

**K161437 VITEK 2 AST Gram Negative Cefotaxime ( $\leq 0.25$  -  $\geq 64$  ug/mL)**Feb 16, 2017  
268 days to decisionK161437 · Product code: **LON** · Microbiology  
Source: <https://www.510kdatabase.net/k161437/>**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 24, 2016  |
| Decision date         | Feb 16, 2017  |
| Days to decision      | 268 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>bioMerieux, Inc.</b>                   |
| Location       | Mchenry, IL, US                           |
| Contact        | KAREN RUSSELL                             |
| 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/k161437/>; 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