

K251875 LifeScale Gram Negative Kit (LSGN) with the LifeScale AST system

Oct 27, 2025
131 days to decision

K251875 · Product code: **SAN** · Microbiology
Source: <https://www.510kdatabase.net/k251875/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Antimicrobial Susceptibility Test System For Positive Blood Culture Samples (SAN)
Date received	Jun 18, 2025
Decision date	Oct 27, 2025
Days to decision	131 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251875/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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