

K213931 VITEK 2 AST-Gram Negative Omadacycline (≤ 0.25 - ≥ 16 $\mu\text{g/mL}$)Jun 3, 2022
169 days to decisionK213931 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k213931/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Dec 16, 2021
Decision date	Jun 3, 2022
Days to decision	169 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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