

**K241324 LifeScale Gram Negative Kit (LSGN) with the LifeScale
AST system**Oct 23, 2024
166 days to decisionK241324 · Product code: **SAN** · Microbiology
Source: <https://www.510kdatabase.net/k241324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Antimicrobial Susceptibility Test System For Positive Blood Culture Samples (SAN)
Date received	May 10, 2024
Decision date	Oct 23, 2024
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Affinity Biosensors, LLC
Location	Santa Barbara, CA, US
Contact	Ken Babcock
510(k) history	2 submissions · 2 cleared · 2024-2025

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