INTRODUCTION
A multicenter study was performed to evaluate the performance for MicroScan Dried Gram Negative MIC Panels with a revised formulation of imipenem using gram-negative efficacy isolates which included various members of the Enterobacteriaceae group, Acinetobacter spp., and Pseudomonas aeruginosa.

METHODS (Continued)
Study Design
• Clinical isolate testing
• MSDGN panels were tested concurrently with a CLSI frozen broth microdilution reference panel at four sites using both the turbidity and Prompt™ inoculation methods.
• A total of 419 clinical efficacy isolates:
  • 39 Acinetobacter spp.
  • 295 Enterobacteriaceae including specific isolates with known mechanisms of resistance.
• Reference panels were prepared and frozen following CLSI/VISO recommendations.
• Reproducibility organisms with known results on-scale for imipenem were tested in triplicate (for each inoculation method) on the MSDGN panels and singly on the frozen reference panel on three different days at each site.
• MSDGN panels were tested using both the turbidity and Prompt inoculation methods and read manually, on the WalkAway system, and the autoSCAN-4 instrument.

Quality Control
• Quality control (QC) testing was performed daily using ATCC 25922 E. coli and ATCC 27853 P. aeruginosa using FDA QC ranges.

Quality Control Expected Results
• E. coli ATCC 29222: ≤0.25 µg/mL.
• P. aeruginosa ATCC 27853: 1.4 µg/mL.

Panel Inoculation, Incubation, and Reading
• All isolates were subcultured in trypticase soy agar (TSA) with 5% sheep blood and incubated for 18-24 hours at 35-37°C prior to testing. Isolates from frozen stocks were subcultured twice before testing.
• Inoculum suspensions for each strain were prepared with the direct standardization (turbidity standard) method for MSDGN panels and frozen reference panels. MSDGN panels were also inoculated using the Prompt Inoculation method.
• Following inoculation, MSDGN panels were also incubated at 35 ± 2°C in WalkAway system. All panels were read manually, on the WalkAway system, and the autoSCAN-4 instrument.
• Frozen reference panels were read and at 16-20 hours for all organisms except Acinetobacter spp., which were read at 20-24 hours.
• Read times for the MSDGN panels were at 18 hours for all species

RESULTS

Table 1 Imipenem FDA Interpretive Breakpoints (µg/mL)

<table>
<thead>
<tr>
<th>Organism Group</th>
<th>No.</th>
<th>%</th>
<th>No.</th>
<th>%</th>
<th>No.</th>
<th>%</th>
<th>No.</th>
<th>%</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enterobacteriaceae</td>
<td>295</td>
<td>99.7</td>
<td>281</td>
<td>95.3</td>
<td>14</td>
<td>4.7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Acinetobacter spp.</td>
<td>39</td>
<td>100</td>
<td>36</td>
<td>92.3</td>
<td>3</td>
<td>7.7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>85</td>
<td>97.6</td>
<td>82</td>
<td>96.5</td>
<td>2</td>
<td>2.4</td>
<td>1</td>
<td>1.2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Efficacy (Tables 2,3,4,5,6 and 7)

• A total of 419 clinical efficacy isolates were tested among three sites using the turbidity and Prompt inoculation method by manual read, on the WalkAway System and the autoSCAN-4 instrument. Performance data is presented as mapped dilution range of 0.25 – 8 µg/mL.

Table 3 Efficacy – WalkAway Read, Prompt Inoculation Method

<table>
<thead>
<tr>
<th>Organism Group</th>
<th>MIC (µg/mL)</th>
<th>Ref</th>
<th>Turbidity</th>
<th>Prompt</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. coli ATCC 25922</td>
<td>0.25</td>
<td>98.9</td>
<td>96.8</td>
<td>95.7</td>
</tr>
<tr>
<td>P. aeruginosa ATCC 27853</td>
<td>1-4</td>
<td>98.4</td>
<td>100</td>
<td>99.5</td>
</tr>
</tbody>
</table>

Reproducibility

Overall agreement (within ±two fold dilution) between all sites for the reproducibility phase was 95% for all combinations when compared to a frozen reference panel tested the same day (expected value.)

Table 9 Reproducibility

<table>
<thead>
<tr>
<th>Method</th>
<th>Inoculation Method</th>
<th>No. (%) Agreement</th>
<th>All Sites Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual Read</td>
<td>Turbidity</td>
<td>270/270 (100)</td>
<td></td>
</tr>
<tr>
<td>WalkAway</td>
<td>autoSCAN-4</td>
<td>268/268 (99.6)</td>
<td>269/269 (98.5)</td>
</tr>
<tr>
<td>Prompt™</td>
<td>269/269 (98.5)</td>
<td></td>
<td></td>
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</tbody>
</table>

CONCLUSION
This multicenter study showed that the improved imipenem MIC results for Gram negative bacilli obtained with the MSDGN panel correlate well with MICs obtained using frozen reference panels.

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