

**K232967 VITEK 2 AST-Yeast Voriconazole (<= 0.03125 - >= 4 µg/mL)**Jun 12, 2024  
265 days to decisionK232967 · Product code: **NGZ** · Microbiology  
Source: <https://www.510kdatabase.net/k232967/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Plate, Antifungal (NGZ)
Date received	Sep 21, 2023
Decision date	Jun 12, 2024
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232967/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026