

GeneProof®



Neuroinfections



Immunocompromised
Transplanted Panel

GeneProof Varicella-Zoster Virus (VZV) PCR Kit



EXCELLENT QUALITY

- The highest possible diagnostic sensitivity (100.00%) and diagnostic specificity (97.37%)

QUALITATIVE AND QUANTITATIVE DETECTION

- Quantification of viral load provides additional information for management of VZV infection

SIMPLE LABORATORY WORKFLOW

- Easily combinable with other GeneProof PCR kits in one run

EASY-TO-USE CONCEPT

- Single tube Ready-to-Use Master Mix contains all components for PCR amplification
- No additional PCR reagents pipetting necessary

CONTAMINATION PREVENTION

- Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating carryover contamination

ORDER INFORMATION

REF	PACKAGE
VZV/GP/025	25 reactions
VZV/GP/100	100 reactions



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof Varicella-Zoster Virus (VZV) PCR Kit

- + GeneProof Cytomegalovirus (CMV) PCR Kit
- + GeneProof Epstein-Barr Virus (EBV) PCR Kit
- + GeneProof BK/JC Virus (BK/JC) PCR Kit
- + GeneProof BK Virus (BKV) PCR Kit
- + GeneProof JC Virus (JCV) PCR Kit
- + GeneProof Adenovirus PCR Kit
- + GeneProof Aspergillus PCR Kit
- + GeneProof Parvovirus B19 PCR Kit
- + GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit
- + GeneProof Human Herpesvirus 6/7 (HHV-6/7) PCR Kit
- + GeneProof Human Herpesvirus 8 (HHV-8) PCR Kit
- + GeneProof Varicella-Zoster Virus (VZV) PCR Kit

INDICATION	<i>in vitro</i> diagnostic medical device				
REGULATORY STATUS	CE ₂₇₉₇ IVD / Regulation (EU) 2017/746				
INTENDED USER	For professional use in laboratories with trained staff				
TECHNOLOGY	Real-time PCR				
TYPE OF ANALYSIS	Qualitative and quantitative				
TARGET SEQUENCE	ORF31 gene				
ANALYTICAL SPECIFICITY	Varicella-Zoster Virus (VZV), 100%				
ANALYTICAL SENSITIVITY (LoD with 95% probability)	Sample processing	Plasma	Serum	Whole blood	CSF
	GeneProof PathogenFree DNA Isolation Kit	113.05 cp/ml	66.10 cp/ml	119.89 cp/ml	66.37 cp/ml
	croBEE 201A Nucleic Acid Extraction Kit	218.84 cp/ml	166.48 cp/ml	170.37 cp/ml	175.13 cp/ml
	myCROBE/croBEE 2.0 Universal Extraction Kit	133.79 cp/ml	61.21 cp/ml	143.17 cp/ml	109.12 cp/ml
DIAGNOSTIC SPECIFICITY	97.37 % (CI _{95%} : 84.57 % - 99.86 %)				
DIAGNOSTIC SENSITIVITY	100.00 % (CI _{95%} : 97.57 % - 100.00 %)				
POSITIVE PREDICTIVE VALUE	99.48 % (CI _{95%} : 96.72 % - 99.97 %)				
NEGATIVE PREDICTIVE VALUE	100.00 % (CI _{95%} : 88.29 % - 100.00 %)				
LINEAR RANGE [cp/ml]	Sample processing	Plasma	Serum	Whole blood	CSF
	with precision of ± 0.8 log				
	GeneProof PathogenFree DNA Isolation Kit		(10 ¹⁰ - 10 ²)	(10 ¹⁰ - 10 ^{2.5})	
	croBEE 201A Nucleic Acid Extraction Kit	(10 ¹⁰ - 10 ^{2.5})	(10 ¹⁰ - 10 ^{2.5})	(10 ¹⁰ - 10 ^{2.5})	(10 ¹⁰ - 10 ^{2.5})
	myCROBE/croBEE 2.0 Universal Extraction Kit		(10 ¹⁰ - 10 ^{2.5})	(10 ¹⁰ - 10 ³)	
DYNAMIC RANGE	(10 ¹⁰ - LoD) cp/ml (LoD varying according to the extraction and material used)				
TRUENESS (of expected concentration)	Sample processing	Plasma	Serum	Whole blood	CSF
		CI _{95%}	CI _{95%}	CI _{95%}	CI _{95%}
	GeneProof PathogenFree DNA Isolation Kit	-0.01 log (-0.15 - 0.14) log	-0.06 log (-0.18 - 0.05) log	-0.09 log (-0.20 - 0.01) log	-0.01 log (-0.14 - 0.12) log
	croBEE 201A Nucleic Acid Extraction Kit	-0.07 log (-0.15 - 0.00) log	-0.01 log (-0.14 - 0.12) log	-0.10 log (-0.17 - -0.02) log	-0.04 log (-0.14 - 0.05) log
	myCROBE/croBEE 2.0 Universal Extraction Kit	0.02 log (-0.14 - 0.18) log	0.00 log (-0.14 - 0.13) log	-0.07 log (-0.17 - 0.03) log	-0.01 log (-0.14 - 0.11) log
PRECISION - REPEATABILITY	Intra-assay SD of log concentration = 0.076 (CI _{95%} : 0.061 - 0.099)				
PRECISION - REPRODUCIBILITY	Inter-assay SD of log concentration = 0.079 (CI _{95%} : 0.051 - 0.174) Inter-lot SD of log concentration = 0.081 (CI _{95%} : 0.052 - 0.177) Total SD of log concentration = 0.081 (CI _{95%} : 0.052 - 0.179)				
REPORTING UNITS	cp/ml				
CONVERSION FACTOR	Not applicable				
METROLOGICAL TRACEABILITY	AcroMetrix™ VZV Plasma Panel				
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control (IC)				
VALIDATED SPECIMEN	DNA extracted from CSF, plasma, serum, whole blood (EDTA), vesicular swab*				
STORAGE	(-20 ± 5) °C				
VALIDATED EXTRACTION METHOD	croBEE 201A Nucleic Acid Extraction Kit myCROBE/croBEE 2.0 Universal Extraction Kit GeneProof PathogenFree DNA Isolation Kit				
APPLIED INSTRUMENTS	croBEE Real-Time PCR System AMPLilab Real-Time PCR System Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96 Real-Time PCR System CFX Connect™ / CFX96™/ Dx Real-Time PCR Detection System CFX Opus 96 Real-Time PCR System Gentier 96E/96R Real-Time PCR System		LightCycler® 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cycler QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / Q SLAN® Real-Time PCR System StepOne™ / StepOne Plus™ Real-Time PCR System		
DETECTION CHANNELS	FAM (VZV), HEX/JOE/VIC (IC)				
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com				

*NOTE: Qualitative detection only.