

DECLARATION OF VERIFICATION

Diagnostic medical devices *in vitro*



Manufacturer:

GeneProof a.s.,

Vídeňská 101/119, Dolní Heršpice, 619 00 Brno, Czech Republic, www.geneproof.com

hereby declares that following products are verified together with the devices:

GeneProof PCR kits	croBEE Real-Time PCR System	AMPLiLab Real-Time PCR System	Applied Biosystems 7300 Real-Time PCR System	Applied Biosystems 7500 Real-Time PCR System	AriaMx Real-Time PCR System	BioQuant-96 Real-Time PCR System	CFX Connect™ Real-Time PCR Detection System	CFX96™ / Dx Real-Time PCR Detection System	CFX Opus 96 Real-Time PCR System	DT lite Real-Time PCR System	Genier 96E/96R Real-Time PCR System	LightCycler® 2.0	LightCycler® 480	LineGene 9600	LineGene 9600 Plus	Mic qPCR Cycler	Montania 4896 Real-Time PCR thermocycler	QuantStudio™ 3 Real-Time PCR System	QuantStudio™ 5 Real-Time PCR System	Rotor-Gene 3000 (9)	Rotor-Gene 6000 (10)	Rotor-Gene Q (11)	SLAN® Real-Time PCR System	StepOne™ / StepOne Plus™ Real-Time PCR System	Stratagene Mx3005P qPCR System	
Bloodborne Infections																										
GeneProof Hepatitis B Virus (HBV) PCR Kit									-																	X
GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit									-	X		-		-				X					X	-		X
GeneProof HIV type 1 (HIV-1) PCR Kit									-	X		-		-				X			X	13)	13)		-	X
GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit									-	X		-		-				X		-		X		-		X
Immunocompromised / Transplanted																										
GeneProof Aspergillus PCR Kit			X				X		-	X		X						X	X			X		X		X
GeneProof BK Virus (BKV) PCR Kit									-	X		X		-				X				X		-		X
GeneProof BK/JC Virus (BK/JC) PCR Kit 16)			X				X		-	X		X		-			X	X	X			X		X		X
GeneProof Cytomegalovirus (CMV) PCR Kit										X																X
GeneProof Epstein-Barr Virus (EBV) PCR Kit										X												X				X
GeneProof Herpes Simplex Virus 1 (HSV-1) PCR Kit										X								X								X
GeneProof Herpes Simplex Virus 2 (HSV-2) PCR Kit									-	X								X								X
GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit			X				X			X		X						X	X			X		X		X
GeneProof Human Herpesvirus 6/7 (HHV-6/7) PCR Kit			X				X			X		X						X	X		X	X		X		X
GeneProof Human Herpesvirus 8 (HHV-8) PCR Kit									-	X		-						X			X					X
GeneProof JC Virus (JCV) PCR Kit									-	X		X						X				X		-		X
GeneProof Parvovirus B19 PCR Kit									-	X		-						X								X
GeneProof Varicella-Zoster Virus (VZV) PCR Kit										X								X				X				X
Sexually Transmitted Infections																										
GeneProof Chlamydia trachomatis PCR Kit									-									X								X
GeneProof CT/NG/MG Multiplex PCR Kit			X			X	X		-	X		X	X					X	X			X		X	X	X
GeneProof Gardnerella vaginalis PCR Kit									-	X		X						X						-		X
GeneProof Human Papillomavirus (HPV) Screening PCR Kit		1)	-	1)	1)	X	2)		-	X	1)	-	2)			X	X	8)	1)	-	-	7)	3)	-	1)	
GeneProof MH/UU/UP Multiplex PCR Kit			X		-		X		-	X		X	X				X	X		X	X	X	X	X	X	X
GeneProof Mycoplasma genitalium/hominis PCR Kit			X				4)		-	X		X					X	4)			4)			4)	X	
GeneProof Neisseria gonorrhoeae PCR Kit									-	X								X							X	
GeneProof Treponema pallidum PCR Kit					-				-	X		-						X				X			X	
GeneProof Trichomonas vaginalis PCR Kit					-				-	X		-						X							X	
GeneProof Ureaplasma PCR Kit			X				5)		-	X		X					X	5)			5)			5)	X	

DECLARATION OF VERIFICATION

Diagnostic medical devices *in vitro*

GeneProof®

GeneProof PCR kits	croBEE Real-Time PCR System	AMPLIab Real-Time PCR System	Applied Biosystems 7300 Real-Time PCR System	Applied Biosystems 7500 Real-Time PCR System	AriaMx Real-Time PCR System	BioQuant-96 Real-Time PCR System	CFX Connect™ Real-Time PCR Detection System	CFX96™ / Dx Real-Time PCR Detection System	CFX Opus 96 Real-Time PCR System	DT lite Real-Time PCR System	Genier 96E/96R Real-Time PCR System	LightCycler® 2.0	LightCycler® 480	LineGene 9600	LineGene 9600 Plus	Mic qPCR Cycler	Montania 4896 Real-Time PCR thermocycler	QuantStudio™ 3 Real-Time PCR System	QuantStudio™ 5 Real-Time PCR System	Rotor-Gene 3000 (9)	Rotor-Gene 6000 (10)	Rotor-Gene Q (11)	SLAN® Real-Time PCR System	StepOne™ / StepOne Plus™ Real-Time PCR System	Stratagene Mx3005P qPCR System	
Neuroinfections																										
GeneProof Borrelia PCR Kit 15)										-	X							X								X
Respiratory Infections																										
GeneProof Adenovirus PCR Kit										-	X		X					X				X				X
GeneProof Bordetella pertussis/parapertussis PCR Kit			X				X			-	X		X					X	X			6)			X	X
GeneProof Chlamydia pneumoniae PCR Kit										-	X							X								X
GeneProof Enterovirus PCR Kit										-	X							X								X
GeneProof Flu Multiplex PCR Kit		X	X				X			-	X	X	X				X		-	-	X	X	X	X		X
GeneProof Legionella pneumophila PCR Kit										-	X							X				X				X
GeneProof Mycoplasma pneumoniae PCR Kit										-	X							X								X
GeneProof Mycobacterium tuberculosis PCR Kit 17)						-				-	X							X							-	X
GeneProof SARS-CoV-2 PCR Kit			X				X			-	X		X	12)			X	X	X			X			X	X
GeneProof SARS-CoV-2 Advanced PCR Kit			X	X			X			-	X		X				X	X			X			X	X	
GeneProof SARS-CoV-2 Screening PCR Kit										-	X		X				X	X			X				-	X
Antibiotic Resistance																										
GeneProof MRSA PCR Kit			X			-	X			-	X		X				X	X	X			X		X	X	X
GeneProof VRE PCR Kit			X				X			-	X		X				X	X				X		X	X	X
Thrombotic Mutations																										
GeneProof Factor II Prothrombin PCR Kit		-				-				-	X				X			X								X
GeneProof Factor V Leiden PCR Kit		-				-				-	X				X			X								X
GeneProof Factor XIII V34L PCR Kit		-				-				-	X				X			X								X
GeneProof MTHFR A1298C PCR Kit						-				-	X		X		X			X						-	-	X
GeneProof MTHFR C677T PCR Kit						-				-	X		X		X			X						-	-	X
GeneProof PAI-1 Genotyping PCR Kit		-				-				-	X				X			X								X

Legend:

	Verified
X	Not compatible system (for technical reasons)
x	Not supported system (not verified)
-	Not tested yet

DECLARATION OF VERIFICATION

GeneProof®


Diagnostic medical devices *in vitro*

Notes:

- 1) The device allows detection of high risk HPV with differentiation of HPV 16 and HPV 18.
- 2) The device allows detection of high risk HPV without differentiation.
- 3) The device allows detection of high risk HPV with differentiation of HPV 16.
- 4) The device allows detection of *M. genitalium* only.
- 5) The device does not allow to distinguish between *U. parvum* and *U. urealyticum*.
- 6) Only device model which allows 3-channel detection (FAM, HEX, Cy5).
- 7) The device allows detection of high-risk HPV and presence HPV18,16 and 45 but it does not distinguish coinfection of types 16, 18 and 45 respect to the cross-talk between the channels TEX/Cy5 and Cy5/CY5.5
- 8) The device allows detection of high risk HPV with differentiation of HPV 18.
- 9) Verified on a 4-channel model device. (FAM, HEX, Cy5, TexRed).
- 10) Verified on a 2-channel model device. (FAM, HEX).
- 11) Verified on a 5-channel model device. (FAM, HEX, Cy5, TexRed, Cy5.5).
- 12) The Kit is valid only with the Universal PCR Profile.
- 13) The third channel must also be set to switch on.
- 14) In Rotor-Gene instruments, leave all detection channels on.
- 15) GeneProof *Borrelia burgdorferi* PCR Kit was replaced by GeneProof *Borrelia* PCR Kit.
- 16) Device verification is valid for the innovated version of the GeneProof BK/JC Virus (BK/JC) PCR Kit.
- 17) Device verification is valid for the innovated version of the GeneProof *Mycobacterium tuberculosis* PCR Kit.

Products, together with the devices are verified to comply with the requirements of the specified or expected use (i.e. it complies with the verification requirements), according to the Council and European Parliament Directive 98/79/EC dated October 27, 1998, on *in vitro* diagnostic medical devices, requirements of which were adopted in the Czech Government Regulation No. 56/2015 Coll. establishing technical requirements for *in vitro* diagnostic medical devices.

Mgr. Petra ŠVÁSTOVÁ
Research & Development
Head of Device Characterization
(Name, position and signature of authorized person)


21-11-22

Manufacturer's stamp:

