

DECLARATION OF VERIFICATION

Diagnostic medical devices *in vitro*



Manufacturer:
GeneProof a.s.,
 Videňská 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	AriaMix 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	Gentier 96E/96R Real-Time PCR System	LightCycler® 2.0	LightCycler® 480	LineGene 9600	LineGene 9600 Plus	Mic qPCR Cycler	Montania 4896 Real-Time PCR Instrument	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			X
GeneProof™ HIV type 1 (HIV-1) PCR Kit						-			-	X		X		-			X				X	13)	13)			X
GeneProof™ HIV type 1 (HIV-1) Diagnostic PCR Kit									-	X		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 ^{IVDR}										X		X														X
GeneProof™ Cytomegalovirus (CMV) PCR Kit										X																X
GeneProof™ Epstein-Barr Virus (EBV) PCR Kit ^{IVDR}										X		X									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 ^{IVDR}			X				X			X		X					X	X			X			X	X	X
GeneProof™ Herpes Simplex Virus (HSV-1/2) PCR Kit			X				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
GeneProof™ JC Virus (JCV) PCR Kit										X		X					X				X				-	X
GeneProof™ Parvovirus B19 PCR Kit										X		X					X									X
GeneProof™ Varicella-Zoster Virus (VZV) PCR Kit ^{IVDR}										X		X					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	X
GeneProof™ Gardnerella vaginalis PCR Kit										-	X		X				X									X
GeneProof™ Human Papillomavirus (HPV) Screening PCR Kit		1)	-	1)	1)	X	2)			-	X	1)	X	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

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Sexually Transmitted Infections																										
GeneProof™ Neisseria gonorrhoeae PCR Kit									-	X							X									X
GeneProof™ Treponema pallidum PCR Kit					-				-	X		X		-			X				X					X
GeneProof™ Trichomonas vaginalis PCR Kit					-				-	X		X		-			X									X
GeneProof™ Ureaplasma PCR Kit			X				5)		-	X		X					X	5)			5)				5)	X
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								-	X
GeneProof™ Flu Multiplex PCR Kit		X	X				X		-	X	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								-	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
Antibiotic Resistance																										
GeneProof™ MRSA PCR Kit			X			-	X		-	X		X	X			X	X	X			X			X	X	X
GeneProof™ VRE PCR Kit			X				X		-	X		X					X	X			X				X	X
Thrombotic Mutations																										
GeneProof™ Factor II Prothrombin PCR Kit		-				-			-	X	-			X			X				14)	14)	14)			X
GeneProof™ Factor V Leiden PCR Kit		-				-			-	X	-			X			X				14)	14)	14)			X
GeneProof™ Factor XIII V34L PCR Kit		-				-			-	X	-			X			X				14)	14)	14)			X
GeneProof™ MTHFR A1298C PCR Kit						-			-	X		X		X			X				14)	14)	14)	-	-	X
GeneProof™ MTHFR C677T PCR Kit						-			-	X		X		X			X				14)	14)	14)	-	-	X
GeneProof™ PAI-1 Genotyping PCR Kit						-			-	X				X			X				14)	14)	14)			X

Legend:

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

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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,.

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Mgr. Petra ŠVÁSTOVÁ
Research & Development
Head of Device Characterization

(Name, position and signature of authorized person)



4. 5. 2023

Manufacturer's stamp:

