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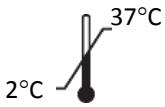
savyonDIAGNOSTICS
member of the Gamida Diagnostics Division

savvy•gen GI Parasite Panel

REF **619-01L / 619-01H**

Test kit for 48 determinations



For Professional Use Only IVD CE

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Intended Use

The Savvygen™ GI Parasite Panel test allows the qualitative detection and differentiation of *Cryptosporidium, Giardia lamblia and/or Entamoeba histolytica* by Real-Time PCR in human stool specimens. The product is intended for use in the diagnosis of *Cryptosporidium, Giardia lamblia and/or Entamoeba histolytica* infections alongside clinical data of the patient and other laboratory test.outcomes.

For *in-vitro* professional diagnostic use.

Background

Cryptosporidium, Giardia lamblia and Entamoeba histolytica are the major etiological agents of the enteric protozoa. These are the most commonly encountered parasitic diseases affecting millions of people each year and causing significant morbidity and mortality worldwide.

Giardia lamblia and *Cryptosporidium spp*. are both protozoan parasites, which can be present without symptoms or cause diarrhea and abdominal discomfort with weight loss and malabsorption. *Entamoeba histolytica* is a unicellular parasite responsible for intestinal and hepatic amoebiasis and occasionally affects other organs. Clinical symptoms of intestinal amoebiasis range from colitis to dysentery or an ameboma, but can be asymptomatic as well. These three parasites can lead to human infection via fecal–oral transmission of the cysts through contaminated food and water and person-to-person contact. They are common in both developed and developing countries, but with an increased risk in the latter due to poor sanitation standards.

Microscopy has been considered to be the gold standard method for diagnosis of these parasites. However, Real-time PCR assay is less labor-intensive with better accuracy and provides better detection of enteric pathogens.

Principles of the Procedure

The Savvygen™ GI Parasite Panel test is a ready-to use 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 *Cryptosporidium, Giardia lamblia and/or Entamoeba histolytica* in human stool specimens and for aiding in the assessment of infections caused by these parasites.

Savvygen™ GI Parasite 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 18S rRNA gene for *Cryptosporidium*, *Giardia lamblia and Entamoeba histolytica* respectively. Following extraction of these parasites' 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 *Cryptosporidium, Giardia lamblia and/or Entamoeba histolytica* 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.

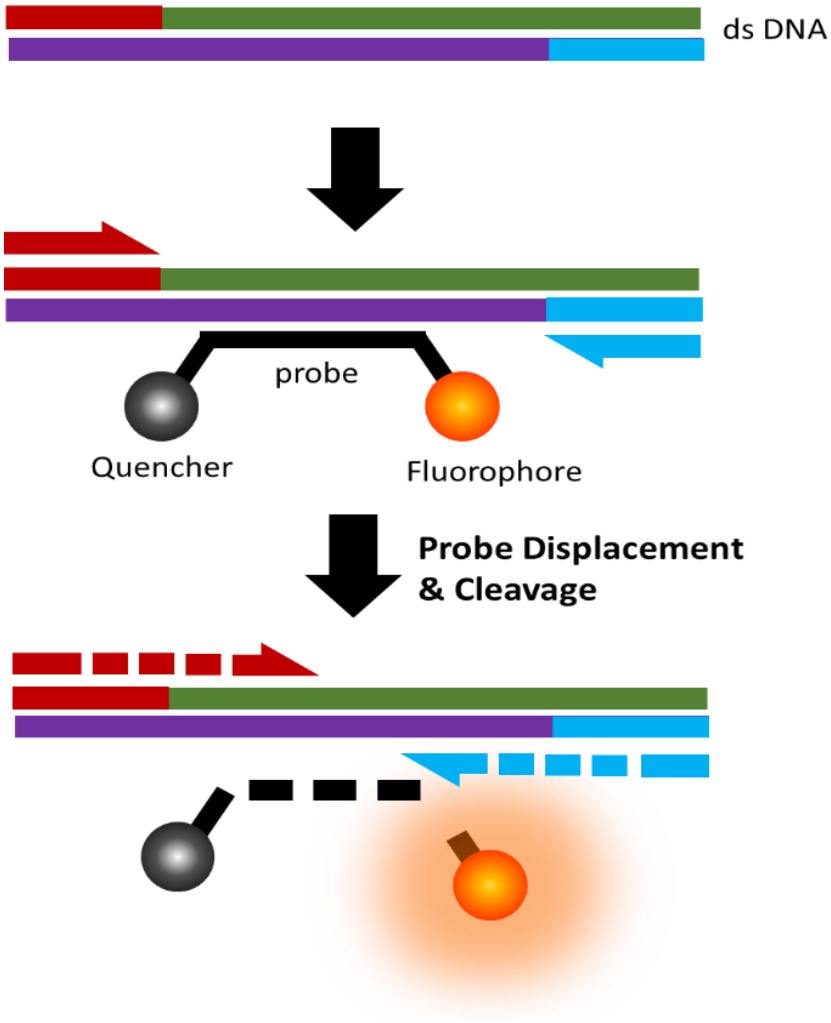

Figure 1. *Principle of the Savvygen assay*

Savvygen™ GI Parasite 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 internal 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. parasites target and optical channel detection;

Target	Optical channel
Giardia	FAM
E. histolytica	ROX
Cryptosporidium	Cy5
Internal Control	*HEX, VIC or JOE

Materials/ Reagents Provided

Product Description	Contents
Savvygen™ GI Parasite Panel *48 reactions. Cat.# 619-01H (High profile)* *48 reactions. Cat.# 619-01L (Low profile)*	6 x GI Parasite 8-well strip
	1x GI Parasite Positive Control (lyophilized)
	1x Water RNAse/DNAse free 1mL
	1x Rehydration Buffer 1.8 mL
	1x 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 instrument (see table 2A+2B for compatible RT-PCRs).

Table 2A. Compatible Real-Time PCR instruments (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 Parasite 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 moved 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, and 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

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 Parasite Positive Control (tube with red cap) with 100 µL of Water RNAse/DNAse free (transparent cap vial) that is supplied. To ensure a complete resuspension, vortex the tube thoroughly. After the 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.

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 RT-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/plate.
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 Parasite 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.

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

RT- 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 of the tested parasites targets, which validates the reaction, while the negative control well should demonstrate an absence of signal (except internal control target)*

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

Interpretation	Cryptosporidium (Cy5)	Giardia lamblia (FAM)	E. histolytica (ROX)	Internal control (HEX, VIC or JOE)	Negative control	Positive control
Cryptosporidium, Giardia lamblia and E. histolytica **Positive**	POS	POS	POS	POS / NEG	NEG	POS
Cryptosporidium, Giardia lamblia and E. histolytica **Negative**	NEG	NEG	NEG	POS	NEG	POS
Cryptosporidium **Positive**, Giardia lamblia and E. histolytica **Negative**	POS	NEG	NEG	POS / NEG	NEG	POS
Giardia lamblia **Positive**, Cryptosporidium and E. histolytica **Negative**.	NEG	POS	NEG	POS / NEG	NEG	POS
E. histolytica **Positive**, Cryptosporidium and Giardia lamblia **Negative**.	NEG	NEG	POS	POS / NEG	NEG	POS
Cryptosporidium and Giardia lamblia **Positive**, E. histolytica **Negative**.	POS	POS	NEG	POS / NEG	NEG	POS
Giardia lamblia and E. histolytica **Positive**, Cryptosporidium **Negative**.	NEG	POS	POS	POS / NEG	NEG	POS
Cryptosporidium and E. histolytica **Positive**, Giardia lamblia **Negative**.	POS	NEG	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 if the Ct value is less than 40.

Negative sample- A sample is considered a negative for the target if there is no evidence of amplification signal in the detection system but the internal control is positive.

Internal control- The Internal Controls must show an amplification curve, which verify the correct functioning of the amplification mix. Sometimes, the detection of internal control is not necessary because a high copy number of the pathogen DNA template can cause preferential amplification of target sequence.

Positive control- The positive controls used in each run must show an amplification curve for the 3 parasites, which validates the reaction.

Negative control- The negative controls included in each run must show the absence of signal for the 3 parasites, which validate 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 internal 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 *Cryptosporidium, Giardia and/or E. histolytica* infection. 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 l 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 Internal Control (IC) 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 172 fecal samples from symptomatic patients was conducted to evaluate the performance of the Savvygen™ GI Parasite Panel test for the detection and differentiation the presence of the parasites *Cryptosporidium, Giardia spp. and E. histolytica*. Clinical specimens were previously characterized by two commercial CE approved kits for the above pathogens- i) RIDA®GENE Parasitic Stool Panel II (r-Biopharm). ii) FTD Stool parasites (fast-track DIAGNOSTICS).

The results were as follow: *Cryptosporidium* was detected in 38 out of 39 positive samples by the Savvygen™ GI Parasite Panel test. Three additional samples, which were detected by the Savvygen™ GI Parasite Panel test, were not detected by the other commercial tests. For discrepant analysis, these 4 samples were

evaluated by an additional in-house Real-Time PCR (Hadfield et al., 2011), which confirmed the Savvygen™ GI Parasite Panel test results (table 6).

Giardia was detected in 58 positive samples (58/58) the Savvygen™ GI Parasite Panel. Two additional samples were detected as positive by the Savvygen™ GI Parasite Panel test, while obtaining negative results by the two commercial tests (table 6)..

E. histolytica was detected in the 8 positive samples (2 samples were spiked with EH cells prior to testing by the Savvygen™ GI Parasite Panel test). One additional sample was detected as positive, while obtaining negative results fromthe commercial tests (table 6).

Table 6. Results interpretation

Pathogen	Positive Agreement		Specificity	
	TP/ (TP+FN)	Percent	TN/ (TN+FP)	Percent
Cryptosporidium spp.	38/39	97.4%	130/133	97.7%
Giardia lamblia	58/58	100%	112/114	98.2%
E. histolytica	8/8	100%	163/164	99.3%

The results show a high sensitivity and specificity to detect *Cryptosporidium, Giardia and E. histolytica* using the Savvygen™ GI Parasite Panel test.

Analytical sensitivity

In a series of experiments to establish the limit of detection for each pathogen- *Cryptosporidium, Giardia and E. histolytica,* a 10-fold dilution of 10^7 to 10^1 copies/reaction was conducted for each target. According to the results, the Savvygen GI Parasite Panel has a detection limit of ≥50 DNA copies per reaction for *Cryptosporidium* and ≥10 DNA copies per reaction for *Giardia lamblia* and *Entamoeba histolytica* (Figure 1, 2 and 3).

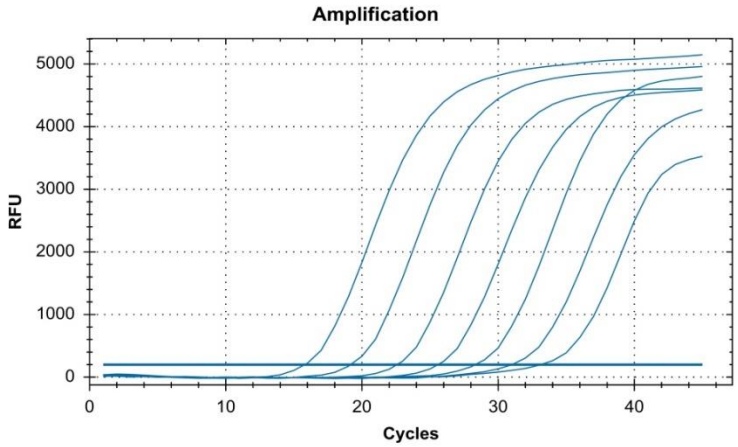

Figure 1. Amplification plot for 10-fold dilution series of *Giardia lamblia* template ranging from 10^7 to 10^1 copies/rxn (FAM channel).

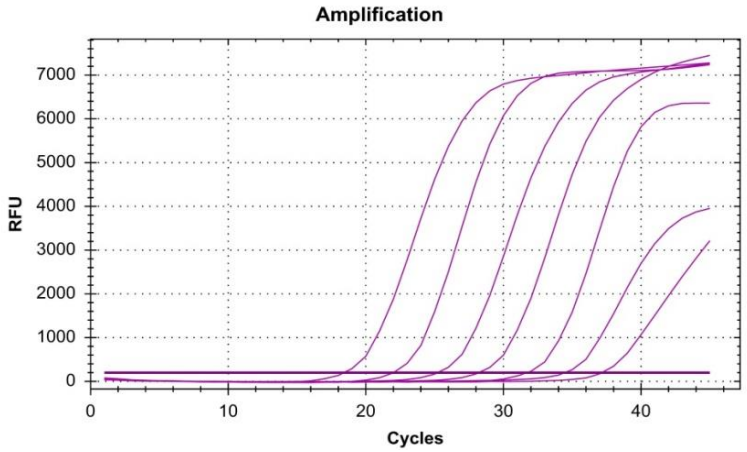

Figure 2. Amplification plot for 10-fold dilution series of *Cryptosporidium* template ranging from 10^7 to 10^2 copies/rxn (Cy5 channel).

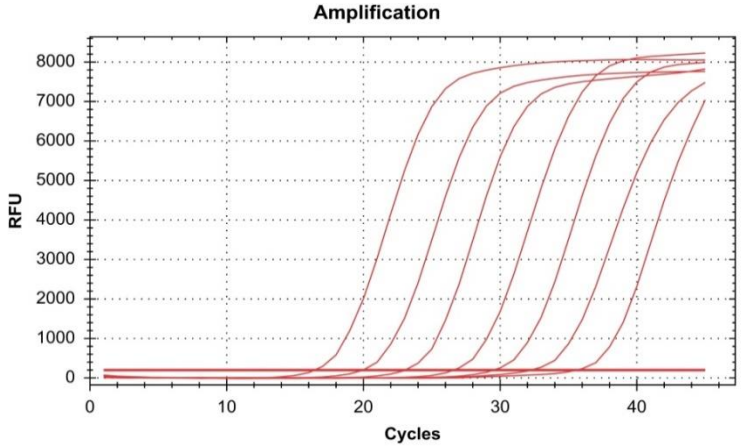

Figure 3. Amplification plot for 10-fold dilution series of *Entamoeba histolytica* template ranging from 10^7 to 10^1 copies/rxn (ROX channel).

Analytical specificity

The analytical specificity for *Cryptosporidium, Giardia lamblia and Entamoeba histolytica* was evaluated by a panel of the following microorganisms using the Savvygen™ GI Parasite Panel test, and no cross-reactivity was seen between any of the following species.

Table 7. Cross-reactivity testing.

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

Vibrio parahaemolyticus	-	-	-
Y. enterocolitica O:3 / O:9	-	-	-

Analytical reactivity

The reactivity of the Savvygen™ GI Parasite Panel test for *Cryptosporidium* was confirmed by the Real-Time amplification using *Cryptosporidium parvum* showing positive results.
The reactivity of Savvygen™ GI Parasite Panel test for *Giardia lamblia* was confirmed by the Real-Time amplification using *Giardia lamblia* showing positive results.
The reactivity of Savvygen™ GI Parasite Panel test for *Entamoeba histolytica* was confirmed by the Real-Time amplification using *Entamoeba histolytica* strain DS4-868, showing positive results.

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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		