Performance Evaluations of the LifeScale Rapid AST Across Pediatric and Adult Patient Populations

*E. Hennessee, M. Akbari, J. Tedesco, C. Schneider, K. Babcock

Affinity Biosensors. 222 East Canon Perdido Street, Santa Barbara, CA. 93101

Abstract

Background:
Rapid Antimicrobial Susceptibility Tests (rASTs) are essential for delivering lifesaving, targeted treatments and mitigating the spread of antimicrobial resistance. The LifeScale AST system (Affinity Biosensors) is an FDA-cleared, microfluidic-based rAST that provides phenotypic AST results for Gram-negative organisms directly from positive blood culture (PBC). Eight hospitals assessed the accuracy and time-to-results of the LifeScale AST system's LSGN Panel compared to their standard-of-care (SOC) automated AST platforms. A total of 838 clinical PBCs (576 prospective and 262 spiked), sourced from adult and pediatric patients, were included.

Methods:
PBCs positive for Gram-negative bacteremia were tested on the LifeScale and the automated SOC AST platforms at eight sites: University of Louisville, Baylor Scott and White (Temple, TX), New York-Presbyterian - Columbia University Irving Medical Center, and Memorial Sloan Kettering Cancer Center: MicroScan WalkAway (Beckman Coulter); Associated Regional and University Pathologists and Spartanburg Medical Center: Phoenix (Becton Dickinson); Nationwide Children's Hospital and Northwestern Memorial Hospital: Vitek II (bioMérieux). Samples included prospective patient specimens and seeded resistant challenge strains. Pediatric samples were tested using adult blood culture bottles. MICs and interpretations for 14 antibiotics on the LSGN panel were compared to SOC results for *Enterobacterales*, *P. aeruginosa*, and *Acinetobacter species*. Very Major and Major discrepancies were adjudicated using CLSI reference broth microdilution (rBMD).

Results:
The studies tested 576 prospective and 262 seeded challenge samples, resulting in 8,879 organism/antibiotic combinations. Following adjudication by rBMD, Essential agreement to the SOC platforms was 96.37% and Categorical agreement was 94.59%. Performance was consistent for adult and pediatric samples, with a slightly longer average time-to-results for pediatric samples (5.5 hr vs. 4.9 hr).

Conclusions:
Conducted from November 2021 to May 2025 across eight hospitals, these studies demonstrated that the LifeScale AST system provides rapid and reliable results for both adult and pediatric samples. Compared to Ref BMD, LifeScale error rates are approximately half of the SOCs.

Introduction

The LifeScale AST System (Affinity Biosensors) is an FDA-cleared, phenotypic rAST platform that delivers direct-from-blood-culture susceptibility results for Gram-negative organisms, providing faster results without compromising accuracy[1]. In this comparative evaluation eight clinical laboratories assessed the LifeScale AST in adult and pediatric patient populations compared to their Standard-of-Care (SOC) automated AST platforms. A total of 838 clinical PBCs (576 prospective and 262 contrived) were included. Results showed that the LifeScale error rate is approximately half that of the SOC error rate when compared to rBMD.
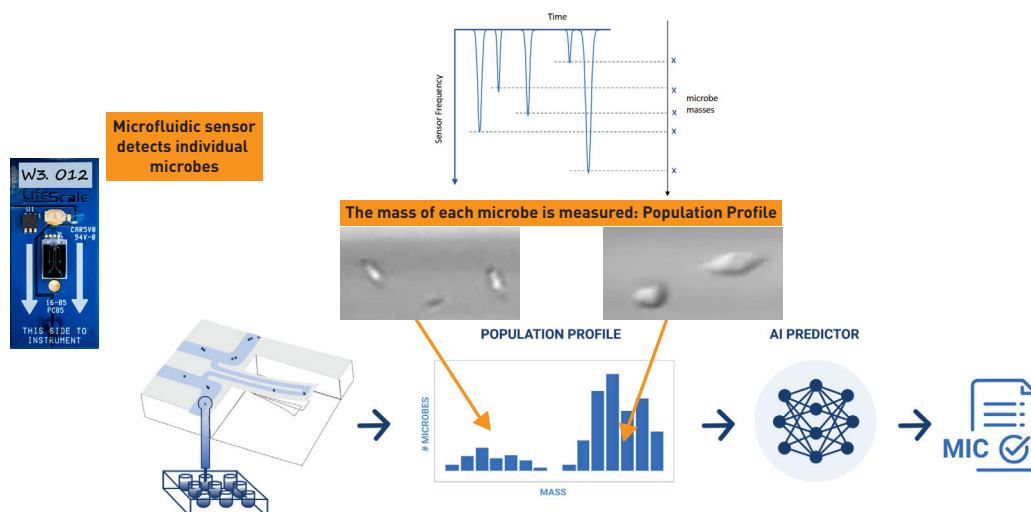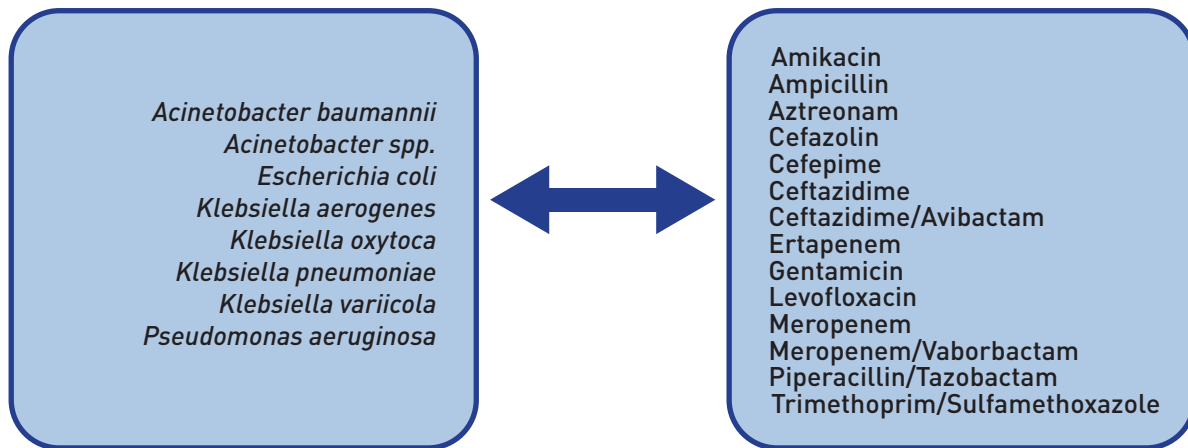

Figure 1, The LifeScale AST system utilizes population profiling to generate MIC results in under 5 hours

Method

Acinetobacter baumannii
Acinetobacter spp.
Escherichia coli
Klebsiella aerogenes
Klebsiella oxytoca
Klebsiella pneumoniae
Klebsiella variicola
Pseudomonas aeruginosa

Amikacin
Ampicillin
Aztreonam
Cefazolin
Cefepime
Ceftazidime
Ceftazidime/Avibactam
Ertapenem
Gentamicin
Levofloxacin
Meropenem
Meropenem/Vaborbactam
Piperacillin/Tazobactam
Trimethoprim/Sulfamethoxazole

The LifeScale AST System is FDA cleared for use on 93% of species/antibiotic combinations that are indicated for use, not intrinsically resistant and have FDA breakpoints available.

Method

Blood culture samples detected positive by an FDA approved continuous-monitoring blood culture system and confirmed as Gram-negative by Gram stain were enrolled in the study. Blood cultures were processed on the LifeScale AST system and FDA approved Standard-of-Care (SOC) AST system at each site (MicroScan WalkAway, VITEK 2, BD Pheonix). Performance was assessed for 14 antimicrobial agents;

- Amikacin
- Ampicillin
- Aztreonam
- Cefazolin
- Cefepime
- Ceftazidime
- Ceftazidime-avibactam
- Ertapenem
- Gentamicin
- Levofloxacin
- Meropenem-vaborbactam
- Piperacillin-tazobactam
- Trimethoprim-sulfamethoxazole

Performance of the LifeScale AST system was evaluated using three key metrics:

- Essential agreement (EA) which measured the percentage of MIC values within +/- 1 doubling dilution against the Standard-of-Care

- Categorical Agreement (CA), representing the proportion on interpretive results (S/SDD/I/R) that matched the SOC categories

- Frequency of categorical errors, including minor, major, and very major errors
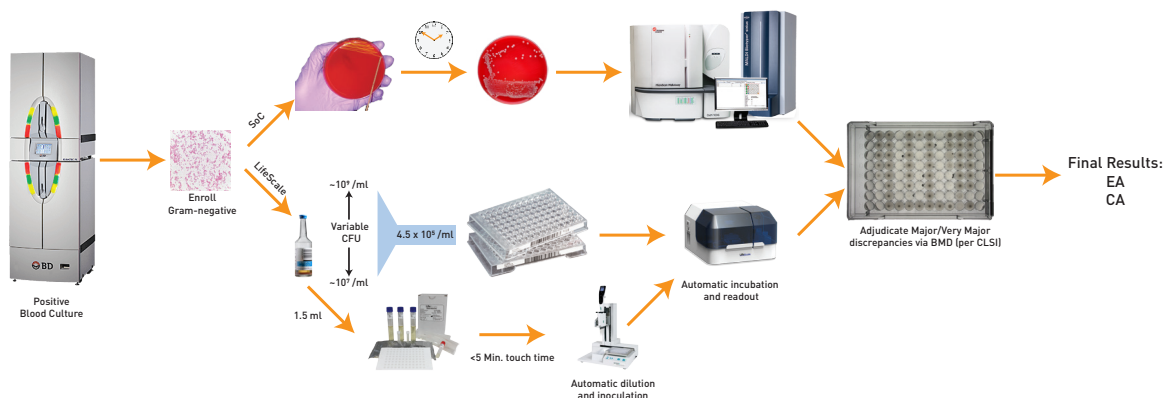
Discrepancies were adjudicated using broth micro dilution.

Figure 2, The LifeScale AST system workflow for direct from positive blood culture samples

Results

A total of 838 positive blood culture samples (576 prospective, 262 contrived), representing 8,879 organism/antimicrobial agent combinations were tested. The isolate collection included major Gram-negative pathogens such as *Escherichia coli* (n=387), *Klebsiella pneumoniae* (n=188), *Pseudomonas aeruginosa* (n=115), and various *Acinetobacter spp.* (Table 7).

Overall, the LifeScale AST system achieved an essential agreement of 96.37% and categorical agreement of 94.59% versus the SOC reference methods, with an overall resistance prevalence of 21.18% (Table 1). Overall categorical error rates were low; very major errors were 0.51% (9/1,776), major errors were 0.35% (22/6,302), and minor errors were 5.04% (417/8,280), with all discrepancies resolved by broth microdilution (Table 1).

When compared side-by-side with the SOC platform, LifeScale exhibited lower error frequencies: very major errors 5.00% vs. 9.66%, major errors 0.34% vs. 3.93%, and minor errors 4.65% vs. 8.50% (Table 3). Interpretive category distributions were highly concordant between LifeScale and SOC methods: susceptible results in 74.54% vs. 76.11%, intermediate in 4.13% vs. 2.44%, and resistant in 21.33% vs. 21.18% of isolates, respectively (Table 8).

Table 1, LifeScale AST overall performance, Walkaway: 4, Phoenix: 2, Vitek: 2

Essential Agreement[1]	Categorical Agreement	VMEs	MEs	mEs	Resistance
96.37%	94.59%	9/1776 (0.51%)	22/6302 (0.35%)	417/8280 (5.04%)	21.18%

Table 2, LifeScale AST overall performance of pediatric samples, Vitek: 1

Essential Agreement[1]	Categorical Agreement	VMEs	MEs	mEs	Resistance	Average TTR
93.02%	92.45%	0/178 (0.00%)	0/431 (0.00%)	48/636 (7.55%)	26.95%	5:29

Table 3, LifeScale error rate less than SOC compared to rBMD. When compared to Ref BMD, LifeScale error rates are approximately half of the SOCs

	LifeScale	SOCs
Very Major Errors	28/560 (5.00%)	54/559 (9.66%)
Major Errors	33/1253 (2.63%)	55/1238 (4.44%)

Results

Table 4, Average time to results to report all antibiotics by genus

Genus	Species	Time to Result H:MM
Escherichia	*coli*	4:48
Klebsiella	*species*	4:58
Pseudomonas	*aeruginosa*	5:12
Acinetobacter	*species*	5:10
	Average	4:56
	Average (removing stacked delay)	4:37

Table 5, LifeScale performance by species

Genus	No. Evaluated EA	No. Evaluated CA	Essential Agreement[1]	Categorical Agreement	Resistance
Acinetobacter	206	205	92.23%	89.27%	23.49%
Escherichia	4692	4689	97.38%	94.92%	23.86%
Klebsiella	2632	2660	96.73%	95.71%	17.55%
Pseudomonas	703	726	89.47%	89.81%	12.26%

Table 6, LifeScale performance by antibiotic

	Essential Agreement[1]	Categorical Agreement	VMEs	MEs	mEs	Resistance
All	96.37%	94.59%	9/1776 (0.51%)	22/6302 (0.35%)	417/8280 (5.04%)	21.18%
Amikacin	97.90%	95.95%	0/21 (0.00%)	1/690 (0.14%)	28/716 (3.91%)	2.93%
Ampicillin	99.74%	98.97%	0/258 (0.00%)	0/130 (0.00%)	4/388 (1.03%)	66.49%
Aztreonam	95.17%	95.76%	0/143 (0.00%)	2/366 (0.55%)	20/519 (3.85%)	27.55%
Cefazolin	94.20%	83.50% / 96.13%*	1/248 (0.40%)	3/319 (0.94%)	94/594 (15.82%)	38.87%
Cefepime	92.51%	95.24%	0/186 (0.00%)	1/555 (0.18%)	35/757 (4.62%)	24.57%
Ceftazidime	95.61%	91.95%	0/194 (0.00%)	2/578 (0.35%)	63/807 (7.81%)	24.04%
Ceftazidime/Avibactam	99.23%	99.22%	1/20 (5.00%)	1/238 (0.42%)	0/258 (0.00%)	7.75%
Ertapenem	98.53%	99.16%	0/47 (0.00%)	0/427 (0.00%)	4/477 (0.84%)	9.85%
Gentamicin	96.34%	97.91%	1/110 (0.91%)	1/647 (0.15%)	14/767 (1.83%)	14.34%
Levofloxacin	98.27%	90.07% / 99.13%*	0/195 (0.00%)	2/555 (0.36%)	78/806 (9.68%)	24.19%
Meropenem	96.32%	96.84%	1/81 (1.23%)	0/700 (0.00%)	24/791 (3.03%)	10.24%
Meropenem/Vaborbactam	98.06%	98.44%	1/3 (33.33%)	0/250 (0.00%)	3/256 (1.17%)	1.17%
Piperacillin/Tazobactam	93.99%	91.29%	3/81 (3.70%)	5/558 (0.90%)	50/666 (7.51%)	12.16%
Trimethoprim/Sulfamethoxazole	98.12%	98.95%	1/189 (0.53%)	4/289 (1.38%)	0/478 (0.00%)	39.54%

Results

Table 7, Organisms tested

Genus	Species	Number Enrolled
Acinetobacter	*baumannii/baumannii complex*	42
Acinetobacter	*lwoffii*	2
Acinetobacter	*radioresistens*	3
Acinetobacter	*species*	4
Acinetobacter	*ursingii*	2
Acinetobacter	*pittii*	1
Escherichia	*coli*	387
Klebsiella	*aerogenes*	39
Klebsiella	*oxytoca*	54
Klebsiella	*pneumoniae*	188
Klebsiella	*variicola*	1
Pseudomonas	*aeruginosa*	115
	Total	**838**

Table 8, Resistance reported by SOC vs LifeScale

Category	SOC	LifeScale
S	76.11%	74.54%
I	2.44%	4.13%
R	21.18%	21.33%

Conclusions

Conducted from November 2021 to May 2025 across eight hospitals, these studies demonstrated that the LifeScale AST system provides rapid and reliable results for both adult and pediatric samples. Notably, results showed that compared to rBMD, LifeScale error rates are approximately half that of the SOCs (MicroScan WalkAway, Vitek, Pheonix).

References

1. Snyder JW et al., Performance of the LifeScale automated rapid phenotypic antimicrobial susceptibility testing on Gram-negative rods directly from positive blood cultures. J Clin Microbiol. 2024 Dec
2. CLSI. Performance Standards for Antimicrobial Susceptibility Testing, 34th ed. CLSI supplement M100. Clinical and Laboratory Standards Institute; 2025.
3. CLSI. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, 12th ed. CLSI standard M07. Clinical and Laboratory Standards Institute; 2024.