Comparison of methicillin-resistant *Staphylococcus aureus* (MRSA) detection from positive blood cultures by PCR using a Research Use Only (RUO) prototype of the BIOFIRE FILMARRAY BCID2 Panel and the Cepheid Xpert MRSA/SA BC test

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**Background:** Methicillin resistance in *Staphylococcus aureus* is conferred by the meca/C gene found in the staphylococcal cassette chromosome mec (SCCmec). In cases of *S. aureus* bacteremia, timely distinction between *S. aureus* that is methicillin sensitive (MSSA) and resistant (MRSA) aids quicker implementation of appropriate therapy. Co-detection of *S. aureus*, the right-extremity junction (MREJ) of SCCmec, and meca/C increases accuracy of MRSA reporting. The BioFire® FilmArray® Blood Culture Identification 2 (BCID2) Panel, a highly multiplexed PCR test for 43 analytes from positive blood cultures (PBCs), combines detection of *S. aureus*, meca/C, and MREJ for an algorithm to report MRSA in a clinical PBC.

**Materials/methods:** The MRSA detection algorithm of the BioFire BCID2 Panel was evaluated by testing seeded PBC (BACT/ALERT® 3D (bioMérieux, Inc.)) of 85 characterized isolates (53 MRSA). Samples were tested on both the BioFire BCID2 Panel and the Cepheid® Xpert® MRSA/SA BC test. Additionally, 91 archived residual clinical PBCs, characterized through various culture methods from eight different sites, were similarly evaluated.

**Results:** Compared to the known characterizations of the 85 isolates, the Xpert® test had an 86% overall percent agreement (OPA) for MRSA detections while the BioFire BCID2 panel had a 91% OPA. The Xpert® test had a higher incidence of false positive and false negative results. Between the two PCR systems, the BioFire BCID2 Panel had a 93% OPA with the Xpert® MRSA results for these isolates. Compared to culture results for the 91 residual clinical PBCs, the BioFire BCID2 Panel and the Xpert® test both yielded 96% OPA for MRSA detection, with two false positives and two false negatives on each system. The BioFire BCID2 Panel had 100% OPA for *S. aureus* detection and 98% OPA for MRSA detection with the Xpert® test in clinical PBCs.

**Conclusions:** The BioFire BCID2 Panel algorithm yields highly reliable MRSA results comparable to standard culture methods. High agreement was also observed between the BioFire BCID2 Panel and the FDA cleared Cepheid Xpert® MRSA/SA BC test.

The RUO version of BioFire® FilmArray® BCID2 Panel used here has not been evaluated by the FDA or other regulatory agencies for In Vitro Diagnostic use.