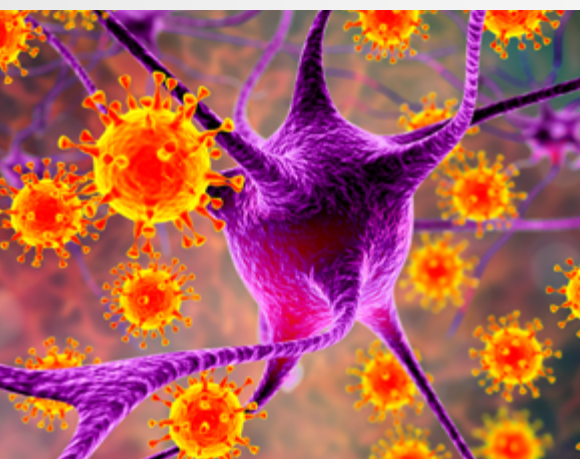




Immunocompromised
Transplanted

GeneProof®

GeneProof Epstein-Barr Virus (EBV) PCR Kit



PART OF I/T PANEL

- Easily combinable with other PCR kits from the Immunocompromised / Transplanted Panel in one workflow
- Simplifies laboratory workflow

EASY-TO-USE CONCEPT

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

CONTAMINATION PREVENTION

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

W.H.O. STANDARD BASED QUANTIFICATION



- Precise and fully traceable quantification according to WHO 1st International Standard NIBSC 09/260

ORDER INFORMATION

REF	PACKAGE
EBV/ISEX/025	25 reactions
EBV/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 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 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

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 WITH 95 % PROBABILITY)	Performed on EBV NIBSC 09/260	manual extraction GeneProof PathogenFree DNA Isolation Kit	automatic extraction croBEE 201A Nucleic Acid Extraction Kit
	Plasma	196.1 IU/ml	289.5 IU/ml
	Whole blood	129.2 IU/ml	250.2 IU/ml
	CSF	110.8 IU/ml	586.1 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	10 ¹⁰ - 10 ^{2.5} IU/ml with precision of ± 0.5 log (using manual extraction GeneProof PathogenFree DNA Isolation Kit) 10 ¹⁰ - 10 ^{2.5} IU/ml with precision of ± 0.5 log (using automatic extraction croBEE 201A Nucleic Acid Extraction Kit)		
DYNAMIC RANGE	10 ¹⁰ - 196.1 IU/ml (using manual extraction GeneProof PathogenFree DNA Isolation Kit) 10 ¹⁰ - 289.5 IU/ml (using automatic extraction croBEE 201A Nucleic Acid Extraction Kit)		
TRUENESS	-0.07 log (CI _{95%} : -0.13 - 0.00) of expected concentration using manual extraction GeneProof PathogenFree DNA Isolation Kit -0.08 log (CI _{95%} : -0.13 - 0.03) of expected concentration 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/μl		
CONVERSION FACTOR	1 IU = 1 cp		
METROLOGICAL TRACEABILITY	EBV NIBSC 09/260 (1st WHO International Standard for Epstein-Barr Virus for Nucleic Acid Amplification Techniques)		
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control		
VALIDATED SPECIMEN	BAL**, CSF, plasma, 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 LightCycler® 2.0 / 480	LineGene 9600 / 9600 Plus Mic qPCR Cycler Montania 4896 Real-Time PCR termocykler 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, 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		

* EBV persists latently in memory B-cell at low viral level. Therefore, even healthy individuals can carry measurable EBV load in their peripheral blood.
 ** Due to the possible inhomogeneity in the BAL collection, the product is intended only for qualitative determination from this material.