



GeneProof

GeneProof Epstein-Barr Virus (EBV) PCR Kit



EXCELLENT EQA PANEL RESULTS

- The highest possible diagnostic sensitivity (100.00%) and diagnostic specificity (100.00%) confirmed by analysis of EQA panel reports from 2008 to present (including infrequently detected rare samples with very low concentrations)

UNIVERSAL PCR PROFILE

- Easily combinable with other PCR kits from the Immunocompromised / Transplanted group
- Simplifies laboratory workflow

FULL TRACEABLE SENSITIVITY AND QUANTIFICATION

- Sensitivity was established with WHO certified strain (WHO International Standard NIBSC 09/260)
- Precise and fully traceable quantification according to NIBSC 09/260

CONTAMINATION ELIMINATION

- Ready-to-Use Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating possible contamination with amplification products



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof Epstein-Barr Virus (EBV) PCR Kit

- + Human Herpesvirus 6/7 (HHV-6/7) PCR Kit
- + Herpes Simplex Virus 1 (HSV-1) PCR Kit
- + Aspergillus PCR Kit
- + Cytomegalovirus (CMV) PCR Kit
- + Herpes Simplex Virus 2 (HSV-2) PCR Kit
- + BK/JC Virus (BK/JC) PCR Kit
- + Epstein-Barr Virus (EBV) PCR Kit
- + Herpes Simplex Virus (HSV-1/2) PCR Kit
- + Parvovirus B19 PCR Kit
- + Varicella Zoster Virus (VZV) PCR Kit
- + Human Herpesvirus 8 (HHV-8) PCR Kit

TECHNOLOGY	real-time PCR
TYPE OF ANALYSIS	qualitative and quantitative
TARGET SEQUENCE	DNA sequence of the single copy gene encoding the nuclear antigen 1 (EBNA1)
ANALYTICAL SPECIFICITY	Epstein-Barr virus, 100%
ANALYTICAL SENSITIVITY (LOD)	reaches up to 196.088 IU/ml with the probability of 95% (on NIBSC EBV 09/260 using manual extraction GeneProof PathogenFree DNA Isolation Kit) reaches up to 289.46 IU/ml with the probability of 95% (on NIBSC EBV 09/260 using automatic extraction croBEE NA16 Nucleic Acid Extraction System)
DIAGNOSTIC SPECIFICITY	100% (CI _{95%} : 83.98% - 100%) according to EQA panels results 90.91% (CI _{95%} : 79.29% - 96.60%) according to Clinical performance analysis 2019
DIAGNOSTIC SENSITIVITY	100% (CI _{95%} : 96.53% - 100%) according to EQA panels results 98.08% (CI _{95%} : 88.42% - 99.90%) according to Clinical performance analysis 2019
LINEAR RANGE	10 ¹⁰ - 10 ^{2.5} IU/ml with precision of ± 0.5 log (using manual extraction GeneProof PathogenFree DNA Isolation Kit) 10 ¹⁰ - 10 ^{2.46} IU/ml with precision of ± 0.5 log (using automatic extraction croBEE NA16 Nucleic Acid Extraction System)
DYNAMIC RANGE	10 ¹⁰ - 196.088 IU/ml (using manual extraction GeneProof PathogenFree DNA Isolation Kit) 10 ¹⁰ - 289.46 IU/ml (using automatic extraction croBEE NA16 Nucleic Acid Extraction System)
REPORTING UNITS	cp/μl
CONVERSION FACTOR	1 IU = 1 cp
METROLOGICAL TRACEABILITY	EBV NIBSC 09/260
EXTRACTION / INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control (ISEX version)
VALIDATED SPECIMEN	CSF, plasma, whole blood, BAL
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE NA16 Nucleic Acid Extraction System 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 LightCycler® 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cyclers QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / Q SLAN® Real-Time PCR System StepOne™ / StepOnePlus™ Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM, HEX
EXTERNAL QUALITY ASSESSMENT	regularly tested by QCMD and Instand e.V. External Quality Assessment panels - results at www.geneproof.com
REGULATORY STATUS	CE IVD

*Validated instruments

PRODUCT NAME	TECHNOLOGY	ORDER NO.		
		25 REACTIONS	50 REACTIONS	100 REACTIONS
GeneProof Epstein-Barr Virus (EBV) PCR Kit	real-time PCR	EBV/ISEX/025	EBV/ISEX/050	EBV/ISEX/100