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Oxoid Meropenem/Vaborbactam Disc (30µg), MEV30 Performance Data Supplement

Intended Use/Indications for Use

Thermo Scientific™ Oxoid™ Antimicrobial Susceptibility Test (AST) Discs are used in the semi quantitative agar diffusion test method for in vitro susceptibility testing.

The Oxoid Meropenem/Vaborbactam Disc (30µg) MEV 30 can be used to determine susceptibility to Meropenem/Vaborbactam against the following bacteria for which Meropenem/Vaborbactam has been shown to be active both clinically and *in vitro*:

Escherichia coli

Klebsiella pneumoniae

Enterobacter cloacae species complex

Meropenem/Vaborbactam interpretive criteria and quality control ranges;

Disk Diffusion Zone Diameter Chart – Meropenem-Vaborbactam MEV30								
Antimicrobial Agent (Concentration, Code)	Organism(s)	Zone Diameter Interpretive Criteria (mm)			QC Zone Diameter Ranges (mm)			
		Resistant	Intermediate	Susceptible	<i>Escherichia coli</i> ATCC 25922	<i>Klebsiella pneumoniae</i> ATCC 700603 ^b	<i>Klebsiella pneumoniae</i> ATCC BAA-1705 ^{a, b}	<i>Klebsiella pneumoniae</i> ATCC BAA-2814 ^a
Meropenem-Vaborbactam (30µg, MEV30)	<i>Enterobacteriaceae</i>	≤13	14 - 16	≥17	31-37	29-35	21-27	16-20

^aEither strain may be used for routine QC of this antimicrobial agent.

^bRefer to the current CLSI M100 for β-Lactam combination agents QC integrity maintenance information.

Performance Characteristics

The Oxoid Meropenem/Vaborbactam disc (30 µg, MEV30) was compared with a cleared disk (predicate) of the same antimicrobial, mass and concentration. The study included 300 clinical and 75 challenge isolates. The category agreement (CA) with the predicate was as follows:

Organism(s)	Total	CA (#)	CA (%)
<i>Enterobacteriaceae</i> ^{1, 2, 3}	375	372	99.2

¹ Including indicated organisms *K. pneumoniae* (184), *Escherichia coli* (121), and *Enterobacter cloacae* spp. Complex (35).

² The safety and efficacy of meropenem/vaborbactam in treating clinical infections due to Gram-Negative organisms other than *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae* species complex may or may not have been established in adequate and well-controlled clinical trials. The clinical significance of such susceptibility information in those instances is unknown.





³ The performance of Oxoid Meropenem/Vaborbactam disk (30 µg) MEV30 is unknown for *Enterobacteriaceae* with the following resistance mechanisms: overexpression of efflux pumps and/or lower expression of porins.

Reproducibility

The reproducibility study was performed by testing 15 *Enterobacteriaceae* isolates with two disk lots on three separate days. Each test was visually read by three independent readers. The reproducibility was 100% between disk lots and across readers.

