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)*

K183551

Device Name

VITEK® 2 AST-Gram Negative Minocycline (≤ 0.5 - ≥ 32 µg/mL)

Indications for Use *(Describe)*

VITEK® 2 AST-Gram Negative Minocycline 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 Minocycline is a quantitative test. Minocycline 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:

*Acinetobacter* spp.
*Klebsiella* (*Enterobacter*) aerogenes
*Escherichia coli*
*Klebsiella* spp.

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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