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)*

K183524

Device Name

VITEK AST-Gram Negative Delafloxacin (≤0.06 - ≥4 ug/mL)

Indications for Use *(Describe)*

VITEK 2 AST-Gram Negative Delafloxacin 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 Delafloxacin is a quantitative test. Delafloxacin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

Active both *in vitro* and in clinical infections
Escherichia coli
Enterobacter cloacae
Klebsiella pneumoniae
Pseudomonas aeruginosa

The VITEK 2 Gram-negative Susceptibility Card is intended to 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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