

## LIPSGENE® HCV Kit

### Intended use

The LIPSGENE® HCV Kit is intended for real-time quantification of Hepatitis C Virus (*HCV*) RNA in human EDTA/citrate plasma or serum samples. Hepatitis C is a viral infection of the liver, which had been referred to as "parenteral transmitted *non A, non B hepatitis*" until the identification of the causative agent in 1989. *HCV* infection accounts for the majority of post-transfusion and sporadic hepatitis.

There is a high frequency of progressive chronic hepatitis. The level of *HCV* RNA in serum and plasma can be used in conjunction with other clinical markers and clinical findings to distinguish between acute and chronic *HCV* infection and to assess the viral response to antiviral treatment. The detection kit is not intended for screening of blood or blood products for *HCV* RNA or for confirming a *HCV* infection.

### Kit contents

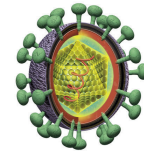
- ✓ Lyophilized oligonucleotide mix containing *HCV* and RNA control (RC) specific primers and probes, PCR vessels containing stabilized synthetic *HCV* standard RNA (ready-to-use reference curves), sample PCR tubes, nucleic acids extraction tubes containing stabilized RC provided in a separate bag (shipped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

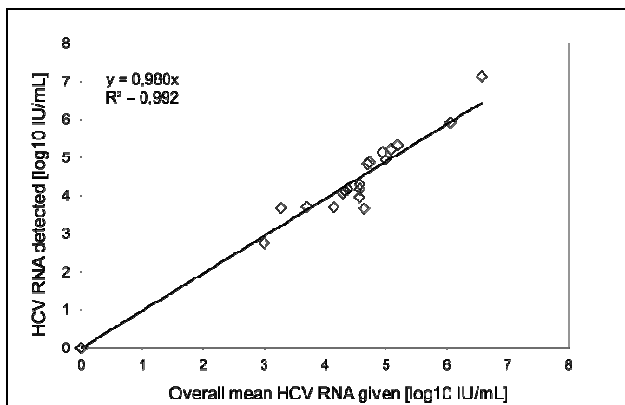
Assessment criterion	Sample type	Performance
Analytical sensitivity	Synthetic <i>HCV</i> RNA	≥5 copies/run
	PEI <i>HCV</i> plasma	~250 IU/ml
Linear range	Synthetic <i>HCV</i> RNA	>8 logs
Recovery rate	Synthetic <i>HCV</i> RNA	100% over 6 logs
Genotype recognition	Genotype panel (Univ. Essen)	Genotypes 1a, 1b, 2a, 2b, 2c, 2i, 3a, 4, 5a and 6
Analytical specificity	Various virus DNA or RNA	100%
Diagnostic specificity	<i>HCV</i> negative plasma	100%
Robustness: failure rate of the system	PEI <i>HCV</i> plasma	0%
Serum/ plasma equivalence	<i>HCV</i> positive patient samples	100%

# 1. LIPSGENE® – PATHOGEN DETECTION



**Table 1.2:** Specificity and recovery testing of relevant *HCV* genotypes.

Genotype	Source	<i>HCV</i> RNA given [IU/mL]	<i>HCV</i> (FAM)	RC (ROX)
1a	Virology, Essen	1.98 x 10 <sup>5</sup>	+	+
1b	Virology, Essen	9.9x 10 <sup>4</sup>	+	+
2a	Virology, Essen	7.52x 10 <sup>4</sup>	+	+
2b	Virology, Essen	7.38x 10 <sup>4</sup>	+	+
2c	Virology, Essen	4.35x 10 <sup>4</sup>	+	+
2i	Virology, Essen	4.77x 10 <sup>4</sup>	+	+
3a	Virology, Essen	2.3 x 10 <sup>4</sup>	+	+
4	Virology, Essen	1.73 x 10 <sup>5</sup>	+	+
5a	Virology, Essen	8.9 x 10 <sup>4</sup>	+	+
6	Virology, Essen	1.09 x 10 <sup>5</sup>	+	+
1	Batch 3443/04, PEI, Langen	8.0x 10 <sup>4</sup>	+	+



**Figure 1.12:** Diagnostic evaluation: comparison of the LIPSGENE® *HCV* Kit with the Cobas TaqMan *HCV* kit (sample purification with the LIPSPREP® Virus Purification Kit). The correlation of quantitative results from both tests (n=20) was analysed by linear regression. PEI = PEI reference material, 1000 IU/mL. The equation of the respective regression line is included in the figure.

## Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	RUO	RUO	RUO	RUO	RUO	RUO	RUO
120 tests	1010001RP-120	1010001ST-120	1010001LP-120	1010001LC-120	1010001SC-120	1010001SP-120	1010001RS-120
60 tests	1010001RP-060	1010001ST-060	1010001LP-060	1010001LC-060	1010001SC-060	1010001SP-060	1010001RS-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]).