



Neuroinfections



Immunocompromised
Transplanted Panel

GeneProof[®]

GeneProof Varicella-Zoster Virus (VZV) PCR Kit



EXCELLENT QUALITY

- The highest possible diagnostic sensitivity (100.00%) and diagnostic specificity (97.44%)

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

- Ready-to-Use Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating possible carryover contamination

ORDER INFORMATION

REF	PACKAGE
VZV/ISEX/025	25 reactions
VZV/ISEX/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 IVD				
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	CSV
	GeneProof PathogenFree DNA Isolation Kit	113.1 cp/ml	66.1 cp/ml	119.9 cp/ml	66.4 cp/ml
	croBEE 201A Nucleic Acid Extraction Kit	218.8 cp/ml	166.5 cp/ml	170.4 cp/ml	175.1 cp/ml
DIAGNOSTIC SPECIFICITY*	97.44 % (CI _{95%} : 84.92 % - 99.87 %)				
DIAGNOSTIC SENSITIVITY*	100.00 % (CI _{95%} : 97.52 % - 100.00 %)				
POSITIVE PREDICTIVE VALUE*	99.47 % (CI _{95%} : 96.65 % - 99.97 %)				
NEGATIVE PREDICTIVE VALUE*	100.00 % (CI _{95%} : 88.57 % - 100.00 %)				
LINEAR RANGE	10 ¹⁰ - 102.5 cp/ml with precision of ± 0.8 log				
DYNAMIC RANGE	10 ¹⁰ - LoD cp/ml (LoD varying according to the extraction and material used)				
TRUENESS	-0.01 log (CI _{95%} : -0.15 - 0.14) using manual extraction GeneProof PathogenFree DNA Isolation Kit -0.07 log (CI _{95%} : -0.15 - 0.00) using automatic extraction croBEE 201A Nucleic Acid Extraction Kit				
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				
METROLOGICAL TRACEABILITY	AcroMetrix™ VZV Plasma Panel (cat. no. 954530)				
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Standard (IS)				
VALIDATED SPECIMEN	CSF, plasma, serum, whole blood (EDTA), vesicular swab				
STORAGE	-20 ± 5 °C				
VALIDATED EXTRACTION METHOD	croBEE 201A Nucleic Acid Extraction System GeneProof PathogenFree DNA Isolation Kit				
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		Gentier 96E/96R Real-Time PCR System LightCycler® 480 LineGene 9600 / 9600 Plus Mic qPCR Cycler QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q StepOne™ / StepOne Plus™ Real-Time PCR System SLAN® Real-Time PCR System		
REQUIRED DETECTION CHANNELS	FAM (VZV), HEX/JOE/VIC (IS)				
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com				