DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K183360

Device Name

VITEK® 2 AST-Gram Negative Meropenem/Vaborbactam (≤0.5/8 – ≥64/8 µg/mL)

Indications for Use *(Describe)*

VITEK® 2 AST-Gram Negative Meropenem/Vaborbactam is designed for antimicrobial susceptibility testing of Gram-negative bacilli and is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK® 2 AST-Gram Negative Meropenem/Vaborbactam is a quantitative test. Meropenem/Vaborbactam has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

Active *in vitro* and in clinical infections:
Enterobacter cloacae complex
Escherichia coli
Klebsiella pneumoniae

In vitro data are available, but clinical significance is unknown:
Citrobacater freundii
Citrobacter koseri
Klebsiella (Enterobacter) aerogenes
Klebsiella oxytoca
Morganella morganii
Proteus mirabilis
Providencia spp.
Serratia marcescens

The VITEK® 2 Gram-Negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

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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