

Luminex

xTAG[®] Gastrointestinal Pathogen Panel (GPP)

Highly scalable gastrointestinal test with customizable detection of bacterial, viral, and parasitic pathogens to rule out the causes of infectious diarrhea.

One Test, Fourteen Confident Results

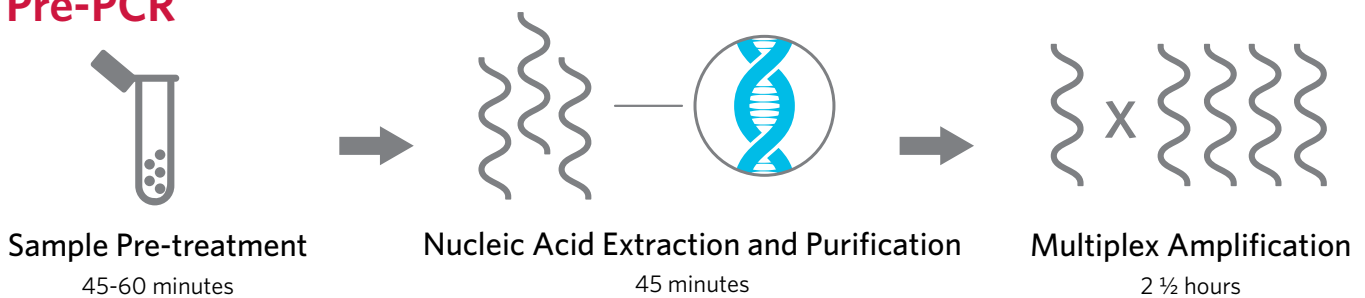


xTAG[®] Gastrointestinal Pathogen Panel (GPP)

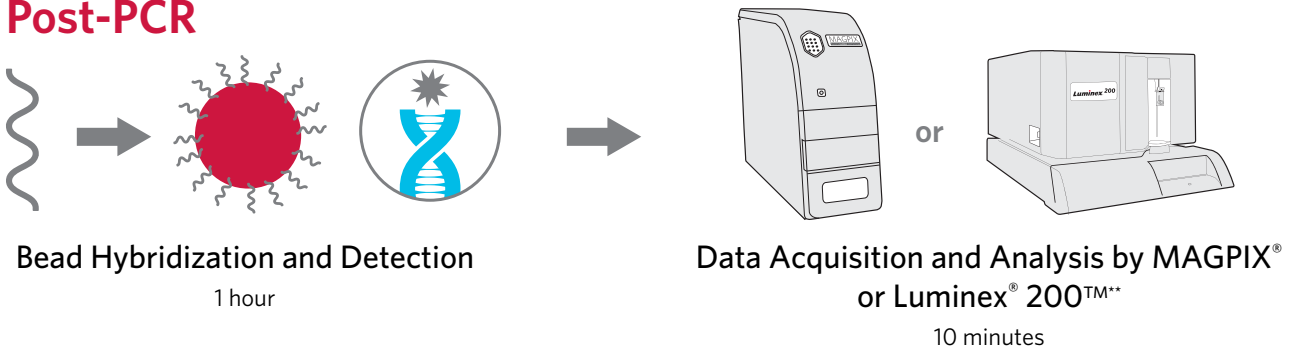
- **Get Fast, Comprehensive Results:** Detect and identify >90% of the causative bacterial, viral, and parasitic agents of gastroenteritis within 5 hours.*
- **Simplify Your Detection Process:** One test provides answers for 14 pathogens. Eliminate the hassle of managing multiple samples and testing methods.
- **Optimize Your Resources:** Minimize labor, reduce expenses, and improve overall laboratory and hospital efficiency, by reducing hands-on time and overall turnaround time.

A simple workflow that provides answers **within 5 hours*** validated on both raw stool and Cary-Blair medium

Pre-PCR



Post-PCR



*Time estimate of within 5 hours is for 24 samples.

xTAG® GPP

More results per test than traditional methods, in time to affect patient care.

| Method | Tests For | Turnaround Time | Percent Positive |
|---|---|--|--|
| Stool culture | Bacterial pathogens | 2-3 days | Up to 6% ¹ |
| Ova and parasite (O&P) exam | Parasitic pathogens | Several days – sample must be collected over multiple days | Up to 3% ^{2,3} |
| 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 | Varies; depends on the pathogen target, performance of assay, and number of assays |
| ELISA | Single antigen/antibody per test | 6-24 hours | Varies |
| xTAG® GPP | 14 bacterial, viral, and parasitic pathogens in a single test | Under 5 hours [†] | ~35% - All 14 targets ⁴ |

xTAG® GPP – A highly scalable gastrointestinal test with customizable detection of bacterial, viral and parasitic pathogens to rule out infectious diarrhea.

[†]Time estimate of within 5 hours is for 24 samples.

Same Day Detection with xTAG® GPP as Compared to Traditional Methods

| Laboratory | Method | Pathogens Detected | Average Time to Results |
|--------------|--------------------------------|---|--|
| Molecular | xTAG® GPP | <ul style="list-style-type: none"> Adenovirus 40/41 <i>Campylobacter</i> (<i>C. jejuni</i>, <i>C. coli</i>, and <i>C. lari</i> only) <i>Clostridium difficile</i> (<i>C. difficile</i>) toxin A/B <i>Cryptosporidium</i> (<i>C. parvum</i> and <i>C. hominis</i> only) <i>Entamoeba histolytica</i> (<i>E. histolytica</i>) <i>Escherichia coli</i> (<i>E. coli</i>) O157 Enterotoxigenic <i>E. coli</i> (ETEC) LT/ST <i>Giardia</i> (<i>G. lamblia</i> only, also known as <i>G. intestinalis</i> and <i>G. duodenalis</i>) Norovirus GI/GII Rotavirus A <i>Salmonella</i> <i>Shigella</i> (<i>S. boydii</i>, <i>S. sonnei</i>, <i>S. flexneri</i>, and <i>S. dysenteriae</i>) Shiga-like Toxin producing <i>E. coli</i> (STEC) <i>stx1/stx2</i> <i>Vibrio cholerae</i> (<i>V. cholerae</i>) cholera toxin gene (<i>ctx</i>) | 5 Hr |
| Virology | Single-plex PCR | <ul style="list-style-type: none"> Adenovirus 40/41 Norovirus GI/GII Rotavirus A | 6 Hrs ^{5,6} |
| Microbiology | EIA and/or PCR and/or Culture | <ul style="list-style-type: none"> <i>Clostridium difficile</i> toxin A/B | 2 Hrs ⁵ 48 Hrs ⁷ |
| Microbiology | Culture | <ul style="list-style-type: none"> <i>Campylobacter</i> <i>Escherichia coli</i> O157 Enterotoxigenic <i>E. coli</i> (ETEC) <i>Salmonella</i> Shiga-like Toxin producing <i>E. coli</i> (STEC) <i>Shigella</i> Shiga-like Toxin producing <i>E. coli</i> (STEC) <i>Vibrio cholerae</i> | 48 Hrs ⁸ |
| Microbiology | EIA and/or Ova & Parasite Exam | <ul style="list-style-type: none"> <i>Cryptosporidium</i> <i>Entamoeba histolytica</i> <i>Giardia lamblia</i> | 1 Hr ⁹ 60 Hrs ¹⁰ |

The xTAG® GPP Can Detect the Following Pathogens:

| Bacteria & Bacterial Toxins | Viruses |
|--|---|
| <i>Campylobacter</i> (<i>C. jejuni</i> , <i>C. coli</i> and <i>C. lari</i> only) | Adenovirus 40/41 |
| <i>Clostridium difficile</i> (<i>C. difficile</i>) toxin A/B | Norovirus GI/GII |
| <i>Escherichia coli</i> (<i>E. coli</i>) O157 | Rotavirus A |
| Enterotoxigenic <i>E. coli</i> (ETEC) LT/ST | Parasites |
| Shiga-like Toxin producing <i>E. coli</i> (STEC) <i>stx1/stx2</i> | <i>Cryptosporidium</i> (<i>C. parvum</i> and <i>C. hominis</i> only) |
| <i>Salmonella</i> | <i>Entamoeba histolytica</i> (<i>E. histolytica</i>) |
| <i>Shigella</i> (<i>S. boydii</i> , <i>S. sonnei</i> , <i>S. flexneri</i> , and <i>S. dysenteriae</i>) | <i>Giardia</i> (<i>G. lamblia</i> only - also known as <i>G. intestinalis</i> and <i>G. duodenalis</i>) |
| <i>Vibrio cholerae</i> , cholera toxin gene (<i>ctx</i>) | |

Ordering Information*

| Product Name | Part Number |
|---|----------------------|
| xTAG® Gastrointestinal Pathogen Panel (GPP) Kit | I032C0316 (96 tests) |
| MAGPIX® System | MAGPIX-XPONENT |
| Luminex® 200™ System with xPONENT® | LX200-XPON3.1 |

*Products are FDA Cleared for IVD Use.

DISCLAIMER: xTAG GPP positive results are presumptive and must be confirmed by FDA cleared tests or other acceptable reference methods. xTAG GPP is not intended to monitor or guide treatment for *C. difficile* infections. Please refer to the IVD package insert for the complete intended use and indications for uses.

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Luminex
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