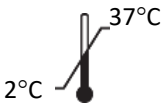
savyon DIAGNOSTICS

savvy•gen HSV1+2 / VZV

REF 622-01L / 622-01H

Test kit for 48 determinations



For Research Use Only

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Intended Use

The Savvygen™ HSV1+2 / VZV test allows the qualitative detection and differentiation of *herpes simplex virus types 1* and *2 (HSV-1 and -2)* and *varicella zoster virus (VZV)* in clinical samples from patients with signs and symptoms of *HSV-1, HSV-2* and/or *Varicella Zoster* infection. This test is intended to be used as an aid in the diagnosis of HSV-1, HSV-2 and/or Varicella Zoster in combination with clinical and epidemiological risk factors.

For *in-vitro* professional diagnostic use.

Background

Herpes simplex virus types 1 and 2 (HSV-1 and -2) and varicella-zoster virus (VZV) are alphaherpesviruses that infect, establish latency in, and subsequently reactivate from human sensory nerve ganglia. Following reactivation from latent ganglia reservoirs, each of these herpesviruses may cause significant clinical disease in the individual and may spread to uninfected persons. Symptomatic VZV reactivation is an infrequent, usually once-in-a-lifetime event that results in zoster (shingles), while HSV-1 and -2 reactivation occurs frequently and results in numerous symptomatic and asymptomatic recurrences of oral and genital herpes.

Oral infections were most often caused by HSV-1 and genital infections by HSV-2. *Herpes simplex virus* (HSV)-1 and -2 are large, double-stranded DNA viruses that cause lifelong persistent infections characterized by periods of quiescence and recurrent disease. These two HSV types cannot be distinguished clinically. In fact, they share a high degree of genetic homology, but they also have specific regions with small nucleotide variations which may allow discrimination. HSV-1 and HSV-2 infection occurs via inoculation of virus particles into susceptible mucosal surfaces. Afterwards, these neurotropic viruses can become latent in the local sensory ganglion, periodically reactivating to cause symptomatic lesions, or undergo asymptomatic viral release, with the potential for disease transmission and infection. The same treatment is used for both HSV-1 and HSV-2 infections, the location of the lesions and the chronicity of the infection (primary or recurrent) determine dosage and frequency.

Varicella-zoster virus (VZV) is a member of the Herpesviridae family and causes chickenpox (varicella) and herpes zoster (shingles). Chickenpox is highly contagious and causes acute infection. This disease is characterized by a dermal vesiculopustular rash that develops 10–21 days following exposure. Primary infection with VZV results in immunity from subsequent infection; VZV remains latent within sensory neurons and may subsequently reactivate, causing disease (herpes zoster). Herpes zoster is a painful condition that occurs in older non-immune adults or those with waning immunity to VZV and in patients with impaired cellular immunity.

To shorten detection time and improve sensitivity, real-time PCR assays have proven to be a tool for the detection of *Herpes simplex virus types 1* and *2 and Varicella-zoster virus*.

Principles of the Procedure

The Savvygen™ HSV1+2 / VZV test is designed for detection *of Herpes simplex virus types 1* and *2 and Varicella zoster virus* in clinical specimens and to aid in the assessment of infections caused by these viruses.

The Savvygen™ HSV1+2 / VZV test is based on amplification of highly specific conserved fragments in US4 gene for *Herpes simplex virus types 1*, US6 gene for *Herpes simplex virus types 2* and ORF29 gene for varicella zoster virus. Following extraction of h*erpes simplex virus* or *varicella zoster virus* DNA, the conserved fragments are amplified by Taq DNA in 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 is annealing to a viral specific sequence. Upon primer elongation, Taq DNA Polymerase displaces and hydrolyzes the probe, thus releasing and activating the fluorophore. The presence of H*erpes simplex virus* or *Varicella zoster virus* 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 thermocycler.

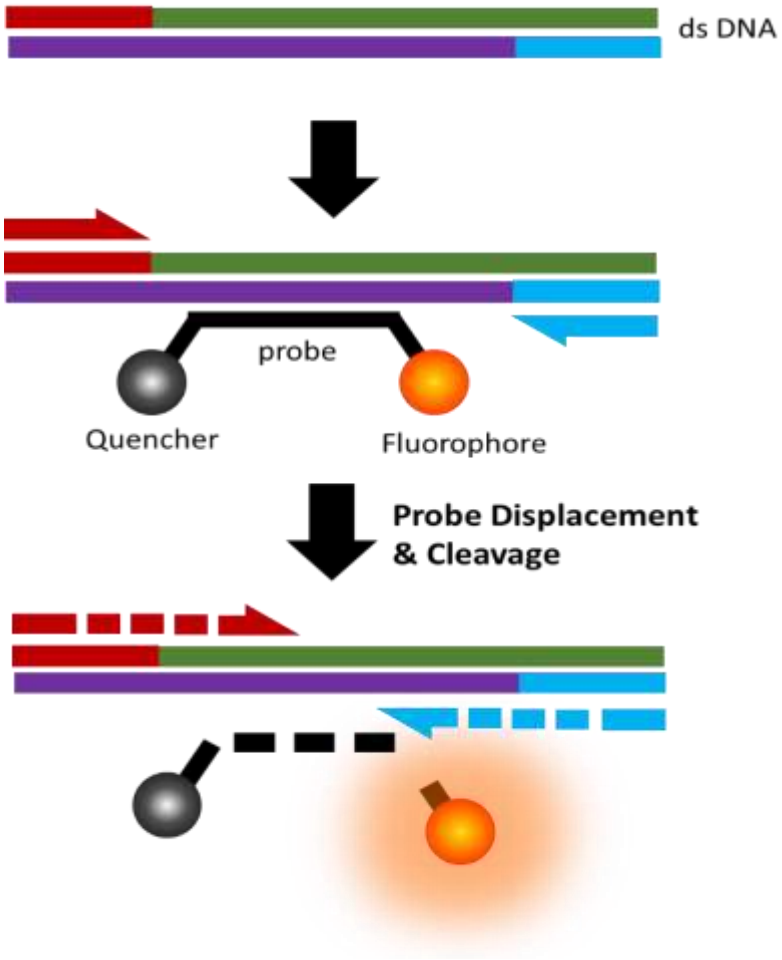

Figure 1. Principle of the Savvygen assay

The Savvygen™ HSV1+2 / VZV test is a ready-to-use assay containing in each well all the necessary reagents for the reaction in a stabilized format. An Interanl Control allows the identification of a possible inhibition of the reaction due to amplification inhibitores. The optical channels used for multiplexed detection of the amplified fragments are outlined in table 1 below:

Table 1. Savvygen™ HSV1+2 / VZV target and optical channel detection

Target	**Optical channel**
Herpes simplex virus types 1 (HSV1)	FAM
Herpes simplex virus types 2 (HSV2)	ROX
Varicella zoster virus (VZV)	Cy5
Internal Control	*HEX, VIC or JOE

(*) Depending on the equipment used, the proper detection channel should be selected (see table 4).

Materials/ Reagents Provided

Product Description	Contents
Savvygen™ HSV1+2 / VZV ***48 reactions*.** **REF# 622-01L, 622-01H**	6 x Savvygen™ HSV1+2 / VZV strips
	1x HSV1+2 / VZV Positive Control
	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™ HSV1+2 / VZV *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 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 stored at -20ºC once resuspended in order to avoid freeze & thaw cycles.
Keep all reagents in the dark

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 dedicated lab equipment for each stage. Prepare samples in a laminar flow hood using dedicated equipment to minimize contamination. Set up the post-amplification area in a low-traffic area with dedicated 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 in which 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. 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.
7. Do not use after the expiration date stated on the box.
8. For professional in vitro diagnostic use.

Test Procedure

Positive Control Preparation

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

Open the Positive control pouch to re-suspend the lyophilized HSV1+2 / VZV Positive Control (red cap vial) with 100 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.

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 specimens should be transported as fast as possible and to be stored at the indicated temperatures conditions.

Nucleic Acid (NA) Extraction: for pre-treatment and NA isolation, it is recommended to use an appropriate DNA extraction kit according to manufacturer´s protocol. NA Extraction may be carried out manually or automatically using commercially available extraction kits. Several extraction systems were validated for this kit including:

- Savvygen Extractor (Savyon Diagnostics), Savvygen Respiratory Extraction kit.
- NucleoMag® Pathogen (Macherey Nagel).
- NucleoSpin RNA Virus (Macherey Nagel).
- Invisorb® Spin Universal Kit (Stratec).
- MagDEA Dx SV kit, using the magLEAD® 6gC instrument (Precision System Science Co.)
- ZP02012 MagPurix Viral/Pathogen Nucleic Acids Extraction Kit B, using the MagPurix 12A instrument (Zinexts Life Science Corp.).

***PCR Protocol Program*.**

Set your thermocycler to the following conditions below:

Table 3. Real time RT-PCR profile

Step	Temperature	Time	Cycles
Initial denaturation	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 (Herpes simplex virus type 1), ROX (Herpes simplex virus type 2), Cy5 (Varicella zoster virus) and HEX, JOE or VIC channels (CI). Depending on the equipment used select the proper detection channel (see table 4). In the Applied Biosystems 7500 Fast Real-Time PCR System and Stratagene Mx3005P™ Real Time PCR System check that the passive*

reference option for ROX is none. In the Applied Biosystems 7500 Fast Real-Time PCR System select Ramp Speed Standard in Select New Experiment/Advanced Setup/Experiment Properties.

Preparing Reaction Wells

A. Reconstitute the required reaction wells.

Calculate the number of required reactions including samples and controls

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 HSV1+2 / VZV Positive Control (red cap vial) into each positive control well.
3. Pipette 5 µL of Negative Control (orange cap vial) 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	
DNA-Technology DTlite / DTprime	FAM	FAM	
	VIC	HEX	
	ROX	ROX	
	Cy5	Cy5	
Agilent AriaMx	FAM	FAM	
	HEX	HEX	
	ROX	ROX	
	Cy5	Cy5	

Interpretation of results

Interpretation of results (table 5) can be automatically performed if programed by the user using the RT-PCR instrument software following 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 targets which validates the reaction while the negative control well should demonstrate an absence of signal (except Internal Control target).*

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 Internal Control amplification curve signal is also shown.
Please note that in some cases of positive sample the Internal 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 negative for the target if there is no evidence of amplification curve signal in the detection system and the Internal Control is positive.

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

Positive control- The positive control used in each run is expected to show an amplification curve for *HSV-1, HSV-2* and *Varicella Zoster* which validates the reaction (figure 2).

Negative control- The negative control included in each run is expected to show no amplification curve signal for the 3 viruses which validates the reaction (figure 2). The Internal Control must show an amplification curve.

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

Note: If an amplification curve for the Internal control is not shown in negative samples, it may be due to PCR inhibitors. In such case, the sample should be retested by dilution of the original sample 1:10. Alternatively, it is recommended to repeat the nucleic acid extraction.

Table 5. Results interpretation

Herpes simplex virus type 1 (FAM)	Herpes simplex virus type 2 (ROX)	Varicella zoster virus (Cy5)	Internal control (HEX)	Negative Control	Positive Control	Interpretation
POS	POS	POS	POS / NEG	NEG	POS	Herpes simplex virus type 1, Herpes simplex virus type 2 and Varicella zoster virus Positive
NEG	NEG	NEG	POS	NEG	POS	Herpes simplex virus type 1, Herpes simplex virus type 2 and Varicella zoster virus Negative
POS	NEG	NEG	POS / NEG	NEG	POS	Herpes simplex virus type 1 Positive, Herpes simplex virus type 2 and Varicella zoster virus Negative
POS	POS	NEG	POS / NEG	NEG	POS	Herpes simplex virus type 1 and Herpes simplex virus type 2 Positive, and Varicella zoster virus Negative
POS	NEG	POS	POS / NEG	NEG	POS	Herpes simplex virus type 1 and Varicella zoster virus Positive, and Herpes simplex virus type 2 Negative
NEG	POS	NEG	POS / NEG	NEG	POS	Herpes simplex virus type 2 Positive, Herpes simplex virus type 1 and Varicella zoster virus Negative
NEG	POS	POS	POS / NEG	NEG	POS	Herpes simplex virus type 2 and Varicella zoster virus Positive, Herpes simplex virus type 1 Negative
NEG	NEG	POS	POS / NEG	NEG	POS	Varicella zoster virus Positive, Herpes simplex virus type 1 and Herpes simplex virus type 2 Negative
POS	POS	POS	POS	POS	POS	Invalid run
NEG	NEG	NEG	NEG	NEG	NEG	Invalid run

POS: **presents of an amplification signal**
NEG: **No amplification signal**

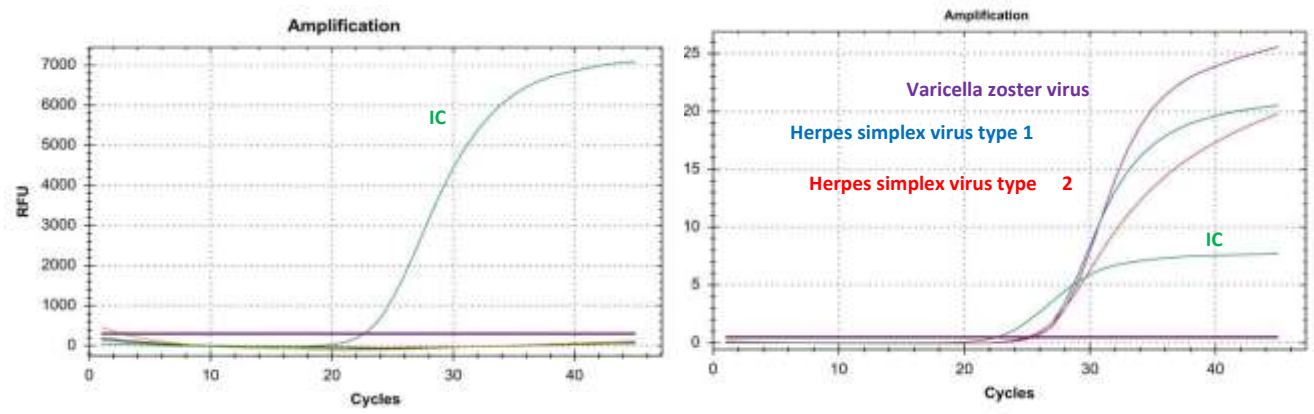

Figure 2. Correct run of negative and positive control on the Bio-Rad CFX96™ Real-Time PCR Detection System.

Limitations of the test

- The results of the test should be evaluated by a health care professional in the context of medical history, clinical symptoms and other diagnostic tests.
- Although this assay can be used with other types of samples, it has been validated only with samples in transport medium, urogenital swabs, urine, plasma and CSF. 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 should be included in each reaction. Besides, a positive and a negative control must be included in each assay to interpret the results correctly.

Performance Characteristics

Clinical Sensitivity and Specificity

The clinical performance of the Savvygen™ HSV1+2 / VZV test was evaluated using 5 different QCMD panels (QCMD 2017 Central Nervous System I EQA Pilot Study, QCMD 2017 Neonatal Infections EQA Pilot Study, QCMD 2017 Varicella-Zoster virus DNA EQA Program, QCMD 2017 Herpes Simplex Virus DNA EQA Program and QCMD 2017 Sexually Transmitted Infections II EQA Pilot Study) and 2 additional INSTAND panels (INSTAND Virus Genome Detection – Herpes Simplex Virus Type 1/Type 2 (nº 363) and INSTAND Virus Genome Detection - Varicella Zoster Virus (nº 366)).

The total panel consisted of 91 clinical specimens (including samples in transport medium, swabs, urine and plasma). The results were compared with the QCMD and INSTAND final reports. Seventeen samples from the panels were positive for *Herpes simplex virus type 1*, 16 samples were positive for *Herpes simplex virus type 2* and an additional 25 samples were positive for *Varicella Zoster Virus* using the Savvygen™ HSV1+2 / VZV test. All results have shown 100% accordance to the EQA reports.

In conclusion, the results show high accuracy for the detection of herpes simplex virus types 1, 2 and varicella zoster virus using the Savvygen™ HSV1+2 / VZV test

Analytical Sensitivity

A serial dilution test was conducted to evaluate the analytical sensitivity of the Savvygen™ HSV1+2 / VZV test for *Herpes simplex virus types 1, 2* and *Varicella zoster virus*. This assay has a detection limit of ≥10 DNA copies per reaction (Figure 3, 4 and 5).

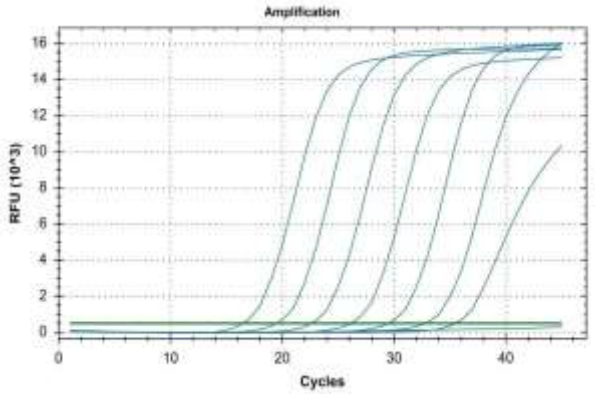

Figure 3. Amplification plot for 10-fold dilution series of *herpes simplex virus type 1* template ranging from 10^7 to 10^1 copies/reaction (FAM channel).

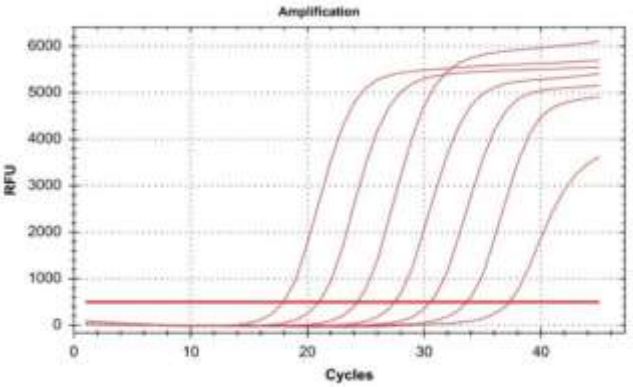

Figure 4. Amplification plot for 10-fold dilution series of *herpes simplex virus type 2* template ranging from 10^7 to 10^1 copies/reaction (ROX channel).

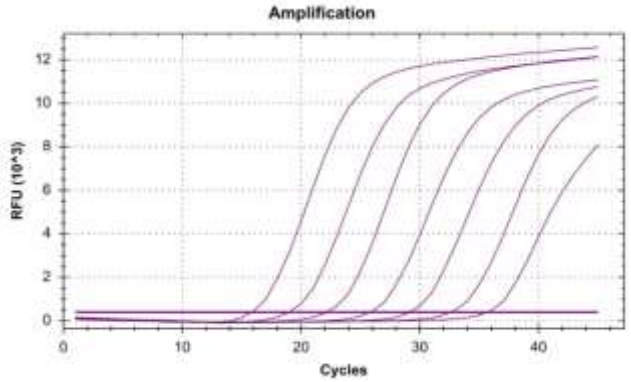

Figure 5. Amplification plot for 10-fold dilution series of *varicella zoster virus* ranging from 10^7 to 10^1 copies/reaction (channel Cy5).

Analytical Specificity

The specificity of the Savvygen™ HSV1+2 / VZV test was confirmed by testing a panel consisting of different microorganisms representing the most common pathogens that can cause meningitis and affect immunosuppressive patients in particular. No cross-reactivity was detected between almost any of the following microorganisms tested, except the targeted pathogens of each assay (table 6).

Table *6*. Cross-reactivity testing**.**

Pathogen	Analytical-Reactivity Test		
	Savvygen™ HSV1+2 / VZV		
	HSV1	HSV2	VZV
E. coli 0.1285;O18:H7:K1	-	-	-
Listeria innocua Serotype 6a/strain CCUG 15531	-	-	-
Listeria ivanovii Serovar 5/strain CCUG 15528	-	-	-
Listeria monocytogenes Serotype 1/2b	-	-	-
Listeria monocytogenes Serovar 4b/Strain CIP 59.53	-	-	-
Bacteroides fragilis	-	-	-
Pseudomonas aeruginosa	-	-	-
Yersinia enterocolitica O:3	-	-	-
Klebsiella oxytoca	-	-	-
Enterobacter cloacae Serotype Cloaca A	-	-	-
Enterobacter aerogenes Serotype Cloaca B	-	-	-
Enterococcus durans	-	-	-
Enterococcus faecalis	-	-	-
Enterococcus faecium serotype 11	-	-	-
Acinetobacter baumannii	-	-	-
Candida albicans	-	-	-
Aspergillus fumigatus	-	-	-
Pneumocystis jirovecii Type A1	-	-	-
Pneumocystis jirovecii g885652	-	-	-
Staphylococcus aureus subsp *aureus*	-	-	-
Streptococcus agalactiae Z019	-	-	-
Streptococcus pneumoniae Z022	-	-	-
Plasmodium falciparum 3D7	-	-	-
Cryptococcus gatti Z156	-	-	-
Haemophilus influenzae MinnA	-	-	-
Neisseria meningitidis serogroup A	-	-	-
Treponema pallidum	-	-	-
Toxoplasma gondii Type II	-	-	-
Enterovirus type 68	-	-	-
Enterovirus type 71	-	-	-
Epstein-Barr virus	-	-	-
BK Virus Type Ib2	-	-	-
BK Virus Type IV	-	-	-
JC Virus Type 2B	-	-	-
JC Virus Type 1A	-	-	-
Citomegalovirus strain AD-169	-	-	-
Coxsackievirus type A24	-	-	-
Coxsackievirus type A9	-	-	-
Coxsackievirus type B3	-	-	-
Parechovirus Type 3	-	-	-
Parvovirus B19	-	-	-
St Louis Encephalitis Virus strain 17D	-	-	-
Tick-Borne encephalitis virus strain Neudorfl	-	-	-

Chikungunya virus (S27 Petersfield)	-	-	-
Dengue 1 (Hawaii A strain)	-	-	-
Dengue 2 (New Guinea C strain)	-	-	-
Dengue 3 (H87)	-	-	-
Dengue 4 (H241)	-	-	-
West Nile Virus (Heja)	-	-	-
West Nile Virus (NY99)	-	-	-
West Nile Virus (Ug37)	-	-	-
Yellow Fever Virus (17D strain)	-	-	-
Echovirus Type 30	-	-	-
Echovirus Type 11	-	-	-
HSV-1 strain MacIntyre	+	-	-
HSV-2 MS	-	+	-
HHV6 strain Z29	-	-	-
HHV6 Type A	-	-	-
HHV6 Type B	-	-	-
Varicella-Zoster Virus Ellen	-	-	+
Varicella Zoster Virus OKA	-	-	+

Analytical Reactivity

The reactivity of the Savvygen™ HSV1+2 / VZV test for herpes simplex virus type 1 was evaluated against HSV-1 strain MacIntyre showing positive result.

The reactivity of the Savvygen™ HSV1+2 / VZV test for herpes simplex virus type 2 was evaluated against HSV-2 MS showing positive result.

The reactivity of the Savvygen™ HSV1+2 / VZV test for varicella zoster virus was evaluated against Varicella-Zoster Virus Ellen and Varicella Zoster Virus OKA showing a positive result.

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Explanation of Symbol

	Manufacturer		Use by		
LOT	Lot number		Temperature limitation		Consult instructions for use
REF	Catalogue number		Contains sufficient for <n> test	DIL	Buffer (sample diluent)
	Keep Dry				