

Seegene Gastrointestinal Solutions

Personalized real-time PCR solution for a more precise and effective testing



Why is the PCR a better way to diagnose gastrointestinal infection?

Testing becomes more efficient

Gastrointestinal infection can be caused by a wide range of bacterial, viral, and/or parasitic pathogens, and has signs and symptoms such as watery diarrhea, nausea, vomiting, and fever. Conventional testing methods such as diagnostic cultures and microscopy have low-throughput and require a lot of manual steps and trained specialists. Using PCR methods on the other hand, testing can be done faster with better accuracy compared to conventional testing methods, providing much better diagnostic efficiency.

Fast and high-throughput testing¹⁾

Culture vs. Real-time PCR* for bacteria



Microscopy vs. Real-time PCR for parasites





Cost of labor for 90 samples (avg. wage \$27/hour)



Maximum sample processing capacity per staff in a day

*Real-time PCR is based on Seegene Allplex[™] PCR assays

Real-time PCR, a more efficient method for GI infection diagnosis²⁾⁻⁶⁾

Many guidelines and studies have supported that real-time PCR method is a more efficient than conventional methods with its high sensitivity and specificity in detecting viral, bacterial, and parasitical pathogens associated with gastrointestinal infections.





Real-time PCR

Conventional methods (culture and/or microscopy)

How are Seegene PCR assays better?

Personalized diagnosis with high convenience

Seegene has diverse PCR assays covering all fields of gastrointestinal infection. Assays can be used to provide personalized diagnosis based on patient condition or medical history. Seegene provides a full syndromic combination for detecting the exact causative pathogens among similar symptoms, bacteria screening solution for mass screening during outbreak of bacterial infection, and *H. pylori* testing solution for helping more accurate prescription for *H. pylori* infection. In addition, HAI (Healthcare-associated infection) testing solution is available for identifying the presence of antimicrobial resistant genes in bacteria infected while in healthcare settings. Most of all, tests can be run in a highly convenient manner with Seegene's fully automated workflow.

The widest GI pathogen coverage in one streamlined system providing fully automated workflow

Full GI product lineup available to meet various testing needs



Seegene's gastrointestinal PCR solutions

Full syndromic testing solution for symptomatic patients

📵 Allplex™ Gastrointestinal Panel Assays

ollplex™ GI-Helminth(I) Assay @

Comprehensive testing to find the exact causative pathogen

· The widest coverage of pathogens that can cause gastrointestinal infection

· Short TAT of 4 hours from extraction to result analysis

· Fully automated workflow using Seegene STARlet-AIOS



Analytes Specimen Allplex™ Allplex™ - Human stool Allplex™ Allplex™ Allplex™ **GI-Virus Assay** GI-Bacteria(I) Assay GI-Bacteria(II) Assay **GI-Parasite Assay** GI-Helminth(I) Assay - Adenovirus - E. coli 0157 - Aeromonas spp. - Blastocystis hominis - Ancylostoma spp. - Astrovirus - Campylobacter spp. - STEC (stx1/2) - Ascaris spp. - Cryptosporidium spp. - Clostridium difficile toxin B - EAEC (aggR) - Norovirus GI - Enterobius vermicularis - Cyclospora cayetanensis - Norovirus GII - Salmonella spp. - EPEC (eaeA) - Enterocytozoon spp. / - Dientamoeba fragilis - Rotavirus - Shigella spp./EIEC - ETEC (*lt/st*) Encephalitozoon spp. - Entamoeba histolvtica - Sapovirus - Vibrio spp. - Hypervirulent - Hymenolepis spp. - Giardia lamblia - Yersinia enterocolitica Clostridium difficile - Necator americanus - Strongyloides spp. - Taenia spp.

Optimized solution for more precise diagnosis

Even when similar gastrointestinal symptoms are shown, causative pathogens can be different. Also, when infected, the treatment must be carefully prescribed based on pathogen type, patient condition, and the severity of a symptom. Annually, more than 1.5 million people have died annually from diarrheal diseases worldwide⁷⁰, which demonstrates the needs for appropriate treatment. Seegene gastrointestinal panel assays can accurately identify the causative pathogens using syndromic testing to help provide the most effective treatment before the symptoms get worse.



from diarrheal diseases annually⁷⁾



Antibiotics used for different causative pathogens ⁸⁾

Pathogen	Antibiotics
Campylobacter spp.	Azithromycin
Non-typhoidal Salmonella	Usually not indicated
Salmonella entericaTyphi or Paratyphi	Ciprofloxacin or Ceftriaxone
Shigella spp.	Azithromycin, Ciprofloxacin or Ceftriaxone
Vibrio cholerae	Doxycycline

- Trichuris trichiura

Bacteria screening solution for preemptive diagnosis

Ilplex[™] GI-EB Screening Assay

Mass screening of major bacterial outbreaks including food-borne disease and water-borne disease

Analytes		Specimens	
- Campylobacter spp.	- Clostridium difficile toxin A/B	- Human stool	
- E. coli 0157	- Salmonella spp.		
- Shigella spp./EIEC	- STEC (<i>stx1</i> /2)		
- Yersinia enterocolitica			



HAI testing solution for effective hospital disease control

o Allplex™ Entero-DR Assay

Early prevention of infection spread associated with antimicrobial resistance that can occur in healthcare settings

Analytes		Specimens	
Carbapenemase-producing Enterobacteriaceae (CPE)	Vancomycin-resistant Enterococci (VRE)	ESBLs – producing Enterobacteriaceae (ESBL)	- Rectal swab - Bacterial colo
- KPC - OXA-48 - VIM - NDM - IMP	- VanA - VanB	- CTX-M	



H. pylori testing solution for successful eradication of H. pylori

Specimens

- Human stool

- Gastric biopsy

o Allplex™ H. pylori & ClariR Assay

Screening and antimicrobial resistance testing in a single test for helping more appropriate prescription



Analytes

- A2142C
- A2142G
- A2143G

References

- 1) Rebbapragada, Advances for routine molecular diagnosis of gastrointestinal infections. 2016; Seegene integrated symposium in ECCMID 2016
- 2) CDC. Norovirus Guidelines for Healthcare Settings. 2011; Available from https://www.cdc.gov/infectioncontrol/guidelines/norovirus/
- 3) WHO. Manual of rotavirus detection and characterization methods. 2019; Available from https://apps.who.int/iris/handle/10665/70122
- WGO. World Gastroenterology Organisation Global Guidelines Helicobacter pylori. 2021; Available from https://www.worldgastroenterology.org/guidelines/helicobacter-pylori
- 5) Rijsman. et al., Clinical consequences of polymerase chain reaction-based diagnosis of intestinal parasitic infections. Journal of Gastroenterology and Hepatology. 2016;31:1808-1815.
- 6) Roberts. et al., Comparison of Microscopy, Culture, and Conventional Polymerase Chain Reaction for Detection of *Blastocystis* sp. in Clinical Stool Samples. The American Society of Tropical Medicine and Hygiene. 2011;84(2):308-312.
- 7) Our World in Data. Diarrheal diseases. 2019; Available from https://ourworldindata.org/diarrheal-diseases
- Kim. et al., Guideline for the Antibiotic Use in Acute Gastroenteritis. Infect Chemother. 2019;51(2):217-243.

Ordering information

Product	Size	Cat. No.
Allplex™ GI-Virus Assay	100 rxns 25 rxns	GI9701X GI10184Z
Allplex™ GI-Bacteria(I) Assay	100 rxns 25 rxns	GI9801X GI10201Z
Allplex [™] GI-Bacteria(II) Assay	100 rxns 25 rxns	GI9702X GI10183Z
Allplex [™] GI-Parasite Assay	100 rxns 50 rxns 25 rxns	GI9703X GI9703Y GI10202Z
Allplex [™] GI-EB Screening Assay	100 rxns 25 rxns	GI10198X GI10196Z
Allplex [™] GI-Helminth(I) Assay	100 rxns 50 rxns 25 rxns	GI10191X GI10190Y GI10189Z
Allplex [™] Entero-DR Assay	100 rxns 25 rxns	CR9700X CR10384Z
Allplex [™] H. pylori & ClariR Assay	100 rxns 25 rxns	HC10200X HC10389Z

Instrument	Cat. No.
CFX96 [™] Dx	1845097-IVD 1841000-IVD
Seegene NIMBUS	65415-03
Seegene STARlet	67930-03
Seegene STARlet-AIOS	SG72100
SEEPREP32™	SG71100
Maelstrom [™] 9600	M9600

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