Detection of Viral Diarrheal Pathogens by the FilmArray GI Panel

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INTRODUCTION

BioFire Diagnostics has brought to market a new diagnostic system, the FilmArray®, that integrates RT-PCR-based multiple pathogen identification from unprocessed specimens in about an hour. A FilmArray Panel for detection of gastrointestinal pathogens (FilmArray GI Panel) is currently under development and aims to simultaneously detect 23 GI pathogens from stool, including 5 enteric viruses: Adenovirus (F40/F41), Human Astrovirus (serotypes I-IV), Norovirus (GI and GII), Rotavirus A, and Sapovirus (serotypes I, II, IV, V). The purpose of this study was to evaluate the stability of the FilmArray GI Panel for detection of 23 GI pathogens, and to demonstrate its superiority over previously tested, archived stool samples.

THE FILMARRAY GI PANEL

Simultaneous detection of 23 pathogens:

- **Bacteria**
  - *Aeromonas*
  - *Campylobacter*
  - *Cholitomias* (Adeno F)
  - *Pseudomonas* (Glamblia)
  - Salmonella
  - *Vibrio*
  - *Shigella*
  - *Campylobacter* (EPEC)
  - *E. coli O157*

- **Viruses**
  - *Adenovirus F40/41*
  - *Human Astrovirus*
  - *Norovirus GII/GGI*
  - *Rotavirus A*
  - *Sapovirus*

- **Protozoa**
  - *Entamoeba histolytica*
  - *Giardia lamblia*

- **Filamentous**
  - Cryptosporidium
  - Cyclospora
c

**The FilmArray System**

The FilmArray is a lab-in-a-pouch medium-scale fluid manipulation system performed in a self-contained, disposable, thin-film plastic pouch. The FilmArray platform processes a single sample, from nucleic acid purification to result, in a fully automated fashion.

The FilmArray GI pouch has a footprint (A) containing all needed thermocycles and reagents that allow amplification of the target region of the virus. Two amplification types (B) are based on nucleic acid amplification by PCR. PCR-specific assay is used to detect 23 pathogens in one reaction and a second-stage PCR amplification detects 34 pathogens in a single reaction. The second-stage PCR products are then used in a melting curve analysis using a fluorescent double-stranded DNA melting dye, LCGreen™.

**Assessment of FilmArray GI Pouch for Detection of Viral Pathogens**

**Pathogens Detected by the FilmArray GI Panel in Residual Specimens from 410 Symptomatic Children, Salt Lake City, UT**

<table>
<thead>
<tr>
<th>Virus</th>
<th>FilmArray GI Positive/ F40/41</th>
<th>% Positive agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norovirus G/GGI</td>
<td>9/13</td>
<td>9/13</td>
</tr>
<tr>
<td>Rotavirus A</td>
<td>13/14</td>
<td>13/14</td>
</tr>
<tr>
<td>Sapovirus</td>
<td>8/13</td>
<td>8/13</td>
</tr>
<tr>
<td><em>Giardia</em></td>
<td>13/14</td>
<td>13/14</td>
</tr>
<tr>
<td><em>C. difficile</em></td>
<td>26/27</td>
<td>26/27</td>
</tr>
<tr>
<td><em>E. coli O157</em></td>
<td>18/19</td>
<td>18/19</td>
</tr>
</tbody>
</table>

**的优势 of simultaneous testing for a broad number of pathogens provided by the FilmArray GI Panel was demonstrated by the detection of a number of pathogens for which testing was not requested by a clinician.**

**Advantage of Multi-Target Approach: Greater Detection of Multiple Pathogens**

- Multi-target testing by the FilmArray GI Panel detected multiple pathogens in about 30% of tested specimens, with up to 5 pathogens detected in a single specimen. Detection of two or more viruses in a single specimen and combinations of bacterial, viral, and protozoal pathogens was significant.

**CONCLUSION**

Current gastrointestinal pathogen testing methods are limited in breadth and have low throughput. The FilmArray GI panel is an easy to use and rapid test for the detection and identification of multiple pathogens from a single specimen. Broader and more accurate pathogen detection may improve patient treatment and may reduce inappropriate antibiotic use and associated complications. Public health may benefit from more rapid detection of GI pathogen related outbreaks and a broader understanding of the etiology of enteric illness.

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