

Performance of the GI PCR Assay in Hospitalized Adults

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ABSTRACT

The BioFire FilmArray GI Panel Assay is a PCR-based diagnostic test capable of detecting 22 different gastrointestinal pathogens. However, the majority of pathogens detected by the GI PCR assay in hospital-acquired gastroenteritis is largely due to *Clostridium difficile* and *Norovirus*, both of which can be assayed individually with less expensive tests. Previous studies favor a cost-saving '3-day rule,' that instructs laboratories to discontinue GI PCR tests ordered on inpatient adults following the 3rd day of hospitalization. However, the previous studies performed a limited analysis of pathogens (viruses, EPAC, and cryptosporidium were not considered), and certain high-risk patients may go undetected if the 3-day rule were enforced. Thus there is a need to identify certain patient characteristics that would indicate when breaking the 3-day rule and ordering a full GI panel assay is warranted.

OBJECTIVES

The aim of this study was to define the appropriate use of the GI panel assay for the evaluation of hospital-acquired diarrhea in adult patients. We hypothesized there would be a decreasing yield in the detection of gastrointestinal pathogens (excluding *C. difficile* and *Norovirus*) by the FilmArray GI Panel assay when testing hospitalized adult patients more than 3 days following hospital admission, compared to those tested within the first 3 days of hospitalization or those tested as outpatients.

MATERIALS & METHODS

This is a two-part study. Part one is a retrospective study of the yield of the FilmArray GI Panel in detecting GI pathogens in adults who have been hospitalized for > 3 days and tested between June 2016 and May 2017 at the University of Colorado Hospital Molecular Laboratory. Part two is an observational study intended to analyze the patient subset from part one who were positive for pathogens after 72 hours. We used Fisher's exact test to compare proportions of positive and negative tests among inpatient and outpatient patients, patients who were or were not immunocompromised, and patients with or without medical co-morbidities.

RESULTS

We found that of the 586 tests that were performed on adults hospitalized for > 72 hours, 486 were negative for all pathogens, and 125 analytes were positive from 118 tests (due to tests positive for more than one enteropathogen). Of the 118 positive tests performed, 85 were positive for *C. difficile* and *Norovirus*, and 26 were positive for pathogens other than *C. difficile* and *Norovirus*.

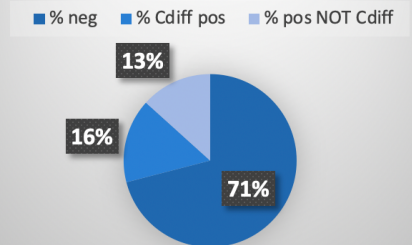
Pathogen	% Positive GI PCR
<i>C. diff</i>	46%
EPEC	14%
Noro	13.4%
EAEC	6.9%
Sapovirus	5.3%
Campylobacter	4.8%
Giardia	3%
Rotavirus	3%
All Others	<1%

Fig 1. Breakdown of All Positive GI PCR Results from both Inpatient and Outpatient Populations

CONCLUSIONS

Based on the results of our retrospective study, the University of Colorado Hospital implemented restrictions on the use of the BioFire FilmArray GI PCR panel in 2018, that conformed to a '3-day rule,' which instructs laboratories to discontinue GI PCR tests ordered on inpatient adults following the 3rd day of hospitalization. A subsequent observational study to determine the clinical significance of the GI PCR findings is presently underway.

Inpatient Results



Outpatient Results

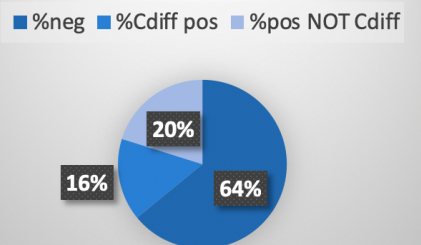


Fig 2 Yield of GI PCR in All Patients Irrespective of Time

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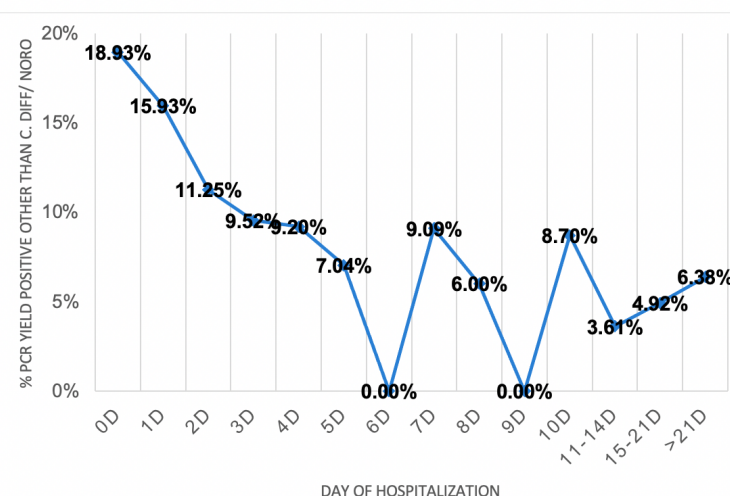


Fig. 3. Percentage of Inpatient Tests Positive for Analyte Other than *C. diff* Per Day of Admission