

K201675 VITEK 2 AST-Gram Negative Meropenem (<= 0.25 - >=16 µg/mL)Jul 9, 2021
385 days to decisionK201675 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k201675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Jun 19, 2020
Decision date	Jul 9, 2021
Days to decision	385 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	Debra Broyles
510(k) history	251 submissions · 250 cleared · 1983-2026

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