

**K213241 VITEK 2 AST-Yeast Fluconazole (<=0.5->=64 µg/mL),  
VITEK 2 AST-YS Fluconazole (<=0.5->=64 µg/mL), VITEK 2 AST-  
YS Fluconazole**Feb 25, 2022  
148 days to decisionK213241 · Product code: **LON** · Microbiology  
Source: <https://www.510kdatabase.net/k213241/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Sep 30, 2021
Decision date	Feb 25, 2022
Days to decision	148 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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