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 to obtain a specimen at the time of the patient visit, requiring them to return a stool specimen at a later date.

The objective of this study was to evaluate the Copan FecalSwab™(FS), as a rectal swab collection device, 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 assay.

Methods

- To date, 487 consented pediatric ER patients have been prospectively enrolled in the multi-center GI IMPACT Study.
- Rectal swabs (FS) in addition to Cary-Blair (CB)stool specimens were collected at 3 sites.
- Enrollment is ongoing
- To date results of 135-paired FS and CB stool specimens have been compared

Results

- Of 135 patients, 37 (27.4%) had no pathogens detected and 98 (72.6%) were positive for 131 and 126 pathogens from CB and FS, respectively.
- In 95 (70.4%) there was complete agreement between sample types. Figures 1-3 show the organism distribution and the % of pathogens in the 2 major categories, viruses and bacteria, respectively.
- There were 22 CB and 21 FS specimens where additional or different pathogens were detected.
- 58 additional pathogens were detected from FS in patients where CB was unable to be obtained. Table 1 and Figure 4 demonstrate these pathogens. Most notably, *Giardia* was not detected with FS in 2 patients and in 8 patients Adenovirus was detected in FS but not CB.
- Significantly, 22 reportable pathogens, including 16 Norovirus and 6 bacterial/shiga toxin positive patients were detected with FS when a CB was unable to be submitted.
- The age range for FS collection was .02 to 17.2 years (median 1.33). Discrepant analysis (culture and alternate PCR) is ongoing.

Fig1

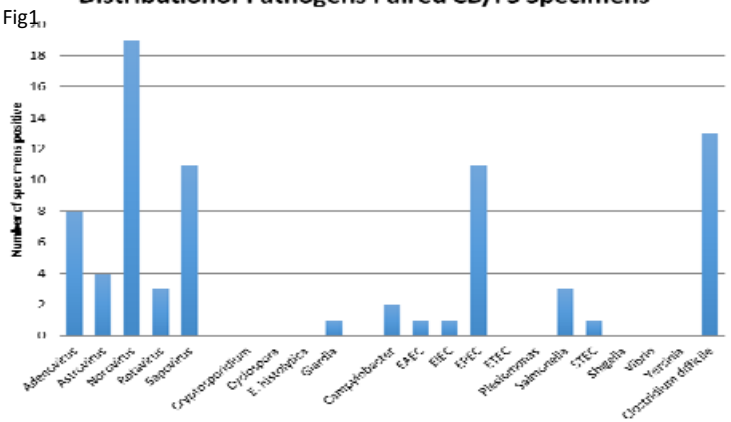


Fig 2

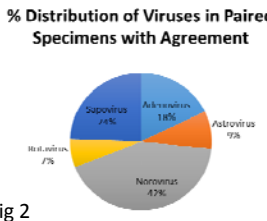


Fig 3

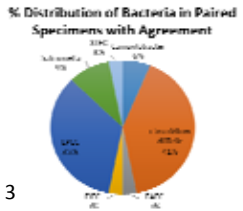
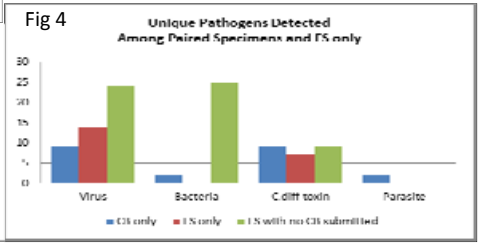


Table 1. Different Pathogens from Paired CB/FS and FS only

Pathogens	CB	FS	FS *
Viruses	9	14	24
Bacteria	2	0	25
C. difficile toxin	9	7	9
Parasites	2	0	0
Total	22	21	58

*Only FS submitted, Patient s unable to provide CB

Fig 4



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
- Importantly, there were no discrepancies for bacterial or STEC targets with FS and CB
- The FS used as a rectal swab collection device at the time of the patient visit, enables rapid testing and the generation of actionable results in the acute care setting, when a CB stool specimen cannot be provided

Copan Diagnostics provided FS Collection devices for the study