To evaluate the accuracy of the Accelerate Pheno™ system and PhenoTest™ BC kit (AXDX) for identification (ID) and antimicrobial susceptibility testing (AST) of blood pathogens in the pediatric patient population compared to standard of care (SOC) methods.

**Methods**

**SOC Methods.** Blood culture bottles were incubated using the BACTEC™ automated blood culture system (BD Diagnostics, Sparks, MD). Microorganism ID from positive blood cultures was performed using the Bruker MALDI Biotyper Molecular Identification System (BrukerDaltonics, Billerica, MA) and biochemical testing when appropriate. AST was performed using the Microscan WalkAway-96 Plus system (Beckman Coulter, Brea, CA) and the Gram-positive PM29 and Gram-negative NM43 panels. AST interpretation was done using the Clinical Laboratory Standards Institute 2016 M100 criteria.

**Accelerate.** Positive blood culture broth from routine clinical care was used for testing on the Accelerate Pheno™ system following the manufacturer’s instructions. The resulting data was analyzed using the pre-FDA clearance Accelerate Pheno™ system software (v1.0) producing ID results within 90 minutes and AST results within 7 hours.

**Discrepancy Testing.** Microorganism ID was performed using the Vitek®2 (BioMérieux, Durham, NC). AST was performed using broth-micro dilution performed in triplicate to determine the minimal inhibitory concentration. Cefoxitin disk diffusion testing was performed for methicillin resistance determination.

**Identification of Microorganisms From Blood Culture**

**Antimicrobial Susceptibility Testing**

**Conclusions**

The Accelerate Pheno™ system and PhenoTest™ BC kit correctly identified ~83% of Gram-positive and Gram-negative microorganisms recovered from blood cultures by SOC methods.

- **Overall ID sensitivity of 96.0% and specificity of 99.1%.**
- **The majority of false positive ID results were due to off panel targets that were phylogenetically related to targets on the AXDX.**
- **The majority of false negative ID results were observed in polymicrobial blood cultures.**

**Antibiotic susceptibility testing results in an overall essential agreement of 96.3% and categorical agreement of 94.8%.** Compared to SOC testing, AXDX had 7 very major errors (S-R), 7 major errors (R>S), and 51 minor errors.

**FDA approved software v1.2 improves erythromycin AST results and antimicrobial susceptibility testing (AST) of blood pathogens in the pediatric patient population compared to standard of care (SOC) methods.**

**To evaluate the accuracy of the Accelerate Pheno™ system and PhenoTest™ BC kit (AXDX) for identification (ID) and antimicrobial susceptibility testing (AST) of blood pathogens in the pediatric patient population compared to standard of care (SOC) methods.**

**Microorganism Targets and Antibiotics Tested by Accelerate Pheno™ system and PhenoTest™ BC kit**

**Methicillin and MLSb Antimicrobial Resistance Testing**

**Table 7. Antimicrobial susceptibility testing for β-lactam and inducible clindamycin resistance for S. aureus and CNS spp.**

**Table 8. Organisms identified by SOC methods but not targeted on the AXDX (false runs).**

**Table 9. List of Gram-negative bacteria and antibiotics evaluated by AXDX**

**Table 10. Results of individual antibiotic susceptibility testing for Gram-negative bacteria**

**Table 11. List of Gram-negative bacteria and antibiotics evaluated by AXDX**

**Table 12. Results of individual antibiotic susceptibility testing for Gram-negative bacteria**

**Table 13. Correlation of microorganisms identified by AXDX and SOC**

**Table 14. Discrepancy results between AXDX and SOC**

**Table 15. Results of individual antibiotic susceptibility testing for Gram-positive bacteria**

**Table 16. Results of individual antibiotic susceptibility testing for Gram-negative bacteria**

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