

**K163006 VITEK 2 AST-GN Tigecycline (<0.5->8 ug/mL)**Jan 24, 2017  
88 days to decisionK163006 · Product code: **LON** · Microbiology  
Source: <https://www.510kdatabase.net/k163006/>**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	Oct 28, 2016
Decision date	Jan 24, 2017
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>bioMerieux, Inc.</b>
Location	Mchenry, IL, US
Contact	Jennifer Jines
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/k163006/> 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