Performance of the LifeScale Rapid AST vs. Clinical Standard of Care

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Background

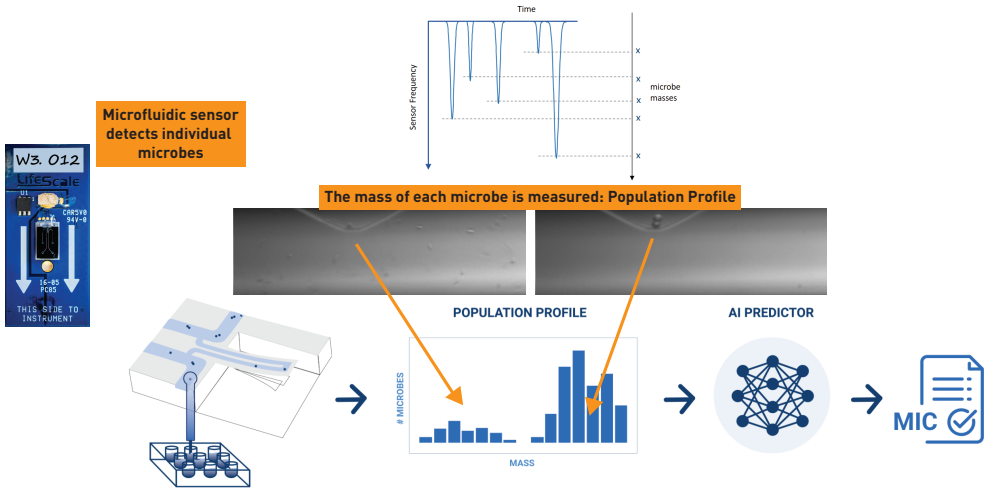
Rapid ASTs (rASTs) must meet the challenge of reducing time to results without compromising accuracy. Six hospitals evaluated the LifeScale AST system (Affinity Biosensors), an FDA-cleared rAST that provides phenotypic AST results for Gram-negative organisms direct from blood cultures. Its performance was compared to each site's standard-of-care (SOC) automated AST platform.

Introduction

Bloodstream infections are a significant cause of death and a major burden on hospitals. Furthermore, treatment using unnecessary broad-spectrum or combination regimens are associated with adverse effects and select for antimicrobial resistance. For these reasons, there is a strong need for shorter turnaround times required to perform AST. LifeScale AST system is an FDA cleared rapid AST shown to produce accurate results within 5 hours[1]. The systems accuracy, ease-of-use and time to results were evaluated at the following institutions:

- University of Louisville, Louisville KY
- Baylor Scott and White , Temple, TX
- New York-Presbyterian - Columbia University Irving Medical Center, New York, NY
- Associated Regional and University Pathologists (ARUP), Salt Lake City, UT
- Spartanburg Medical Center, Spartanburg, SC
- Northwestern Memorial Hospital, Chicago, IL

LifeScale



The LifeScale AST system counts and weighs the mass of individual microbes. This allows for an accurate representation of the microbes' response to differing concentrations of antibiotics within a shorter incubation period.

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.

Results

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

Essential Agreement	Categorical Agreement	VMEs	MEs	mEs	Resistance
95.53%	94.74%	7/1410 (0.50%)	18/5019 (0.36%)	320/6582 (4.86%)	21.66%

Table 2. LifeScale error rate less than for SOC c.f rBMD

	LifeScale	SOCs
Very Major Errors	23/449 (5.12%)	38/449 (8.46%)
Major Errors	28/1024 (2.73%)	41/1013 (4.05%)

Table 3. Average time to results to report all antibiotics by genus

Genus	Species	Time to Result H:MM
Escherichia	*coli*	4:48
Klebsiella	*species*	4:57
Pseudomonas	*aeruginosa*	5:11
Acinetobacter	*species*	4:50
	Average	**4:54**
	Average (removing stacked delay)	**4:32**

Table 4. LifeScale AST performance by species.

Genus	No. Evaluated EA[1]	No. Evaluated CA	Essential Agreement	Categorical Agreement	Resistance
Acinetobacter	164	164	95.73%	90.85%	45.12%
Escherichia	3956	3952	96.76%	94.86%	23.56%
Klebsiella	1968	1978	95.12%	95.75%	18.10%
Pseudomonas	466	488	86.70%	90.98%	9.63%

Table 5. LifeScale AST performance by antibiotic.

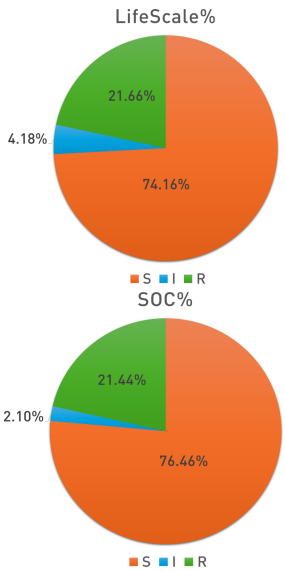
	Essential Agreement[1]	Categorical Agreement	VMEs	MEs	mEs	Resistance
All	95.53%	94.74%	7/1410 (0.50%)	18/5019 (0.36%)	320/6582 (4.86%)	21.66%
Amikacin	91.13%	96.14%	0/19 (0.00%)	0/522 (0.00%)	21/544 (3.86%)	2.94%
Ampicillin	99.69%	99.08%	0/215 (0.00%)	0/112 (0.00%)	3/327 (0.92%)	65.75%
Aztreonam	95.01%	95.70%	0/121 (0.00%)	2/312 (0.64%)	17/442 (3.85%)	27.83%
Cefazolin	94.00%	82.53%	1/187 (0.53%)	2/264 (0.76%)	80/475 (16.84%)	38.95%
Cefepime	90.29%	95.47%	0/145 (0.00%)	1/439 (0.23%)	25/596 (4.19%)	25.00%
Ceftazidime	96.01%	92.64%	0/140 (0.00%)	2/457 (0.44%)	44/625 (7.04%)	23.36%
Ceftazidime/Avibactam	97.14%	99.04%	1/20 (5.00%)	1/189 (0.53%)	0/209 (0.00%)	10.53%
Ertapenem	98.75%	99.50%	0/38 (0.00%)	0/361 (0.00%)	2/401 (0.50%)	9.98%
Gentamicin	96.17%	97.67%	1/80 (1.25%)	1/514 (0.19%)	12/601 (2.00%)	13.31%
Levofloxacin	97.13%	89.65%	0/156 (0.00%)	1/435 (0.23%)	64/628 (10.19%)	25.32%
Meropenem	97.29%	97.93%	1/64 (1.56%)	0/561 (0.00%)	12/629 (1.91%)	10.65%
Meropenem/Vaborbactam	96.69%	97.77%	1/2 (50.00%)	0/174 (0.00%)	3/179 (1.68%)	1.12%
Piperacillin/Tazobactam	94.38%	92.08%	1/66 (1.52%)	5/453 (1.10%)	37/543 (6.81%)	11.79%
Trimethoprim/Sulfamethoxazole	98.17%	98.96%	1/157 (0.64%)	3/226 (1.33%)	0/383 (0.00%)	39.69%

[1] Essential agreement adjusted for differences in panel ranges.

Results Cont.

Table 6. The studies tested 477 prospective and 179 seeded challenge samples comprising 7,188 organism/antibiotic combinations of which 21.4% were resistant.

Genus	Species	Number Enrolled
Acinetobacter	*baumannii/baumannii complex*	34
Acinetobacter	*lwoffii*	2
Acinetobacter	*radioresistens*	2
Acinetobacter	*species*	3
Acinetobacter	*ursingii*	1
Escherichia	*coli*	329
Klebsiella	*aerogenes*	21
Klebsiella	*oxytoca*	38
Klebsiella	*pneumoniae*	147
Klebsiella	*variicola*	1
Pseudomonas	*aeruginosa*	78
	Total	656



Conclusions

LifeScale AST produced rapid results from positive blood cultures in under 5 hours that were in excellent agreement with three major standard-of-care ASTs. Notably, LifeScale's rate of Very Major and Major errors was lower than for the SOCs, demonstrating that its speed does not compromise accuracy, and that its rapid results can be relied upon to improve antimicrobial stewardship and patient outcomes.

Acknowledgments

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References

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Links

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Information

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