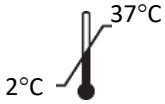
savyonDIAGNOSTICS
member of the Gamida Diagnostics Division

savvy•gen GI Bacteria Panel

REF **620-01LE / 620-01HE**

Test kit for 48 determinations



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Intended Use

The Savvygen™ GI Bacteria Panel allows the qualitative detection and differentiation of *Salmonella, Campylobacter and Shigella/enteroinvasive Escherichia coli (EIEC)* by Real-Time PCR in human stool specimens. The product is intended for use in the diagnosis of *Salmonella, Campylobacter and/or Shigella/EIEC* infections alongside clinical data of the patient and other laboratory test outcomes.

For *in-vitro* professional diagnostic use.

Background

Gastroenteritis is a major cause of morbidity and mortality, worldwide, both in children 5 years old and in the general population.

Campylobacter are gram negative, slender, spirally curved microaerophilic bacteria that live as commensal organisms in the gastrointestinal tract of many domestic and wild birds and mammals. *C. jejuni* and *C. coli* are by far the most important human pathogens in the genus and account for more than 95% of all clinical isolates worldwide.

The genus *Salmonella* contains two distinct species, designated *Salmonella enterica* (divided into six subspecies) and *Salmonella bongori. Salmonella* species are a leading bacterial cause of acute gastroenteritis.

Shigellosis produces inflammatory reactions and ulceration on the intestinal epithelium followed by bloody or mucoid diarrhea. It is caused by *enteroinvasive E. coli (EIEC*) as well as any species of the genus *Shigella*, namely*, S. dysenteriae, S. flexneri, S. boydii, and S. sonnei*. Shigellosis is endemic in many developing countries and also occurs in epidemics causing considerable morbidity and mortality.

Principles of the Procedure

The Savvygen™ GI Bacteria Panel test is a ready-to used test, which contains in each well all the necessary reagents for Real-Time PCR assay in a stabilized format. The test is designed for the diagnosis of *Salmonella, Campylobacter and Shigella/enteroinvasive Escherichia coli (EIEC)* in human stool specimens to aid in the assessment of infections caused by these bacteria.

Savvygen™ GI Bacteria Panel test detection is done in a one step Real-Time format where the test is based on the amplification of highly specific conserved fragments of the conserved region of the invA gene (*Salmonella*), 16S rRNA gene (*Campylobacter*) and ipaH gene (*Shigella/EIEC*). Following extraction of these bacteria's DNA, the conserved fragments are amplified by Taq DNA in a Polymerase Chain Reaction (PCR). The assay is based on the 5'→3' exonuclease activity of Taq DNA Polymerase (figure 1). A fluorophore/quencher dual-labeled probe anneals to an internal specific sequence. Upon primer elongation, Taq DNA Polymerase displaces and hydrolyzes the probe, thus releasing and activating the fluorophore. The presence of GI Bacteria Panel is detected by an increase in observed fluorescence during the reaction. The resulting increase in fluorescence signal is proportional to the amount of amplified product in the sample and detected by the real-time PCR instrument.

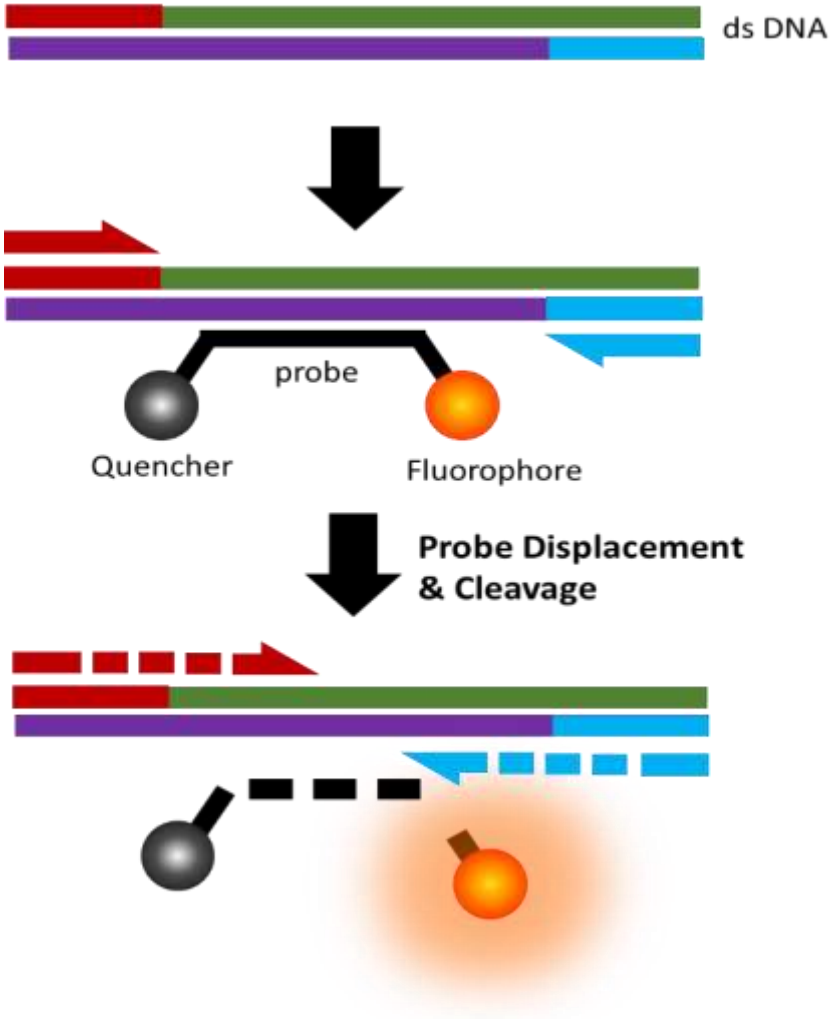

Figure 1. *Principle of the Savvygen assay*

Savvygen™ GI Bacteria Panel test is a ready-to used test, which contains in each well all the necessary reagents for Real-Time PCR assay in a stabilized format In addition, an Extraction Control allows the detection of a possible reaction inhibition. The optical channels used for multiplexed detection of the amplified fragments are outlined in Table 1 below:

Table 1: Bacteria target and optical channel detection;

Target	Optical channel
Salmonella	FAM
Shigella/EIEC	ROX
Campylobacter	Cy5
Extraction Control	*HEX, VIC or JOE

Materials/ Reagents Provided

Product Description	Contents
Savvygen™ GI Bacteria Panel *48 reactions. Cat.# 620-01HE (High profile)* *48 reactions. Cat.# 620-01LE (Low profile)*	6 x GI Bacteria 8- well strip
	1 x GI Bacteria Positive Control (lyophilized)
	1 x GI Bacteria Extraction Control
	1 x Water RNAse/DNAse free 1mL
	1 x Rehydration Buffer 1.8 mL
	1 x Negative Control 1 mL
	Optical caps

Additional Equipment and Material Required

- DNA extraction kit.
- Centrifuge for 1.5 mL tube.
- Vortex.
- Micropipettes (0.5-20 µL, 20-200 µL).
- Powder-free disposal gloves
- Real-Time PCR instruments (see table 2A+2B for compatible Real-Time PCRs).

Table 2A: Compatible Real-Time PCR instrument (Low-Profile)

Bio-Rad	***Applied Biosystems***
CFX96 Touch™ Real-Time PCR Detection System	7500 Fast Real-Time PCR System
Roche	7500 Fast Dx Real-Time PCR System
LightCycler ®480 Real-Time PCR System	QuantStudio™ 12K Flex 96-well Fast
LightCycler ®96 Real-Time PCR System	QuantStudio™ 6 Flex 96-well Fast
Agilent Technologies	QuantStudio™ 7 Flex 96-well Fast
AriaMx Real-Time PCR System	QuantStudio™ 5 Real-Time PCR System
DNA-Technology	ViiA™ 7 Fast Real-Time PCR System
DTlite Real-Time PCR System	***Cepheid***
DT prime Real-Time Detection Thermal Cycler	SmartCycler®*
	Qiagen
	*Rotor-Gen® Q**

Table 2B: Compatible Real-Time PCR instrument (High-Profile)

Bio-Rad	***Applied Biosystems***
CFX96 Touch Deep Well Real-Time PCR Detection System	*7500 Real-Time PCR System*
iCycler iQ Real-Time PCR Detection System	*QuantStudio™ 12K Flex 96-well*
iCycler iQ 5 Real-Time PCR Detection System	*QuantStudio™ 6 Flex 96-well*
DNA-Technology	*QuantStudio™ 7 Flex 96-well*
DTlite Real-Time PCR System	*QuantStudio™ 5 Real-Time PCR System*
DT prime Real-Time Detection Thermal Cycler	*ViiA™ 7 Real-Time PCR System*
Stratagene /Agilent Technologies	***Qiagen***
Mx3000P™ Real-Time PCR System	*Rotor-Gen® Q**
Mx3005P™ Real-Time PCR System	***Cepheid***
Analytik Jena Biometra	*SmartCycler®**
TOptical	***Abbot***
qTOWER 2.0	*Abbot m2000 RealTime System*

* Once the product has been reconstituted following the appropriate procedure, transfer it into the specific Rotor-Gene® Q or SmartCycler® tubes.

Note: *Savvygen™* GI Bacteria Panel *test has been validated on the following equipment: Applied Biosystems 7500 Fast Real-Time PCR System, Bio-Rad CFX96 Touch™ Real-Time PCR Detection System, Agilent Technologies AriaMx Real-Time PCR System, DNA-Technology DTprime Real-time Detection Thermal Cycler, DNA-Technology DTlite Real-time Detection Thermal Cycler, Rotor-Gene® Q (Qiagen), SmartCycler® (Cepheid),*

Transport and Kit Storage

The Savvygen kits can be shipped and stored at 2-37ºC until the expiration date stated in the label.

After resuspension of the Positive Control, store at -20ºC. Avoid repeated freeze/thaw cycles. It is recommended to make aliquots of the positive control and store at -20ºC once resuspended, in order to avoid freeze & thaw cycles.

Precautions

Amplification technologies can amplify target nucleic acid sequences over a billion-fold and provide a means of detecting very low concentrations of target. Care must be taken to avoid contamination of samples with target molecules from other samples, or amplicons from previous amplifications. Follow these recommendations to help control contamination.

1. Separate pre-amplification steps from post-amplification steps. Use separate locations for pre- and post-amplification. Use suitable lab equipment for each stage. Prepare samples in a laminar flow hood using suitable equipment to minimize contamination. Set up the post-amplification area in a low-traffic area with suitable equipment.

2. The laboratory process must be one-directional, it should begin in the Extraction Area and then move to the Amplification and Detection Areas. Do not return samples, equipment and reagents to the area where the previous step was performed.
3. Use disposable containers, disposable barrier pipette tips, disposable bench pads, and disposable gloves. Avoid washable lab wear.
4. Use a diluted bleach solution (0.2% sodium hypochlorite) to treat waste from the post-amplification and detection areas, as the waste contains amplicon. Use the bleach solution to wipe down equipment and bench areas, as well as to treat drains used to dispose of liquid waste.
5. Use negative controls to monitor for possible contamination during reaction setup. If reagent contamination is detected, dispose of the suspect reagents.
6. Do not use after expiration date.
7. Specimens must be treated as potentially infectious as well as all reagents and materials that have been exposed to the samples and handled in the same manner as an infectious agent. Take necessary precautions during the collection, storage, treatment and disposal of samples.

Test Procedure

Extraction Control Preparation

Note: *The Water RNAse/DNAse free vial must be utilized first to reconstitute the lyophilized Extraction Control* ***in pre-PCR laboratory area****, and subsequently, it can be used for reconstitute the* GI Bacteria *Positive Control in a dedicated area away from the other components.*

Open the Extraction Control pouch to re-suspend the lyophilized GI Bacteria Extraction Control (green cap vial) with 500 µl of Water RNase/DNase free (transparent cap vial) supplied. To ensure a complete re-suspension, vortex the vial thoroughly. After first use, dispense into aliquots in order to avoid multiple freeze-thaw cycles, and store them at -20ºC. It is recommended after the first use, to dispense into aliquots, in order to avoid multiple freeze-thaw cycles and store them at -20ºC.

Positive Control Preparation

Note: *The Positive Control vial contains a high copy number template of the assay targets with a contamination risk. Therefore, it is recommended to resuspend the vial in a separate laboratory area or a special cabinet.*

Open the Positive control pouch to resuspend the lyophilized GI Bacteria Positive Control (tube with red cap) with 100 µL of Water RNAse/DNAse free (transparent cap vial) supplied. To ensure a complete resuspension, vortex the tube thoroughly. After first use, dispense into aliquots, in order to avoid multiple freeze-thaw cycles, and store them at -20ºC.

Specimen Collection, Processing and DNA Extraction

In order to obtain an adequate sample, the procedure for sample collection must be followed closely and according to the manufacturer's instructions. The stool samples should be collected in clean containers and processed as soon as possible to guarantee the quality of the test. However, samples can be frozen at -20ºC for long storage. Ensure only the amount needed is thawed because freezing and thawing cycles are not recommended.

Extraction Control: If the GI Bacteria Extraction Control is used as an extraction control for the sample preparation procedure and as PCR inhibition control, add **5µl** of the Extraction Control to the specimen and/or lysis buffer mixture. (clinical specimen, as well as, positive control and/or negative control). If the GI Bacteria

Extraction Control is used only as a PCR inhibition control, only **1µ**l should be added to the reconstituted Reaction-Mix.

Nucleic Acid (NA) Extraction: for pretreatment and NA isolation, it is recommended to use an appropriate DNA extraction kit according to the manufacturer´s protocol. NA extraction may be carried out manually or automatically using commercially available extraction kits.

- QIAamp DNA Mini Kit (Qiagen).
- QIAamp DNA Stool Mini Kit (Qiagen).
- Maxwell®RSC Blood DNA Kit, using the Maxwell® 16 instrument (Promega).
- Invisorb® Spin Universal Kit (Stratec).
- RIDA® Xtract (R-biopharm).

PCR protocol program

Set your thermocycler following the conditions below:

Table 3: Real-Time PCR profile

Step	Temperature	Time	Cycles
Polymerase activation	95ºC	2 min	1
Denaturation	95ºC	10 sec.	45
Annealing/Extension*****	60ºC	50 sec.	

Note: *Set the fluorescence data collection during the extension step (*) through the FAM, ROX, Cy5, and HEX, JOE or VIC channels.*Depending on the equipment used select the proper detection channel (*table 4*). For the Applied Biosystems 7500 Fast Real-Time PCR system or the Stratagene Mx3005P™ Real-Time PCR System check that passive reference option ROX is not marked.

Preparing reaction wells

A. Reconstitute the required reaction wells.

Calculate the number of required reactions including samples and controls. It is highly recommended to run at least one positive and one negative control per run.

1. Peel off protective aluminum seal from the strips
2. Pipette 15 µL of Rehydration Buffer (Blue cap vial) into each well.

B. Add samples and controls according to real-time PCR experimental plate set up.

1. Pipette 5 µL of DNA sample into each sample well
2. Pipette 5 µL of resuspended GI Bacteria Panel Positive Control (tube with red cap) into the positive control well.
3. Pipette 5 µL of Negative Control (tube with orange cap) into each negative control well.
4. Cover the wells with the caps provided. Spin down briefly if needed.

Note: *If using the GI Bacteria Extraction Control as PCR inhibition control, add now 1µl of the Extraction Control to the sample/ negative control/ positive control wells.*

C. Performing PCR.

1. Place the strips in the Real-Time PCR instrument.
2. Start the run.

The fluorescence detection channels of common Real-Time PCR Thermocyclers are specified in Table 4.

Table 4: Detection fluorescence channels of different Real-Time PCR systems

Real-Time PCR THERMOCYCLER	***System Detection channels***	***Savvygen probes channels***	***Remarks***
Roche LightCycler® 96 or LightCycler®480II	465/510	FAM	Color Compensation is required only for LC480 system
	533/580	HEX	
	533/610	ROX	
	618/660	Cy5	
Applied Biosystems ABI 7500 fast	FAM	FAM	Passive reference option ROX is not mark
	VIC	HEX	
	ROX	ROX	
	Cy5	Cy5	
Bio-Rad CFX96 ™	FAM	FAM	
	HEX	HEX	
	ROX	ROX	
	Cy5	Cy5	
Agilent AriaMx	FAM	FAM	
	HEX	HEX	
	ROX	ROX	
	Cy5	Cy5	
DNA-Technology DTlite / DTprime	FAM	FAM	
	HEX	HEX	
	ROX	ROX	
	Cy5	Cy5	
Smartcycler® Cepheid	Channel 1	FAM	
	Channel 2	HEX	
	Channel 3	ROX	
	Channel 4	Cy5	
Abbott m2000rt	FAM	FAM	
	HEX	HEX	
	ROX	ROX	
	Cy5	Cy5	
Rotor-Gene®Q Qiagen	Green	FAM	
	Yellow	HEX	
	Orange	ROX	
	Red	Cy5	

Interpretation of results

Interpretation of results can be automatically performed if programed by the user using the RT-qPCR instrument software following the manufacturer´s instructions. It is required to run assay controls (positive and negative controls) in each run to validate the reaction.

Note: *The positive controls used in each run, must show an amplification curve for* GI Bacteria Panel *targets which validates the reaction, while the negative control well should demonstrate an absence of signal (except Extraction Control target).*

Table 5: Results interpretation for the Savvygen™ GI Bacteria Panel assay

Interpretation	Salmonella (FAM)	Campylobacter (Cy5)	Shigella (ROX)	Extraction control (HEX, VIC or JOE)	Negative control	Positive control
Salmonella, Campylobacter & Shigella/EIEC **Positive**	POS	POS	POS	POS / NEG	NEG	POS
Salmonella, Campylobacter & Shigella/EIEC **Negative**	NEG	NEG	NEG	POS	NEG	POS
Campylobacter **Positive**, Salmonella & Shigella/EIEC **Negative**	NEG	POS	NEG	POS / NEG	NEG	POS
Salmonella **Positive** Campylobacter & Shigella/EIEC **Negative**.	POS	NEG	NEG	POS / NEG	NEG	POS
Shigella/EIEC **Positive**, Salmonella & Campylobacter **Negative**.	NEG	NEG	POS	POS / NEG	NEG	POS
Salmonella & Campylobacter **Positive**, Shigella/EIEC **Negative**.	POS	POS	NEG	POS / NEG	NEG	POS
Salmonella & Shigella/EIEC **Positive**, Campylobacter **Negative**.	POS	NEG	POS	POS / NEG	NEG	POS
Campylobacter & Shigella/EIEC **Positive**, Salmonella **Negative**.	NEG	POS	POS	POS / NEG	NEG	POS
Invalid run	POS	POS	POS	POS	POS	POS
Invalid run	NEG	NEG	NEG	NEG	NEG	NEG

POS: presence of Amplification signal
NEG: No amplification signal

Positive sample- A sample is considered a positive for the target in the presence of amplification curve signal below a threshold cycle (Ct) 40 and the Extraction Control amplification curve signal is also shown.
Note: *in some cases of positive sample the Extraction Control amplification curve signal is negative due to high copy number of the target DNA template which can cause competition in the reaction.*

Negative sample- A sample is considered a negative for the target if there is no evidence of amplification signal in the detection system and the Extraction Control is positive.

Extraction Control- The Extraction Control must show an amplification curve, which verifies the correct function of the extraction and amplification mix. It should be noted that the detection of Extraction Control may not be necessary in case of positive results in one or more of the pathogens**.**

Positive control- The positive controls used in each run must show an amplification curve for GI Bacteria Panel, which validates the reaction.

Negative control- The negative controls included in each run, must show the absence of signal for 3 bacteria targets, which validates the reaction.

Invalid run- The assay should be considered as invalid and a new run should be performed if there is signal of amplification for one of the pathogens in the negative control well or absence of signal in the positive control well.

Note: If an amplification curve for the Extraction Control is not shown, the sample should be retested by dilution of the original sample 1:10. Alternatively it is recommended to repeat the nucleic acid extraction due to possible problems caused by PCR inhibitors.

Limitations of the test

- This test provides a presumptive diagnosis of *Salmonella, Campylobacter and Shigella/ enteroinvasive Escherichia coli (EIEC)* pathogens. All results must be interpreted together with other clinical information and laboratory findings available to the physician
- This assay should be used only with fecal samples. The use of other samples has not been established.
- Error results may occur from improper sample collection, handling, storage, technical error, sample mix-up, or because the number of organisms in the sample is below the analytical sensitivity of the test.
- The presence of PCR inhibitors may cause invalid results.
- A false positive result with other targets is possible due to contamination with PCR products from previous testing.
- As with all PCR-based *in-vitro* diagnostic tests, extremely low levels of target below the analytical sensitivity of the assay may be detected, but results may not be reproducible.
- If a certain sample result is Invalid then the sample should be repeated from DNA extraction.

Quality Control

In order to confirm the appropriate performance of the molecular diagnostic technique, an Extraction Control is included in each reaction. This is in addition to the positive and negative controls in order to interpret the results correctly.

Performance Characteristics

Clinical sensitivity and specificity

A retrospective clinical study of 400 faecal samples from symptomatic patient was conducted to evaluate the performance of the Savvygen™ GI Bacteria Panel test for the detection and differentiation of the enteric bacteria *Salmonella, Campylobacter and Shigella/enteroinvasive Escherichia coli (EIEC)*. Clinical specimens were previously characterized by a commercial CE approved kit for the above pathogens- RIDA®GENE Bacterial Stool Panel (r-Biopharm)

The results were as follow: *Salmonella* was detected in 21 out of 21 positive samples by the Savvygen™ GI Bacteria Panel test. One additional sample which obtained a positive indication for *Salmonella* by the Savvygen™ GI Bacteria Panel test, was not detected by the RIDA®GENE test (See table 6).

Campylobacter spp. was detected in 58 positive samples (58/58) by the Savvygen™ GI Bacteria Panel test. 13 additional samples presented positive signals for *Campylobacter* by the Savvygen™ GI Bacteria Panel, while obtaining a negative result by the RIDA®GENE test. . For discrepant analysis, these 13 samples were evaluated by an additional commercial Real-Time PCR ((Mericon-Campylobacter spp Kit; QIAGEN)), which confirmed the Savvygen™ GI Bacteria Panel positive results for the bacteria (See table 6).

Shigella or EIEC pathogens were detected in only 1 positive sample by the Savvygen™ GI Bacteria Panel test (See table 6).

Table 6: Results interpretation

Pathogen	Positive Agreement		Specificity	
	TP/ (TP+FN)	Percent	TN/ (TN+FP)	Percent
Salmonella	21/21	100%	378/379	99.7%
Campylobacter	58/58	100%	329/342	96.2%
Shigella/EIEC	1/1	N/A	399/399	100%

The results show a high sensitivity and specificity to detect *Salmonella, Campylobacter and Shigella / enteroinvasive Escherichia coli (EIEC)* using the Savvygen™ GI Bacteria Panel test.

Analytical sensitivity

In a series of experiments to establish the limit of detection of the Savvygen™ GI Bacteria Panel for each pathogen, a 10-fold dilution of 10^7 to 10^1 copies/reaction was conducted for each target. According to the results, this assay has a detection limit of ≥10 DNA copies per reaction for *Salmonella, Campylobacter and Shigella / enteroinvasive Escherichia coli (EIEC*. (Figure 1, 2 and 3).

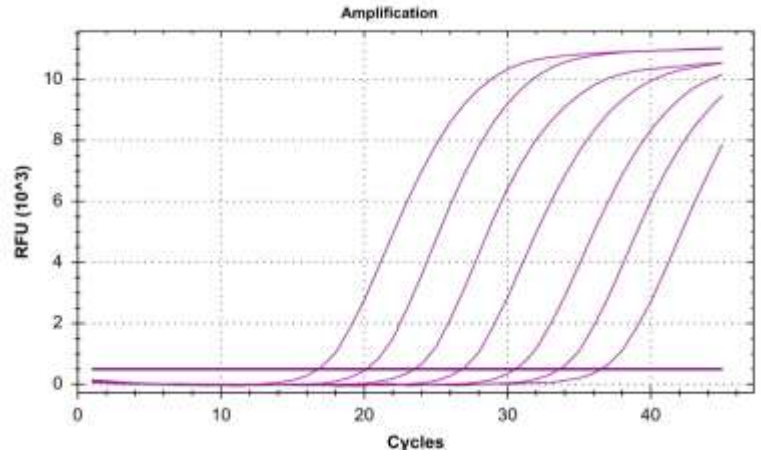

Figure 1. Amplification plot for 10-fold dilution series of *Salmonella* template ranging from 10^7 to 10^1 copies/rxn (FAM channel).

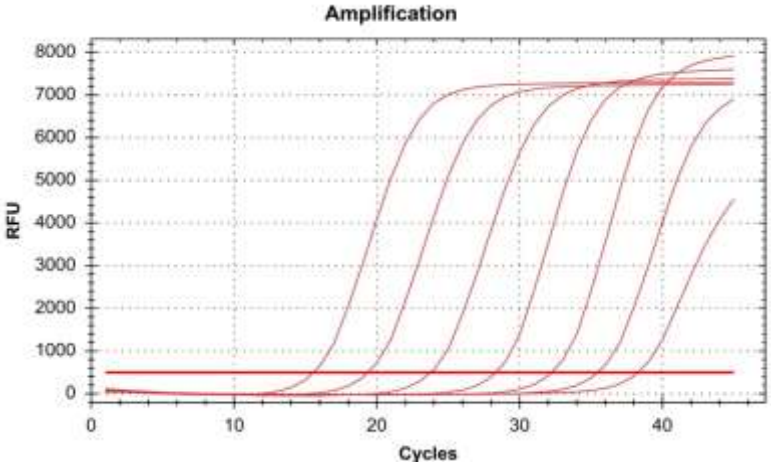

Figure 2. Amplification plot for 10-fold dilution series of *Campylobacter* template ranging from 10^7 to 10^1 copies/rxn (Cy5 channel).

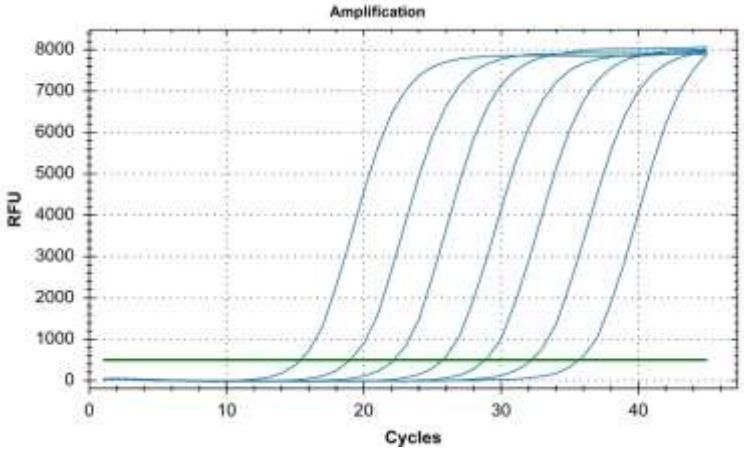

Figure 3. Amplification plot for 10-fold dilution series of *Shigella/EIEC* template ranging from 10^7 to 10^1 copies/rxn (ROX channel).

Analytical specificity

The analytical specificity of the Savvygen™ GI Bacteria Panel for *Salmonella, Campylobacter and Shigella/EIEC* was evaluated within the panel of following microorganisms. No cross-reactivity was seen between any of the following species (table 7).

Table 7: Cross-reactivity testing.

Pathogen	*Cross-Reactivity Test*		
	Savvygen™ GI Bacteria Panel		
	Salmonella	*Campylobacter*	*Shigella/EIEC*
Adenovirus 40/41	-	-	-
Astrovirus Genotype I-VIII	-	-	-
Norovirus GI and GII	-	-	-
Rotavirus A	-	-	-
Aeromonas hydrophila	-	-	-
Arcobacter butzleri	-	-	-
Bacteroides fragilis	-	-	-
Campylobacter lari	-	N/A	-
Campylobacter fetus	-	N/A	-
Campylobacter coli	-	N/A	-
Campylobacter jejuni	-	N/A	-
Campylobacter upsaliensis	-	N/A	-
Cryptosporidium parvum	-	-	-
Candida albicans	-	-	-
Citrobacter freundii	-	-	-
Clostridium difficile	-	-	-
Clostridium perfringens	-	-	-
Entamoeba histolytica	-	-	-
Enterococcus faecalis	-	-	-
Enterotoxigenic E. coli (ETEC)	-	-	-
Enteropathogenic E. coli (EPEC)	-	-	-
Giardia intestinalis	-	-	-
Helicobacter pylori	-	-	-
Helicobacter hepaticus	-	-	-
Helicobacter cinaedi	-	-	-
Helicobacter heilmannii	-	-	-
Klebsiella oxytoca	-	-	-
Listeria monocytogenes	-	-	-
Pseudomonas aeruginosa	-	-	-
Proteus vulgaris	-	-	-
Salmonella typhi	N/A	-	-
Salmonella paratyphi A	N/A	-	-
Salmonella paratyphi B	N/A	-	-
Salmonella typhimurium	N/A	-	-
Salmonella bongori	N/A	-	-
Salmonella enteritidis	N/A	-	-

Salmonella enterica	N/A	-	-
Salmonella pullorum	N/A	-	-
Salmonella gallinarum	N/A	-	-
Serratia liquefaciens	-	-	-
Shigella flexneri	-	-	N/A
Shigella dysenteriae	-	-	N/A
Staphylococcus aureus	-	-	-
Vibrio parahaemolyticus	-	-	-
Y. enterocolitica O:3 / O:9	-	-	-

Analytical reactivity

The analytical reactivity of the Savvygen™ GI Bacteria Panel test was evaluated with various subtypes of *Salmonella, campylobacter spp. and Shigella/EIEC*. The tested microorganisms are as listed in table 8:

Table 8: Analytical-reactivity testing.

Pathogen	*Analytical-Reactivity Test*		
	Savvygen™ GI Bacteria Panel		
	Salmonella	*Campylobacter*	*Shigella/EIEC*
Salmonella typhi	+	-	-
Salmonella paratyphi A	+	-	-
Salmonella paratyphi B	+	-	-
Salmonella typhimurium	+	-	-
Salmonella bongori	+	-	-
Salmonella enteritidis	+	-	-
Salmonella enterica	+	-	-
Salmonella pullorum	+	-	-
Salmonella gallinarum	+	-	-
Salmonella mbandaka	+	-	-
Salmonella braenderup	+	-	-
Campylobacter lari	-	+	-
Campylobacter fetus	-	+	-
Campylobacter coli	-	+	-
Campylobacter jejuni	-	+	-
Campylobacter upsaliensis	-	+	-
Campylobacter concisus	-	+	-
Campylobacter hyointestinalis	-	+	-
Campylobacter gracilis	-	+	-
Campylobacter helveticus	-	+	-
Campylobacter curvus	-	+	-
Campylobacter rectus	-	+	-
Shigella dysenteriae	-	-	+
Shigella flexneri	-	-	+
Shigella boydii	-	-	+
Shigella sonnei	-	-	+

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12. S. Ghosh et al. Genetic characterization of Shigella spp. isolated from diarrhoeal and asymptomatic children. Journal of Medical Microbiology 2014; 63: 903-910.Symbols for IVD Components and Reagents

Symbols for IVD Components and Reagents

Manufacturer	Use by	For i*n vitro* diagnostic use only
Lot number	Temperature limitation	Consult instructions for use
Catalogue number	Contains sufficient for <n> test	Buffer (sample diluent)
Keep Dry		