Evaluation of the Accelerate Pheno™ System: Results of a Large Academic Medical Center

Cassiana Bittencourt, MD1, Erin McElvania Tekippe, PhD, D(ABMM)2,3,4, Dominick Cavuoti, DO5, Joseph Daniel Lutgring, MD6, Eileen M. Burd, PhD, D(ABMM)6, Rita Hollaway, PhD, D(ABMM)2,3,4,5
1Department of Pathology, University of California, Irvine, CA, USA, Departments of Pathology2 and Pediatrics3, University of Texas Southwestern Medical Center, Dallas, Texas, 4Children’s Health, Children’s Medical Center, Dallas, Texas, USA, Departments of Infectious Diseases and Pathology5, Emory University School of Medicine, Atlanta, GA, USA.

Introduction

Sepsis is a major cause of mortality, morbidity, and the most expensive condition treated in U.S. hospitals. Rapid diagnosis and susceptibility results can provide adequate therapy in a timely manner, improve outcomes and reduce costs. Current laboratory identification and antimicrobial susceptibility testing (AST) are based primarily on bacterial culture. Molecular testing has been used less extensively but has enabled faster pathogen identification and detection of some antimicrobial resistance genes, however phenotypic antimicrobial susceptibility testing (AST) is not provided.

The Accelerate Pheno™ system (Accelerate Diagnostics, Inc. Tucson, AZ) uses a broad panel of fluorescent in-situ hybridization assays for microorganism identification and MOMP (edited Carlson-Analyis (MCA)) using time-lapse imaging for antimicrobial susceptibility testing (AST). The system can identify 16 organisms (six Gram positive and eight Gram negative bacteria as well as two Candida species) from positive blood cultures. It provides results in 2.25 hours for identification (ID), and AST and resistance phenotypes in about 7 hours.

We present results from one academic center comparing the identification sensitivity and specificity, susceptibility testing and time to results of the Accelerate PhenoTest™ BC kit (Accelerate) to our standard of care (SOC).

Methods

From March-September 2016, 140 positive blood culture samples were included in the study and compared to our standard of care (SOC).

Blood culture bottles were inoculated in the VenusTREK™ system (TREK Diagnostic Systems, Cleveland, Ohio).

The SOC included subcultures of the positive blood culture bottles onto agar plates. Identification was achieved using the Microscan WalkAway-96 plus system (Microscan® Siemens Health Diagnostics, Inc., Deerfield, Ill.) from March to (SOC 2016) and MALDI-TOF (MaldiBta LT, Bruker Daltonics, Germany) for the subsequent months. Antimicrobial susceptibility testing was performed using Microscan panels (Phe Combi III-

The AST results for the SOC and Accelerate were interpreted according to the guidelines set by CLSI M100-S26. All samples and bacterial isolates were frozen and sent to Accelerate for further analysis, when necessary. Additional testing for discrepant results was performed using the VITEK® 2 system (bioMérieux, France) for ID and broth microdilution for AST.

Results: Identification and AST Performance

Figure 1: Accelerate Pheno™ system reportability

Table 1: Identification Performance

<table>
<thead>
<tr>
<th>Organism</th>
<th>Pheno</th>
<th>SOC</th>
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</thead>
<tbody>
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<td>Gram Positive</td>
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<tr>
<td>Staphylococcus aureus</td>
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<td>100%</td>
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<tr>
<td>Enterococcus faecalis</td>
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<tr>
<td>Gram Negative</td>
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<td>Klebsiella pneumoniae</td>
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<td>Stenotrophomonas maltophilia</td>
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Discussion and Conclusions

- Accelerate PhenoTest™ BC kit provided identification and antimicrobial susceptibility testing in 92% and 73% of the eligible samples, respectively.
- Corrected identities of 106 of 112 on-panel organisms and showed:
  - Sensitivity: 94.5%
  - Specificity: 99.1%
  - Positive predictive value: 88%
  - Negative predictive value: 99.6%
- The AST and resistance phenotype markers performance showed:
  - Categorical agreement: 94%
  - Major errors: 1.2%
  - Minor errors: 5%
  - Catheter & S. aureus agreement: 100%
  - Cathelic & CNS agreement: 75%
- Identification and antimicrobial susceptibility results were an average of 36 and 44 hours faster than SOC.
- The present study shows that the Accelerate Pheno™ system is a rapid and fully automated method with high performance in identification and phenotypic antimicrobial susceptibility for microorganisms and antimicrobials represented in the assay compared to SOC methods.
- Accelerate Pheno™ system is designed based on a modular architecture and allows for one run per module. Laboratories with a large number of positive blood cultures like ours should carefully assess workflow and capacity needs before implementation.
- Additional studies are necessary to determine the real impact of a fast phenotypic antimicrobial susceptibility on clinical decision making and patient outcomes.

References

2. last seen 5/16/2017