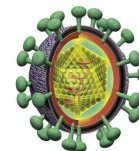


# 1. LIPSGENE® – PATHOGEN DETECTION



## LIPSGENE® CCHF Kit

### Intended use

The LIPSGENE® CCHF Kit is intended for real-time PCR detection/quantification of Crimean–Congo hemorrhagic fever (*CCHF*), a widespread tick-borne viral disease. The pathogen is a RNA virus, especially common in East and West Africa. Clinical disease is rare in infected mammals, but commonly severe in infected humans, with a 30% mortality rate. Based on the sequence data seven genotypes have been recognized.

Real-time PCR testing is more accurate than antigen detection and of diagnostic value particularly during the acute phase of the illness.

The quantification kit is not intended for screening of blood or blood products for *CCHF* RNA or for confirming a *CCHF* infection.

### Kit contents

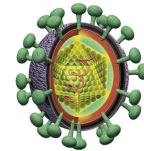
- ✓ Lyophilized oligonucleotide mix containing *CCHF* specific primers and probes, PCR vessels containing stabilized synthetic *CCHF* standard RNA (ready-to-use reference curves), sample PCR tubes (shipped at room temperature).
- ✓ RT-PCR enzyme mix, reaction mix, Mg-sulfate solution, PCR grade water, 10x ROX, 10x BSA (shipped in a separate box on dry ice).
- ✓ Sufficient to run either 120 or 60 tests.

### Performance assessment

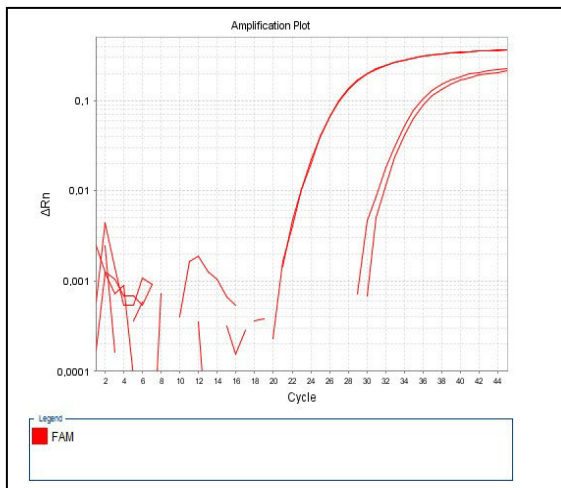
The LIPSGENE® CCHF Kit was evaluated according to the requirements of the EU Directive 98/79/EC about *in vitro* diagnostic medical devices.

Assessment criterion	Sample type	Performance
Analytical sensitivity	Synthetic <i>CCHF</i> RNA	≥10 copies/run
Linear range	Synthetic <i>CCHF</i> RNA	8 logs

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## Typical run results



**Figure 1.5:** LIPSGENE® CCHF Kit. Amplification of  $10^6$  and  $10^7$  copies of synthetic *CCRF* RNA (n=2) using 7500 Fast Real Time PCR System.

## Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	-	-	RUO	-	-	-	-
120 tests	-	-	1010010LP-120	-	-	-	-
60 tests	-	-	1010010LP-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]).