

## GeneProof Epstein-Barr Virus (EBV) PCR Kit



### W.H.O. STANDARD BASED QUANTIFICATION

- Precise and fully traceable quantification according to WHO 1<sup>st</sup> 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	in vitro diagnostic medical device						
REGULATORY STATUS	CE <sub>2797</sub> 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 <sub>95%</sub> : 86.35 % – 97.84 %)						
DIAGNOSTIC SENSITIVITY	99.10 % (CI <sub>95%</sub> : 96.45 % – 99.84 %)						
POSITIVE PREDICTIVE VALUE	97.79 % (CI <sub>95%</sub> : 94.63 % – 99.18 %)						
NEGATIVE PREDICTIVE VALUE	94.59 % (CI <sub>95%</sub> : 90.76 % – 99.58 %)						
LINEAR RANGE	Extraction method	Precision	Plasma	Whole blood	BAL	Precision	CSF
	GeneProof PathogenFree DNA Isolation Kit	± 0.5 log	10 <sup>10</sup> – 10 <sup>2.5</sup> IU/ml	10 <sup>10</sup> – 10 <sup>2.5</sup> IU/ml	10 <sup>10</sup> – 10 <sup>2.5</sup> IU/ml	± 0.6 log	10 <sup>10</sup> – 10 <sup>2.5</sup> IU/ml
	croBEE 201A Nucleic Acid Extraction Kit		10 <sup>10</sup> – 10 <sup>3</sup> IU/ml	10 <sup>10</sup> – 10 <sup>3</sup> IU/ml	10 <sup>10</sup> – 10 <sup>3</sup> IU/ml		10 <sup>10</sup> – 10 <sup>3</sup> IU/ml
DYNAMIC RANGE	10 <sup>10</sup> – LoD IU/ml (LoD varying according to the extraction method and material used)						
TRUENESS	-0.07 log (CI <sub>95%</sub> : -0.13 – 0.00) using manual extraction GeneProof PathogenFree DNA Isolation Kit -0.08 log (CI <sub>95%</sub> : -0.13 – 0.03) using automatic extraction croBEE 201A Nucleic Acid Extraction Kit						
PRECISION – REPEATABILITY	Intra-assay SD of log concentration = 0.084 (CI <sub>95%</sub> : 0.068 – 0.110)						
PRECISION – REPRODUCIBILITY	Inter-assay SD of log concentration = 0.092 (CI <sub>95%</sub> : 0.059 – 0.202) Inter-lot SD of log concentration = 0.112 (CI <sub>95%</sub> : 0.072 – 0.246) Total SD of log concentration = 0.115 (CI <sub>95%</sub> : 0.074 – 0.254)						
REPORTING UNITS	IU/ml						
CONVERSION FACTOR	1 IU = 1 cp						
METROLOGICAL TRACEABILITY	1 <sup>st</sup> 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 <b>BAL, CSF, plasma, whole blood (EDTA)*</b>						
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 CFX Opus Real-Time PCR System Gentier 96E/96R Real-Time PCR System			LightCycler® 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cycler Montania 4896 Real-Time PCR thermocycler QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / Q 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 <a href="http://www.geneproof.com">www.geneproof.com</a>						

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