

GeneProof®



Immunocompromised
Transplanted Panel

GeneProof Epstein-Barr Virus (EBV) PCR Kit



W.H.O. STANDARD BASED QUANTIFICATION

- Precise and fully traceable quantification according to WHO 1st International Standard NIBSC 09/260
- Enables reliable viral load monitoring

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

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
EBV/GP/025	25 reactions
EBV/GP/100	100 reactions



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof Epstein-Barr Virus (EBV) 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	EBNA1							
ANALYTICAL SPECIFICITY	Epstein-Barr virus, 100 %							
ANALYTICAL SENSITIVITY (LoD with 95% probability)	Sample processing	Plasma	Whole blood	CSF	BAL			
	GeneProof PathogenFree DNA Isolation Kit	196.1 IU/ml	129.2 IU/ml	110.8 IU/ml	206.0 IU/ml			
	croBEE 201A Nucleic Acid Extraction Kit	289.5 IU/ml	250.2 IU/ml	586.1 IU/ml	138.1 IU/ml			
DIAGNOSTIC SPECIFICITY	94.19 % (CI _{95%} : 86.35 % - 97.84 %)							
DIAGNOSTIC SENSITIVITY	99.10 % (CI _{95%} : 96.45 % - 99.84 %)							
POSITIVE PREDICTIVE VALUE	97.79 % (CI _{95%} : 94.63 % - 99.18 %)							
NEGATIVE PREDICTIVE VALUE	94.59 % (CI _{95%} : 90.76 % - 99.58 %)							
LINEAR RANGE	Extraction method	Precision	Plasma	Whole blood	BAL	Precision	CSF	
	GeneProof PathogenFree DNA Isolation Kit	± 0.5 log	10 ¹⁰ - 10 ^{2.5} IU/ml	10 ¹⁰ - 10 ^{2.5} IU/ml	10 ¹⁰ - 10 ^{2.5} IU/ml	± 0.6 log	10 ¹⁰ - 10 ^{2.5} IU/ml	
	croBEE 201A Nucleic Acid Extraction Kit		10 ¹⁰ - 10 ³ IU/ml	10 ¹⁰ - 10 ³ IU/ml	10 ¹⁰ - 10 ³ IU/ml		10 ¹⁰ - 10 ³ IU/ml	
DYNAMIC RANGE	10 ¹⁰ - LoD IU/ml (LoD varying according to the extraction method and material used)							
TRUENESS	-0.07 log (CI _{95%} : -0.13 - 0.00) using manual extraction GeneProof PathogenFree DNA Isolation Kit -0.08 log (CI _{95%} : -0.13 - 0.03) using automatic extraction croBEE 201A Nucleic Acid Extraction Kit							
PRECISION - REPEATABILITY	Intra-assay SD of log concentration = 0.084 (CI _{95%} : 0.068 - 0.110)							
PRECISION - REPRODUCIBILITY	Inter-assay SD of log concentration = 0.092 (CI _{95%} : 0.059 - 0.202) Inter-lot SD of log concentration = 0.112 (CI _{95%} : 0.072 - 0.246) Total SD of log concentration = 0.115 (CI _{95%} : 0.074 - 0.254)							
REPORTING UNITS	IU/ml							
CONVERSION FACTOR	1 IU = 1 cp							
METROLOGICAL TRACEABILITY	1 st WHO International Standard for Epstein-Barr Virus for Nucleic Acid Amplification Techniques, code: EBV NIBSC 09/260							
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency by Internal Control (IC)							
VALIDATED SPECIMEN	DNA extracted from BAL, CSF, plasma, whole blood (EDTA)*							
STORAGE	(-20 ± 5) °C							
VALIDATED EXTRACTION METHOD	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree DNA Isolation Kit							
INSTRUMENTS	croBEE Real-Time PCR System	LightCycler® 2.0 / 480					LineGene 9600 / 9600 Plus	
	AMPLilab Real-Time PCR System	Applied Biosystems 7300 / 7500 Real-Time PCR System					Mic qPCR Cycler	
	AriaMx Real-Time PCR System	Montania 4896 Real-Time PCR thermocycler					QuantStudio™ 3 / 5 Real-Time PCR System	
	BioQuant-96 Real-Time PCR System	CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System					Rotor-Gene 3000 / Q	
	CFX Opus Real-Time PCR System	Gentier 96E/96R Real-Time PCR System					SLAN® Real-Time PCR System	
							StepOne™ / StepOne Plus™ Real-Time PCR System	
REQUIRED DETECTION CHANNELS	FAM (EBV), HEX/JOE/VIC (IC)							
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com							

* EBV persists latently in memory B-cell at low viral level. Therefore, even healthy individuals can carry measurable EBV loads in their peripheral blood.