

LIPSGENE® EBV Kit

Intended use

The LIPSGENE® EBV DNA Kit is intended for real-time PCR quantification of Epstein-Barr virus (*EBV*) DNA in human blood or tissue samples. *EBV* is associated to the etiopathogenesis of an increasing number of tumors, e.g. B-cell non-Hodgkin lymphoma and Burkitt's lymphoma. Detection/quantification of *EBV* in pathological samples is relevant as its high prevalence in some cancers makes the virus a promising target for monitoring the success of specific therapies. The quantification kit is not intended for screening of blood or blood products for *EBV* DNA or for confirming an *EBV* infection.

Kit contents

- ✓ Lyophilized oligonucleotide mix containing *EBV* and DNA control (DC) specific primers and probes, PCR vessels containing stabilized synthetic *EBV* standard DNA (ready-to-use reference curves), sample PCR tubes, Nucleic acids extraction tubes containing stabilized DC provided in a separate bag (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® EBV 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>EBV</i> DNA	≥10 copies/run
	Reference plasma; Genomic DNA	~5,000 copies per ml; proviral <i>EBV</i> genomes in the DNA of the human B cell line RAJI (ATCC Number: CCL-86) diluted to 0.01 ng per run
Linear range	Synthetic <i>EBV</i> DNA	>6 logs
Analytical specificity	<i>EBV</i> neg. pathogen samples	100%
Diagnostic specificity	<i>EBV</i> neg. plasma	100%

1. LIPSGENE® – PATHOGEN DETECTION

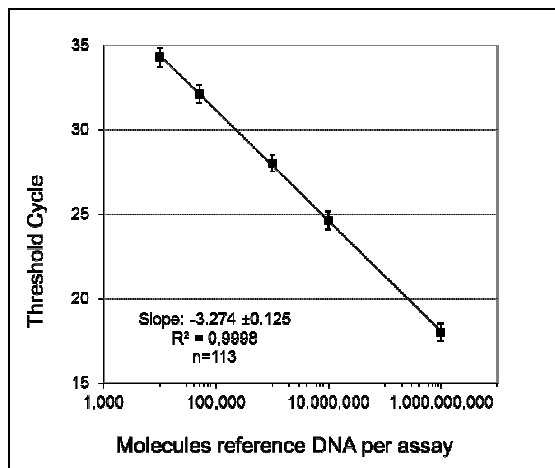
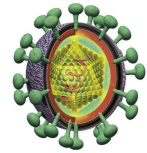


Figure 1.7: The linearity of the assay was >5 logs as determined by the linear regression of the \log_{10} calculated with the \log_{10} of the nominal concentrations. The equation of the respective regression line is included in the figure.

Typical run results

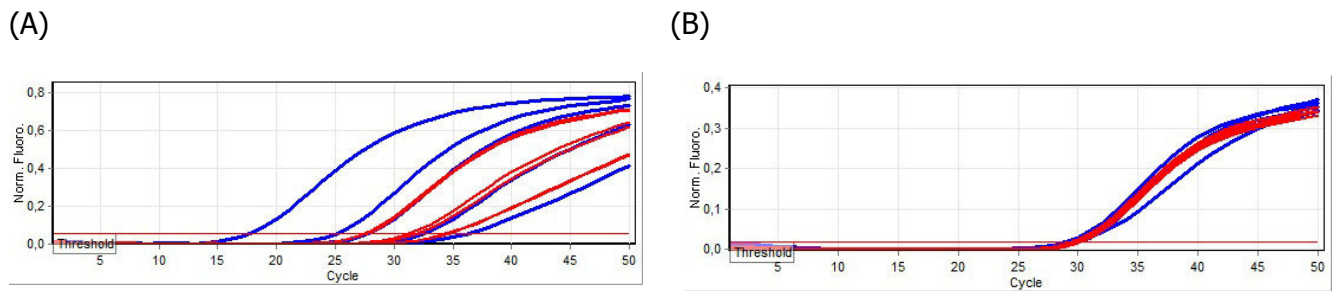


Figure 1.8: Quantification of EBV genomes using a Rotor-Gene 6000. Saturation curves. A) Standards (10^6 , 10^5 , 10^4 , 2.5×10^3 , 10^3 copies, blue curves) and EBV DNA purified from the OptiQuant EBV plasma panel 94-2017 (10^7 , 10^6 , 10^5 copies per ml, red curves) amplified with the EBV Kit. B) Corresponding DC amplification curves.

Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	RUO	RUO	RUO	-	-	-	-
120 tests	1010007RP-120	1010007ST-120	1010007LP-120	-	-	-	-
60 tests	1010007RP-060	1010007ST-060	1010007LP-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]).