

K250084 MicroScan Dried Gram-Negative MIC/Combo Panels with Aztreonam (AZT) (0.5-64 µg/mL)Jul 18, 2025
186 days to decisionK250084 · Product code: LTT · Microbiology
Source: <https://www.510kdatabase.net/k250084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Panels, Test, Susceptibility, Antimicrobial (LTT)
Date received	Jan 13, 2025
Decision date	Jul 18, 2025
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	Elaine Duncan
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...