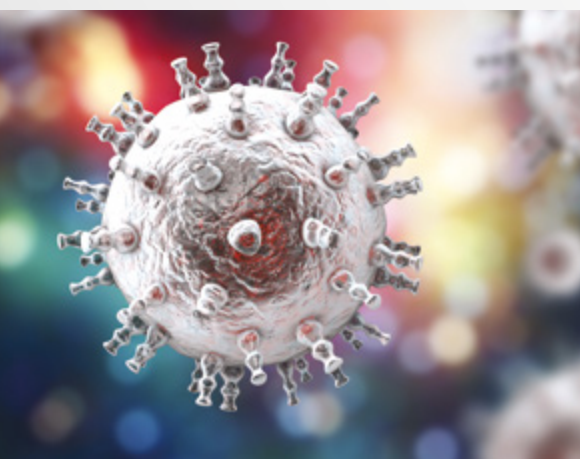




Immunocompromised  
Transplanted

# GeneProof®

## GeneProof Human Herpesvirus 8 (HHV-8) PCR Kit



### DUAL TARGET DETECTION

- Dual targeting prevents a detection failure caused by the occurrence of mutations

### 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

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

### QUALITATIVE AND QUANTITATIVE DETECTION

- Unique possibility to quantify viral load

### SIMPLE LABORATORY WORKFLOW

- Easily combinable with other GeneProof PCR kits in one workflow

#### ORDER INFORMATION

REF	PACKAGE
HHV8/ISEX/025	25 reactions
HHV8/ISEX/100	100 reactions



COMPATIBLE WITH A WIDE  
RANGE OF REAL-TIME PCR  
DEVICES



CERTIFIED  
DIAGNOSTIC TEST

[www.geneproof.com](http://www.geneproof.com)

ISO 13485

GUARANTEED CONTROL OVER  
THE COMPLETE PROCESS OF DEVELOPMENT,  
MANUFACTURING AND DISTRIBUTION OF ALL  
THE OFFERED GENEPROOF PRODUCTS



# GeneProof Human Herpesvirus 8 (HHV-8) 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 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

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	ORF26 gene, ORF73 gene		
ANALYTICAL SPECIFICITY	Human Herpesvirus 8 (HHV-8), 100 %		
ANALYTICAL SENSITIVITY	0.47 cp/μl		
DIAGNOSTIC SPECIFICITY	92.86 % (CI <sub>95%</sub> : 64.17 % - 99.63 %)		
DIAGNOSTIC SENSITIVITY	100.00 % (CI <sub>95%</sub> : 69.87 % - 100.00 %)		
POSITIVE PREDICTIVE VALUE	92.31 % (CI <sub>95%</sub> : 62.09 % - 99.60 %)		
NEGATIVE PREDICTIVE VALUE	100.00 % (CI <sub>95%</sub> : 71.65 % - 100.00 %)		
LINEAR RANGE	10 <sup>9</sup> - 10 <sup>4</sup> cp/ml with precision of ± 0.5 log		
DYNAMIC RANGE	10 <sup>9</sup> - LoD cp/ml (LoD varying according to the extraction and material used)		
PRECISION - REPEATABILITY	Intra-assay SD of log concentration = 0.063 (CI <sub>95%</sub> : 0.050 - 0.084)		
PRECISION - REPRODUCIBILITY	Inter-assay SD of log concentration = 0.078 (CI <sub>95%</sub> : 0.049 - 0.191)	Inter-lot SD of log concentration = 0.088 (CI <sub>95%</sub> : 0.055 - 0.216)	Total SD of log concentration = 0.084 (CI <sub>95%</sub> : 0.052 - 0.205)
REPORTING UNITS	cp/ml		
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Standard (IS)		
VALIDATED SPECIMEN	CSF, plasma, saliva, 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 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 Gentier 96E/96R Real-Time PCR System	LightCycler® 480 LineGene 9600 / 9600 Plus Mic qPCR Cyclor Montania 4896 Real-Time PCR termocycler QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System StepOne™ / StepOnePlus™ Real-Time PCR System	
REQUIRED DETECTION CHANNELS	FAM (HHV-8), HEX/JOE/VIC (IS)		
EXTERNAL QUALITY ASSESSMENT	Regularly tested in Instand e.V. External Quality Assessment Panels - results at <a href="http://www.geneproof.com">www.geneproof.com</a>		