

GI-EB Screening Assay

Comprehensive assay for the detection and identification of 7 gastrointestinal bacteria using One-step real-time PCR

Bacterial gastrointestinal infections continue to cause illness and death and contribute to economic loss in most parts of the world, including high-income countries that have developed surveillance and control programs. The symptoms of acute bacterial intestinal infection are usually mild to moderate, and spontaneous remission occurs¹⁾, but in some cases, the disease can cause rapid deterioration of a patient's condition. Almost of all bacteria spread via the fecal-oral route through person-to-person transmission.

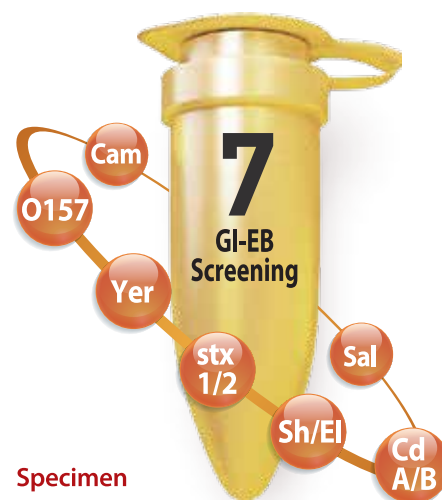
Allplex™ GI-EB Screening Assay detects and identifies 7 key bacterial pathogens associated with gastroenteritis. Based on Seegene's proprietary MuDT™ technology, this assay reports multiple Ct values of each pathogen in a single channel using real-time PCR instruments.

Key features

- Short TAT (4 hours) from extraction to the final
- Simplified procedure and maximized throughput in a single test
- Informative data with individual Ct values for each analyte
- Automated data interpretation with Seegene Viewer
- Expandable to a total solution related to gastrointestinal tract infection up to virus and parasite

Analytes

- | | | |
|---------------------------------------|-----------------------------------|--|
| - <i>Y. enterocolitica</i> (Yer) | - <i>E. coli</i> O157 (O157) | - <i>C. difficile</i> toxin A/B (Cd A/B) |
| - <i>stx1/2</i> (stx1/2) | - <i>Campylobacter</i> spp. (Cam) | - Internal Control (IC) |
| - <i>Shigella</i> spp. / EIEC (Sh/EI) | - <i>Salmonella</i> spp. (Sal) | |



Specimen

- Stool

Compatible instrumentation

- Automated Extraction & PCR Setup
NIMBUS IVD (Hamilton)
STARlet IVD (Hamilton)
- Automated Extraction
NucliSENS® easyMAG® (BioMérieux)
- Real-time PCR
CFX96™ (Bio-Rad)

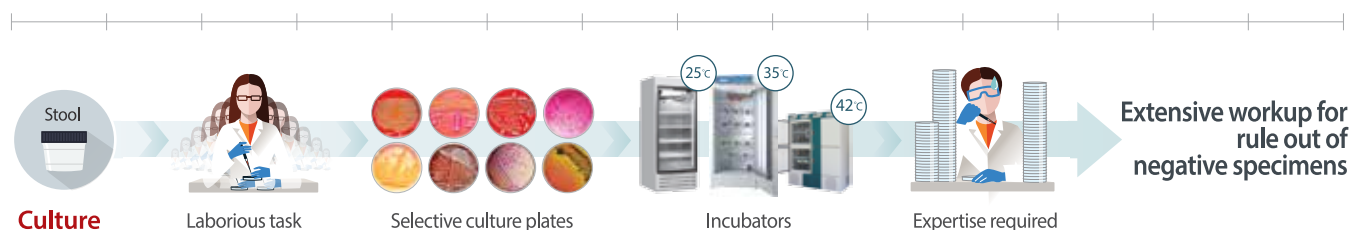
Seegene System vs. Culture

→ Real-time PCR → Culture



Seegene System

- Reducing total test cost
- Reducing waste disposal cost
- Effortless procedure



Seegene's solution for diagnosing bacterial infection in stool

Need fast, accurate, and easy way to rule out negatives?



GI-EB Screening

Use based on patient status, history and clinical presentation?



GI-Bacteria(I)

E.coli +
For E.coli typing?



GI-Bacteria(II)

Target pathogens		Features and Related Diseases	Allplex™ GI		
			EB	B(I)	B(II)
<i>Salmonella</i> spp. ²⁾		- Cause bloody diarrhea and fever - More serious illness in elderly, infants, patient with chronic disease	○ ⁺	○	
<i>Campylobacter</i> spp. ¹⁰⁾		- Cause gastroenteritis, sepsis, meningitis, arthritis, endocarditis - Resembling viral diarrhea (mild)	○ ⁺⁺	○	
<i>Vibrio</i> spp. ¹⁰⁾		Associated with eating undercooked seafood		○	
<i>Clostridium difficile</i> ^{3), 4), 10)}	Toxin A	- Hard to culture 20% of cases of antibiotic-associated diarrhea	○		
	Toxin B	- Toxin A(enterotoxin): damaging the intestinal mucosa - Toxin B(cytotoxin): inducing actin depolymerization		○	
	Hypervirulent ⁴⁾	NAP1/027 mutant (Fluoroquinolone-R) associated with higher symptoms and mortality			○
<i>Yersinia enterocolitica</i> ¹⁰⁾		Cause watery or bloody diarrhea and fever, resembling appendicitis or salmonella or shigella infection	○	○	
<i>Aeromonas</i> spp. ^{5), 6)}		- Acute, severe illness in children, whereas chronic diarrhea in adults - Commonly found in aquatic environments (river, lakes, ponds, ground water)		○	
<i>E.coli</i> ^{7), 8), 10)}	<i>E. coli</i> O157	- Diarrhea causative types are classified into ETEC, EPEC, EIEC, EHEC, and EAEC - Except chronic diarrhea, mass attack among the newborn and fatal cases, NOT recommended using antibiotics (Using antibiotics increase HUS and aggravate symptoms)	○		○
	EHEC (<i>stx1/2</i>)		○		○
	EAEC (<i>aggR</i>)				○
	EPEC (<i>eaeA</i>)				○
	ETEC (<i>lt/st</i>)				○
		EIEC			
<i>Shigella</i> spp. ⁹⁾		- Cause a syndrome that is identical to shigellosis - No toxins, but severely damage the intestinal wall through cell destruction	○ ⁺⁺⁺	○	
		- One of the leading bacterial causes of diarrhea worldwide - Cause severe inflammation and death of the cells			

+ Inclusivity: *S. bongori*, *S. enterica*, *S. typhimurium*, *S. typhi*, *S. Stanley*, *S. choleraesuis*, *S. enteritidis*, *S. enterica* subsp. (*houteana*, *arizona*, *diarizonae*, *enterica* serovar *Saintpaul*, *Agona*, *enterica* serovar *Paratyphi* C)

++ Inclusivity: *C.coli*, *C.jejuni*, *C.lari*, *Cupsaliensis*

+++ Inclusivity: *S. boydii*, *S. dysenteriae*, *S.flexneri*, *S. sonnei*

Solution for unmet needs?

Category	Product	Package Volume	Cat. No.
Allplex™	GI-EB Screening Assay	25 rxns*	GI10196Z
		50 rxns	GI10197Y
		100 rxns*	GI10198X

* For use with NIMBUS IVD and STARlet IVD only

* Reference

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- S. D. Puthucheary et al. PLoS One. 2012;7(2): e30205
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- Palaniappan et al. Clin Microbiol. 2006;Apr;44(4):1495-501
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