Accuracy and Time-to-Results of the LifeScale Rapid AST System Across 10 U.S. Hospitals

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Abstract

Background:

Bloodstream infections (BSIs) are a major cause of morbidity and mortality, and antimicrobial therapy is typically initiated empirically and adjusted once diagnostics become available. Conventional turnaround times for antimicrobial susceptibility testing (AST) in BSIs are ≥ 2 days, delaying the initiation of targeted therapy. Rapid Antimicrobial Susceptibility Tests (rASTs) are therefore critical for enabling timely treatment, and for mitigating the emergence and spread of antimicrobial resistance. The LifeScale AST system (Affinity Biosensors) is an FDA-cleared, microfluidic-based rAST platform that provides phenotypic susceptibility results for Gram-negative organisms directly from positive blood cultures (PBCs)[1]. This multi center aggregate study involving ten hospitals evaluated the accuracy and time-to-results of the LifeScale LSGN Panel compared with standard-of-care (SOC) automated AST platforms.

Methods:

PBCs positive for Gram-negative bacteremia were tested using the LifeScale AST system and each site's SOC automated AST platforms: MicroScan WalkAway (Beckman Coulter), Phoenix (Becton Dickinson), or Vitek II (bioMérieux). Ten U.S. sites participated in the study, testing a total of 1,308 samples, including 1,038 prospective clinical specimens and 270 seeded resistant challenge strains. Minimum inhibitory concentrations (MICs) and categorical interpretations for 14 antibiotics on the LifeScale LSGN panel were compared with SOC results for Enterobacterales, Pseudomonas aeruginosa, and Acinetobacter species. Very Major and Major discrepancies were adjudicated using CLSI reference broth microdilution (rBMD)[2].

Results:

Across 10 sites, 1,308 samples generated 12,004 organism-antibiotic combinations. The overall resistance rate across the study set was 20.8%, representing a particularly challenging sample population. Following rBMD adjudication, essential agreement with the SOC platforms was 96.56% and categorical agreement was 95.03%. The average time-to-results was 4 hours 53 minutes.

Conclusions:

Across 10 hospitals from November 2021 to May 2025, the LifeScale AST demonstrated rapid and reliable AST results involving 21 Gram-negative pathogens, highlighting its potential to accelerate targeted antimicrobial therapy and enhance antimicrobial stewardship.

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, ten clinical laboratories assessed the LifeScale AST compared to their standard-of-care (SOC) automated AST platforms. The SOC platforms assessed were MicroScan WalkAway (Beckman Coulter), Vitek (bioMérieux), and Phoenix (BD). A total of 1,308 clinical PBCs including (1,038 prospective and 270 contrived) were included.

Population profiles are generated for all antibiotics and antibiotic concentrations on the LifeScale panel, Figure 1. LifeScale's powerful Artificial Intelligence Predictor (AI-Predictor) analyzes this rich dataset to produce the correct MIC, even in cases where analyzing growth alone is insufficient, Figure 2.

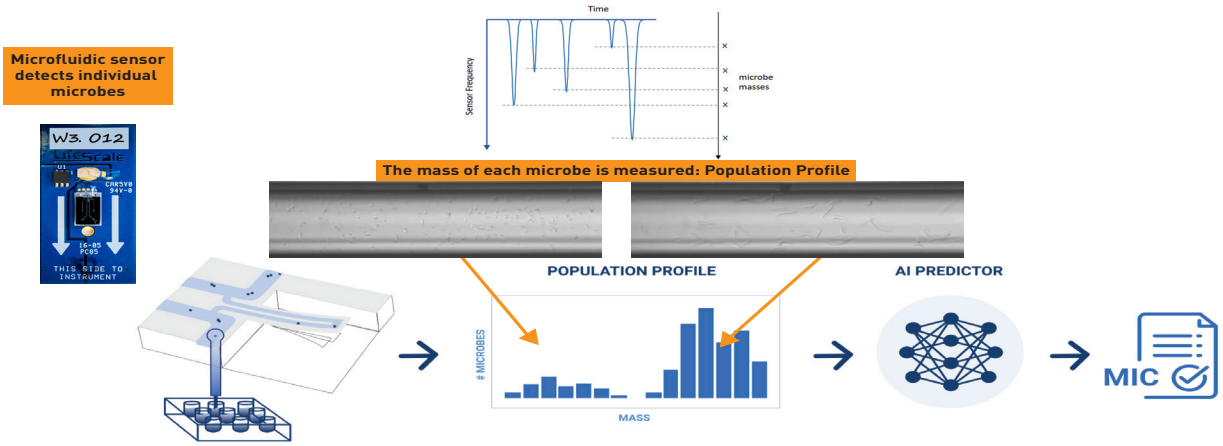

Figure 1. The LifeScale AST system utilizes population profiling to generate MIC results in under 5 hours

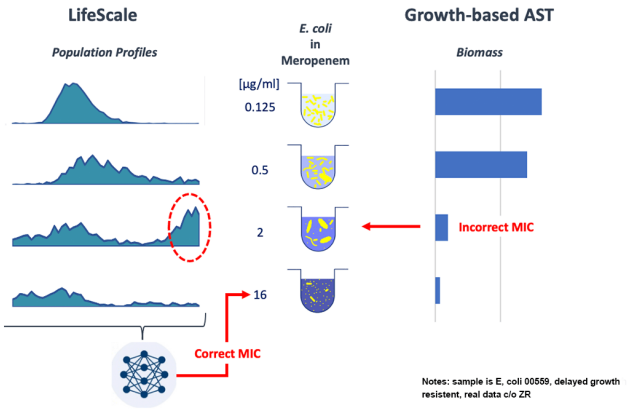

Figure 2. Standard growth-based AST

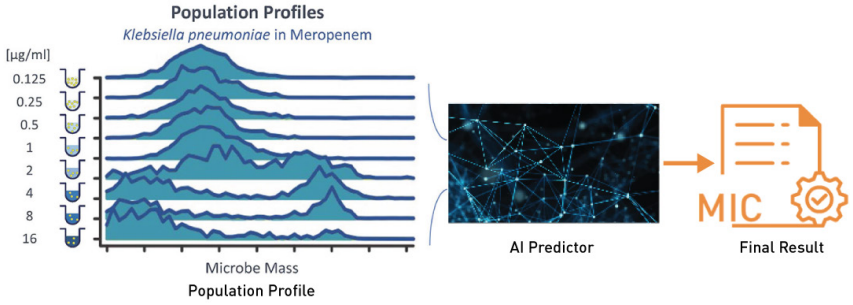

Figure 3. AI processing of population profile data

By combining the population profile data with advanced AI, LifeScale can determine correct MICs even for delayed-growth phenotypes, Figure 3. The key is the information contained in individual cell masses. Delayed-growth strains may not replicate for several hours; however, during LifeScale's short incubation time, microbes still respond to antibiotics by changing their morphology and mass producing filamentous forms or spheroplasts. LifeScale's population profiles clearly reveal these responses, whereas a growth-based AST can miss them, since they occur prior to replication and visible biomass increase.

Methods

Blood culture samples detected positive by 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 Phoenix).

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

1. MIC Agreement (MA) which measured the percentage of MIC values within +/- 1 doubling dilution against the SOC
2. Categorical Agreement (CA), representing the proportion of interpretive results (S/SDD/I/R) that matched the SOC categories
3. Frequency of categorical errors, including minor, major, and very major errors

Discrepant results were adjudicated using CLSI-guided broth microdilution (BMD) testing. In addition, reference BMD (rBMD) testing was performed on all samples tested at the representative Columbia site to provide a comprehensive assessment of error rates relative to the reference method when comparing LifeScale and the SOC system (MicroScan WalkAway), Table 3.

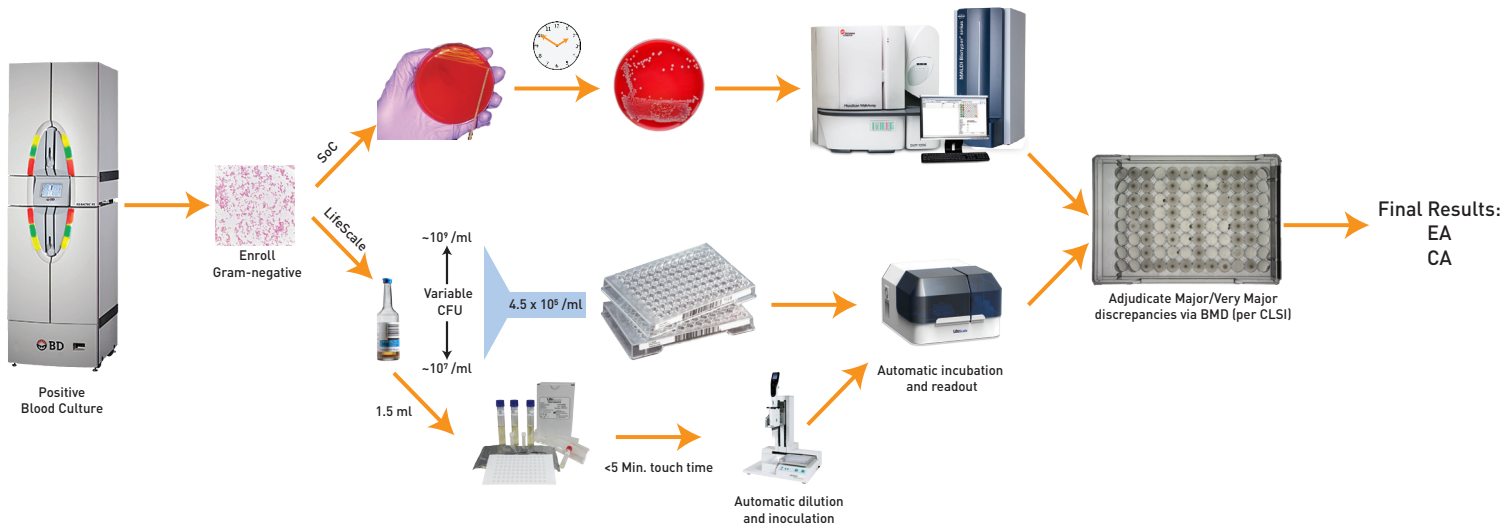

Figure 4. The LifeScale AST system workflow for direct from positive blood culture samples

Performance was assessed for 14 antimicrobials;

Acinetobacter baumannii
Acinetobacter spp.
Escherichia coli
Klebsiella aerogenes
Klebsiella oxytoca
Klebsiella pneumoniae
Klebsiella variicola
Pseudomonas aeruginosa
Citrobacter freundii
Citrobacter koseri
Enterobacter cloacae
Enterobacter cloacae complex
Morganella morganii
Proteus mirabilis
Providencia stuartii
Salmonella species
Serratia marcescens

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

Results

A total of 1,308 positive blood culture isolates, representing 12,004 organism/antimicrobial agent combinations evaluated for MA and 12,004 combinations evaluated for CA, were tested. The isolate collection included major Gram-negative pathogens such as *Escherichia* (n=582), *Klebsiella* (n=407), *Pseudomonas* (n=136), and *Acinetobacter* spp. (n=73), together with less prevalent genera including *Citrobacter*, *Enterobacter*, *Morganella*, *Proteus*, *Providencia*, *Salmonella*, and *Serratia,* Table 5.

Overall, the LifeScale AST system achieved an essential agreement (MIC agreement) of 96.56% and CA of 95.03% versus the SOC reference methods, with an overall resistance prevalence of 20.43%, Table 1. Overall categorical error rates remained low, with very major errors of 0.61% (15/2,452), major errors of 0.36% (33/9,259), and minor errors of 4.57% (549/12,004), Table 1. When compared side by-side with SOC platforms, LifeScale demonstrated lower error frequencies, with very major error rates of 4.72% versus 9.77% and major error rates of 3.27% versus 6.31%, respectively, Table 2.

Genus-specific performance remained consistently high, with MA ranging from 90.46% to 100.00% and CA ranging from 90.00% to 100.00% across evaluated genera, Table 5. As well as antibiotic specific performance with MA ranging from 93.86% to 99.68% and CA ranging from 92.02% to 99.68%, Table 6. The average time to results was 4 hours and 53 minutes, and when removing any delay due to stacking the average time to results was 4 hours and 36 minutes, Table 4.

Table 1. LifeScale AST overall performance, Walkaway: 5, Phoenix: 2, Vitek: 3

MIC Agreement[1]	CA	VMEs	MEs	mEs	Resistance
96.56%	95.03%	15/2452 (0.61%)	33/9259 (0.36%)	549/12004 (4.57%)	20.43%

Table 2. Error rates compared to rBMD of samples where discrepancies were adjudicated

	LifeScale	SOCs
Very Major Errors	31/657 (4.72%)	64/655 (9.77%)
Major Errors	48/1470 (3.27%)	92/1459 (6.31%)

Table 3. Error rates compared to rBMD of the 168 samples enrolled at Columbia

	LifeScale	MicroScan WalkAway
Very Major Errors	9/433 (2.08%)	11/431 (2.55%)
Major Errors	7/1155 (0.61%)	24/1109 (2.16%)

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

Genus	Species	Time to Result H:MM
Escherichia	*coli*	4:45
Klebsiella	*species*	4:57
Pseudomonas	*aeruginosa*	5:07
Acinetobacter	*species*	5:00
Citrobacter	*species*	5:19
Enterobacter	*species*	4:39
Morganella	*morganii*	5:16
Proteus	*mirabilis*	5:07
Providencia	*stuartii*	4:48
Salmonella	*species*	5:00
Serratia	*marcescens*	4:48
	Average	**4:53**
	Average (removing stacked delay)	**4:36**

Table 5. LifeScale performance by species

Genus	# Samples	No. Evaluated MA	No. Evaluated CA	MIC Agreement[1]	CA	Resistance
Escherichia	582	6532	6520	97.64%	95.26%	23.63%
Klebsiella	407	3544	3544	96.61%	95.94%	17.44%
Pseudomonas	136	912	952	90.46%	90.55%	12.08%
Acinetobacter	73	263	260	92.40%	90.00%	42.69%
Citrobacter	11	67	66	95.52%	90.91%	19.70%
Enterobacter	33	251	250	98.01%	98.40%	6.00%
Morganella	4	22	22	95.45%	95.45%	0.00%
Proteus	32	248	249	93.55%	94.78%	15.26%
Providencia	3	18	18	94.44%	94.44%	11.11%
Salmonella	13	12	12	100.00%	100.00%	8.33%
Serratia	14	110	110	95.45%	97.27%	0.91%

Table 6. LifeScale performance by antibiotic post discrepant analysis

	MIC Agreement[1]	CA	VMEs	MEs	mEs	Resistance
All	96.56%	95.03%	15/2452 (0.61%)	33/9259 (0.36%)	549/12004 (4.57%)	20.43%
Amikacin	98.20%	97.65%	0/12 (0.00%)	0/155 (0.00%)	4/170 (2.35%)	7.06%
Ampicillin	99.19%	98.70%	0/376 (0.00%)	1/238 (0.42%)	7/615 (1.14%)	61.14%
Aztreonam	95.47%	95.15%	1/202 (0.50%)	4/622 (0.64%)	36/846 (4.26%)	23.88%
Cefazolin	94.87%	96.70%*	1/326 (0.31%)	4/446 (0.90%)	123/817 (15.06%)	39.90%
Cefepime	93.86%	95.19%	0/252 (0.00%)	2/879 (0.23%)	54/1164 (4.64%)	21.65%
Ceftazidime	94.54%	92.32%	1/267 (0.37%)	3/896 (0.33%)	89/1211 (7.35%)	22.05%
Ceftazidime/Avibactam	99.68%	99.68%	1/26 (3.85%)	1/592 (0.17%)	0/618 (0.00%)	4.21%
Ertapenem	98.55%	98.87%	0/59 (0.00%)	0/643 (0.00%)	8/708 (1.13%)	8.33%
Gentamicin	96.88%	98.27%	1/147 (0.68%)	2/998 (0.20%)	17/1156 (1.47%)	12.72%
Levofloxacin	97.91%	99.03%*	0/296 (0.00%)	4/868 (0.46%)	107/1240 (8.63%)	23.87%
Meropenem	96.82%	97.24%	2/107 (1.87%)	1/1078 (0.09%)	30/1197 (2.51%)	8.94%
Meropenem/Vaborbactam	98.53%	98.96%	1/6 (16.67%)	0/471 (0.00%)	4/480 (0.83%)	1.25%
Piperacillin/Tazobactam	94.78%	92.02%	5/117 (4.27%)	6/865 (0.69%)	70/1015 (6.90%)	11.53%
Trimethoprim/Sulfamethoxazole	98.17%	99.09%	2/259 (0.77%)	5/508 (0.98%)	0/767 (0.00%)	33.77%

1 MIC agreement adjusted for differences in panel ranges *Corrected CA when mEs in EA

Conclusions

Across 10 hospitals from November 2021 to May 2025, the LifeScale AST demonstrated rapid and reliable AST results involving 21 Gram-negative pathogens, highlighting its potential to accelerate targeted antimicrobial therapy and enhance antimicrobial stewardship. LifeScale error rates were less than those of the standard-of care for adjudicated samples as well as all samples tested at Columbia.

Acknowledgment

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