

K193299 VITEK 2 AST-Gram Negative Ceftazidime (≤ 0.5 - $\Rightarrow 32$ $\mu\text{g/mL}$)Sep 28, 2020
306 days to decisionK193299 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k193299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Nov 27, 2019
Decision date	Sep 28, 2020
Days to decision	306 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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