

**K211630 VITEK 2 AST-Gram Negative Piperacillin / Tazobactam  
( $\leq 4$  -  $\Rightarrow 128$   $\mu\text{g/mL}$ )**Aug 30, 2021  
95 days to decisionK211630 · Product code: **LON** · Microbiology  
Source: <https://www.510kdatabase.net/k211630/>**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	May 27, 2021
Decision date	Aug 30, 2021
Days to decision	95 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	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/k211630/> 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