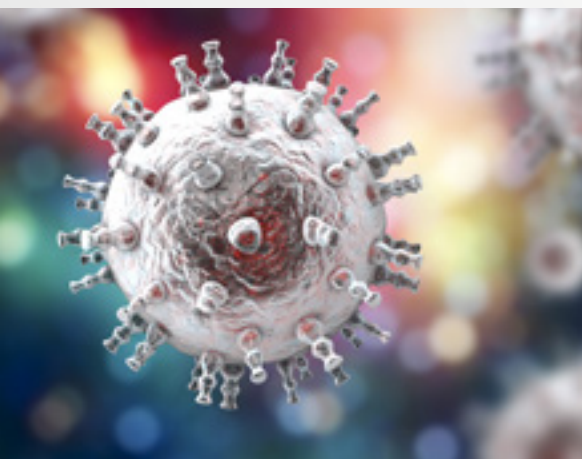




Immunocompromised
Transplanted

GeneProof®

GeneProof BK Virus (BKV) PCR Kit



W.H.O. STANDARD BASED QUANTIFICATION

- Precise and fully traceable quantification according to 1st WHO International Standard NIBSC BKV 14/212
- Enables reliable viral load monitoring

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
BKV/GP/025	25 reactions
BKV/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 BK Virus (BKV) 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 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 Parvovirus B19 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	<i>T-Ag</i> gene encoding large tumor antigen			
ANALYTICAL SPECIFICITY	BK virus (BKV), 100 %			
ANALYTICAL SENSITIVITY (LoD with 95% probability)	Sample Processing	CSF	Plasma	Whole blood
	GeneProof PathogenFree DNA Isolation Kit	240.9 IU/ml	297.0 IU/ml	251.8 IU/ml
	croBEE 201A Nucleic Acid Extraction Kit	532.1 IU/ml	644.7 IU/ml	908.6 IU/ml
DIAGNOSTIC SPECIFICITY	100.00 % (CI _{95%} : 86.27 % - 100.00 %)			
DIAGNOSTIC SENSITIVITY	96.30 % (CI _{95%} : 79.11 % - 99.81 %)			
POSITIVE PREDICTIVE VALUE	100.00 % (CI _{95%} : 83.98 % - 100.00 %)			
NEGATIVE PREDICTIVE VALUE	96.88 % (CI _{95%} : 82.00 % - 99.84 %)			
LINEAR RANGE	10 ¹⁰ - 10 ³ IU/ml with precision of ± 0.5 log (using manual or automatic extraction from plasma, CSF and whole blood)			
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	-0.11 log (CI _{95%} : -0.20 - -0.02)	-0.07 log (CI _{95%} : -0.14 - -0.01)	-0.04 log (CI _{95%} : -0.14 - -0.01)
	croBEE 201A Nucleic Acid Extraction Kit	-0.12 log (CI _{95%} : -0.23 - -0.01)	-0.06 log (CI _{95%} : -0.12 - 0.00)	-0.07 log (CI _{95%} : -0.15 - 0.00)
PRECISION - REPEATABILITY	Intra-assay SD of log concentration = 0.061 (CI _{95%} : 0.050 - 0.080)			
PRECISION - REPRODUCIBILITY	Inter-assay SD of log concentration = 0.112 (CI _{95%} : 0.072 - 0.246) Inter-lot SD of log concentration = 0.206 (CI _{95%} : 0.133 - 0.454) Total SD of log concentration = 0.243 (CI _{95%} : 0.157 - 0.536)			
REPORTING UNITS	IU/ml			
CONVERSION FACTOR	1 IU = 1 cp			
METROLOGICAL TRACEABILITY	1 st WHO International Standard for BK virus DNA (NIBSC code 14/212)			
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 Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx Real-Time PCR System		CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System LineGene 9600 Plus 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			