510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Beckman Coulter
Contact name:	Elaine Duncan, Senior Analyst Regulatory Affairs
Phone:	916-374-3279
Fax:	916-374-2480
Date prepared:	November 02, 2018
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan Dried Gram-Negative MIC/Combo Panels with Meropenem/Vaborbactam (0.03/8-64/8 µg/mL)
Intended Use:	To determine antimicrobial agent susceptibility
Classification:	Class II
Product Code:	LTT
510(k) Notification:	New antimicrobial agent – Meropenem/Vaborbactam
Predicate device:	MicroScan Dried Gram-Negative MIC/Combo Panels Ceftazidime/Avibactam – (K172337)

510(k) Summary:

MicroScan Dried Gram-Negative MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-negative bacilli.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in broth and dehydrated. Various antimicrobial agents are diluted in broth to concentrations bridging the range of clinical interest. Panels are rehydrated with water after inoculation with a standardized suspension of the organism. After incubation in a non-CO_2 incubator for 16-20 hours, the minimum inhibitory concentration (MIC) for the test organism is read by determining the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan Dried Gram-Negative MIC/Combo Panel demonstrated substantially equivalent performance when compared with a CLSI frozen Reference Panel, as defined in the FDA document ”Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA”, dated August 28, 2009. The Premarket Notification (510[k]) presents data in support of the MicroScan Dried Gram-Negative MIC/Combo Panel with meropenem/vaborbactam.

The external evaluations were conducted with fresh, recent and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed Dried Gram-Negative Panel by comparing its performance with a CLSI frozen Reference panel. The Dried Gram-Negative Panel demonstrated acceptable performance with an overall Essential Agreement of 98.3% for meropenem/vaborbactam when compared with the frozen Reference panel.

Inoculum and instrument reproducibility testing demonstrated acceptable reproducibility and precision with meropenem/vaborbactam, regardless of which inoculum method (i.e., Turbidity or Prompt®), or instrument (autoSCAN-4 instrument or WalkAway system) was used.

Quality Control testing demonstrated acceptable results for meropenem/vaborbactam.

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

Prompt® is a registered trademark of 3M Company, St. Paul, MN USA