- bladOXA and bladOXA as well as the mobile colistin resistance gene, mcr-1, were not detected during this study by both the BioFire BCID2 Panel as well as alternate PCR assays.

Carbapenemase gene detections:

- 12 carbapenemase genes (5 bladOXA, 5 bladOXA, and 2 bladOXA) were detected in 11/16 PBC containing carbapenemase resistant isolates and verified by comp-PCR.
- Comp-PCR did not detect any on-panel carbapenemase genes in the 5 remaining PBC.
- K. pneumoniae isolates yielded all bladOXA and bladOXA detections
- bladOXA and bladOXA as well as the mobile colistin resistance gene, mcr-1, were not detected during this study by both the BioFire BCID2 Panel as well as alternate PCR assays.

Carbapenemase gene detections:

- 12 carbapenemase genes (5 bladOXA, 5 bladOXA, and 2 bladOXA) were detected in 11/16 PBC containing carbapenemase resistant isolates and verified by comp-PCR.
- Comp-PCR did not detect any on-panel carbapenemase genes in the 5 remaining PBC.
- K. pneumoniae isolates yielded all bladOXA and bladOXA detections
- bladOXA and bladOXA as well as the mobile colistin resistance gene, mcr-1, were not detected during this study by both the BioFire BCID2 Panel as well as alternate PCR assays.

Carbapenemase gene detections:

- 12 carbapenemase genes (5 bladOXA, 5 bladOXA, and 2 bladOXA) were detected in 11/16 PBC containing carbapenemase resistant isolates and verified by comp-PCR.
- Comp-PCR did not detect any on-panel carbapenemase genes in the 5 remaining PBC.
- K. pneumoniae isolates yielded all bladOXA and bladOXA detections
- bladOXA and bladOXA as well as the mobile colistin resistance gene, mcr-1, were not detected during this study by both the BioFire BCID2 Panel as well as alternate PCR assays.

Carbapenemase gene detections:

- 12 carbapenemase genes (5 bladOXA, 5 bladOXA, and 2 bladOXA) were detected in 11/16 PBC containing carbapenemase resistant isolates and verified by comp-PCR.
- Comp-PCR did not detect any on-panel carbapenemase genes in the 5 remaining PBC.
- K. pneumoniae isolates yielded all bladOXA and bladOXA detections
- bladOXA and bladOXA as well as the mobile colistin resistance gene, mcr-1, were not detected during this study by both the BioFire BCID2 Panel as well as alternate PCR assays.

Carbapenemase gene detections:

- 12 carbapenemase genes (5 bladOXA, 5 bladOXA, and 2 bladOXA) were detected in 11/16 PBC containing carbapenemase resistant isolates and verified by comp-PCR.
- Comp-PCR did not detect any on-panel carbapenemase genes in the 5 remaining PBC.
- K. pneumoniae isolates yielded all bladOXA and bladOXA detections
- bladOXA and bladOXA as well as the mobile colistin resistance gene, mcr-1, were not detected during this study by both the BioFire BCID2 Panel as well as alternate PCR assays.

Carbapenemase gene detections:

- 12 carbapenemase genes (5 bladOXA, 5 bladOXA, and 2 bladOXA) were detected in 11/16 PBC containing carbapenemase resistant isolates and verified by comp-PCR.
- Comp-PCR did not detect any on-panel carbapenemase genes in the 5 remaining PBC.
- K. pneumoniae isolates yielded all bladOXA and bladOXA detections
- bladOXA and bladOXA as well as the mobile colistin resistance gene, mcr-1, were not detected during this study by both the BioFire BCID2 Panel as well as alternate PCR assays.