

**K163083 VITEK 2 AST-GN Tobramycin (</=1->/= 16 ug/mL)**Feb 1, 2017  
90 days to decisionK163083 · Product code: **LON** · Microbiology  
Source: <https://www.510kdatabase.net/k163083/>**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	Nov 3, 2016
Decision date	Feb 1, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary
Other names	VITEK 2 AST-Gram Negative Tobramycin (</=1->/=16 ug/mL)

**APPLICANT**

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Company	<b>bioMerieux, Inc.</b>
Location	Mchenry, IL, US
Contact	Mary Beth Anheuser
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/k163083/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026