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.


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.

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