

Direct Comparison between Two Blood Culture Identification Systems in a High Throughput Laboratory

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Background and Aims

Northwell Health laboratories is the largest health system in the New York City metropolitan area. The microbiology lab performs over 600 blood culture orders and around 50 blood culture identification panels (BCID) every day.

Although not clinically possible to differentiate between Gram-positive and Gram-negative bacteremia, or even fungemia, rapid blood culture identification panels provide an excellent molecular tool for fast identification of most pathogens encountered in septicemia cases. Accurate, and fast detection and identification of pathogens and potential contaminants is paramount for targeted and specific antibiotic regimens. The new GenMark Dx ePlex BCID Panels (GM) show great promise with a total of 55 bacterial and fungal targets and 10 resistance markers.

This study compared the performance of the ePlex research use only (RUO) BCID Panels with the BioFire FilmArray (FA) BCID panel and blood culture, and was focused on blood culture contaminants, Gram-positive rods, yeasts and polymicrobial cultures.

Methods and Materials

From July 22nd 2018 to September 22nd 2018, a total of 324 positive blood culture samples (205 Aerobic, 113 Anaerobic and 6 Ped Plus bottles) were selected for evaluation.

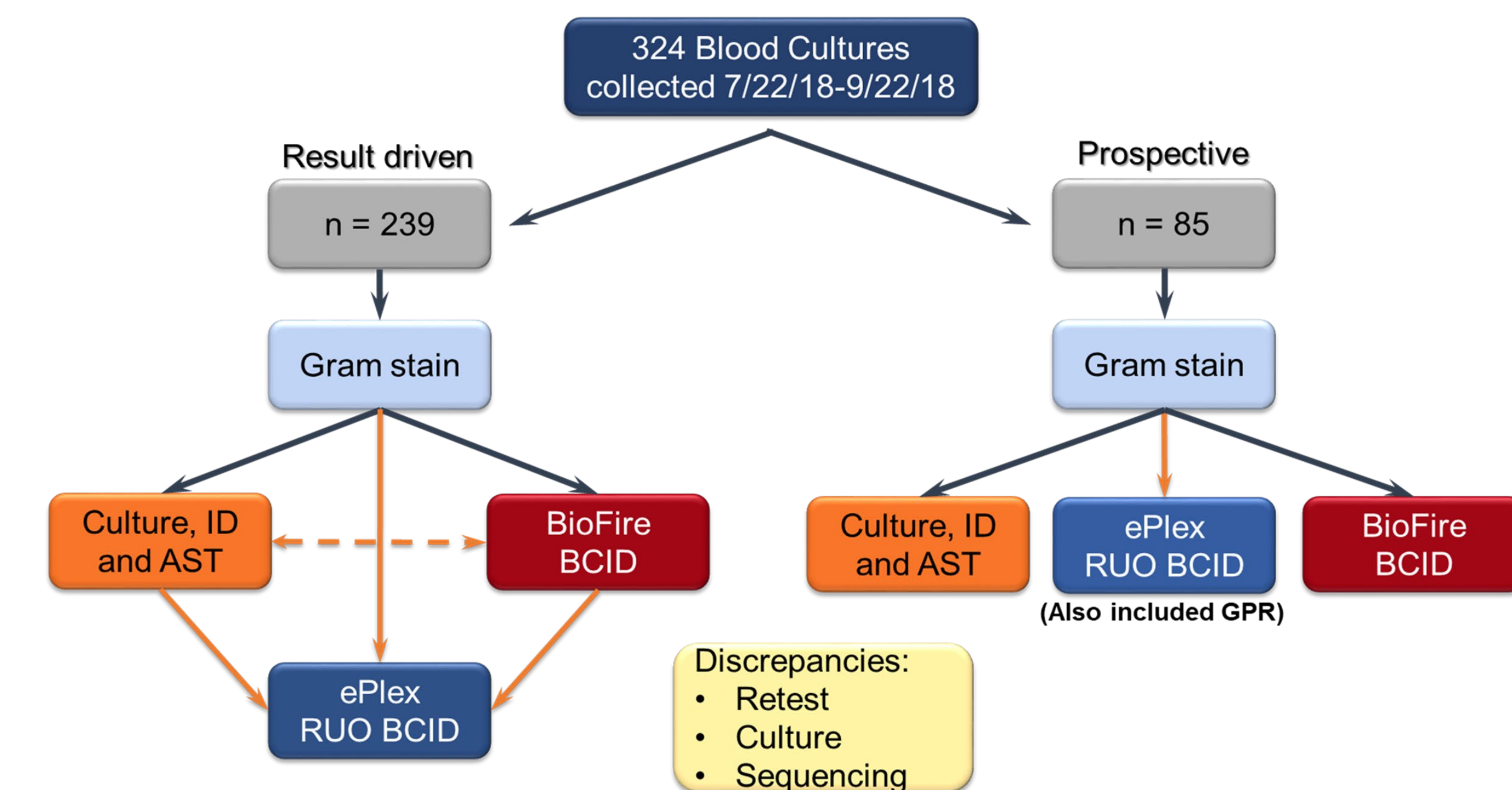
239 samples were tested in parallel with both, FA and culture, with an additional 85 prospective positive samples were collected and tested directly from the standard laboratory workflow.

Culture was considered the gold-standard and all discordant results were arbitrated by sequencing. Gram positive rods were only tested on ePlex RUO BCID, due to the lack of targets on FA-BCID panel. Culture results not targeted on either panel are not depicted in detail.

All panels for this study were provided by GenMark.

Results: Correlation of Assays

Gram Stain	Culture Organisms	GenMark					BioFire					Comments		
		ePlex	FN	FP	PPA	NPA	FA	FN	FP	PPA	NPA			
Gram-positive cocci n = 141 resistance markers n = 24	<i>Enterococcus</i>	28	27 ^a	1	96%	100%	27 ^a	1	96%	99%			^a One culture resulted as mixed with both <i>E. faecalis</i> & <i>E. faecium</i> . FA could not differentiate both species and resulted as "Enterococcus" (1).	
	<i>Enterococcus faecalis</i>	15	14	1	93%	100%	NA							
	<i>Enterococcus faecium</i>	12	12		100%	100%	NA							
	<i>vanA/B</i> (vancomycin resistance)	12	12 ^b		100%	100%	12		100%	100%			^b <i>E. faecalis</i> (4) and <i>E. faecium</i> (8)	
	<i>Streptococcus</i>	29	28	1	97%	100%	28	1	97%	100%				
	<i>Streptococcus agalactiae</i>	7	7		100%	100%	7		100%	100%				
	<i>Streptococcus anginosus group</i>	5 ^c	5		100%	100%	NA						^c Culture result: alpha-hemolytic Streptococcus	
	<i>Streptococcus pneumoniae</i>	2	2		100%	100%	2		100%	100%				
	<i>Streptococcus pyogenes</i>	4	4		100%	100%	4		100%	100%				
	<i>Micrococcus</i>	9	9		100%	100%	NA							
	<i>Staphylococcus</i>	76	75	1 ^d	99%	100%	62	12	2	84%	98%		^d Positive result was confirmed by 16S Sequencing	
	<i>Staphylococcus aureus</i>	24	24		100%	100%	24	1	100%	99%				
	<i>mecA</i> (methicillin resistance)	12	12		100%	100%	12		100%	100%				
Coag neg <i>Staphylococcus</i>	52	51 ^e	1	98%	100%	36	12	1	75%	99%		^e No routine ID & AST performed on CoNS		
<i>mecA</i> (methicillin resistance)	28					26								
<i>Staphylococcus epidermidis</i>	22					NA								
<i>Staphylococcus lugdunensis</i>	1					NA								
Gram-positive or variable rods n = 52	<i>Bacillus cereus</i> group	21	21		100%	100%	NA							
	<i>Corynebacterium</i>	11	11		100%	100%	NA							
	<i>Cutibacterium acnes</i>	4	4		100%	100%	NA							
	<i>Lactobacillus</i>	2	2		100%	100%	NA							
	<i>Listeria monocytogenes</i>	2	2		100%	100%	1 ^f		100%	100%			^f One FA BCID was not performed	
	Other Gram-positive organisms	24	Not Detected				Not Detected							
	Total Gram-positives	206	179	3	98%	100%	118	13	3	90%	89%		Includes off panel organisms	
	Gram-negative rods or coccobacilli n = 127 resistance markers n = 20	Enterobacteriaceae						11 ^{g,j}						^g Includes <i>Citrobacter</i> and <i>Salmonella</i>
		<i>Citrobacter</i>	6	6		100%	100%	NA ^g						^g FA only resulted as "Enterobacteriaceae"
		<i>Enterobacter cloacae</i> complex	9	9		100%	100%	9		100%	100%			
<i>Escherichia coli</i>		29	28	1	97%	100%	28	1	97%	100%				
<i>E. coli</i> ESBL (CTX-M)		8	8		100%	100%	NA							
<i>Klebsiella oxytoca</i>		3	3		100%	100%	3		100%	100%				
<i>Klebsiella pneumoniae</i>		23	23		100%	100%	23	1	100%	99%				
<i>K. pneumoniae</i> ESBL		6	4 ^h		100%	100%	NA						^h CTX-M presence confirmed by sequencing (n=4)	
Carbapenem Res (KPC)		1	1		100%	100%	1	1	100%	99%				
<i>Proteus mirabilis</i>		9	9		100%	100%	9 ⁱ	8	100%	93%			ⁱ <i>Proteus</i> was not routinely reported due to FA FP.	
<i>Salmonella</i>		5	5		100%	100%	NA ^l						^l FA only resulted as "Enterobacteriaceae"	
<i>Serratia marcescens</i>		8	8		100%	100%	8		100%	100%				
Other ESBL (CTX-M)		2	2 ^k		100%	100%	NA						^k <i>P. mirabilis</i> ESBL (1), <i>E. cloacae</i> ESBL (1).	
<i>Acinetobacter baumannii</i>		6	5	1	83%	100%	6		100%	100%				
Carbapenem Res (OXA)		3	3		100%	100%	NA							
<i>Bacteroides fragilis</i>		2	2	1	100%	99%	NA							
<i>Fusobacterium nucleatum</i>		1	1		100%	100%	NA							
<i>Haemophilus influenzae</i>	5	5		100%	100%	5	1	100%	99%					
<i>Pseudomonas aeruginosa</i>	17	13	4 ^l	76%	100%	17		100%	100%			^l 2/4 co-infections, 2/4 had GP only seen on GS		
<i>Morganella morganii</i>	3	3		100%	96%	NA						^m Cartridge manufacturing issue, resolved during study		
<i>Stenotrophomonas maltophilia</i>	1	1		100%	100%	NA								
Other Gram-negative organisms	25	Not Detected				Not Detected								
Total Gram-negatives	152	121	6	4	95%	86%	120	1	6	99%	81%	Includes off panel organisms		
Yeast n = 20	<i>Candida albicans</i>	3	3		100%	100%	3		100%	100%				
	<i>Candida auris</i>	3	3		100%	100%	NA							
	<i>Candida glabrata</i>	6	5	1	83%	100%	6			100%				
	<i>Candida parapsilosis</i>	4	4		100%	100%	4	2	100%	92%				
	<i>Candida tropicalis</i>	2	2		100%	100%	2		100%	100%				
	<i>Candida krusei</i>	0						1		94%				
Total Yeasts	18	17	1		94%	15	3	100%	40%					



Out of 141 Gram-positive cocci, the GM ePlex assay identified 29/28 *Enterococcus* spp and differentiated 14 *E. faecalis* and 12 *E. faecium*. GM accurately identified 18/18 *Streptococcus* spp. and 100% of *S. agalactiae*, *S. anginosus* group, *S. pneumoniae* and *S. pyogenes*. 100% agreement was observed for *Staphylococcus aureus* and *mecA*, but 12/52 CoNS were missed by FA (22%). GM identified additional nine *Micrococcus* spp.

Out of 52 specimens with Gram-positive rods, GM ePlex identified 40/52 (77%) compared to 2/52 BF (4%).

Out of 127 Gram-negative rods. GM ePlex identified 17 ESBL organisms (OXA and CTX-M positive). Six *Citrobacter* spp and five *Salmonella* spp were fully identified by GM, but only as "Enterobacteriaceae" by FilmArray.

94% of yeasts (*Candida*) were correctly identified on the GM fungal panel. ePlex correctly detected three *C. auris* that is not a target on BioFire panel.

Conclusions

❖ The ePlex BCID panels provided more comprehensive information than the comparator assay in 26% of tests and correctly detected 29% more targets. The ePlex BCID Panels represent an advantageous alternative for fast and reliable results.

- More inclusivity of organisms
- Greater speciation and differentiation

❖ All three GenMark BCID panels have been cleared by the US Food and Drug Administration