Evaluation of an Automated Platform for Rapid Identification and Antibiotic Sensitivity Testing of Bacteria Directly from Positive Blood Culture Bottles

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Introduction
Early diagnosis of sepsis by blood culture is a critical component of sepsis care. However, current methods cannot provide time-critical results needed to impact early patient management. Rapid PCR-based tests are available to identify bacteria and fungi from positive blood cultures and may provide predictive antibiotic susceptibility by detecting genes associated with antibiotic resistance; however, the number of organisms detected and antibiotic resistance information are limited.

The Accelerate Pheno™ system is a fully automated instrument that can detect and identify (ID) a broad range of organisms associated with sepsis and utilizes morphokinetic cellular analysis (MCA) to provide susceptibility (AST) results and MICs to an extended panel of antibiotics. IDs are available in 1.5 hours and AST results within 7 hours. This study was performed to determine the performance of this system in a hospital clinical microbiology laboratory.

Method
A total of 72 positive blood culture samples were tested on the Accelerate Pheno™ system using software v1.2 according to the manufacturer's instructions (see Figure 1). A set of 37 different Gram-positive and -negative challenge organisms were spiked into blood culture bottles with 10 mL of blood to verify the manufacturer’s claims.

An additional 35 prospective clinical samples were evaluated in this study. Positive blood culture samples were inoculated into blood culture bottles with yeast and time-critical results needed to impact early patient management. Rapid PCR-based tests are available to identify bacteria and fungi from positive blood cultures and may provide predictive antibiotic susceptibility by detecting genes associated with antibiotic resistance; however, the number of organisms detected and antibiotic resistance information are limited.

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Results (ID)
Of the 72 samples tested, 65 were evaluable for ID and AST performance assessment, and 7 were excluded (3 technical errors, 2 samples that were tested >8 hours post positivity, 1 kit exclusion, 1 ID failure).

Table 1: Identification Performance

<table>
<thead>
<tr>
<th>Organism</th>
<th>ID</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>5/5</td>
<td>100%</td>
<td>98.1%</td>
</tr>
<tr>
<td>Klebsiella pneumonia</td>
<td>3/3</td>
<td>100%</td>
<td>98.1%</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>6/6</td>
<td>100%</td>
<td>98.1%</td>
</tr>
<tr>
<td>Staphylococcus lugdunensis</td>
<td>10/10</td>
<td>100%</td>
<td>98.1%</td>
</tr>
<tr>
<td>Enterococcus faecalis</td>
<td>2/2</td>
<td>100%</td>
<td>98.1%</td>
</tr>
</tbody>
</table>

There were 2 competitive organisms in the fresh prospective samples.

Results (AST)

Table 2: Antimicrobial Susceptibility Testing Performance (Region-Discerning Testing)

For AST, overall Essential Agreement (EA) was 97.4% and Categorical Agreement (CA) was 96.2% when compared to VITEK® 2 results. One (1) very major error and 3 major errors were resolved in favor of the Accelerate Pheno™ system based on broth micro-dilution (BMD)

For AST, overall Essential Agreement (EA) was 97.4% and Categorical Agreement (CA) was 96.2% when compared to VITEK® 2 results. One (1) very major error and 3 major errors were resolved in favor of the Accelerate Pheno™ system based on broth micro-dilution (BMD).

Table 3: Resistance Detection Performance

Table 4: Difference in Time to Results Reporting

Conclusion
The Accelerate Pheno™ system demonstrated high performance when compared to conventional culture based ID and AST methods while significantly reducing time to results for positive blood cultures. This will allow physicians to modify treatment decisions considerably faster than with traditional methods, which should have a significant impact on patient care and antimicrobial stewardship efforts.