2026

Performance Verification of the Accelerate Pheno System™ for Rapid Identification and Antimicrobial Susceptibility Testing from Positive Blood Culture in a Pediatric Population.

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Background

Since septic shock is an important cause of mortality, early diagnosis and initiation of targeted antibiotic therapy is crucial when treating pediatric patients with bacteremia. Studies show that mortality increases for each hour of delay in initiation of antibiotic therapy.[1] Therefore, early administration of appropriate antibiotics remains critical in reducing mortality from septic shock.

While identification (ID) and antimicrobial susceptibility testing (AST) of bloodstream pathogens are critical to optimizing therapy, conventional methods can take up to 48 hours or more. Empiric therapy is often administered within a few hours and can result in prolonged and sometimes inappropriate use of broad-spectrum antibiotics. Identification using polymerase chain reaction (PCR), MALDI-TOF, or PNA-FISH tests can be rapid, but antibiotic susceptibility information is limited. Phenotypic AST provides more rapid results and is a valuable tool in providing optimal antimicrobial therapy.

The automated Accelerate Pheno™ system (AXDX) provides ID in <90 min using fluorescence *in situ* hybridization (FISH), and phenotypic AST in <7 hrs directly from positive blood culture (PBC).[2,3] Rapid AST results enable clinicians to optimize antibiotic therapy sooner to improve patient outcomes. In addition, the unique AXDX monomicrobial call effectively rules out polymicrobial samples by indicating that only one species of bacteria is present in the PBC.

This study verifies AXDX performance compared with current laboratory ID and AST methods.

Method/Design

A total of 59 pediatric PBC were tested within 8 hours of positivity (35 spiked and 24 fresh). Testing utilized the Accelerate Pheno™ system (AXDX; Software version 1.2.0.69) and the Accelerate PhenoTest™ BC kit following the manufacturer's instructions.

A 0.5-mL aliquot was placed in the sample vial and run on AXDX (Figures 1 and 2). The sample was prepared by the system using gel electrofiltration (GEF). The system then performed FISH for identification of bacteria. Eligible bacteria were exposed to a panel of antimicrobials, and the system analyzed bacterial growth to determine susceptibility.

Current laboratory methods for ID (VITEK® 2, or MALDI-TOF) and AST (VITEK®2 or Microscan) were run in parallel as comparators.

Sensitivity (SN) and specificity (SP) were calculated for ID. Essential (EA) and/or categorical agreement (CA), major errors (ME) and very major errors (VME) were calculated for AST. Positive predictive value (PPV) for the monomicrobial call in fresh samples was calculated.

Table 1. Identification Performance

Organism	Probe	Sensitivity		Specificity	
Gram-Positive					
Coagulase-negative Staph	CNS	5/5	100%	52/52	100%
Enterococcus faecalis	EFS	1/2	50%	55/55	100%
Enterococcus faecium	EFM	11/11	100%	46/46	100%
Staphylococcus aureus	SAU	13/13	100%	44/44	100%
Staphylococcus lugdunensis	SLU	0/0	NA%	57/57	100%
Streptococcus spp.	STR	0/0	NA%	57/57	100%
Gram-Negative					
Acinetobacter baumannii	ABA	1/1	100%	56/56	100%
Citrobacter spp.	CIT	1/1	100%	56/56	100%
Enterobacter spp.	ENT	4/4	100%	53/53	100%
Escherichia coli	ECO	5/5	100%	52/52	100%
Klebsiella spp.	KLE	6/6	100%	51/51	100%
Proteus spp.	PRO	2/2	100%	55/55	100%
Pseudomonas aeruginosa	PAE	4/4	100%	53/53	100%
Serratia marcescens	SMA	1/1	100%	56/56	100%
Yeast					
Candida albicans	CAL	2/2	100%	55/55	100%
Candida glabrata	CGL	0/0	NA%	57/57	100%
Totals					
Gram-Positive		**30/31**	**96.8%**	**311/311**	**100%**
Gram-Negative		**24/24**	**100%**	**432/432**	**100%**
Yeast		**2/2**	**100%**	**112/112**	**100%**
Overall		**56/57**	**98.2%**	**855/855**	**100%**

Table 3. AST Discrepancies

Sample ID	Antibiotic	AXDX Call	VITEK®2 Call	Broth Microdilution S/I/R
041	Erythromycin	MIC: 0.5 S/I/R: S	MIC: ≥8 S/I/R: R	MIC: 0.5 S/I/R: S
044	Erythromycin	MIC: ≥8 S/I/R: R	MIC: ≤0.25 S/I/R: S	MIC: 16 S/I/R: R

Table 4. Time to Result

Overall Time Difference to Results (AXDX vs. SOC)	Improvement (hours)
ID	20.2
AST	34.4

Figure 1. Cassette, sample vial, and reagent cartridge. The operator places 0.5 mL of PBC sample in the sample vial.

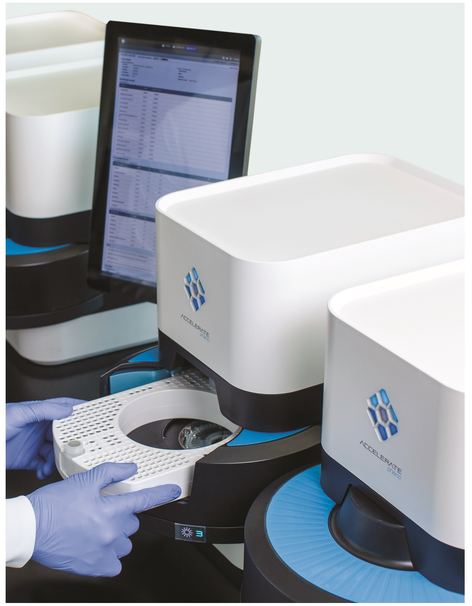

Figure 2. The operator loads the reagent cartridge into the Accelerate Pheno™ system module to start the run.

Table 2. AST Performance

Antibiotic	% EA	% CA	VME	ME
Gram-Positive				
Ampicillin	12/12 (100%)	12/12 (100%)	0	0
Ceftaroline	NA%	NA%	0	0
Daptomycin	NA%	NA%	0	0
Doxycycline	NA%	NA%	0	0
Erythromycin	15/15 (100%)	15/15 (100%)	0	0
Linezolid	27/27 (100%)	27/27 (100%)	0	0
TMP-SMX	10/10 (100%)	10/10 (100%)	0	0
Vancomycin	29/29 (100%)	29/29 (100%)	0	0
Gram-Negative				
Amikacin	18/18 (100%)	20/20 (100%)	0	0
Ampicillin-Sulbactam	0/1 (0%)	1/1 (100%)	0	0
Aztreonam	NA%	NA%	0	0
Cefepime	17/18 (94.4%)	16/20 (80%)	0	0
Ceftazidime	17/18 (94.4%)	15/17 (88.2%)	0	0
Ceftriaxone	NA%	NA%	0	0
Ciprofloxacin	18/18 (100%)	20/20 (100%)	0	0
Colistin	NA%	NA%	0	0
Ertapenem	NA%	NA%	0	0
Gentamicin	18/18 (100%)	20/20 (100%)	0	0
Meropenem	NA%	3/3 (100%)	0	0
Minocycline	NA%	NA%	0	0
Piperacillin-Tazobactam	12/12 (100%)	15/16 (93.8%)	0	0
Tobramycin	16/18 (88.9%)	19/20 (95%)	0	0
Overall	**209/214 (97.7%)**	**236/244 (96.7%)**	**0**	**0**

Table 5. Resistance Phenotype Performance

Resistance Phenotype	(n)	% CA	VME	ME
MRSA/MSSA (Cefoxitin & S. aureus)	11/11	100%	0/4	0/7
MR-CNS/MS-CNS	5/5	100%	0/2	0/3

Results

Two samples were excluded due to technical failures. A total of 57 samples were evaluated and analyzed (31 Gram-positive, 24 Gram-negative, and 2 yeast. There was 1 off-panel species.

Following adjudication of discrepant results, AXDX demonstrated 98.2% SN and 100% SP for identification (Table 1). There was one false negative result for *Enterococcus faecalis*. The PPV for the Monomicrobial call was 98%, but would have been 100% if evaluated in conjunction with a Gram stain.

Two *C. albicans* and one off-panel organism did not report AST results. One *S. aureus* sample had an AST failure. AST results for remaining samples showed an overall EA of 97.7%, and CA of 96.7% when compared with current laboratory methods (Table 2). There was one VME and one ME; both were adjudicated to AXDX (Table 3) using broth microdilution.

Overall times to ID and AST were reduced by 20.2 hours and 34.4 hours, respectively (Table 4).

For resistance phenotype performance, overall CA was 100% (11/11) for MRSA/MSSA detection and 100% (5/5) for MR-CNS/MS-CNS (Table 5).

Conclusions

- The Accelerate Pheno™ system demonstrated high performance for both ID and AST of pediatric PBC much faster than current laboratory methods.
- Implementing this system could allow laboratories to provide clinicians with actionable results much sooner, enabling them to optimize therapy earlier to improve patient outcomes.
- Faster implementation of appropriate antimicrobial therapy should have a significant impact on antimicrobial stewardship.

References

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