Introduction:
Loftishem (Rosello de Abatuzzo, Italy) manufactures MIC test strips (MTS) for a variety of antimicrobial agents, including meropenem/vaborbactam. The Loftishem MIC test strip is a quantitative agar-based diffusion assay for determining the minimum inhibitory concentration (MIC).

This study was performed as part of a 510(k) study for “in vitro diagnostic use” label in the U.S.

This study compared the meropenem/vaborbactam (M/V) MTS with broth microdilution MIC (BMD) for Enterobacteriaceae and Enterococcus faecalis species complex. Enterobacter cloacae and Klebsiella pneumoniae were included in the study as the most common Enterobacteriaceae species and as a positive control, respectively.

Methods:
This study compared the meropenem/vaborbactam (M/V) MIC Test Strip (MTS, Loftishem, Roseto degli Abruzzi, Italy) with the broth microdilution (BMD, CLSI Approved Method) MIC method for Enterobacteriaceae and Enterococcus faecalis species complex. Enterobacter cloacae and Klebsiella pneumoniae were included in the study as the most common Enterobacteriaceae species and as a positive control, respectively. The Loftishem MIC test strip is a quantitative agar-based diffusion assay for determining the minimum inhibitory concentration (MIC).

The study was performed at a single site in the U.S. The study population consisted of 100 microorganisms, including enterobacteria and enterococci. The study was conducted under the Clinical Laboratory Improvement Amendments (CLIA) and was approved by the institutional review board.

A total of 100 microorganisms were tested in the study, including 88 Enterobacteriaceae and 25 Pseudomonas aeruginosa. The microorganisms were tested by BMD with frozen panels (according to CLSI M7-A10 and M100-S27) and by MTS. The reproducibility isolates were tested each day of testing and a total 20 replicates/site were tested.

Results:
• M/V MTS trended up to 1 dilution higher compared to the BMD MICs, particularly at the very low end of the MIC range (i.e., 0.016/8-256/8 µg/mL).
• For reproducibility isolates, 97% of M/V MTS results were within a doubling dilution of BMD MIC results for Enterobacteriaceae and 75% for Pseudomonas aeruginosa. The number of challenge organisms with molecular characterization resistance statuses were as follows: E. coli (n = 15), 139/150 (95.1%), K. pneumoniae (n = 26, 104/105 (95.1%), P. aeruginosa (n = 25, 128/128 (100%).
• Overall, 96% of all M/V MTS results were within ±1 doubling dilution of BMD MIC results for Enterobacteriaceae species with QA results for 75% of P. aeruginosa.

Conclusions:
The meropenem/vaborbactam MTS was cleared for in vitro diagnostic use by the FDA. The MTS trended up to 1 dilution higher compared to BMD MICs, particularly at the very low end of the MIC range. This study showed that the MTS results were well above the 90% acceptance criteria (96%), however, overall there was trend for higher MTS results.

Acknowledgement:
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References:

Table 1. Meropenem-Vaborbactam BMD and MTS Quality Control Results by Testing Site

<table>
<thead>
<tr>
<th>Site</th>
<th>Recovery</th>
<th>E. coli</th>
<th>P. aeruginosa</th>
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<tbody>
<tr>
<td>Site 1</td>
<td>95.6%</td>
<td>97.1%</td>
<td>95.6%</td>
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</table>

Figure 1. Meropenem-vaborbactam MTS compared to BMD MIC for 478 Enterobacteriaceae (150 EA, evaluable results of 167 EA, Note: )

Figure 2. Meropenem-vaborbactam MTS compared to BMD MIC for 121 P. aeruginosa (120 EA, evaluable results of 118 EA, Note: )

Figure 3. Meropenem-vaborbactam MTS compared to BMD MIC for 100 E. coli (100 EA, evaluable results of 100 EA, Note: )

Figure 4. Meropenem/vaborbactam MTS MIC compared to M/V BMD MIC for 478 Enterobacteriaceae* (number of results at each MIC)

Figure 5. Meropenem/vaborbactam MTS MIC compared to M/V BMD MIC for 100 P. aeruginosa (number of results at each MIC)