DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190109

Device Name

MicroScan Dried Gram-Negative MIC/Combo Panels with Eravacycline (ERV) (0.016-32 µg/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-CO_2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for the addition of the antimicrobial eravacycline (ERV) at concentrations of 0.016 to 32 µg/mL to the test panel.

The gram-negative organisms which may be used for eravacycline susceptibility testing on this panel are as follows:
Eravacycline 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:
• *Citrobacter freundii*
• *Enterobacter cloacae*
• *Escherichia coli*
• *Klebsiella oxytoca*
• *Klebsiella pneumoniae*

Eravacycline has been shown to be active in vitro only against the gram-negative bacteria listed below according to the FDA drug approved label:
• *Citrobacter koseri*
• *Klebsiella* (Enterobacter) *aerogenes*

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."