

K251579 VITEK 2 AST-Gram Negative Cefazolin (= <1=>32 µg/mL)Aug 21, 2025
90 days to decisionK251579 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k251579/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	May 23, 2025
Decision date	Aug 21, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

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

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