Luminex

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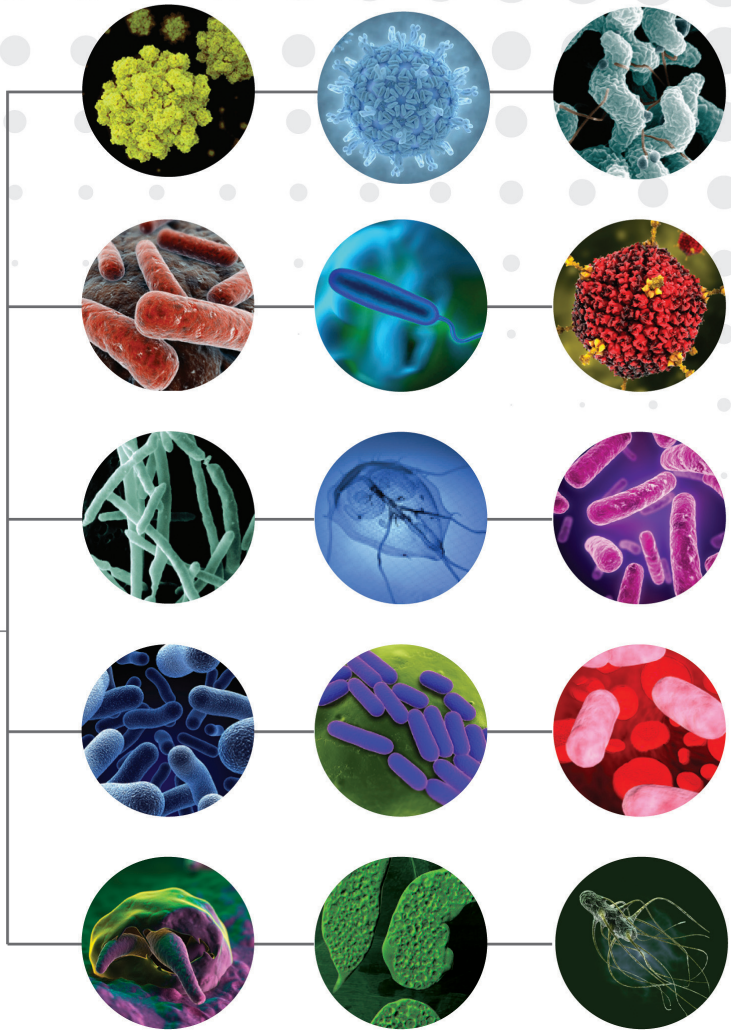
xTAG® Gastrointestinal Pathogen Panel (GPP)

1 sample, 1 test, 5 hours, 14 results

More Answers. Better Decisions.



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.[1,2]
   - 80% of all cases of diarrhea are currently unidentified.[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.**[3]
   - Globally, there are an estimated 2 billion cases of diarrheal disease every year, which kill approximately 1.8 million people annually.[4]
   - In 2010, the U.S. associated cost for the 237,000+ patients suffering from gastrointestinal infections was over $6 billion.[5]

3. **Hospital outbreaks of gastroenteritis may have undesirable consequences.**[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 therapeutics provides favourable conditions for the emergence of resistant organisms.**
   - When infections become resistant to first-line therapeutics, more expensive therapies must be used.
   - Prolonged and severe illness may lead to increased health care costs and financial burden.[6]

GI Diagnostic Challenges and Clinical Consequences

Challenge	Consequence	Solution
• Many causative agents of diarrhea are difficult to diagnose as symptoms are similar	• Risk of delayed or wrong patient treatment • Risk of improper and ineffective treatment with side effects, patient anxiety, inappropriate use of antibiotics and potential for antibiotic resistance	• xTAG GPP simultaneously detects and identifies the bacterial, parasitic, and viral pathogens responsible for over 95% of cases of infectious diarrhea[2] • Patient treatment can be optimized more quickly with improved outcomes
• Traditional laboratory methods are not sensitive or specific enough, and not all samples are tested for all diarrhea-causing pathogens, which can result in a low diagnostic yield (e.g. false negatives)	• Risk of delayed or wrong patient treatment • Pressure on isolation facilities until results are available • Potential for outbreaks if patients with communicable infectious gastroenteritis are not isolated	• xTAG GPP provides higher and better diagnostic yield for more appropriate patient management • Optimized bed management helps control costs and frees up beds for patients that require isolation
• Current methodologies and requesting patterns mean that results take on average 2-3 days to be reported and in some cases more than 1 week • Prevention and control of outbreaks	• Incorrect diagnosis impacting treatment and bed isolation management • Treatment side effects, antibiotic resistance, patient anxiety • Prolonged needless isolation or lack of isolation with risk of outbreaks, (e.g. ward closures, damage to reputation and increased costs)	• xTAG GPP has high negative and positive predictive values for correct and reliable results* • Test takes only 5 hours for immediate action[9]

The sensitivity and specificity data are described in the xTAG GPP package insert.

xTAG GPP : Transforming GI Diagnostics

1 Stool Sample, 1 Test, 14 Results—More results faster, enabling a higher diagnostic yield.

Benefits for physicians

xTAG GPP offers the ability to non-invasively analyze patient stool samples for 14 GI pathogen targets simultaneously and at a much quicker processing time, as compared with conventional industry testing methods. A comparison of existing techniques are summarized below:

Methods	Tests for	Turn-Around Time	Percent Positive
Stool culture	Single bacterial pathogen per test	2–3 days	Up to 6%14
Ova and parasite (O&P) exam	Parasitic pathogens	Several days - sample collected over and up to 3 subsequent days	Up to 3%15, 16
Rapid Tests (Rapid Immunoassays -lateral-flow, immunochromatography, dot blot)	Single pathogen per test	20–30 min	Varies
Real-time PCR	1–3 pathogens per test	Under 5 hours ELISA Single antigen/antibody per test 6 -24 hours	Varies (depends on the pathogen target, individual performance and number of assays)
ELISA	Single antigen antibody per test	6 -24 hours	
xTAG GPP	**Up to 14 bacterial, viral, and parasitic pathogens in a single test**	**Under 5 hours***	**30%**

*Including extraction steps

xTAG GPP : Performance

xTAG GPP—Designed to Give You Confidence in Your Results

Target (Pathogen)	NPV* (Overall NPV = 99.41%)
BACTERIAL/TOXIN (9)	
Clostridium difficile Toxin A/B	99.76%
Shigella	99.78%
Campylobacter	99.32%
Salmonella	97.22%
Enterotoxigenic E.coli (ETEC) LT/ST	100%
Escherichia coli O157	99.75%
Shiga-like Toxin producing E.coli (STEC) stx1/stx2	100%
Yersinia enterocolitica	100%
Vibrio cholera	99.75%
PARASITIC (3)	
Giardia lamblia	100%
Entamoebe histolytica	100%
Cryptosporidium	99.76%
VIRAL (3)	
Rotavirus A	99.88%
Adenovirus 40/41	100%
Norovirus GI/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.*

Intended Use

The xTAG GPP assay is indicated as 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 should be used in conjunction with other clinical and laboratory findings.[18] 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.

Same Day Results for 14 of the Most Common Causes of Infectious Diarrhea

Improve patient outcomes, avoid needless isolation costs, and act fast to prevent outbreak situations with xTAG® GPP—1 Stool Sample, 1 Test, 14 Results.

From a single and simple laboratory test, you can get results for 14 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.

This test is not recommended for in-patients hospitalized for more than 3 days.

Test Overview

- Non-invasive stool test
- Outstanding accuracy
- Helps decrease and contain outbreaks of highly contagious gastrointestinal infections
- Turn-around time of just 24 hours!
- Helps reduce over-prescription of antibiotics
- Provide better patient care
- Patients return specimens to th lab directly via FedEX
- Widely covered by major insurances

Gastrointestinal Pathogen Panel (GPP), PCR
Lab Ordering Code - GPP

Methodology:	Polymerase chain reaction (PCR)
Performed:	Varies
Reported:	24-48 hours
Specimen Required:	Collect : Small amount of fecal material - 2 g. or 2 mL liquid stool. Specimen preparation: Place into screw top Sterile Container. Storage/Transport Temperature: Refrigerated Stability: Refrigerated : 48 hours, Frozen : 2 month NOTE:* This test is not available for New York patients, please refer to test code V600 for specimen requirements.*
CPT Code(s):	87507

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18. Luminex Corporation. xTAG Gastrointestinal Pathogen Panel (GPP) Package Insert CE Marked

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