

LIPSGENE® MTB Kit

Intended use

The LIPSGENE® MTB Kit is intended for qualitative real-time PCR detection of the Mycobacterium tuberculosis complex strains *M. tuberculosis*, *M. bovis*, *M. africanum*, *M. canetti*, *M. pinnipedii* by targeting both the multicopy target *IS6110* insertion element and a common subsequence of the *MTB* genome thus allowing detecting also *MTBC* strains that are lacking the *IS6110*. The test is intended for rapid qualitative detection of purified *MTB* DNA e.g. from sputum, bronchial secretions, bronchialveolar lavage, fasting gastric secretion or tissue biopsies (e.g. lymph nodes or intestine biopsies).

Kit contents

- ✓ Lyophilized oligonucleotide mix containing *MTB* and DNA control (DC) specific primers and probes, PCR vessels containing stabilized synthetic *MTB* standard DNA (ready-to-use cut-off controls), sample PCR tubes, nucleic acids sample preparation tubes containing stabilized DC provided in a Box 2 (shipped at room temperature).
- ✓ Taq Polymerase (shipped in a separate bag on dry ice); 10x PCR buffer, 50 mM 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® MTB Kit was evaluated considering the requirements of the EU Directive 98/79/EC about *in vitro* diagnostic medical devices.

	Synthetic <i>MTB</i> DNA	≥10 copies/run
Analytical sensitivity	Cultured <i>M. tuberculosis</i>	1:10 ⁵ dilution of a purified sample eluate
	<i>M. tuberculosis</i>	down to 0.2 bacteria copies detected by <i>IS6110</i> -specific detection and 1-2 <i>MTB</i> copies by <i>PPE8</i> -specific detection
Linear range	inactivated <i>MTBC</i> strains <i>M. tuberculosis</i> , <i>M. bovis</i> , <i>M. africanum</i> , <i>M. canetti</i> , <i>M. pinnipedii</i>	>6 logs
Analytical specificity	<i>MTB</i> neg. pathogen samples	100%
Diagnostic specificity	Sputum samples of healthy donors	100%

1. LIPSGENE® – PATHOGEN DETECTION

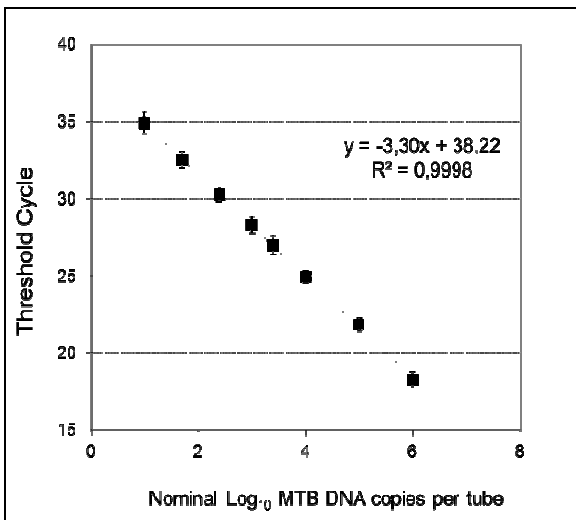
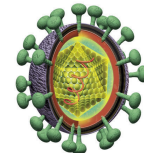
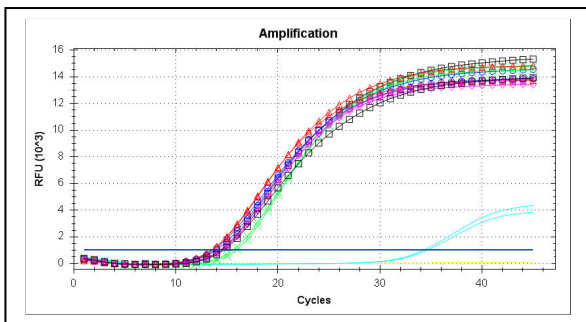


Figure 1.20: Linearity of the LIPSGENE® MTB Kit. The study was performed with synthetic *MTB* DNA specimen and 50 replicates at each level on CFX96. The linearity of the assay was >5 logs as determined by a linear regression of the log₁₀ calculated with the log₁₀ nominal concentrations for the used real time PCR instrument. The equation of the respective regression line is included in the figure.

Typical run results

(A)



(B)

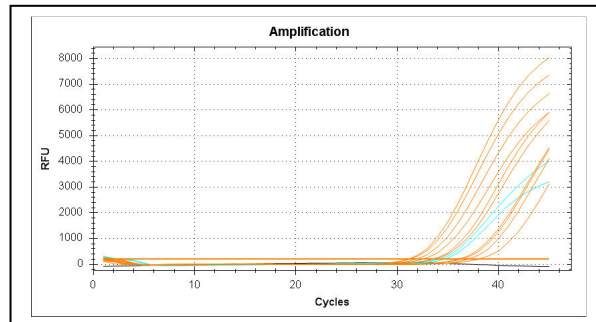


Figure 1.21: Detection of *MTBC* samples using the LIPSGENE MTB Kit. (A) Red curves (triangles): *M. tuberculosis*; Blue curves (circles): *M. africanum*; Green curves (crosses): *M. bovis*; Pink curves (diamonds): *M. pinnipedii*; Black curves (squares): *M. canettii*. Light blue: Positive control DNA (250 *MTB* DNA copies per run); Yellow curve: NTC. (B) Saturation curves of DC DNA.

Ordering information

Kit version	LP	RP	ST	RS	AL	AR	SP	LC	SC
IvD state	RUO	RUO	RUO	RUO	RUO	RUO	RUO	RUO	RUO
120 tests Cat.No.1010015...	...LP-120	...RP-120	...ST-120	...RS-120	...AL-120	...AR-120	...SP-120	...LC-120	...SC-120
60 tests Cat.No.1010015...	...LP-060	...RP-060	...ST-060	...RS-060	...AL-060	...AR-060	...SP-060	...LC-060	...SC-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).