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Clinical Evaluation of the BioFire® FilmArray® Gastrointestinal (GI) Panel for Use with Rectal Swab Specimens in Cary-Blair Media

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BACKGROUND

The BioFire® FilmArray® Gastrointestinal (GI) Panel (bioMérieux, Inc., Salt Lake City, UT) provides results for 22 bacterial, viral, and parasite pathogens responsible for GI infection in about one hour. This test is indicated for use with stool samples in Cary-Blair media (SCB) as a sample type. For many patients, particularly those presenting to outpatient settings, a stool sample can be difficult to provide during a single clinic visit. Rectal swabs in Cary-Blair media (RSCB; an off-label sample type) can be collected during a patient's healthcare visit and may represent a more convenient sample type. However, suitability of RSCB for use with highly-multiplexed PCR tests is largely uncharacterized.

A prospective clinical evaluation was conducted between May 2019 and October 2021 at six US sites (Table 1). A total of 301 paired stool in Cary-Blair media (SCB) and rectal swab in Cary-Blair media (RSCB) samples were successfully enrolled via informed consent from unique patients presenting to outpatient settings with signs and symptoms of gastroenteritis. The enrolled population included both adults and children (Figure 1). Performance was determined by a direct comparison between the results of the BioFire GI Panel when testing RSCB samples to the results when testing the paired SCB samples. Additional analytical studies were performed to confirm reproducibility of the BioFire GI Panel limits of detection (LoD) when testing RSCB, and assess potential interference of endogenous and exogenous substances commonly associated with RSCB collection.

SUMMARY

76.2% PPA and 99.8% NPA
overall when testing RSCB relative to when testing SCB

Identification of at least one analyte in **56.5%** of RSCB samples vs. **65.4%** of SCB samples

RSCB missed **46** total analyte detections in paired samples with polymicrobial results, compared to **5** total missed SCB detections in paired samples with polymicrobial results

BioFire GI Panel exhibited lower diagnostic yield when testing the off-label RSCB sample type than when testing the on-label SCB sample type.

25.2% of consented subjects were unable or unwilling to provide SCB sample within one day of RSCB collection

Analytical studies confirmed BioFire GI Panel accurately detects analytes in **≥95%** of RSCB samples spiked at LoD, with no observed interference from endogenous or exogenous substances commonly associated with RSCB collection

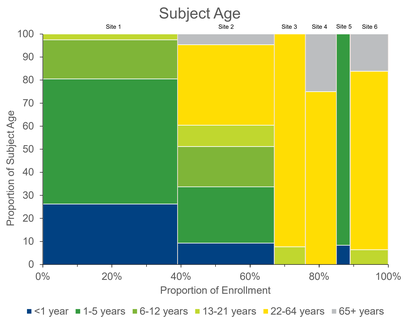
This poster contains data regarding an off-label sample type for the BioFire FilmArray GI Panel that has not been reviewed or approved by regulatory agencies for in vitro diagnostic use.

Acknowledgements: S. Coleman and T. Jones (bioMérieux, Inc.) for providing analytical data.

Table 1. Participating Study Sites

Site	Site Name	Location
1	Children's Mercy Hospital	Kansas City, MO
2	Lifespan Rhode Island Hospital/The Miriam Hospital/Hasbro Children's Hospital	Providence, RI
3	University Health Truman Medical Center	Kansas City, MO
4	New York Center for Travel and Tropical Medicine	New York, NY
5	Children's Hospital Los Angeles	Los Angeles, CA
6	Tampa General Hospital	Tampa, FL

Figure 1. Subject Demographics



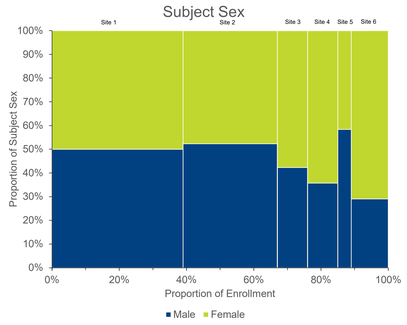


Figure 2. Reasons for Subject Exclusion

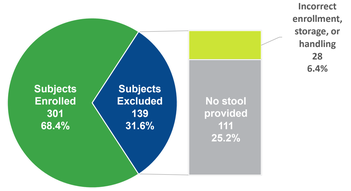


Figure 3. Analyte Prevalence

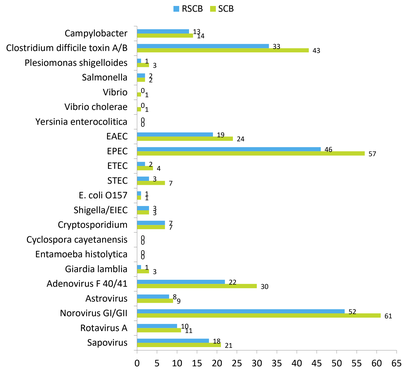


Figure 4. BioFire GI Panel Detections in SCB (outer ring) and RSCB (inner ring)

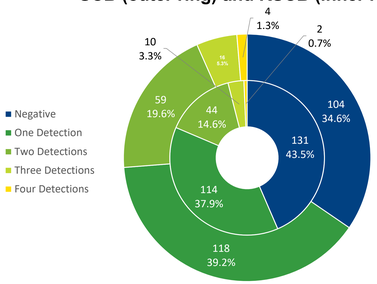


Table 2. BioFire GI Panel Performance When Testing Rectal Swabs in Cary-Blair Media Relative to When Testing Stool in Cary-Blair Media

BioFire GI Panel Analyte	Positive Percent Agreement (PPA)			Negative Percent Agreement (NPA)		
	TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
Bacteria						
Campylobacter	13/14	92.9%	68.5-98.7%	287/287	100%	98.7-100%
Clostridium difficile toxin A/B	32/43	74.4%	59.8-85.1%	257/258	99.6%	97.8-99.9%
Plesiomonas shigelloides	1/3	33.3%	6.1-79.2%	298/298	100%	98.7-100%
Salmonella	2/2	100%	34.2-100%	299/299	100%	98.7-100%
Vibrio	0/1	0%	-	300/300	100%	98.7-100%
Vibrio cholerae	0/1	0%	-	300/300	100%	98.7-100%
Yersinia enterocolitica	0/0	-	-	301/301	100%	98.7-100%
Diarrheagenic E. coli/Shigella						
Enteroaggregative *E. coli* (EAEC)	17/24	70.8%	50.8-85.1%	275/277	99.3%	97.4-99.8%
Enteropathogenic *E. coli* (EPEC)	45/57	78.9%	66.7-87.5%	237/237	100%	98.4-100%
Enterotoxigenic *E. coli* (ETEC) *lt/st*	2/4	50.0%	15.0-85.0%	297/297	100%	98.7-100%
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*	3/7	42.9%	15.8-75.0%	294/294	100%	98.7-100%
E. coli O157	1/1	100%	-	2/2	100%	34.2-100%
Shigella/Enteroinvasive *E. coli* (EIEC)	3/3	100%	43.9-100%	298/298	100%	98.7-100%
Parasites						
Cryptosporidium	7/7	100%	64.6-100%	294/294	100%	98.7-100%
Cyclospora cayetanensis	0/0	-	-	301/301	100%	98.7-100%
Entamoeba histolytica	0/0	-	-	301/301	100%	98.7-100%
Giardia lamblia	1/3	33.3%	6.1-79.2%	298/298	100%	98.7-100%
Viruses						
Adenovirus F 40/41	22/30	73.3%	55.6-85.8%	271/271	100%	98.6-100%
Astrovirus	8/9	88.9%	56.5-98.0%	292/292	100%	98.7-100%
Norovirus GI/GII	47/61	77.0%	65.1-85.8%	235/240	97.9%	95.2-99.1%
Rotavirus A	9/11	81.8%	52.3-94.9%	289/290	99.7%	98.1-99.9%
Sapovirus	17/21	81.0%	60.0-92.3%	279/280	99.6%	98.0-99.9%

Figure 5. Missed Detections in Paired samples with Polymicrobial Detections

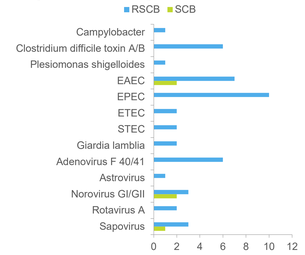


Table 3. Overall Performance of Contrived RSCB Tested at 1x BioFire GI Panel LoD Concentration

Agreement with known analyte composition				
	PPA: TP/(TP+FN)	%	**NPA:** TN/(TN+FP)	%
Overall Agreement	2487/2496	99.6	13087/13344	98.1