LIPSGENE® HBV Kit

Intended use

The LIPSGENE® HBV Kit is intended for real-time PCR quantification of Hepatitis B Virus (*HBV*) DNA in human EDTA plasma or serum samples. The *HB Virus* infects the human liver, proliferating in its cells and lysing them, evoking an inflammation called hepatitis. Chronic carriers are at high risk of long term health complications, including liver cirrhosis and cancer. The level of *HBV* DNA in plasma or serum can be used in conjunction with other clinical markers and findings to distinguish between acute and chronic *HBV* infection and to assess the viral response to antiviral treatment. The viral load of ≥ 2,000 IU per ml is considered as potentially requiring treatment.
The quantification kit is not intended for screening of blood or blood products for *HBV* DNA or for confirming a *HBV* infection.

Kit contents

- ✓ Lyophilized oligonucleotide mix containing *HBV* and DNA control (DC) specific primers and probes, PCR vessels containing stabilized synthetic *HBV* standard DNA (ready-to-use reference curves), 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® HBV 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 *HBV* DNA	≥5 copies/run
	PEI HBV plasma	78 IU/ml
Linear range	Synthetic *HBV* DNA	>8 logs
Recovery rate	Synthetic *HBV* DNA	100% over 2 logs
Genotype recognition	*HBV* genotype reference panel	Genotyps A1, A2, B2, B4, C2, D1, D3, E, F2, G
Analytical specificity	*HBV* neg. pathogen samples	100%
Diagnostic specificity	*HBV* negative plasma	100%
Robustness: failure rate of the system	PEI *HBV* plasma	0%
Serum/ plasma equivalence	*HBV* positive patient samples	100%

Table 1.1: Specificity testing of relevant *HBV* genotypes (1st WHO International Reference Panel for Hepatitis B Virus Genotypes for NAT-based assays, PEI code 5086/08, Version 2, 28.11.2012), 1:2 diluted with *HBV*-negative donor plasma).

Genotype	*HBV* DNA given [log_{10} IU/ml]	*HBV* DNA detected [log_{10} IU/ml]	*HBV* within ± 0.5 log	DC
1 / A1	5,799	5,732	Yes	+
2 / A1	5,559	5,511	Yes	+
3 / A2	5,499	5,430	Yes	+
4 / B2	5,619	5,846	Yes	+
5 / B2	5,479	5,251	Yes	+
6 / B4	3,609	3,879	Yes	+
7 / C2	5,659	5,749	Yes	+
8 / C2	5,789	5,813	Yes	+
9 / C2	5,639	5,872	Yes	+
10 / D1	5,689	5,695	Yes	+
11 / D3	5,709	5,708	Yes	+
12 / D1	5,729	5,652	Yes	+
13 / E	5,559	5,625	Yes	+
14 / F2	4,459	4,836	Yes	+
15 / G	3,479	3,874	Yes	+
D ayw2-3	3,699	3,403	Yes	+

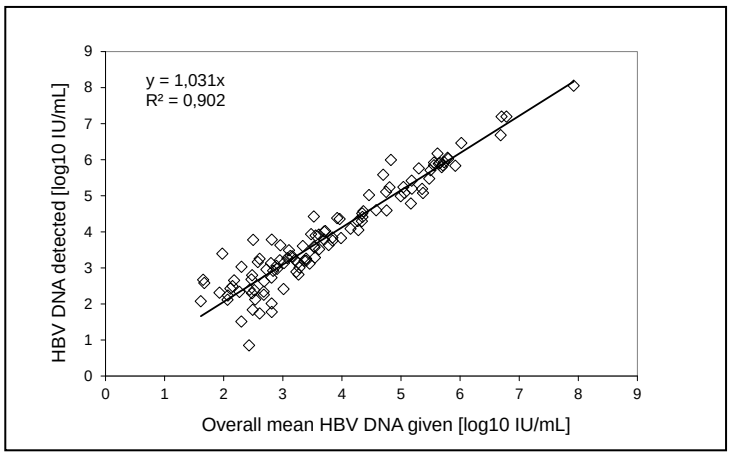

Figure 1.9: Diagnostic evaluation: comparison of the LIPSGENE® HBV Kit with the Cobas AmpliPrep/Cobas TaqMan HBV Kit. The correlation of quantitative results from both tests (n=113) was analysed by linear regression. The equation of the respective regression line is included

Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	RUO	RUO	RUO	RUO	RUO	RUO	RUO
120 tests	1010002RP-120	1010002ST-120	1010002LP-120	1010002LC-120	1010002SC-120	1010002SP-120	1010002RS-120
60 tests	1010002RP-060	1010002ST-060	1010002LP-060	1010002LC-060	1010002SC-060	1010002SP-060	1010002RS-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** = Singe 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]).