Clinical Evaluation of a Multiplex PCR Panel for Simultaneous Detection of Bacteria, Viruses, and Parasites in Stool Specimens

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INTRODUCTION/BACKGROUND

The FilmArray® GI Panel (BioFire Diagnostics, LLC, Salt Lake City, UT) is a rapid (<1 hr) user-friendly, high-throughput test for 22 infectious agents of gastrointestinal origin from stool specimens in Cary Blair enteric transport media. The aim of this study was to establish clinical sensitivity and specificity for each panel member.

Methods

Specimens meeting the following inclusion criteria were selected for the study at four geographically distinct study sites: the specimen was received by the laboratory in Cary Blair enteric transport media, was submitted for clinician ordered investigation of GI pathogen analysis (e.g. stool culture, C. difficile testing, or ova and parasite exam), was of sufficient volume for testing, and could be tested (FilmArray and bacterial culture) within 4 days of specimen collection. Specimens were collected under IRB approved protocols at each site.

Reference/comparator methods to evaluate the performance of the FilmArray GI Panel included stool culture for bacteria (performed at study sites using the media listed in Table 1) or PCR with bi-directional sequencing for C. difficile, enteropathogenic E. coli (EPEC), parasites, and viruses (performed at BioFire, two assays per analyte).

Table 1. Study Culture Media (or their equivalent) for Use in the Study

<table>
<thead>
<tr>
<th>Media</th>
<th>Primary Organisms/Target</th>
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<tbody>
<tr>
<td>CaryBlair</td>
<td>E. coli O157, C. difficile, G. intestinalis, C. upsaliensis, V. cholerae, C. jejuni, C. coli</td>
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<tr>
<td>MacConkey-Sorbitol</td>
<td>E. coli O157, C.jejuni, C. coli</td>
</tr>
<tr>
<td>Differential</td>
<td>E. coli O157, C.jejuni, C. coli</td>
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The FilmArray GI Panel detected at least one potential pathogen in 832 of the 1556 specimens that were tested, yielding a positivity rate of 54%. Multiple pathogens were detected in 18% of specimens (37.5% of the positive specimens) and the greatest number of potential pathogens detected in a single specimen was six (Campylobacter jejuni, faecal adenovirus, EPEC, ETEC, G. intestinalis, and Norovirus).

Figure 1. Positivity Rate and Number of Organisms Per Sample

CONCLUSION

FilmArray GI Panel is highly sensitive and specific test for infectious agents of gastrointestinal illness. The test has the capability of identifying a greater number of pathogens associated with gastrointestinal illness while being faster, more sensitive, more specific, and simpler to perform than standard methods.

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