



## LIPSGENE® HSV Kit

### Intended use

The LIPSGENE® HSV Kit is intended for qualitative real-time PCR detection of Herpes Simplex Virus 1 and 2 (*HSV-1*, *HSV-2*) DNA in human serum, EDTA blood, liquor, blister aspirates, tissue biopsies, and swabs of lesions, rashes or ulcer samples. *HSV-1* and *HSV-2* may cause a variety of clinical symptoms such as mucocutaneous lesions and infections of the central nervous system. *HSV-1* is commonly associated with herpes outbreak on the face known as cold sore or fever blisters, whereas *HSV-2* is more often associated with genital herpes. Neonatal infection following exposure to the virus at delivery can produce severe disseminated infection and death. In immunocompromised patients, the virus leads to severe clinical outcomes, including mucocutaneous disease and pneumonia.

### Kit contents

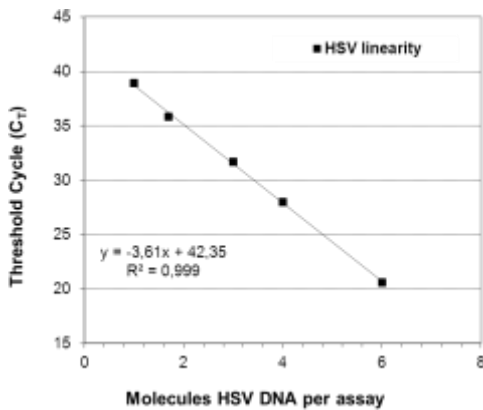
- ✓ Lyophilized oligonucleotide mix containing *HSV* and DNA control (DC) specific primers and probes, PCR vessels containing stabilized synthetic *HSV* standard DNA (*HSV-1/HSV-2* ready-to-use cut-off and positive controls), sample PCR tubes, nucleic acids extraction tubes containing stabilized DC provided in a separate box (shipped at room temperature).
- ✓ Taq Polymerase, 10x PCR buffer, 50 mM Mg-chloride solution, PCR grade water, 10x ROX, 10x BSA (shipped in a separate box on dry ice).
- ✓ Sufficient to run either 120 or 60 tests.

### Performance assessment

The LIPSGENE® HSV Kit was evaluated according to the requirements of the EU Directive 98/79/EC about *in vitro* diagnostic medical devices.

Assessment criterion	Sample type	Performance
Analytical sensitivity	Synthetic <i>HSV</i> DNA	≥10 copies/run
Linear range	Synthetic <i>HSV</i> DNA	>8 logs
Genotype recognition	NIBSC 08/224-004 ( <i>HSV</i> Type 1), NIBSC 08/226-004 ( <i>HSV</i> Type 2)	Genotype 1, 2
Analytical specificity	<i>HSV</i> neg. pathogen samples	100%
Diagnostic specificity	<i>HSV</i> neg. plasma	100%

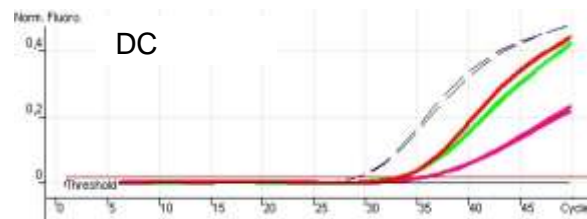
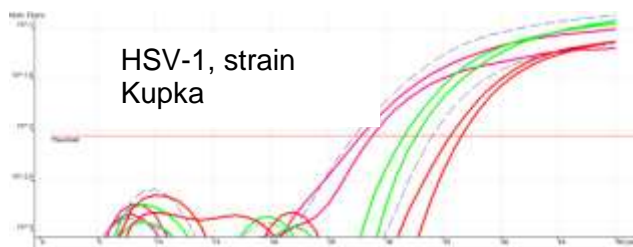
# 1. LIPSGENE® – PATHOGEN DETECTION



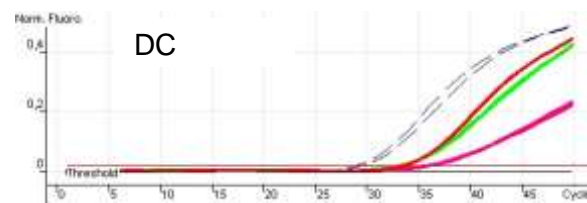
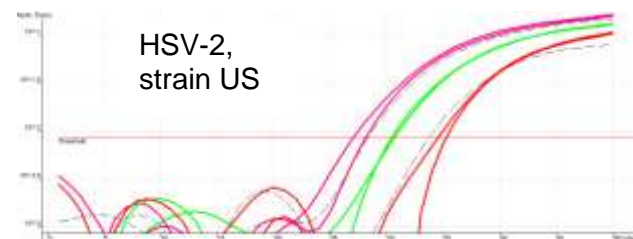
**Figure 1.17:** Linearity of the LIPSGENE® HSV Kit. The study was performed with synthetic HSV DNA specimen and 1 replicate at each level on Rotor-Gene. The linearity of the assay was at least 6 logs. The run parameters are included in the figure.

## Typical run results

A)



B)



**Figure 1.18:** HSV reference strain analysis. (A) HSV Type 1, diluted 1:10 (pink); 1:100 (green) and 1:1000 (red) before DNA purification. (B) HSV Type 2, diluted 1:10 (pink); 1:100 (green) and 1:1000 (red) before DNA purification. Right figures: corresponding DC DNA amplification curves. Dashed lines: positive controls, 10,000 and 100 copies per run, respectively.

## Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	RUO	RUO	RUO	-	-	-	-
120 tests	1010006RP-120	1010006ST-120	1010006LP-120	-	-	-	-
60 tests	1010006RP-060	1010006ST-060	1010006LP-060	-	-	-	-

**RP** = 0.2 ml regular profile 8-well/strip PCR tubes and cap strips (e.g. ABI PRISM® 7000/7300/7700 SDS [Applied Biosystems/Life Technologies], iCycler IQ™; IQ5 [Bio-Rad], MX3000P, Mx3005P [Stratagene]; Mastercycler® ep realplex [Eppendorf]); **ST** = Single 0.2 ml PCR Tube with attached cap (e.g. Rotor-Gene™ 3000/6000, Rotor-Gene Q [Qiagen]; LineGene K [Bioer]); **LP** = 0.1 ml low profile 8-well/strip PCR tubes and cap strips (e.g. , 7500 Fast [Applied Biosystems/Life Technologies], MiniOpticon™, CFX-96 [Bio-Rad]); **LC** = 20 µl LightCycler glass capillaries (LightCycler 2.x, Roche); **SC** = 25 µl SmartCycler tubes (e.g. SmartCycler® [Cepheid]); **SP** = 20 µl DX-12 reaction tubes (Spartan Dx-12); **RS** = 0.1 ml 4-well tube/strips (Rotor-Gene™ 3000/6000, Rotor-Gene Q [Qiagen]).

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