



Neuroinfections



Immunocompromised
Transplanted

GeneProof[®]

GeneProof JC Virus (JCV) PCR Kit



W.H.O. STANDARD BASED QUANTIFICATION

- Precise and fully traceable quantification according to 1st WHO International Standard NIBSC JCV 14/114

EASY-TO-USE CONCEPT

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

SIMPLE LABORATORY WORKFLOW

- Easily combinable with other GeneProof PCR kits in one workflow

CONTAMINATION PREVENTION

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

ORDER INFORMATION

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



COMPATIBLE WITH A WIDE
RANGE OF REAL-TIME PCR
DEVICES



CERTIFIED
DIAGNOSTIC TEST

www.geneproof.com

ISO 13485

GUARANTEED CONTROL OVER
THE COMPLETE PROCESS OF DEVELOPMENT,
MANUFACTURING AND DISTRIBUTION OF ALL
THE OFFERED GENEPROOF PRODUCTS



GeneProof JC Virus (JCV) 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	in vitro 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	t-Ag gene encoding small tumor antigen				
ANALYTICAL SPECIFICITY	JC Virus (JCV), 100%				
ANALYTICAL SENSITIVITY (LoD with 95% probability)	Sample Processing	CSF	Plasma	Whole blood	
	GeneProof PathogenFree DNA Isolation Kit	8.4 IU/ml	12.6 IU/ml	34.4 IU/ml	
	croBEE 201A Nucleic Acid Extraction Kit	19.7 IU/ml	40 IU/ml	22.3 IU/ml	
DIAGNOSTIC SPECIFICITY	97.50 % (CI _{95%} : 85.27 % - 99.87 %)				
DIAGNOSTIC SENSITIVITY	100.00 % (CI _{95%} : 84.5 % - 100.00 %)				
POSITIVE PREDICTIVE VALUE	96.43 % (CI _{95%} : 79.76 % - 99.81 %)				
NEGATIVE PREDICTIVE VALUE	100.00 % (CI _{95%} : 88.83 % - 100.00 %)				
LINEAR RANGE	Extraction method	Precision	CSF	Plasma	Whole blood
	GeneProof PathogenFree DNA Isolation Kit	± 0.5 log	10 ¹⁰ - 10 ² IU/ml	10 ¹⁰ - 10 ² IU/ml	10 ¹⁰ - 10 ² IU/ml
	croBEE 201A Nucleic Acid Extraction Kit			10 ¹⁰ - 10 ^{2.5} IU/ml	
DYNAMIC RANGE	10 ¹⁰ - LoD IU/ml (LoD varying according to the extraction and material used)				
TRUENESS (of expected concentration)	Extraction method	CSF	Plasma	Whole blood	
	GeneProof PathogenFree DNA Isolation Kit	-0.05 log (CI _{95%} : -0.13 - 0.02)	-0.06 log (CI _{95%} : -0.14 - 0.02)	-0.09 log (CI _{95%} : -0.19 - 0.00)	
	croBEE 201A Nucleic Acid Extraction Kit	-0.08 log (CI _{95%} : -0.16 - 0.00)	-0.03 log (CI _{95%} : -0.09 - 0.03)	-0.12 log (CI _{95%} : -0.22 - -0.02)	
PRECISION - REPEATABILITY	Intra-assay SD of log concentration = 0.068 (CI _{95%} : 0.055 - 0.089)				
PRECISION - REPRODUCIBILITY	Inter-assay SD of log concentration = 0.078 (CI _{95%} : 0.050 - 0.171) Inter-lot SD of log concentration = 0.094 (CI _{95%} : 0.061 - 0.208) Total SD of log concentration = 0.086 (CI _{95%} : 0.055 - 0.190)				
REPORTING UNITS	IU/ml				
METROLOGICAL TRACEABILITY	1 st WHO International Standard for JC virus DNA (NIBSC code 14/114)				
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control				
VALIDATED SPECIMEN	CSF, plasma, urine, whole blood				
STORAGE	-20 ± 5 °C				
VALIDATED EXTRACTION METHOD	croBEE 201A Nucleic Acid Extraction Kit 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® 480AriaMx Real-Time PCR System LineGene 9600 Plus Mic qPCR Cycler Rotor-Gene 3000 / Q SLAN® Real-Time PCR System		
REQUIRED DETECTION CHANNELS	FAM, HEX/JOE				
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and INSTAND e.V. External Quality Assessment Panels - results at www.geneproof.com				