

Multiplexed molecular testing for a reliable, actionable result in *under 5 hours*

- xTAG GPP is the only test that simultaneously detects and identifies the bacterial, viral, and parasitic pathogens responsible for over 95% of cases of infectious diarrhea¹
- xTAG GPP provides:
 - More answers per sample than any other method
 - A reliable answer, in time to affect patient care
 - Better use of time and human resources

xTAG GPP – More results per test than any other method, in time to affect patient care

Method	Tests for	Turn-around time	Diagnostic yield
Stool culture	Single bacterial pathogen per test	2–3 days	Up to 6% ²
Ova and parasite (O&P) exam	Parasitic pathogens	Several days – sample must be collected over 3 days	Up to 3% ^{3,4}
Rapid tests	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, individual performance and number of assays
ELISA	Single antigen/antibody per test	6–24 hours	Varies
xTAG GPP	Up to 15 bacterial, viral, and parasitic pathogens in a single test	Under 5 hours*	30%

xTAG GPP – the only available gastrointestinal infection diagnostic that detects bacterial, viral and parasitic pathogens in a single test

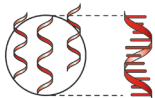
*Including extraction steps

Pinpoint the cause of gastrointestinal infections quickly and efficiently

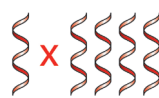
- A single multiplex RT-PCR step amplifies nucleic acids from all three pathogen types: bacterial, viral and parasitic.
- Detection is performed using the award-winning xTAG universal tag sorting system on the simple, reliable, and affordable MAGPIX[®] and proven Luminex[®] 100/200™ instruments

A simple workflow for the xTAG[®] GPP test gives answers within *5 hours*

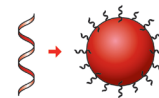
STEP 1:
Extract nucleic acid (10µL):
45 minutes*



STEP 2:
Multiplex RT-PCR (25µL):
2.5 hours*



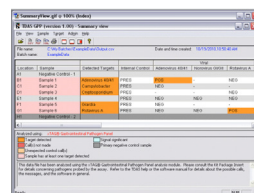
STEP 3: Hybridization/detection using 5 µL RT-PCR product with 20µL bead mix and 75µL 75-fold diluted reporter: 1 hour*



STEP 4: Read on Luminex Analyzer:
Luminex 100/200 or MAGPIX: 20 minutes*



STEP 5: Data analysis



For better patient care

*Time estimates for 24 tests

xTAG GPP – Designed to give you confidence in your results

Enable timely, informed treatment decisions for all diarrhea patients

- xTAG GPP is indicated for use in⁵:
 - All patients with signs and symptoms of infectious gastroenteritis or colitis
 - Acute and chronic diarrhea
 - Inpatient, outpatient and emergency settings
 - Nosocomial surveillance

Get answers you can rely on with a validated, sensitive and specific assay

- Validated and quality controlled (cGMP) reagents that comply with regulatory requirements (CE-IVD) so you can operationalize quickly and efficiently
- Results you can rely on – high sensitivity and specificity for all the target pathogens

xTAG GPP – Excellent sensitivity and specificity performance for all targets⁵

Target (Analyte)	Sensitivity	Specificity
<i>Salmonella</i>	84.6%	98.4%
<i>Shigella</i>	97.7%	97.8%
<i>Campylobacter</i>	97.5%	97.8%
<i>Yersinia enterocolitica</i>	N/A*	100.0%
Enterotoxigenic <i>E. coli</i> (ETEC) LT/ST	N/A*	97.0%
<i>Escherichia coli</i> O157	94.1%	98.8%
Shiga-like Toxin producing <i>E. coli</i> (STEC) stx 1/stx 2	100.0%	98.6%
<i>Clostridium difficile</i> Toxin A/B	97.7%	94.9%
<i>Vibrio cholerae</i>	N/A*	100.0%
Adenovirus 40/41	100.0%	100.0%
Rotavirus A	94.7%	99.8%
Norovirus GI/GII	93.5%	96.4%
<i>Giardia lamblia</i>	100.0%	97.5%
<i>Cryptosporidium</i>	91.7%	99.9%
<i>Entamoeba histolytica</i>	100.0%	98.8%

*Due to low sample size, clinical sensitivity was not assessed for ETEC, *Yersinia enterocolitica* and *Vibrio cholerae*. However, analytical accuracy for these analytes was demonstrated in the limit of detection and reactivity studies with cultural isolates or plasmids.

References: 1. CDC, National Center for Zoonotic, Vector-borne and Enteric Diseases. 2. Slutsker L et al. *Annals of Internal Medicine* 1997; 126(7):505–513. 3. Fotedar R et al. *Journal of Clinical Microbiology* 2007; 45(3):1035–1037. 4. Tuncay S et al. *Türkiye Parazitoloji Dergisi* 2007; 31(3):188–193. 5. Luminex Corporation. xTAG® Gastrointestinal Pathogen Panel (GPP) Package Insert. CE IVD 2011.

To arrange a demonstration or trial of xTAG® GPP, please contact your local Luminex representative, or visit www.luminexcorp.com/gpp

Luminex
xTAG® GPP
Transforming GI diagnostics.