

K202396 VITEK 2 AST-Gram Positive Fosfomycin (<=8 - >=256 ug/mL)Sep 14, 2021
389 days to decisionK202396 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k202396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Aug 21, 2020
Decision date	Sep 14, 2021
Days to decision	389 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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