

## Portrait Staph ID/R: A Novel Molecular Diagnostic Test for Simultaneous Identification of Staphylococcus species and Detection of the *mecA* gene Directly from Positive Blood Cultures.

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**Background:** Staphylococcal bacteremia is associated with high morbidity and mortality. The Portrait Staph ID/R Blood Culture Panel from Great Basin Diagnostics (Salt Lake City, UT) is a rapid, automated, DNA multiplex assay performed on the Portrait Dx Analyzer for simultaneous identification (ID) of *Staphylococcus aureus* and Staphylococcus species and the detection of *mecA* gene directly from positive blood cultures. For the Portrait Staph ID/R test all that is required of the operator is to add an aliquot directly from a positive blood culture bottle. The assay utilizes thermophilic helicase-dependent amplification (tHDA) technology to amplify specific sequences from Staphylococcal genomic DNA. tHDA is coupled with a hot start approach, RN2, which utilizes primers that are inactive until hybridized to target DNA at elevated temperatures, wherein RNase H2 removes a 3'-terminal blocking group, permitting DNA amplification. Multiple species specific staphylococcal DNA probes are immobilized on a modified silicon chip surface to enable eye visible detection of amplified DNA. The combination of isothermal amplification and chip-based eye visible signal creates a low cost, scalable platform. The objective of this preliminary study was to investigate the performance of the Portrait Staph ID/R compared to standard microbiological methods in our laboratory.

**Methods:** Thirty two positive blood culture bottles (BD BACTEC™ PLUS) yielding Gram positive cocci in clusters were analyzed using the Portrait Dx System. Results were simultaneously compared to the coagulase test and VITEK 2 ID/Antibiotic Susceptibility Test (AST) system (bioMerieux) with confirmation of oxacillin (OX) resistance by the CLSI cefoxitin (FOX) disk diffusion test. The time of ID and *mecA* gene detection was evaluated.

**Results:** All blood cultures were positive for *S. aureus* (n=9) or coagulase-negative staphylococci [CNS] (n=23) by conventional culture methods. The Portrait Staph ID/R correctly ID 32/32 to the genus-level and 30/32 to the species-level including 2 mixed cultures. Overall, 16/32 samples were OX/FOX resistant. The Portrait Staph ID/R detected the *mecA* gene in 5/6 OX resistant *S. aureus* and 8/10 FOX resistant CNS. On repeat testing, false negative *mecA* (3 samples) and 3 initial invalid test runs results were all resolved and in agreement by Portrait Staph ID/R and reference methods. The mean time to ID and *mecA* detection by Portrait Staph ID/R was 90 min. with minimal hands-on time.

**Conclusion:** The performance characteristics of the Portrait Staph ID/R in our laboratory compared favorably with conventional culture and AST methods. The described multiplex technology provides valuable information beyond the initial Gram stain in less than 90 min. Having more specific information about the organism could have a positive impact on initial therapy and help discriminate contaminated blood cultures.