

K193567 VITEK 2 AST- Gram Negative Polymyxin B (<=0.25 – >=16 ug/mL)

Feb 14, 2020
53 days to decision

K193567 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k193567/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Dec 23, 2019
Decision date	Feb 14, 2020
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k193567/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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