



Neuroinfections



Immunocompromised
Transplanted

GeneProof®

GeneProof BK/JC Virus (BK/JC) PCR Kit



MORE INFORMATION FROM ONE REACTION

- Detects and distinguishes BK virus and JC virus in a single reaction tube
- Enables qualitative and quantitative detection of both viruses

CONTAMINATION PREVENTION

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

SIMPLE LABORATORY WORKFLOW

- Easily combinable with other GeneProof PCR kits

EASY-TO-USE CONCEPT

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

ORDER INFORMATION

REF	PACKAGE
BKJC/ISEX/025	25 reactions
BKJC/ISEX/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/JC Virus (BK/JC) 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	T-Ag gene encoding large tumor antigen (BKV) and t-Ag gene encoding small tumor antigen (JCV)			
ANALYTICAL SPECIFICITY	BK virus, 100% JC virus, 100%			
ANALYTICAL SENSITIVITY (LoD with 95% probability)	Sample Processing	BKV	JCV	
	GeneProof PathogenFree DNA Isolation Kit	218.73 IU/ml	22.89 IU/ml	
	croBEE 201A Nucleic Acid Extraction Kit	522.70 IU/ml	56.56 IU/ml	
DIAGNOSTIC SPECIFICITY	100.00 % (BKV: CI _{95%} : 67.85 % - 100.00 %; JCV: CI _{95%} : 95.45 % - 100.00 %)			
DIAGNOSTIC SENSITIVITY	100.00 % (BKV: CI _{95%} : 84.50 % - 100.00 %; JCV: CI _{95%} : 98.65 % - 100.00 %)			
POSITIVE PREDICTIVE VALUE	100.00 % (BKV: CI _{95%} : 67.85 % - 100.00 %; JCV: CI _{95%} : 95.45 % - 100.00 %)			
NEGATIVE PREDICTIVE VALUE	100.00 % (BKV: CI _{95%} : 84.50 % - 100.00 %; JCV: CI _{95%} : 98.65 % - 100.00 %)			
LINEAR RANGE	Extraction method	Precision	BKV	JCV
	GeneProof PathogenFree DNA Isolation Kit	± 0.5 log	(10 ¹⁰ - 10 ³) IU/ml	(10 ¹⁰ - 10 ²) IU/ml
	croBEE 201A Nucleic Acid Extraction Kit	± 0.5 log	(10 ¹⁰ - 10 ³) IU/ml	(10 ¹⁰ - 10 ²) IU/ml
DYNAMIC RANGE	10 ¹⁰ IU/ml - LoD (LoD varying according to the extraction)			
PRECISION - REPEATABILITY	• Intra-assay	FAM: SD of log concentration = 0.046 (CI _{95%} : 0.037 - 0.061) Cy5: SD of log concentration = 0.046 (CI _{95%} : 0.037 - 0.060)		
PRECISION - REPRODUCIBILITY	• Inter-assay	FAM: SD of log concentration = 0.044 (CI _{95%} : 0.028 - 0.097) Cy5: SD of log concentration = 0.046 (CI _{95%} : 0.030 - 0.101)		
	• Inter-lot	FAM: SD of log concentration = 0.053 (CI _{95%} : 0.034 - 0.116) Cy5: SD of log concentration = 0.055 (CI _{95%} : 0.036 - 0.122)		
	• Total	FAM: SD of log concentration = 0.050 (CI _{95%} : 0.032 - 0.111) Cy5: SD of log concentration = 0.053 (CI _{95%} : 0.034 - 0.116)		
REPORTING UNITS	IU/ml			
METROLOGICAL TRACEABILITY	1 st WHO International Standard for BK Virus DNA (NIBSC code 14/212) 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 (IC)			
VALIDATED SPECIMEN	CSF, plasma, urine, whole blood			
STORAGE	-20 ± 5 °C			
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree DNA Isolation Kit myCROBE/croBEE 2.0 Universal Extraction Kit			
INSTRUMENTS	croBEE Real-Time PCR System AMPLilab Real-Time PCR System Applied Biosystems 7500 Real-Time PCR System AriaMx Real-Time PCR System CFX96™ / Dx Real-Time PCR Detection System		Gentier 96E/96R Real-Time PCR System LightCycler® 480 LineGene 9600 / 9600 Plus QuantStudio™ 5 Real-Time PCR System Rotor-Gene 3000 / Q SLAN® Real-Time PCR System	
REQUIRED DETECTION CHANNELS	FAM (JCV), Cy5 (BKV), HEX/JOE/VIC (IC)			
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com			