A comparison of Piperacillin-Tazobactam and Colistin ComASP™ (SensiTest) MIC to CLSI Broth Microdilution MICs for Gram Negative Challenge Isolates

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Abstract:

Background: The ComASP™ (previous product name was SenSiTest) was recently developed by Liofilchem to provide a manual broth microdilution option for MIC testing of single antimicrobial agents using a 32-well dried (dessicated) panel. The ComASP was developed by Liofilchem to provide a manual broth microdilution option for MIC testing of single antimicrobial agents using a 32-well dried (dessicated) panel. This method has been shown to provide results similar to those of CLSI broth microdilution methods and was approved by laboratories participating in the CLSI proficiency testing scheme.

Methods:

Piperacillin-Tazobactam

Testing Site: Laboratory Specialists, Inc.

MIC Method: Each study isolate and QC strain was tested once by Reference and Test Methods

Reference Method: CLSI broth microdilution (BMD) (catalog no. 75001, Liofilchem (Waltham, MA))

Test Method: ComASP (catalog no. 75001, Liofilchem (Waltham, MA))

Result: Piperacillin/Tazobactam (P-T) includes a wide range of concentrations (0.008-128 ug/mL), developed by Liofilchem to provide a manual broth microdilution option for MIC testing of a single agent as a supplement to a clinical laboratory’s automated system.

Colistin

MIC Method: Each study isolate and QC strain was tested once by Reference and Test Methods

Reference Method: CLSI broth microdilution (BMD) (catalog no. 75001, Liofilchem (Waltham, MA))

Test Method: ComASP (catalog no. 75001, Liofilchem (Waltham, MA))

Result: Colistin MICs are available in the US for piperacillin-tazobactam (P-T). ComASP is a 32 well broth microdilution MIC panel manually.

Background:

• This study compared the piperacillin/tazobactam and colistin ComASP MIC results to results near the breakpoint, as well as resistant isolates.

• Background: Background used for colistin. This study was performed as an initial evaluation at a single antimicrobial agent using a 32-well dried (dessicated) panel. The ComASP method is a single broth microdilution MIC panel that would use an option, other than gradient dilution, for testing of a single agent as a supplement to a clinical laboratory’s automated system.

Introduction:

• Compact Antimicrobial Susceptibility Panels (ComASP™). Liofilchem, Waltham, MA are available for a select number of antimicrobial agents, including colistin and piperacillin-tazobactam (P-T). ComASP is a 32 well broth microdilution MIC panel which contains reconstituted antimicrobial agents that are reconstituted from dried (dessicated) panels in colon adjusted Mueller Hinton broth (CAMHB), inactivated and read manually.

• This study was performed as an initial evaluation prior to possible further multi-site and/or 510(k) studies. Currently the ComASP products are available in the US for research use only.

• This study compared the piperacillin/tazobactam and colistin ComASP MIC results to broth microdilution MICs for challenge isolates, which included isolates with MIC results near the breakpoint, as well as resistant isolates.

Results:

Piperacillin-Tazobactam

• Clinical isolates: 28 Gram-negative bacteria: 2 E. cloacae, 8 E. coli, 2 K. pneumoniae, 1 P. aeruginosa, 4 A. baumannii, 10 S. maltophilia, 7 P. mirabilis, and 5 isolates were susceptible to P-T.

Colistin

• Clinical isolates: 28 Gram-negative bacteria: 1 C. freundii, 1 C. lari, 4 E. aerogenes, 1 E. cloacae, 4 E. coli, 1 E. cloacae, 1 E. freundii, 2 K. pneumoniae, 2 K. pneumoniae, 4 A. baumannii, 10 P. aeruginosa, 7 P. aeruginosa, 4 P. mirabilis, and 10 isolates were susceptible to colistin.

Conclusions:

• Clinical Isolates:

<table>
<thead>
<tr>
<th>Organism</th>
<th>MIC (ug/mL)</th>
<th>MIC (ug/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. cloacae</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>E. coli</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>K. pneumoniae</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>P. aeruginosa</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Note: MICs determined by CLSI, CLSI reference values not shown.

Quality Control Isolates:

• E. coli ATCC 25922
• E. coli ATCC 35218
• K. pneumoniae ATCC 700603
• P. aeruginosa ATCC 27853

Results:

Piperacillin-Tazobactam

• MIC results were within +/- one doubling dilution for 28/28 isolates (100% essential agreement). The bias in selecting strains near the breakpoint, resulted in a higher ComASP (98.1% essential agreement). Category agreement was 100%. The trending that was observed (slightly higher ComASP results) occurred at lower MICs (0.06-0.12 ug/mL).

Colistin

• MIC results were within +/- one doubling dilution for 27/28 isolates (96.4% essential agreement). The Colistin MIC compared similar to reference BMD against a challenge set of Enterobacteriaceae, P. aeruginosa and A. baumannii isolates. Additional multi-site studies and/or a 510(k) study is warranted.

Figure 1. Piperacillin/Tazobactam ComASP MIC compared to BMD MIC (ug/mL) for 28 Gram negative challenge isolates

Figure 2. Colistin ComASP MIC compared to BMD MIC (ug/mL) for 28 Gram negative challenge isolates*