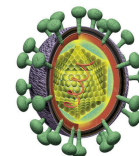


1. LIPSGENE® – PATHOGEN DETECTION



LIPSGENE® DENV Kit

Intended use

The LIPSGENE® DENV Kit is intended for real-time quantification of Dengue Virus (*DENV*) serotypes 1, 2, 3 or 4 RNA from human serum or plasma collected from human patients with signs and symptoms consistent with dengue infection. The present kit version is available for application to "low profile" plastics supporting real time PCR instruments and the CFX96™ Real Time PCR System in particular. The level of *DENV* RNA may be used to study the pathogenesis and severity of dengue disease.

The detection kit is not intended for screening of blood or blood products for *DENV* RNA or for confirming infection with the *DENV* virus.

Kit contents

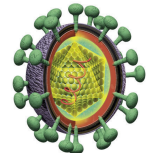
- ✓ Lyophilized oligonucleotide mix containing *DENV* and RNA control (RC) specific primers and probes, PCR vessels containing stabilized synthetic *DENV* standard RNA (ready-to-use reference curves), sample PCR tubes, nucleic acids sample preparation tubes containing stabilized RC provided in a Box 2 (shipped at room temperature).
- ✓ 2x reaction mix, reverse transcriptase (shipped in a separate bag on dry ice); MgCl₂ 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® DENV Kit was evaluated considering the requirements of the EU Directive 98/79/EC about *in vitro* diagnostic medical devices.

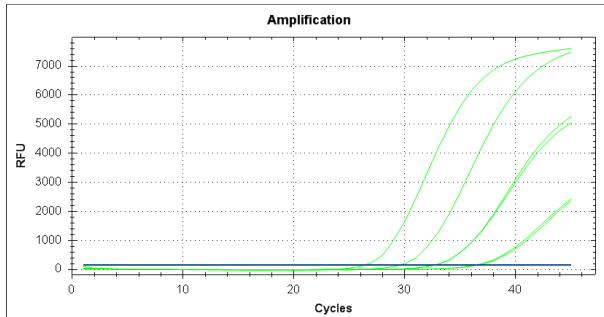
Analytical sensitivity	Synthetic <i>DENV</i> RNA	≥10 copies/run
Linear range	Synthetic <i>DENV</i> RNA	6 logs
Genotype recognition	AMPLIRUN® Dengue 1-4 Virus RNA Control (Vircell)	Dengue Virus serotypes 1, 2, 3 and 4
Analytical specificity	<i>DENV</i> neg. pathogen samples	100%
Diagnostic specificity	<i>DENV</i> negative plasma	100%

1. LIPSGENE® – PATHOGEN DETECTION

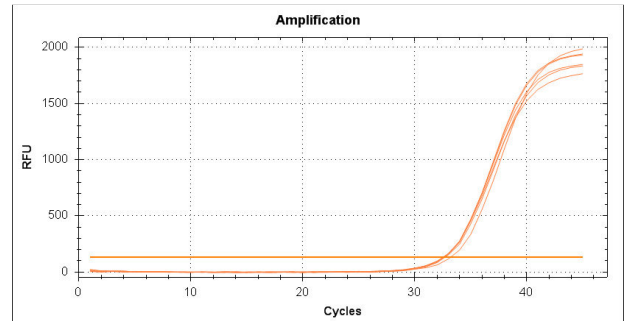


Typical run results

A)



B)



C)

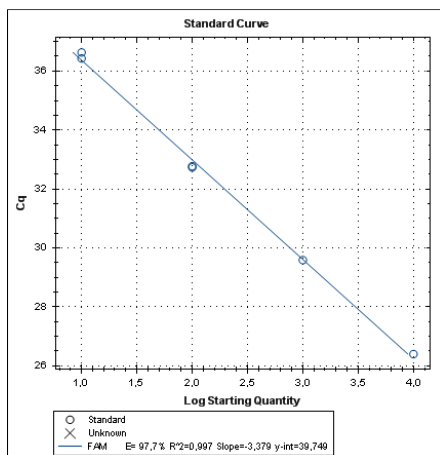


Figure 1.6: LIPSGENE® DENV Kit, LP/CFX96™ kit version. (A) *DENV* RNA standard saturation curves, Blue curves: Quantification standards (1.0×10^4 , 1.0×10^3 , 1.0×10^2 , 10 copies/tube). Blue curve: water blank. (B) RC RNA amplification curves. (C) Typical standard reference curve obtained from the *DENV* standards.

Ordering information

Kit version	LP	RP	ST	RS	AL	AR	SP	LC	SC
IvD state	RUO	-	-	-	RUO	-	RUO	-	-
120 tests Cat.No.1010011...	...LP-120	-	-	-	...AL-120	-	...SP-120	-	-
60 tests Cat.No.1010011...	...LP-060	-	-	-	...AL-060	-	...SP-060	-	-

LP = 0.1 mL low profile 8-well/strip PCR tubes and cap strips (e.g. MiniOpticon™, CFX-96 [Bio-Rad], LightCycler® 96 [Roche]); **RP** = 0.2 mL regular profile 8-well/strip PCR tubes and cap strips (e.g. iCycler IQ™, IQ5 [Bio-Rad], MX3000P, Mx3005P [Agilent/Stratagene]; Mastercycler® ep realplex [Eppendorf]); **ST** = Single 0.2 mL PCR tubes with attached cap (e.g. Rotor-Gene™ 3000/6000, Rotor-Gene Q [Qiagen]; LineGene K [Bioer]), **RS** = 0.1 mL 4-well tube/strips (Rotor-Gene™ 3000/6000, Rotor-Gene Q [Qiagen]); **AL** = 0.1 mL low profile 8-well/strip PCR tubes and cap strips (e.g. 7500 Fast [Applied Biosystems/Life Technologies]); **AR** = 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]); **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).