EntericBio® Dx EBGPDx-US
Molecular Gastrointestinal Panel

GI Panel 7
- Salmonella
- STEC
- Shigella
- Campylobacter
- Vibrio
- Giardia
- Entamoeba histolytica

GI Panel 5
- Salmonella
- STEC
- Shigella
- Campylobacter
- Vibrio
WORKFLOW

Add Samples  Heat Treat  Automated Setup  Amplify & Detect

PERFORMANCE

Performance characteristics of the EntericBio® Dx assay were established in a multi-site clinical study against alternate molecular devices. A total of 1472 fresh prospective specimens and 310 simulated specimens were enrolled during the clinical trial. The EntericBio Dx assay is intended for use with fresh specimens and the performance characteristics for this specimen type are detailed in Table 1 where applicable.

Table 1. Performance characteristics in fresh specimens & simulated specimens

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>POSITIVE % AGREEMENT (95% CI)</th>
<th>NEGATIVE % AGREEMENT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh Prospective Specimens</td>
<td></td>
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<tr>
<td>Salmonella</td>
<td>92.3 (75.9-97.9)</td>
<td>100 (99.7-100)</td>
</tr>
<tr>
<td>Campylobacter</td>
<td>98.0 (89.8 – 99.7)</td>
<td>99.8 (99.4 – 99.9)</td>
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<tr>
<td>Shigella/EIEC</td>
<td>100 (78.5 – 100)</td>
<td>100 (99.7 – 100)</td>
</tr>
<tr>
<td>STEC</td>
<td>100 (67.6 – 100)</td>
<td>99.9 (99.5 – 99.9)</td>
</tr>
<tr>
<td>Giardia lamblia</td>
<td>85.7 (60.1 – 96.0)</td>
<td>99.9 (99.6 – 99.9)</td>
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<tr>
<td>Simulated Specimens</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibrio</td>
<td>100 (96.3 – 100)</td>
<td>100 (98.2 – 100)</td>
</tr>
<tr>
<td>Entamoeba histolytica</td>
<td>98.6 (92.3 – 99.8)</td>
<td>100 (98.4 - 100)</td>
</tr>
</tbody>
</table>

\(^1\)2/2 Salmonella FN observed were negative for Salmonella when tested with an alternative PCR assay.

\(^2\)2/2 Giardia FN observed were negative for Giardia when tested with an alternative PCR assay.

BENEFITS

- 1-30 Samples processed per run
- Less than 30 mins hands on time for 30 samples
- Time to result: under 3 Hours, up to 30 samples
- Consecutive runs of up to 30 samples every hour
- High throughput up to 150 samples in an 8 hour working day

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