

## K201423 MicroScan Dried Gram-Negative MIC/Combo Panels with Meropenem (Mer) (0.004-32 µg/mL)

Jun 29, 2020  
31 days to decision

K201423 · Product code: LTT · Microbiology  
Source: <https://www.510kdatabase.net/k201423/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Panels, Test, Susceptibility, Antimicrobial (LTT)
Date received	May 29, 2020
Decision date	Jun 29, 2020
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Beckman Coulter, Inc.</b>
Location	Chaska, MN, US
Contact	Elaine Duncan
Website	<a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a>
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,...