Rapid Multi-target Detection of Gastrointestinal Pathogens in Patients Presenting with Diarrhea

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ABSTRACT

The FilmArray GI Detection System was developed for rapid simultaneous identification of a broad range of gastrointestinal (GI) pathogens including Food- and Water-borne Category B pathogens. Targeted organisms are viruses, protozoa, and bacteria including 5 diarrheagenic E. coli pathogens. The performance of the FilmArray GI System was compared to conventional diagnostic methods using 1188 real-world stool specimens. The FilmArray GI system was 97% sensitive and 99% specific for stool pathogens. Multi-target detection revealed multiple infections in about 10% of specimens with up to 5 pathogens in a single sample. The FilmArray GI System detected 43 additional pathogens in specimens where corresponding testing was not available or not requested. Additionally, multi-pathogen GI panels make its targeted population very broad, including not only US residents, but also travelers and US military troops around the world.

RESULTS

Clinical testing results of 620 sequential patient stool samples submitted to the Primary Children’s Medical Center laboratory for standard-of-care testing were evaluated. It was found that 13.7% of patients were diagnosed with a causative pathogen leaving 86.3% undiagnosed (Figure 2). A subset of 1188 real-world samples out of the 620 submitted samples were tested using the FilmArray GI Detection System. This subset consisted of 795 negative specimens and 43 specimen in which a causative pathogen had been identified. The FilmArray GI panel testing among these 1188 samples resulted in 95 positively detected organisms compared to 45 detected by standard clinical methods as ordered by a physician (Figure 3). The increased rate of positivity can be attributed to two factors, an improved detection sensitivity of the FilmArray GI Detection System (Figure 4), and simultaneous testing for multiple pathogens for which testing was not requested by a physician (Figure 5). Overall concordance of the FilmArray System and conventional methods was 97%. Detection of multiple organisms was found in approximately 30% of the clinical samples when tested using the FilmArray GI Detection System. When using the FilmArray GI panel, 20% of the 75 previously undiagnosed specimens were found positive with at least one pathogen leading to a potential 26% increase in pathogen detection.

CONCLUSION

The FilmArray GI Detection System may provide rapid, accurate, and comprehensive detection of GI pathogens and improve treatment of patients presenting with diarrhea.

INTRODUCTION

An estimated 211-415 million episodes of diarrheal illness occur each year in the United States, resulting in 73 million physician consultations, 1.8 million hospitalizations, and 3010 deaths.[1] Estimates for the cost of food-borne infections range from $60 to $23 billion in the United States alone.[2] The overwhelming challenge in diagnosing infectious diarrhea is the large number of pathogens that are known to cause diarrhea, viruses, bacteria, and protozoa. Precise diagnosis is difficult because of their large number, short duration of symptoms, and slow. Additionally, many GI pathogens have limited test availability and low sensitivity.

Figure 1

Figure 2: Results of testing by conventional methods (620 patients)

Figure 3: FilmArray GI panel total results

Figure 4: FilmArray GI panel performance compared to conventional methods

Figure 5: FilmArray GI panel detections for tests that were available, but not ordered

Figure 6: FilmArray GI panel detections of less commonly-evaluated pathogens

Figure 7a: FilmArray GI panel detects multiple GI infections

Figure 7b: Lab detection compared to FilmArray GI Pouch

REFERENCES


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