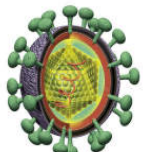


LIPSGENE® SEBOV Kit (Ebola Sudan)
LIPSGENE® ZEBOV Kit (Ebola Zaire)

Intended use

The LIPSGENE® Ebola Kits (*SEBOV*, *ZEBOV*) are intended for real-time PCR quantification of Ebola virus RNA in serum, plasma, amniotic or synovial fluid samples. Ebola hemorrhagic fever (EHF) is a viral hemorrhagic fever and one of the most virulent viral diseases known to humankind. The Ebola virus was first identified in 1976 in the western equatorial provinces of Sudan and in a nearby region of Zaire (now Democratic Republic of the Congo), after significant epidemics in these areas. There are five distinct species of the Ebola virus: Bundibugyo, Côte d'Ivoire, Reston, Sudan and Zaire. Bundibugyo, Sudan and Zaire species have been associated with large outbreaks of Ebola hemorrhagic fever (EHF) in Africa causing death in 25-90% of all clinically ill cases, while Côte d'Ivoire and Reston have not. The Ebola virus is transmitted by direct contact with the blood, body fluids and tissues of infected persons. Transmission of the Ebola virus has also occurred by handling infected sick or dead wild animals (chimpanzees, gorillas, monkeys, forest antelope, fruit bats). The predominant treatment is general supportive therapy.
The quantification kits are not intended for screening of blood or blood products for Ebola RNA or for confirming an Ebola infection.

Kit contents

- ✓ Lyophilized oligonucleotide mix containing either *SEBOV* or *ZEBOV* and RNA control (RC) specific primers and probes, PCR vessels containing stabilized synthetic *SEBOV/ZEBOV* standard RNA (ready-to-use reference curves), sample PCR tubes, nucleic acids sample preparation tubes containing stabilized RC provided in a Box 2 (shipped at room temperature).
- ✓ 2x reaction mix, reverse transcriptase (shipped in a separate bag on dry ice); $MgCl_2$ solution, PCR grade water, 50x ROX, 50x BSA (shipped at room temperature).
- ✓ Sufficient to run either 120 or 60 tests (100/50 clinical samples, 20/10 standards).

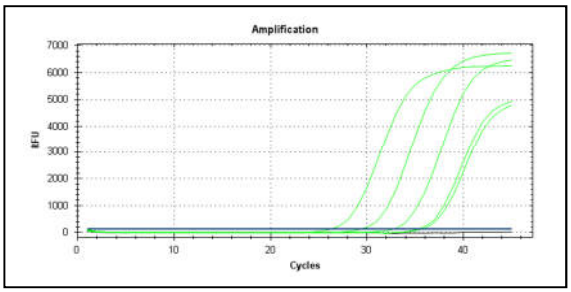
Performance assessment

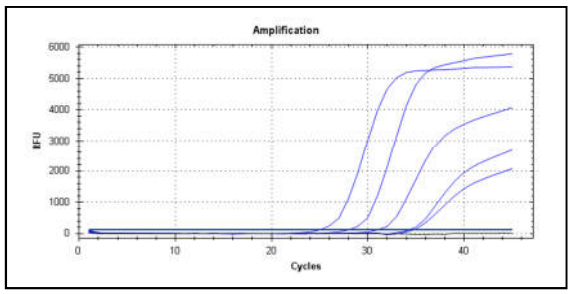
The LIPSGENE® *SEBOV/ZEBOV* Kits were evaluated considering the requirements of the EU Directive 98/79/EC about *in vitro* diagnostic medical devices.

	Sample type	
Analytical sensitivity	Synthetic *SEBOV/ ZEBOV* RNA	≥10 copies/run
Linear range	Synthetic *SEBOV/ ZEBOV* RNA	>8 logs
Analytical specificity	Pathogen negative samples	100%

Typical run results

(A)





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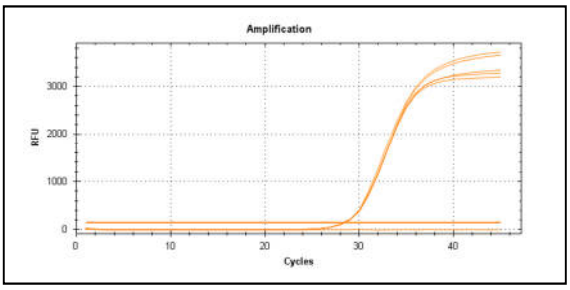

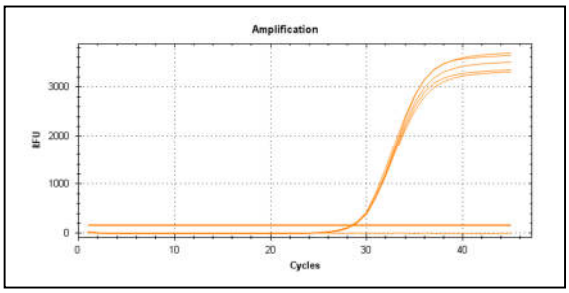

Figure 1.24: LIPSGENE® SEBOV Kit, LP/CFX96™ kit version. (A) *SEBOV* RNA standard saturation curves (1.0x 10^4, 1.0x 10^3, 1.0x 10^2, 10 [duplicate detection]) copies/tube). (B) RC RNA amplification curves.

Figure 1.25: LIPSGENE® ZEBOV Kit, LP/CFX96™ kit version. (A) *ZEBOV* RNA standard saturation curves (1.0x 10^4, 1.0x 10^3, 1.0x 10^2, 10 [duplicate detection]) copies/tube). (B) RC RNA amplification curves.

Ordering information

SEBOV

Kit version	GO	GY	SP
IvD state	RUO	RUO	-
Cat.No. (120 tests)	1010013GO-120	1010013GY-120	-
Cat.No. (60 tests)	1010013GO-060	1010013GY-060	-

ZEBOV

Kit version	GO	GY	SP
IvD state	RUO	RUO	-
Cat.No. (120 tests)	1010014GO-120	1010014GY-120	-
Cat.No. (60 tests)	1010014GO-060	1010014GY-060	-

GO = For use with block and carousel cyclers supporting 25 µL reactions and Green/Orange fluorescence detection (no passive ROX dye); **GY** = For use with block and carousel cyclers supporting 25 µL reactions and 2-channel Green/Yellow fluorescence detection (no passive ROX dye), and multi-channel devices requiring passive ROX dye; **SP** = For use with block and carousel cyclers supporting 20 µL reactions and Green/Orange fluorescence detection (no passive ROX dye).