

**K152075 VITEK 2 AST-Gram Negative Ertapenem ( $\leq 0.12$  -  $\geq 8$  ug/mL)**Apr 15, 2016  
263 days to decisionK152075 · Product code: **LON** · Microbiology  
Source: <https://www.510kdatabase.net/k152075/>**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	Jul 27, 2015
Decision date	Apr 15, 2016
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>bioMerieux, Inc.</b>
Location	Mchenry, IL, US
Contact	Cherece L Jones
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/k152075/>; 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 3, 2026