This study compared the performance of the FilmArray® Gastrointestinal (GI) Panel and the Luminex GPP to that of routine testing using clinical stool samples.

The study included prospective samples (230) and previously characterized samples (72). Among the 230 prospective samples, routine testing was positive for one or more GI pathogens in 19 (8.3%) samples, compared to 69 (30.0%) by the Luminex assay, and 76 (33.0%) by the FilmArray® GI Panel. The 72 previously characterized samples included 243 positive samples and 27 negative samples. For positive samples, the majority of targets on the FilmArray® GI Panel and the Luminex assay showed percent sensitivities of >90%.

This evaluation demonstrated that multiplex GI panels yield an increased percent positive rate compared to routine testing (28% and 20% for the FilmArray® GI Panel and the Luminex assay, respectively, after exclusion of false positive results). This study found that a high percentage of stool samples were positive for two or more pathogens. The FilmArray® GI Panel identified mixed infections in 27% (86/318) samples, compared to 14% (44/312) for the Luminex GPP and 8.3% (19 samples) for routine testing. These results indicate that the presence of multiple pathogens in diarrheal stool samples may be underestimated by current routine tests.

“The ability to cover for a broad spectrum of GI pathogens in a single test is an appealing advantage of multiplex technology.”

**PERFORMANCE**

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**Clinical**

Hypothetical Impact of a Molecular Diagnostic for Pediatric Acute Gastroenteritis: The FilmArray® GI Panel Hy-IMPACT Study.

MI Ardura1, K Everhart1, K Bourzac1, A Leber1

Departments of Pediatrics and Infectious Diseases, Pathology, Nationwide Children’s Hospital and The Ohio State University and BioFire Diagnostics, LLC, Salt Lake City, UT

**ABSTRACT**

Background: Diarrheal disease is common in pediatrics, but an infectious etiology is not always confirmed. The FilmArray® Gastrointestinal Panel (FA) is a rapid, highly multiplexed test for bacteria (8 results; including E. coli O157, diarrheagenic E. coli (DE) (9 results), parasites (4 results), and viruses (5 results).

Methods: We performed a retrospective analysis of stool samples tested by FA and compared with conventional testing (CT) ordered as standard of care. Medical record review was performed in a subset of patients with positive results to model what impact having the FA results at initial presentation might have had on patient management.

Results: An organism was detected in 63% of 793 stool samples; 23% had a positive test for bacteria, for which culture or antigen testing was done. FA detected 47 analytes missed by culture and 12 analytes for E. coli O157/ STEC antigens. For viral and parasitic targets with CT available (Adenes, Rotavirus, norovirus, asthma, and norovirus), an additional 100 targets were detected by FA that were not ordered by the physician; 13 targets detected by FA were missed by CT. Among novel analytes for which CT is not available (Astro, Sapovirus, and DE), 43 (56%) were found by CT. Among novel analytes for which CT is not available (Adenes, Sapovirus, and DE), 43 (56%) were found by CT.

Clinical data was available for review in 172 patients with at least one positive target, 68 (40%) had a positive result by CT. The median age was 3.5 (range 0.2-24); 54 (31%) had an underlying medical condition and presented with a history of fever (n=29, 17%) or blood in stools (n=4, 25%). FA detected an analyte in 72 (42%) patients who did not have a diagnosis found by CT. In 59 (34%) patients, DE was detected and was ordered by the patient; 13 targets detected by FA were missed by CT. Among novel analytes for which CT is not available (Astro, Sapovirus, and DE), 43 (56%) were found by FA.

Conclusions: Application of FA in pediatric patients with GI illness may allow for an improved diagnostic yield, timely and target antimicrobial therapy, and patient education. Further data is needed regarding the implication of DE detection.

**BACKGROUND**

• Diarrheal illnesses are common in the pediatric population, but an infectious etiology is not always ascertained.

• The FilmArray® Gastrointestinal Panel (FA) is a rapid (TAT = 1 hr), highly multiplexed test that allows detection of:

**METHODS**

• Retrospective analysis of stool samples submitted as standard of care for routine stool culture at Nationwide Children’s Hospital from May to Sept.2013.

• Stool samples in Cary Blay media were tested by FilmArray® GI as part of the clinical trial to support product registration (FDA 510k) and compared with conventional testing (CT).

• Medical record review performed by an infectious disease clinician in a subset of patients who were followed at Nationwide Children’s Hospital and had both clinical data available and positive FA results in order to model what impact having the FA results at initial presentation might have had on patient management. GI test included was included in the RLU reports and in this analysis but not a reported analytic in the final IVD product.

**RESULTS**

Study Population

• 793 patients were enrolled in clinical trial for FDA clearance of the GI panel.

• Of 499 positive samples, 172 (22%) had clinical data available for additional chart review.

• 949 positive results.

**Sensitivity**

<table>
<thead>
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<td>205</td>
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**SPECIFICITY**

<table>
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<tr>
<td>409</td>
<td>294</td>
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**KEY POINTS**

• Multiplex GI panels yield an increased percent positive rate compared to routine testing.

• The presence of multiple pathogens in diarrheal stool samples may be underestimated by current routine tests.

• The detection of common viral causes of GI diseases may help reduce the use of antibiotic therapy.