

**K211136 VITEK 2 AST-Gram Negative Imipenem/Relebactam
(<0.25/4 - >16/4 ug/ML)**Jun 14, 2021
59 days to decisionK211136 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k211136/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON) |
| Date received | Apr 16, 2021 |
| Decision date | Jun 14, 2021 |
| Days to decision | 59 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | bioMerieux, Inc. |
| Location | Mchenry, IL, US |
| Contact | Esther Hernandez |
| 510(k) history | 251 submissions · 250 cleared · 1983-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211136/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026