



## Multicenter Evaluation of the BioFire FilmArray® Gastrointestinal Panel for the Etiologic Diagnosis of Infectious Gastroenteritis.

Buss S.N., Leber A., Chapin K., Fey P.D., Bankowski M.J., Jones M.K., Rogatcheva M., Kanack K.J., Bourzac K.M.

This study evaluated the performance of the FilmArray® Gastrointestinal (GI) Panel for detection of 22 enteric pathogens from prospectively collected stool specimens at four, geographically distinct clinical sites across the United States. Performance of the FilmArray® GI Panel was compared to conventional stool culture for common bacterial pathogens and molecular methods for detection of toxigenic *C. difficile*, diarrheagenic *E.coli* and *Shigella*, viruses and parasites.

A total of 1556 specimens were collected between May and September of 2013. Specimens were collected from both adult and pediatric patients, and the majority of the specimens were collected from outpatients.

The FilmArray® GI Panel detected at least one potential pathogen in 832/1556 (53.5%) specimens. The most prevalent organism detected in this study were enteropathogenic *E. coli* (EPEC) (22.4%), *C. difficile* (13.1%), and enteroaggregative *E. coli* (EAEC) (7.0%). Multiple pathogens were detected in 262/832 (31.5%) of the positive specimens and all pathogens detected by the FilmArray® GI panel in this study were observed, to some degree, as part of co-infections.

Limitations to the study included a low number of positive specimens for some of the panel targets, or no positive sample at all (*Entamoeba histolytica*), the potential for misrepresented pathogen presence due to specimens collected only during the spring and summer, and specimens obtained from clinical centers in the United States only. Also, the significance of detected co-infections, as well as the clinical implication of specific pathogens combination, are not well understood. Rapidly determining which potential pathogens a patient harbors is an important step in formulating an effective treatment plan and applying infection control measures.

Overall, this study demonstrates that the FilmArray® GI Panel is a robust, highly sensitive and specific, multiplexed *in vitro* diagnostic device for the simultaneous detection of multiple bacteria, parasites, and viruses from stool specimens.

*“Due to the extensive panel of targeted pathogens and the rapid turnaround time, the FilmArray® GI Panel has the potential to direct appropriate therapy and infection control precautions.”*

### KEY POINTS

- The FilmArray® GI Panel accurately detected bacterial, viral, and parasitic pathogens directly from stool samples in Cary-Blair medium.
- The FilmArray® GI Panel provides a comprehensive, rapid, and streamlined alternative to conventional methods for the etiologic diagnosis of infectious gastroenteritis.
- The FilmArray® GI Panel has the potential to more quickly identify and further reduce transmission in an outbreak of enteric pathogens.