Multi-Site Evaluation of Dalbavancin and Vancomycin MIC Test Strip Compared To Broth Microdilution MICs

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Methods

- **Organism**: S. aureus, E. faecalis, and E. faecium
- **Test Systems**: MTS (Figures 1 and 2) and BMD (Figures 3 and 4)
- **Test Conditions**: MTS MIC results were within +/- one doubling dilution for 97.4% (377/387) of S. aureus, 98.6% (352/353) of E. faecalis, and 99.7% (352/353) of E. faecium.

Results

- **Quality Control (Table 1)**: All S. aureus & E. faecium MTS MIC results were within +/- one doubling dilution for BMD MIC for all isolates with only one exception.
- **Overall EA**: 100.0% for S. aureus, 99.7% for E. faecalis, and 99.7% for E. faecium.
- **Errors**: Minor NA NA, Very Major 0/79 0.0%, Major 0/379 0.0%

Conclusions

- The dalbavancin and vancomycin MTS against S. aureus and Enterococcus spp. performed similarly to BMD testing.
- There was an agreement of 100.0% for dalbavancin and vancomycin MTS against S. aureus and Enterococcus spp.
- The dalbavancin MTS MIC results of 0.25 µg/mL were challenge VISA and VRSA isolates.
- Although essential agreement was 100% for dalbavancin against E. faecalis, based on a high prevalence of very major errors (7/11) for S. aureus with dalbavancin MTS MIC of 0.25 µg/mL, and broth microdilution MIC of 0.5 µg/mL, additional replication testing with one or two additional strains with positive dalbavancin results is warranted.
- The vancomycin MTS was recently cleared for in vitro diagnostic use and the dalbavancin MTS is currently under review by the FDA.

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References


Abstract:

Background: Dalbavancin and vancomycin are antibiotics used for treatment of acute bacterial skin and skin structure infections caused by Gram-positive organisms. This study was performed to evaluate the performance of the dalbavancin and vancomycin MIC test strips (MTS) from Lithifilm(R) (Rossotti degli Abruzzi, Italy) compared to a broth microdilution method (BMD) for FDA 1010s Antimicrobial Activity (AAL). Clinical and Challenge isolates were tested by BMD with frozen panels and by MTS. For dalbavancin, 311 S. aureus and 37 E. faecalis from recent clinical isolates were collected and tested at 3 sites, 76 S. aureus, 39 S. epidermidis and 37 E. faecium challenge isolates were tested at 1 site, and for reproducibility 10 S. aureus and 10 E. faecalis were tested 10 times at 3 sites. For vancomycin, 312 S. aureus, 20 S. epidermidis, 37 E. faecalis, and 62 E. faecium from recent clinical isolates were collected and tested at 3 sites, 78 challenge isolates (41 S. aureus, 5 S. epidermidis, 11 E. faecalis, and 24 E. faecium) were tested at 1 site, and for reproducibility 10 isolates were tested 10 times at 3 sites. QC strains (S. aureus ATCC 29213 and E. faecalis ATCC 29212) were tested a minimum of 20 times by each site (Rossotti). As shown in the table, the challenge isolates were tested in triplicate at 3 sites on 3 days) were within a doubling dilution of reference broth microdilution results.

Introduction

- This study compared the MTS against S. aureus and E. faecalis and less extensive results were obtained for S. epidermidis.
- The Lithifilm/MC test strip is a quantitative agar based diffusion assay for determining the minimum inhibitory concentration (MIC). The study was performed as part of a 510k study (for "in vitro diagnostic use") in the U.S.
- This study compared the dalbavancin MTS to broth microdilution/MIC for the indicated Gram positive organisms: S. aureus and E. faecalis.
- This study compared the dalbavancin MTS to broth microdilution/MIC for the FDA Instated Gram positive organisms: S. aureus, S. epidermidis, E. faecalis and E. faecium.

Table 1. Dalbavancin and Vancomycin MTS Quality Control Results

<table>
<thead>
<tr>
<th>Organism</th>
<th>Vancomycin MTS</th>
<th>Dalbavancin MTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus</td>
<td>0.25 µg/mL</td>
<td>0.25 µg/mL</td>
</tr>
<tr>
<td>E. faecalis</td>
<td>0.5 µg/mL</td>
<td>0.5 µg/mL</td>
</tr>
<tr>
<td>E. faecium</td>
<td>0.5 µg/mL</td>
<td>0.5 µg/mL</td>
</tr>
</tbody>
</table>

Table 2. BMD Reference Results

<table>
<thead>
<tr>
<th>Organism</th>
<th>Category Agreement</th>
<th>Overall EA</th>
<th>Minor</th>
<th>Very Major</th>
<th>Major</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus</td>
<td>99.4%</td>
<td>100.0%</td>
<td>NA</td>
<td>NA</td>
<td>0.0%</td>
</tr>
<tr>
<td>E. faecalis</td>
<td>99.7%</td>
<td>100.0%</td>
<td>NA</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>E. faecium</td>
<td>99.7%</td>
<td>100.0%</td>
<td>NA</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Figure 1. Dalbavancin MTS MIC compared to BMD MIC for S. aureus.
Figure 2. Dalbavancin MTS MIC compared to BMD MIC for E. faecalis.
Figure 3. Vancomycin MTS MIC compared to BMD MIC for S. aureus.
Figure 4. Vancomycin MTS MIC compared to BMD MIC for E. faecalis.