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LIPSGENE® PVB19 Kit

Intended use

The LIPSGENE® PVB19 Kit is intended for real-time PCR quantification of Parvovirus B19 DNA in serum, plasma, amniotic or synovial fluid samples. The detection of *PVB19* DNA assay is recommended on suspicion of Parvovirus infection of pregnant women, trans-placental hydrops fetalis measured in umbilical cord blood, severe fetal anemia, cardiomyopathy and *PVB19*-associated arthritis in synovial fluid of immune suppressed patients with persisting infection. Detection of *PVB19* in clinical samples is relevant in monitoring the success of specific therapies.
The quantification kit is not intended for screening of blood or blood products for *PVB19* DNA or for confirming a *PVB19* infection.

Kit contents

✓ Lyophilized oligonucleotide mix containing *PVB19* and DNA control (DC) specific primers and probes, PCR vessels containing stabilized synthetic *PVB19* standard DNA (ready-to-use reference curves), sample PCR tubes, nucleic acids extraction tubes containing stabilized DC provided in a separate bag (shipped at room temperature).
✓ Taq Polymerase, 10x PCR buffer, 50 mM Mg-chloride 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® PVB19 Kit was 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 *PVB19* DNA	≥10 copies/run
	WHO standard for *PVB19* NAT assay; NIBSC code 99/800; Charge EN63QG	n.d.
Linear range	Synthetic *PVB19* DNA	>6 logs
Genotype recognition	1st WHO International Reference Panel for Parvovirus B19 Genotypes for NAT based assays # 09/110/ PTS110 panel	Genotypes 1, 2, 3a and 3b
Analytical specificity	*PVB19* neg. pathogen samples	100%
Diagnostic specificity	*PVB19* neg. plasma	100%
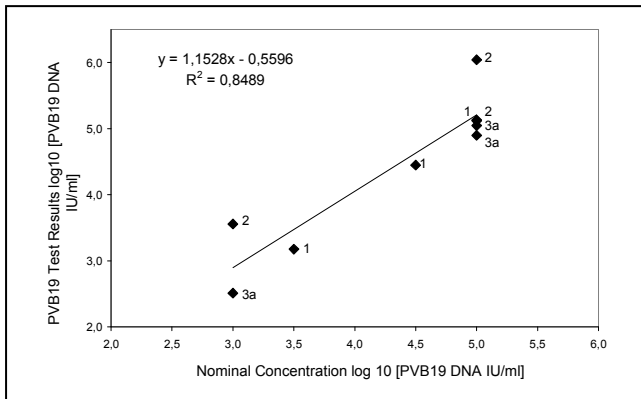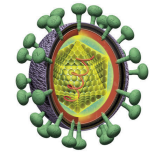
Figure 1.22: Quantitative detection of relevant *PVB19* genotypes. The LIPSGENE® PVB19 Kit allows correct detection of all tested genotypes as measured on SmartCycler. The linearity of the assay was given by the inclusion of all genotype samples as determined by a linear regression of the $\log_{10}$ calculated with the $\log_{10}$ of the nominal concentrations. The equation of the respective regression line is included in the figure. Numbers close to data points: known genotype. For *PVB19* DNA extraction, the QIAamp DNA Blood Kit (Qiagen) was used. Data kindly provided by Dr. Matthias Opp, Laboratoire National de Sante, Luxembourg[1,2].
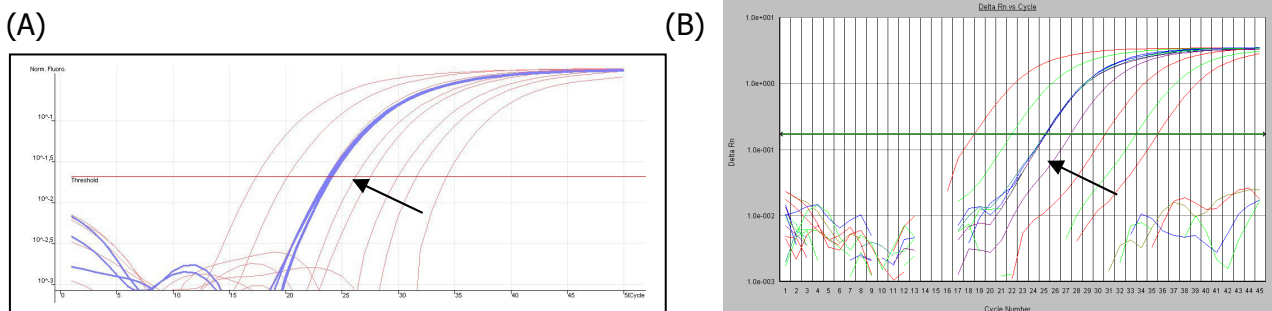
Typical run results

(A)

(B)

Figure 1.23: Quantification of *PVB19* genomes using a Rotor-Gene (A) and ABI PRISM SDS (B). Saturation curves. The data represent the amplification of the ready-to-use *PVB19* DNA controls (9×10^7, 9×10^6, 9×10^5, 2.25×10^5, 9×10^4, 2.25×10^4, 4.5×10^3, 9×10^2 IU per tube) and WHO standard for PVB19 for NAT assay, 1×10^6 IU/ml (indicated by arrow).

References
1. Sally A. Baylis, Li Ma, David J. Padley, Alan B. Heath and Mei-ying W. Yu. Collaborative study to establish a World Health Organization international genotype panel for parvovirus B19 DNA nucleic acid amplification technology (NAT)-based assays. WHO/BS/09.2122.
2. Baylis, S. A., Buchheit, K. H. A proficiency testing study to evaluate laboratory performance for the detection of different genotypes of parvovirus B19. Vox Sanguinis 2009, 97: 13–20.

Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	RUO	RUO	-	-	RUO	-	-
120 tests	1010008RP-120	1010008ST-120	-	-	1010008SC-120	-	-
60 tests	1010008RP-060	1010008ST-060	-	-	1010008SC-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** = Singe 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]).

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