

## LIPSGENE® MARV Kit

### Intended use

The LIPSGENE® MARV Kit is intended for real-time PCR detection/quantification of Marburg virus (*MARV*). *MARV* causes a severe disease in humans and nonhuman primates in the form of viral hemorrhagic fever. The ssRNA virus was first discovered in 1967 in the city of Marburg (Germany), where some lab workers were accidentally exposed to infected green monkey tissues, in the city's former main industrial plant Behring-Werke. After an incubation time of 5-10 days, this highly pathogenic virus causes the stop of the coagulation and damages the organs of the body, thus leading to internal bleeding and, in the most severe cases, to the death of the infected individual. The mortality rate may be up to 90%. Marburg hemorrhagic fevers are difficult to diagnose because many of the early signs and symptoms resemble those of other infectious diseases, such as typhoid and malaria. Most people with Marburg hemorrhagic fever have high concentrations of the virus in their blood. Blood tests based on reverse transcriptase polymerase Real-time PCR can early detect specific genes or the virus.

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

### Kit contents

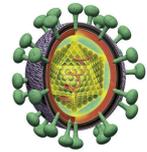
- ✓ Lyophilized oligonucleotide mix containing *MARV* specific primers and probes, PCR vessels containing stabilized synthetic *MARV* standard RNA (ready-to-use reference curves), sample PCR tubes (shipped at room temperature).
- ✓ RT-PCR enzyme mix, reaction mix, Mg-sulfate solution, PCR grade water,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

### Performance assessment

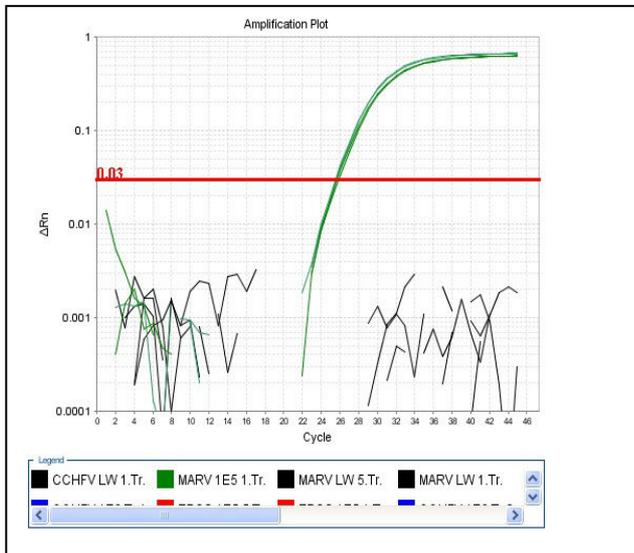
The LIPSGENE® MARV Kit was evaluated according to the requirements of the EU Directive 98/79/EC about *in vitro* diagnostic medical devices.

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

# 1. LIPSGENE® – PATHOGEN DETECTION



## Typical run results



**Figure 1.19:** LIPSGENE® MARV Kit. Amplification of  $10^5$  copies of synthetic *MARV* RNA (n=4) using 7500 Fast Real Time PCR System. Green: *MARV* RNA, Black: NTC.

## Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	-	-	RUO	-	-	-	-
120 tests	-	-	1010012LP-120	-	-	-	-
60 tests	-	-	1010012LP-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]9; **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]).