1214. Evaluation of Two Multiplex Molecular Gastrointestinal Panels Using Rectal Swab Specimens Versus Cary-Blair Stool in Pediatric Patients With Acute Gastroenteritis

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Background. Surprisingly, patients presenting with acute gastroenteritis (AG) are often unable to provide a stool specimen at the time of their visit. Collection of a rectal swab, addresses an unmet clinical need to allow providers to obtain a specimen when evaluating the patient and when testing for gastrointestinal (GI) pathogens is necessary. However, no GI multiplex molecular assays are currently FDA-cleared for use with a rectal swab collection. The purpose of this study was to evaluate two molecular multiplex GI assays, the Film Array Gastrointestinal Panel (FA) (Biofire Diagnostics) a 22 pathogen panel including viruses, bacteria, parasites and the BD MAX Enteric Bacterial Panel (MAX EBP) (Becton Dickinson) which detects *Salmonella*, *Shigella*, *Campylobacter*, and Shiga toxins (SSCST), using a rectal swab as the test sample.

Methods. Pediatric patients presenting with AG were prospectively consented and enrolled to obtain both a rectal swab using the fecal swab (FS) (Copan Diagnostics) and a Cary-Blair (CB) stool. Enrollment is on-going. Both molecular panel assays were performed on all specimens submitted. Culture was done per provider request and/or when bacterial targets were detected by FA or MAX EBP. Percentage agreement between specimen types and analytes for each system were compared. Discrepant results were resolved by positive culture and/or combination of molecular results.

Results. Seventy-four patients consented to date submitted both a rectal swab and CB stool specimen (paired specimens). Twenty-nine patients provided a rectal swab only. Positive specimens were 63.5% (47/74) and 6.7% (5/74) for paired and 72.4% (21/29) and 10.4% (3/29) for rectal swab only for FA and MAX EBP, respectively. Percentage agreement between CB and FS was 48.6% for FA and 100% for MAX EBP. The most common pathogens detected with FA were viruses, *C. difficile* and EPEC. For 9 patients with 10 SSCST pathogens, MAX EBP and FA had 100% agreement. Culture missed 2 Shiga toxins and 1 *Campylobacter*.

Conclusion. Both the Film Array and BD MAX GI pathogen assays showed excellent performance with rectal swabs using the FS collection system compared to CB stool. Use of a rectal swab guaranteed ability to obtain a specimen at the time of the patient visit.

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