

LIPSGENE® HIV-1 Kit

Intended use

The LIPSGENE® HIV-1 Kit is intended for real-time quantification of Human Immunodeficiency Virus type 1 (*HIV-1*) RNA in human EDTA plasma and serum. *HIV* is a RNA virus and belongs to the family of the retroviruses. During its replication step the HIV genome is integrated in the genome of the host cell as DNA provirus. It mutates extensively and shows high gene diversity. *HIV-1* subtype B predominates in the western countries. The level of *HIV-1* RNA in serum and plasma can be used in conjunction with other clinical markers and findings to distinguish between acute and chronic *HIV-1* infection and to assess the viral response to antiviral treatment.

The detection kit is not intended for screening of blood or blood products for *HIV-1* RNA or for confirming a *HIV-1* infection.

Kit contents

- ✓ Lyophilized oligonucleotide mix containing *HIV-1* and RNA control (RC) specific primers and probes, PCR vessels containing stabilized synthetic *HIV-1* standard RNA (ready-to-use reference curves), sample PCR tubes, nucleic acids extraction tubes containing stabilized RC provided in a separate bag (shipped at room temperature).
- ✓ RT-PCR enzyme mix, reaction mix, Mg-sulfate 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® HIV-1 Kit was evaluated according to the common technical specifications (CTS) for *in vitro* diagnostic medical devices (2009/108/EC).

Assessment criterion	Sample type	Performance
Analytical sensitivity	Synthetic <i>HIV-1</i> RNA	≥10 copies/run
	PEI <i>HIV-1</i> positive reference plasma	300 IU/ml
Linear range	Synthetic <i>HIV-1</i> RNA	>8 logs
Genotype recognition	<i>HIV-1</i> genotype panel (National Reference Center for Retroviruses, Erlangen, Germany)	Genotype A, B, C, D1, D2, D3, E1, G and H
Analytical specificity	<i>HIV-1</i> neg. pathogen samples	100%
Diagnostic specificity	<i>HIV-1</i> neg. plasma	100%

1. LIPSGENE® – PATHOGEN DETECTION

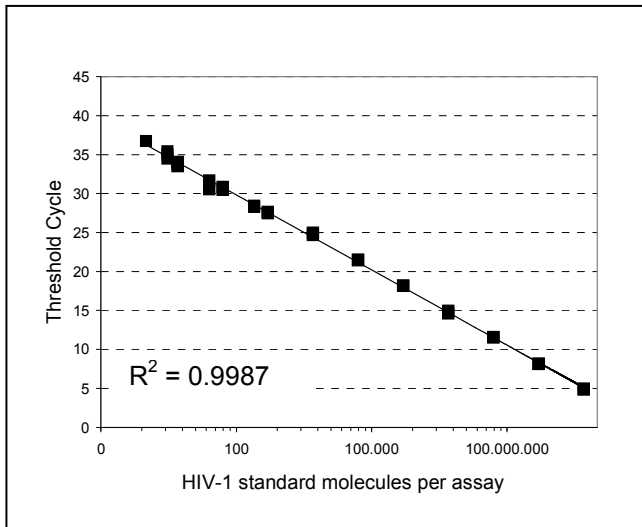
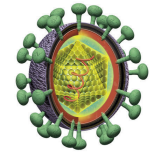


Figure 1.15: Linearity of the LIPSGENE® HIV-1 Kit. The study was performed with synthetic HIV RNA specimen and 3 replicates at each level on Rotor-

Typical run results

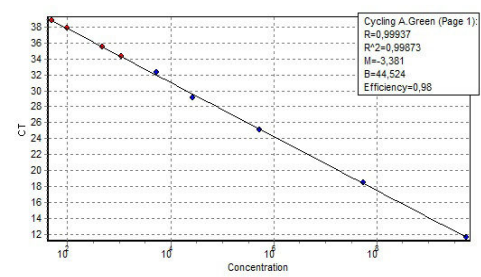
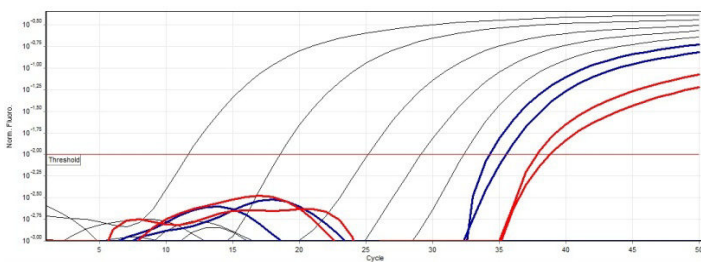


Figure 1.16 : LIPSGENE® HIV-1 Kit. Quantification limits determination using a Rotor-Gene instrument. Blue thick curves: 250 IU per ml of plasma, corresponding to 125 copies per ml; red curves: 125 IU per ml, corresponding to 62.5 copies per ml.

Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	RUO	RUO	RUO	-	RUO	-	-
120 tests	1010004RP-120	1010004ST-120	1010004LP-120	-	1010004SC-120	-	-
60 tests	1010004RP-060	1010004ST-060	1010004LP-060	-	1010004SC-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]).