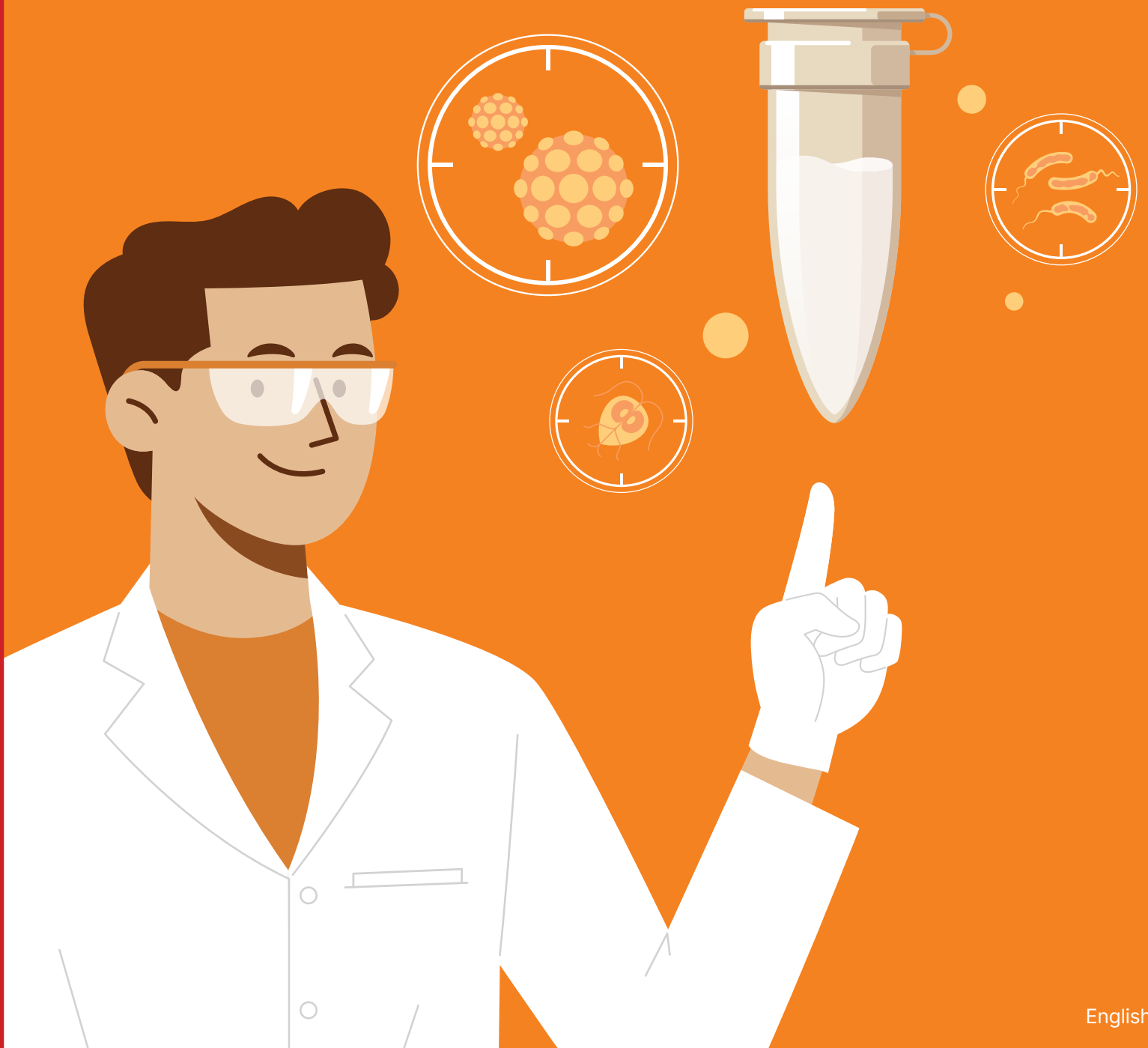


Seegene Gastrointestinal Solutions

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



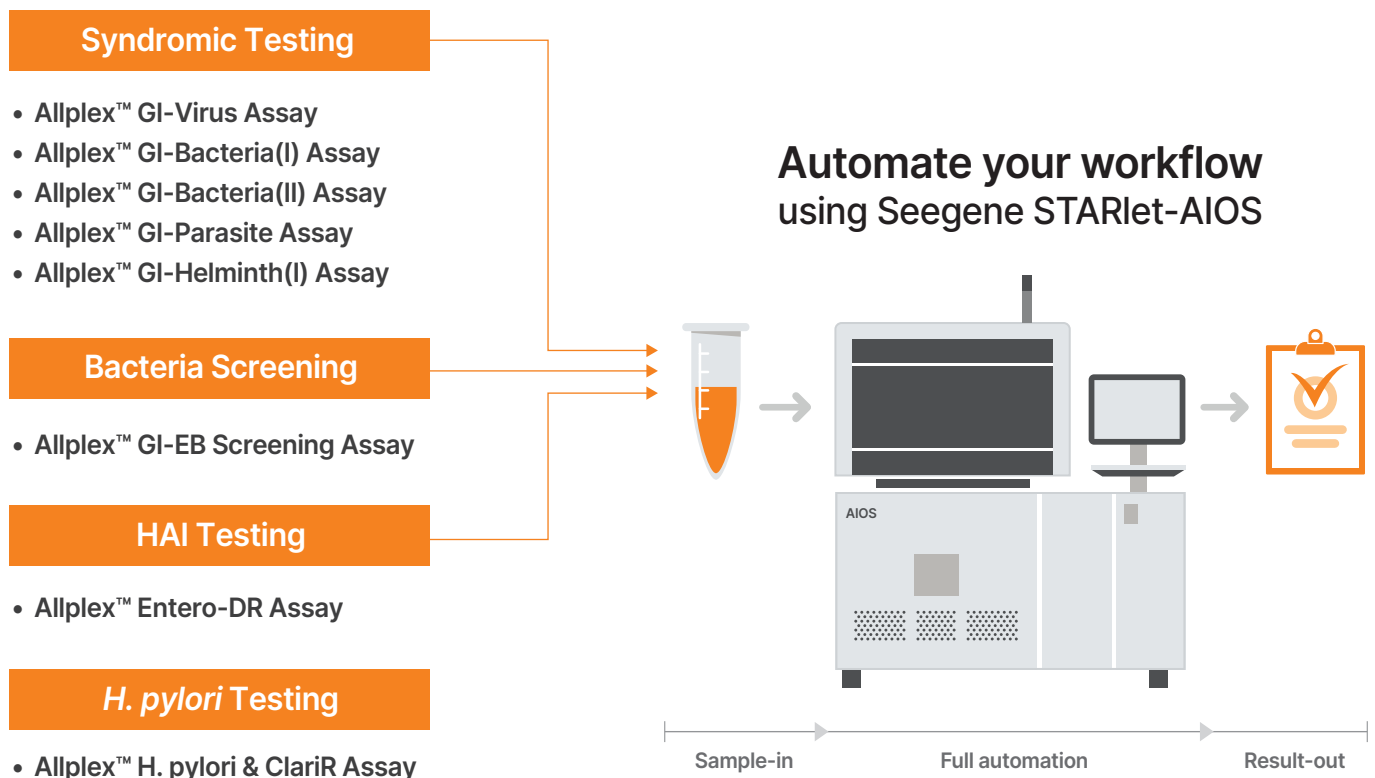
How are Seegene PCR assays better?

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



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

Testing becomes more efficient

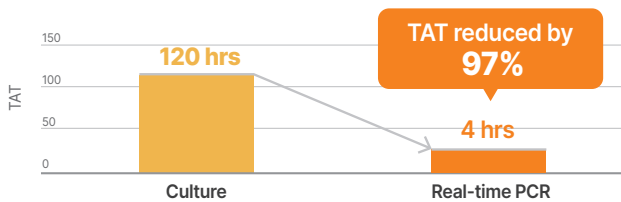
Gastrointestinal infection can be caused by a wide range of bacterial, viral, and/or parasitic pathogens, and has signs and symptoms such as watery diarrhea, nausea, vomiting, and fever. Conventional testing methods such as diagnostic cultures and microscopy have low-throughput and require a lot of manual 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.



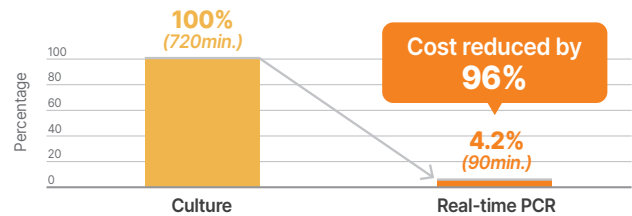
Fast and high-throughput testing¹⁾

Culture vs. Real-time PCR* for bacteria

• Time to result for 24 samples

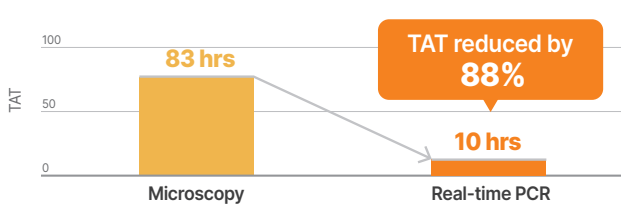


• Cost of labor for 90 samples (avg. wage \$27/hour)

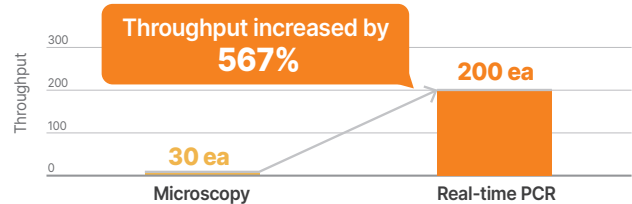


Microscopy vs. Real-time PCR for parasites

• Time to result for 200 samples per staff



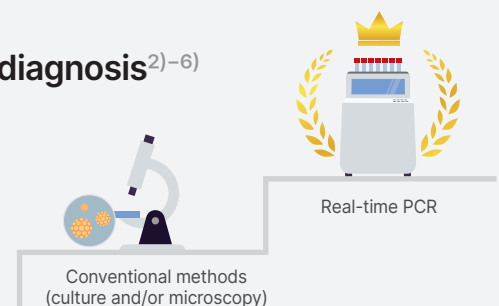
• Maximum sample processing capacity per staff in a day



*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.



Seegene's gastrointestinal PCR solutions

Full syndromic testing solution for symptomatic patients

Allplex™ Gastrointestinal Panel Assays

Allplex™ 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™ GI-Virus Assay	Allplex™ GI-Bacteria(I) Assay	Allplex™ GI-Bacteria(II) Assay	Allplex™ GI-Parasite Assay	Allplex™ GI-Helminth(I) Assay	- Human stool
- Adenovirus - Astrovirus - Norovirus GI - Norovirus GII - Rotavirus - Sapovirus	- <i>Aeromonas</i> spp. - <i>Campylobacter</i> spp. - <i>Clostridium difficile</i> toxin B - <i>Salmonella</i> spp. - <i>Shigella</i> spp./EIEC - <i>Vibrio</i> spp. - <i>Yersinia enterocolitica</i>	- <i>E. coli</i> O157 - STEC (<i>stx1/2</i>) - EAEC (<i>aggR</i>) - EPEC (<i>eaeA</i>) - ETEC (<i>It/st</i>) - Hypervirulent <i>Clostridium difficile</i>	- <i>Blastocystis hominis</i> - <i>Cryptosporidium</i> spp. - <i>Cyclospora cayetanensis</i> - <i>Dientamoeba fragilis</i> - <i>Entamoeba histolytica</i> - <i>Giardia lamblia</i>	- <i>Ancylostoma</i> spp. - <i>Ascaris</i> spp. - <i>Enterobius vermicularis</i> - <i>Enterocytozoon</i> spp. / <i>Encephalitozoon</i> spp. - <i>Hymenolepis</i> spp. - <i>Necator americanus</i> - <i>Strongyloides</i> spp. - <i>Taenia</i> spp. - <i>Trichuris trichiura</i>	

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 worldwide⁷⁾, 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.

1.5 million deaths
from diarrheal diseases annually⁷⁾



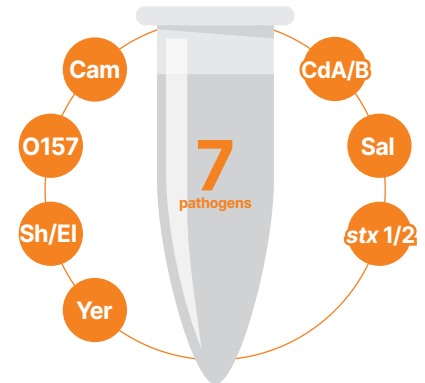
Antibiotics used for different causative pathogens⁸⁾

Pathogen	Antibiotics
<i>Campylobacter</i> spp.	Azithromycin
Non-typhoidal <i>Salmonella</i>	Usually not indicated
<i>Salmonella enterica</i> Typhi or Paratyphi	Ciprofloxacin or Ceftriaxone
<i>Shigella</i> spp.	Azithromycin, Ciprofloxacin or Ceftriaxone
<i>Vibrio cholerae</i>	Doxycycline

Bacteria screening solution for preemptive diagnosis

Allplex™ GI-EB Screening Assay

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



Analytes

- *Campylobacter* spp.
- *E. coli* O157
- *Shigella* spp./EIEC
- *Yersinia enterocolitica*

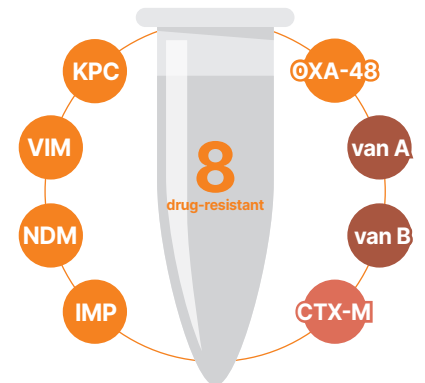
Specimens

- *Clostridium difficile* toxin A/B
- *Salmonella* spp.
- STEC (*stx1/2*)
- Human stool

HAI testing solution for effective hospital disease control

Allplex™ Entero-DR Assay

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



Analytes

Carbapenemase-producing <i>Enterobacteriaceae</i> (CPE)	Vancomycin-resistant <i>Enterococci</i> (VRE)	ESBLs – producing <i>Enterobacteriaceae</i> (ESBL)
- KPC	- VanA	- CTX-M
- OXA-48	- VanB	
- VIM		
- NDM		
- IMP		

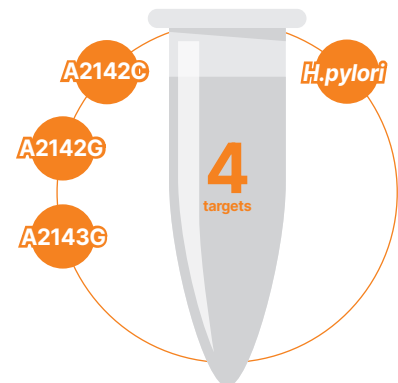
Specimens

- Rectal swab
- Bacterial colony

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

Allplex™ *H. pylori* & ClariR Assay

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



Analytes

- A2142C
- A2142G
- A2143G
- *H. pylori*

Specimens

- Human stool
- Gastric biopsy

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>
- 4) 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>
- 8) Kim. et al., Guideline for the Antibiotic Use in Acute Gastroenteritis. Infect Chemother. 2019;51(2):217-243.

Ordering information

Product	Size	Cat. No.	Instrument	Cat. No.
Allplex™ GI-Virus Assay	100 rxns	GI9701X	CFX96™ Dx	1845097-IVD
	25 rxns	GI10184Z		1841000-IVD
Allplex™ GI-Bacteria(I) Assay	100 rxns	GI9801X	Seegene NIMBUS	65415-03
	25 rxns	GI10201Z	Seegene STARlet	67930-03
Allplex™ GI-Bacteria(II) Assay	100 rxns	GI9702X	Seegene STARlet-AIOS	SG72100
	25 rxns	GI10183Z	SEEPREP32™	SG71100
Allplex™ GI-Parasite Assay	100 rxns	GI9703X	Maelstrom™ 9600	M9600
	50 rxns	GI9703Y		
	25 rxns	GI10202Z		
Allplex™ GI-EB Screening Assay	100 rxns	GI10198X		
	25 rxns	GI10196Z		
Allplex™ GI-Helminth(I) Assay	100 rxns	GI10191X		
	50 rxns	GI10190Y		
	25 rxns	GI10189Z		
Allplex™ Entero-DR Assay	100 rxns	CR9700X		
	25 rxns	CR10384Z		
Allplex™ H. pylori & ClariR Assay	100 rxns	HC10200X		
	25 rxns	HC10389Z		

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