

K190616 VITEK 2 AST-Gram Positive Dalbavancin (<= 0.015 - >= 1 µg/mL)Jun 6, 2019
87 days to decisionK190616 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k190616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Mar 11, 2019
Decision date	Jun 6, 2019
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	Cherece L. Jones
510(k) history	251 submissions · 250 cleared · 1983-2026

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