1 Sample, 1 Test, 15 Results
Gastroenteritis
A Serious Medical and Economic Burden

1 A variety of bacterial, parasitic, and viral organisms may cause infectious gastroenteritis.
   • Diagnostically, it’s difficult to differentiate due to similar symptoms.\textsuperscript{1,2}
   • 80% of all cases of diarrhea are currently unidentified.\textsuperscript{2}

2 Diarrhea inflicts a significant toll on the health care system and can result in a high degree of morbidity and mortality in select populations.\textsuperscript{1}
   • Globally, there are nearly 1.7 billion cases of diarrheal disease every year which kill around 525,000 children under five.\textsuperscript{1,4}
   • In Europe, there are approximately 5,000 deaths from diarrheal disease every year.\textsuperscript{3}

3 Hospital outbreaks of gastroenteritis may have undesirable consequences.\textsuperscript{5}
   • Outbreaks may lead to hospital ward closures or major disruption in routine hospital activity.

4 Diarrhea can also have a major impact in society.
   • Significant number of days may be lost at school or work.

5 Inappropriate use of antibiotics provides favourable conditions for the emergence of resistant organisms.
   • When infections become resistant to first-line antibiotics, more expensive antibiotics must be used.
   • Prolonged and severe illness may lead to increased health care costs and financial burden.\textsuperscript{6}

Gastroenteritis outbreaks have been associated with an average of 13,000 patients and 3,400 staff becoming ill, with 15,000 lost bed-days annually in 2013-2015, according to Hospital Norovirus outbreak Reporting Scheme (HNORS).\textsuperscript{7}
**Same Day Results** for 15 of the Most Common Causes of Infectious Diarrhea

**Improve patient outcomes, avoid needless isolation costs, and act fast to prevent outbreak situations with xTAG® Gastrointestinal Pathogen Panel (GPP)—1 Stool Sample, 1 Test, 15 Results.**

From a single and simple laboratory test, you can get results for 15 of the most common causes of infectious gastroenteritis from a single stool sample in less than 5 hours. xTAG® GPP is a qualitative multiplex test intended for the simultaneous detection and identification of nucleic acids from multiple gastroenteritis-causing viruses, bacteria, and parasites (including toxin gene detection) in human stool samples that are fresh, frozen or in a holding medium, from individuals with signs and symptoms of infectious colitis or gastroenteritis.

The advantages of multiplex molecular diagnostic technology seem clear: it unifies the NHS’s fractured laboratory processes, and in doing so, brings a wealth of financial, medical, and logistical benefits.⁸
In May 2011, an increasing number of cases with gastroenteric symptoms were reported in German hospitals. Until then, available microbiological methods were unsuitable to accurately identify the outbreak. Rapid screening diagnostic methods such as xTAG GPP were essential to ensure timely and appropriate patient management.
A 2015 economic study estimated that the test could reduce the costs of managing these patients by 19%. An additional benefit is the reduction of days in isolation by 11.4%.\textsuperscript{12}

The cost for severe gastroenteritis in the Netherlands in 2009 was estimated at €2,203 per hospitalized child, and €6,834 per hospitalized adult. The overall costs of gastroenteritis in 2009 were estimated at €611-695 million.\textsuperscript{13}
### xTAG GPP

#### Transforming GI Diagnostics

1 Stool Sample, 1 Test, 15 Results—More results faster, enabling a higher diagnostic yield.

<table>
<thead>
<tr>
<th>Methods</th>
<th>Tests for</th>
<th>Turnaround Time</th>
<th>Percent Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stool culture</td>
<td>Single bacterial pathogen per test</td>
<td>2-3 days</td>
<td>Up to 6%&lt;sup&gt;14&lt;/sup&gt;</td>
</tr>
<tr>
<td>Ova and parasite (O&amp;P) exam</td>
<td>Parasitic pathogens</td>
<td>Several days - sample collected over and up to 3 subsequent days</td>
<td>Up to 3%&lt;sup&gt;15,16&lt;/sup&gt;</td>
</tr>
<tr>
<td>Rapid Tests (Rapid Immunoassays -lateral-flow, immunochromatography, dot blot)</td>
<td>Single pathogen per test</td>
<td>20-30 minutes</td>
<td>Varies</td>
</tr>
<tr>
<td>Real-time PCR</td>
<td>1-3 pathogens per test</td>
<td>Under 5 hours</td>
<td>Varies (depends on the pathogen target, individual performance and number of assays)</td>
</tr>
<tr>
<td>xTAG&lt;sup&gt;®&lt;/sup&gt; GPP</td>
<td>Up to 15 bacterial, viral, and parasitic pathogens in a single test</td>
<td>Under 5 hours*</td>
<td>30%</td>
</tr>
</tbody>
</table>

*Including extraction steps

Appropriate isolation: Many ‘low risk’ non-isolated diarrheal patients appear to be positive for communicable gastrointestinal pathogens. In addition to this, many patients in isolation do not contain a communicable gastrointestinal pathogen. xTAG GPP helps optimize bed management and avoid outbreaks.
The ability of xTAG GPP to detect not only several different types of E.coli, but also the presence of the gene for STX2, a key marker of this more severe STEC strain, is allowing rapid identification of patients who may be suffering from an infection of this strain.

We conclude that the assay is useful to prescreen patients suffering from the new EHEC strain.

Patients can be monitored more closely by the clinicians and test results associated to the clinical course of hemolytic-uremic syndrome.¹⁷

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**Target**

**NPV**

(Overall NPV = 99.41%)

**BACTERIAL/TOXIN (9)**

- *Clostridium difficile (C. difficile) toxin A/B* 99.76%
- *Shigella* 99.78%
- *Campylobacter* 99.32%
- *Salmonella* 97.22%
- *Enterotoxigenic E.coli (STEC) LT/ST* 100%
- *Escherichia coli (E. coli) O157* 99.75%
- *Shiga-like toxin producing E.coli (STEC) STX1/STX2* 100%
- *Yersinia enterocolitica* 100%
- *Vibrio cholerae* 99.75%

**PARASITIC (3)**

- *Giardia* 100%
- *Entamoeba histolytica* 100%
- *Cryptosporidium* 99.76%

**VIRAL (3)**

- *Rotavirus A* 99.88%
- *Adenovirus 40/41* 100%
- *Norovirus G1/GII* 99.35%

*NPV is Negative Predictive Value. NPV data are derived from data generated with the Luminex® 100/200™ system. The data generated by the Luminex 100/200 and MAGPIX® systems are described in the xTAG GPP package insert. Data obtained with the MAGPIX system are expected to give comparable NPV values.

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**Ordering Information**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>xTAG® Gastrointestinal Pathogen Panel (GPP)</td>
<td>I032C0324 (96 tests)</td>
</tr>
</tbody>
</table>

*This product is CE Marked for IVD use*
The xTAG GPP assay is an aid in the detection and identification of bacterial, parasitic and viral agents causing gastrointestinal infections in symptomatic (both acute and chronic gastroenteritis) adult and pediatric patients, who are either hospitalized, admitted to emergency departments or who are outpatients with suspected gastroenteritis. The xTAG GPP assay is also indicated for use as an epidemiological surveillance tool in Public Health Laboratories. The xTAG GPP is indicated for use with either the Luminex® 100/200™ or MAGPIX® instruments. The xTAG GPP assay is not indicated as a stand-alone diagnostic tool, and should be used in conjunction with other clinical and laboratory findings.

A trained health care professional should carefully interpret the results from the xTAG GPP in conjunction with patients’ clinical signs, symptoms and results of other diagnostic tests.

References