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

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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.

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.

#### 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<sup>1</sup>. 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.

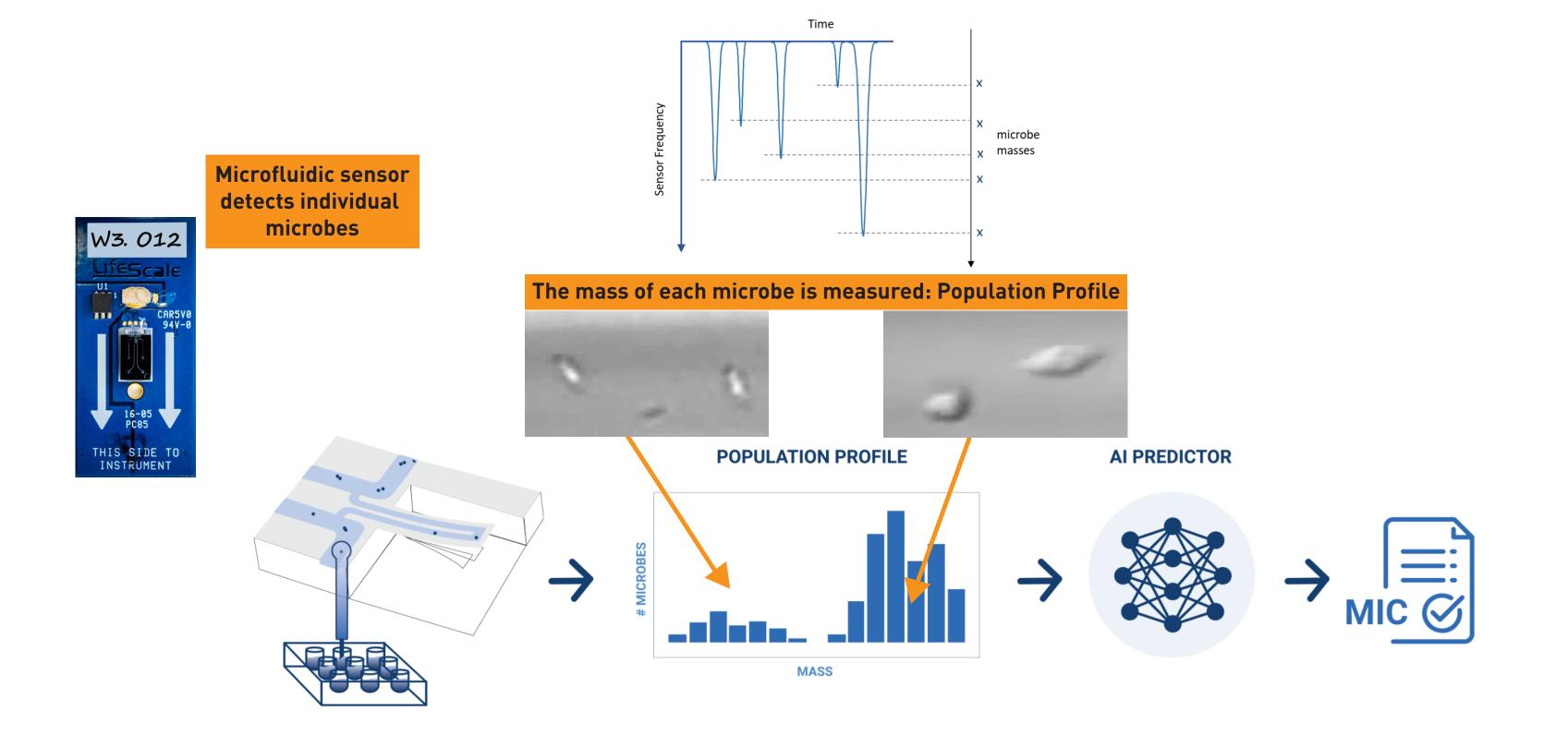
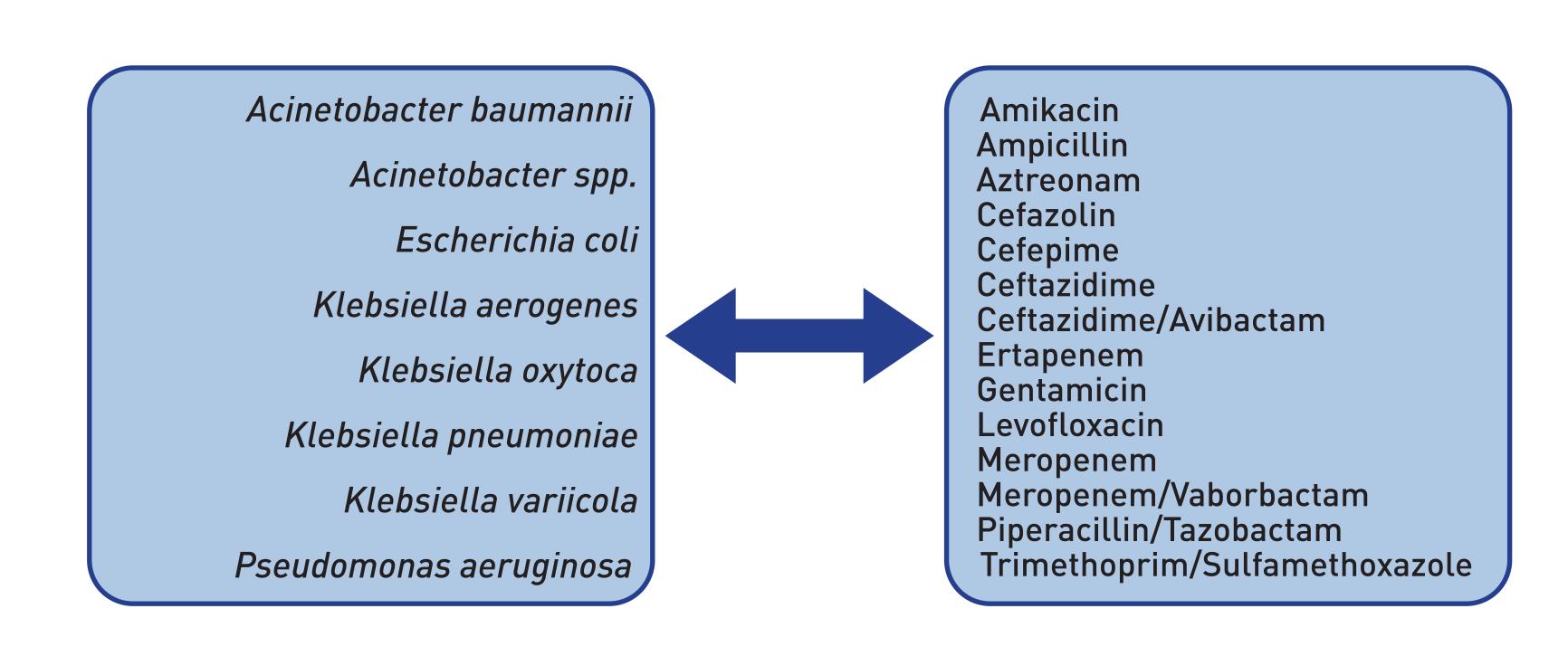


Figure 1, The LifeScale AST system utilizes population profiling to generate MIC results in under 5 hours

### Introduction



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.

# Methods

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

- Gentamicin
- 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
- Frequency of categorical errors, including minor, major, and very major errors

Discrepancies were adjudicated using broth micro dilution.

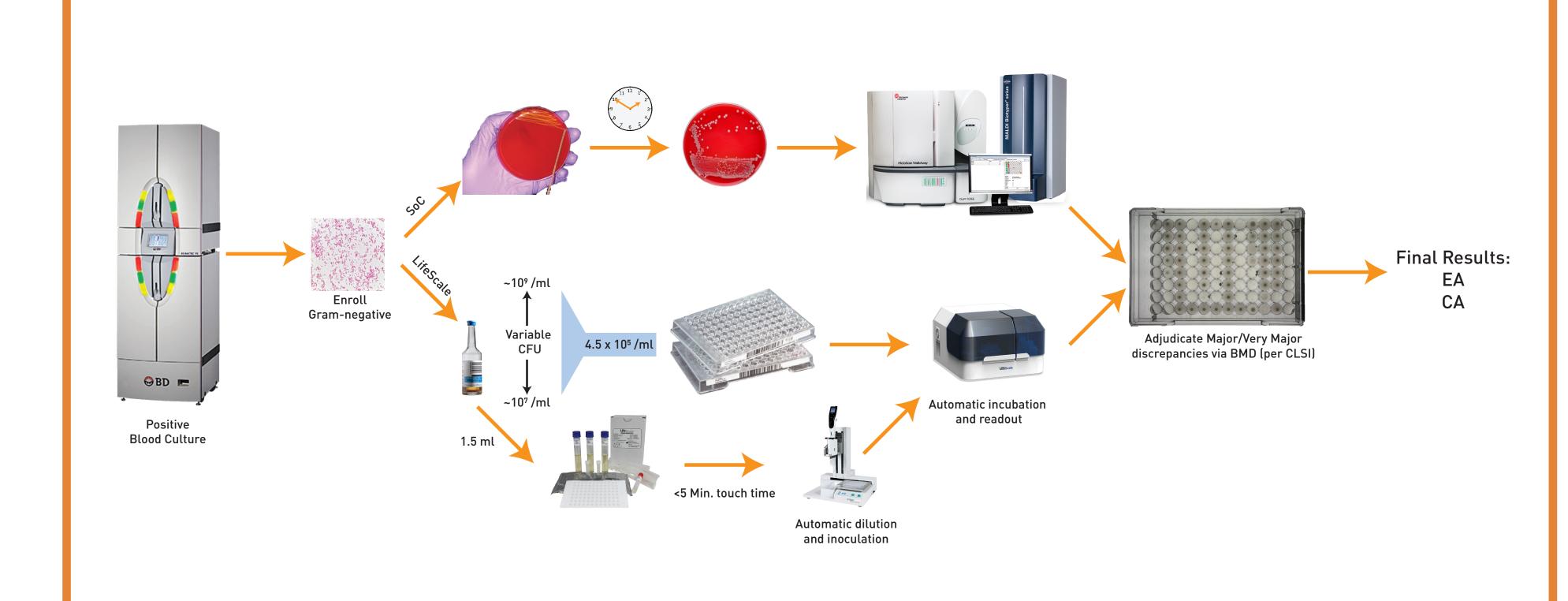


Figure 2, The LifeScale AST system workflow for direct from positive blood culture samples

## 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 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 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. 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

Agreement <sup>1</sup>	Agreement	VIVILS	IVILS	IIILS	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 <sup>1</sup>	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%)

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

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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 <sup>1</sup>	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%

<sup>&</sup>lt;sup>1</sup>Essential agreement adjusted for differences in panel ranges \*Corrected CA for when minor errors are in EA

Table 6, LifeScale performance by antibiotic

	Essential Agreement <sup>1</sup>	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%

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%
	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).

# Acknowledgment

We would like to thank the teams at University of Louisville, Baylor Scott and White, New York-Presbyterian - Columbia University Irving Medical Center, Associated Regional and University Pathologists, Spartanburg Medical Center and Northwestern Memorial Hospital, Nationwide Children's Hospital, and Memorial Sloan Kettering Cancer Center for their collaboration on this work.

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