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Comparison of Results Obtained with the FilmArray GI Panel using Rectal Swabs and Cary-Blair stool from Patients with Gastroenteritis in the Pediatric Emergency Dept.

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Background

Detection of GI pathogens is limited by both sensitivity and timeliness of traditional methods as well as the inability of a patient to be able to provide a specimen at the time of the visit, requiring them to return a stool at a later date. Rectal swab could provide timely results. The objective of this study was to evaluate the Copan FecalSwab™(FS), as a rectal swab collection device obtained at the time of the patient visit compared to results of a stool sample submitted in Cary-Blair (CB) medium, for rapid detection of 22 pathogens using the multiplex FilmArray (FA) gastrointestinal (GI) Panel (BioFire Diagnostics). While the FS is FDA-cleared for transport and culture of GI pathogens, the FS used as a rectal swab collection device is not FDA-cleared for use with any molecular GI diagnostic assay.

Methods

- 959 consented pediatric ED patients presenting with acute gastroenteritis were prospectively enrolled May 2015 – August 2016 in a multi-center study (GI IMPACT Study).
- Rectal swabs (FS) in addition to CB stool specimens were collected at 3 separate hospital sites.
- Results from FA GI panel for 190-paired FS and CB stool specimens were compared.
- A positive FA was considered a true positive if detected from both FS and CB
- Alternate PCR was performed on discordant patient results from both the FS and CB medium.

Results

- Of 190 patients, 52 (27.4%) had no pathogens detected and 138 (72.6%) were positive for 192 and 182 pathogens from CB and FS, respectively.
- Overall agreement between paired specimens for pathogen identified was 82.1% (156/190). Percent agreement for bacterial, viral, C. *difficile* and parasitic targets was 90%, 69.7%, 57.8% and 50%. Figures 1-3 show the organism distribution and the % of pathogens in the 2 major categories of pathogens identified , viruses and bacteria, respectively.
- 32 and 26 additional or different pathogens were detected by CB or FS respectively (Table 1).
- Alternate PCR of discordant specimens was unhelpful in clarifying results due to inconsistent reproducibility from either FS or CB for the original pathogen.

Figure 1. Distribution of Concordant Pathogens Paired CB/FS Specimens

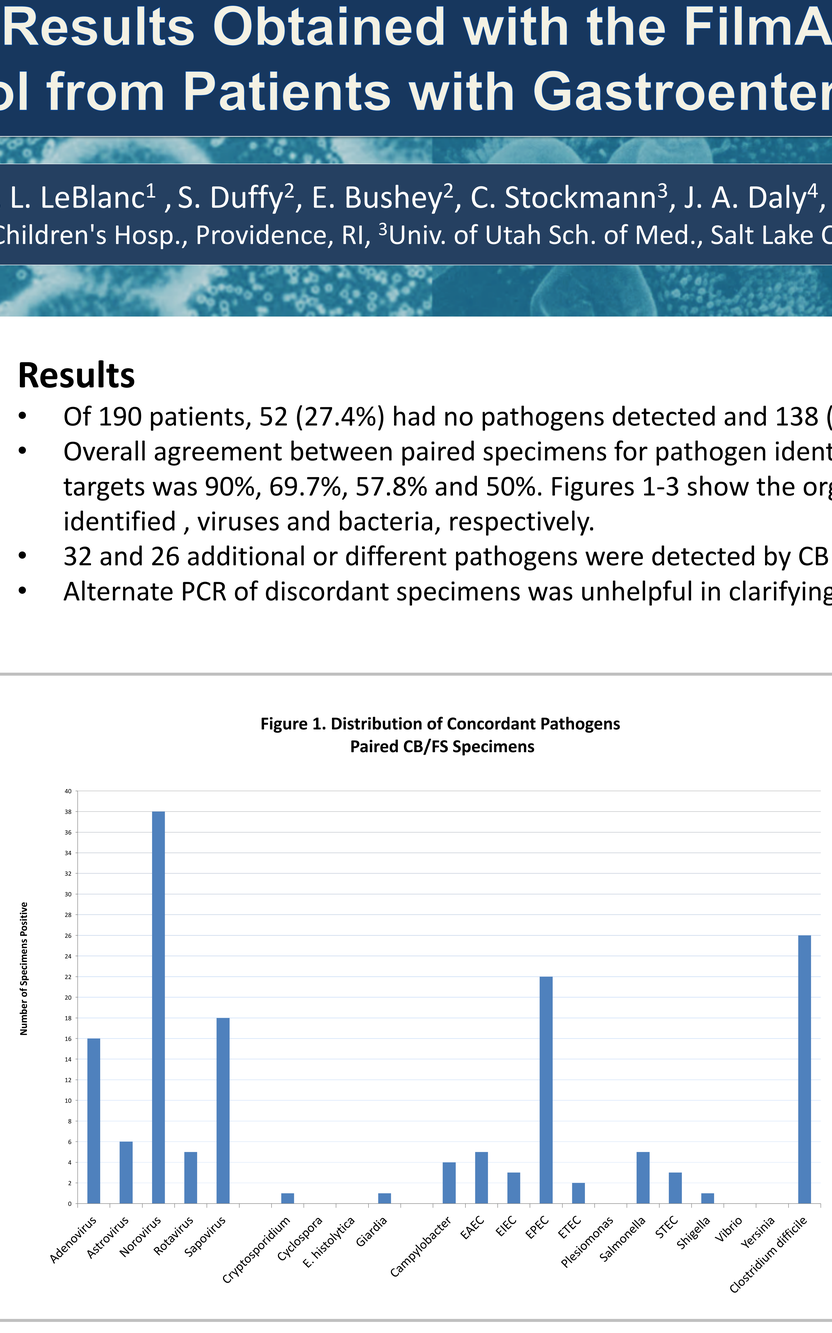

Figure 2. % Distribution of Viruses in Paired Specimens with Agreement

Figure 3. % Distribution of Bacteria in Paired Specimens with Agreement

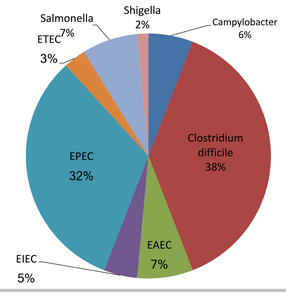

Table 1.

Pathogens	Concordant Paired Results	Discordant Results	
		CB only	FS only
Bacteria	45	5	0
		1 Shigella/EIEC, 2 EPEC, 1 EAEC, 1 Campy	
Viruses	83	20	16
		5 Sapo, 6 Noro, 5 Adeno, 1 Rota, 3 Astro	1 Sapo, 5 Noro, 9 Adeno, 1 Rota
C. *difficile* toxin	26	9	10
Parasites	2	2	0
		2 Giardia	
Total Pathogens	**156**	**36**	**26**

Conclusions

- Performance of the FS, collected as a rectal swab specimen, was comparable to the FDA-cleared CB stool for detection of GI pathogens using the FA GI Panel for bacterial targets.
- Testing of discordant specimens (C. *difficile* toxin and viruses) with alternate PCR assays produced inconsistent results and may have been due to low organism burden and questionable pathogen significance versus carrier state. Low parasite positive patients did not allow determination of significance.
- The FS used as a rectal swab collection device, allows sample collection at the time of the patient visit, and the generation of actionable results for the majority of significant infections in the acute care setting when a CB stool specimen cannot be provided.

Copan provided FS devices

BioFire Diagnostics provided study support