DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K183127

Device Name

MicroScan Dried Gram-Negative MIC/Combo Panels with Meropenem/Vaborbactam (0.03/8 - 64/8µg/mL)

Indications for Use *(Describe)*

The MicroScan Dried Gram-Negative MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-negative bacilli. After inoculation, panels are incubated for 16 – 20 hours at 35°C +/- 1°C in a non-CO2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for the addition of the antimicrobial meropenem/vaborbactam at concentrations of 0.03/8 to 64/8 µg/mL to the test panel.
The gram-negative organisms which may be used for meropenem/vaborbactam susceptibility testing in this panel are as follows:
Meropenem/vaborbactam has been shown to be active both clinically and in vitro against the gram negative bacteria listed below according to the FDA drug approved label:

- *Enterobacter cloacae complex*
- *Escherichia coli*
- *Klebsiella pneumoniae*

Meropenem/vaborbactam has been shown to be active in vitro only against the gram-negative bacteria listed below according to the FDA drug approved label:

- *Citrobacter freundii*
- *Citrobacter koseri*
- *Enterobacter aerogenes*
- *Klebsiella oxytoca*
- *Morganella morganii*
- *Proteus mirabilis*
- *Providencia spp*
- *Serratia marcescens*

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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