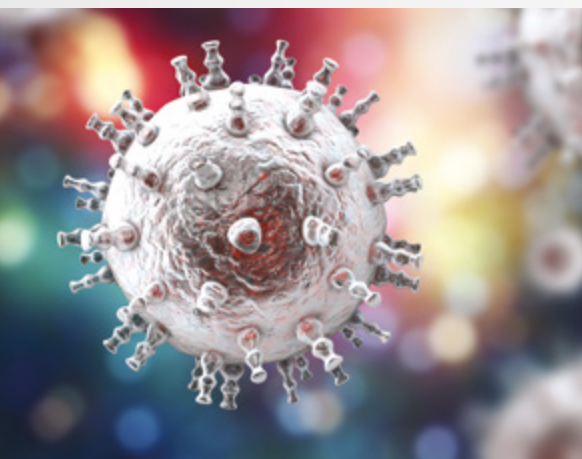


GeneProof®



Immunocompromised
Transplanted Panel

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/GP/025	25 reactions
HHV8/GP/100	100 reactions



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



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 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	ORF26 gene, ORF73 gene				
ANALYTICAL SPECIFICITY	Human Herpesvirus 8 (HHV-8), 100%				
ANALYTICAL SENSITIVITY (LoD with 95% probability)	Sample processing	Plasma	Whole blood	CSF	Saliva
	GeneProof PathogenFree DNA Isolation Kit	238.14 cp/ml	2225.03 cp/ml	229.49 cp/ml	250.67 cp/ml
	croBEE 201A Nucleic Acid Extraction Kit	377.65 cp/ml	287.91 cp/ml	372.70 cp/ml	176.14 cp/ml
	myCROBE/croBEE 2.0 Universal Extraction Kit	269.09 cp/ml	1304.68 cp/ml	179.54 cp/ml	203.77 cp/ml
	<i>NOTE: Performed on EQA panel Instand HHV-8 (406), with the exception of whole blood, GeneProof PathogenFree DNA Isolation Kit - performed on cell culture of HHV-8, SZU, 2017.</i>				
DIAGNOSTIC SPECIFICITY	93.75 % (CI _{95%} : 67.71 % - 99.67 %)				
DIAGNOSTIC SENSITIVITY	100.00 % (CI _{95%} : 73.24 % - 100.00 %)				
POSITIVE PREDICTIVE VALUE	93.33 % (CI _{95%} : 66.03 % - 99.65 %)				
NEGATIVE PREDICTIVE VALUE	100.00 % (CI _{95%} : 74.65 % - 100.00 %)				
LINEAR RANGE [cp/ml]	Sample processing	Precision	Plasma	Whole blood	CSF
	GeneProof PathogenFree DNA Isolation Kit		(10 ⁹ - 10 ³)	(10 ⁹ - 10 ³)	
	croBEE 201A Nucleic Acid Extraction Kit	± 0.8 log	(10 ⁹ - 10 ³)	(10 ⁹ - 10 ³)	(10 ⁹ - 10 ³)
	myCROBE/croBEE 2.0 Universal Extraction Kit		(10 ⁹ - 10 ^{2.5})	(10 ⁹ - 10 ^{3.5})	
DYNAMIC RANGE	(10 ⁹ - LoD) cp/ml (LoD varying according to the extraction and material used)				
TRUENESS (of expected concentration)	Sample processing		Plasma	Whole blood	CSF
			CI _{95%}	CI _{95%}	CI _{95%}
	GeneProof PathogenFree DNA Isolation Kit		0.11 log (-0.14 - 0.37) log	0.07 log (-0.13 - 0.28) log	0.15 log (-0.14 - 0.44) log
	croBEE 201A Nucleic Acid Extraction Kit		0.11 log (-0.13 - 0.34) log	-0.02 log (-0.18 - 0.14) log	0.12 log (-0.14 - 0.39) log
	myCROBE/croBEE 2.0 Universal Extraction Kit		0.05 log (-0.14 - 0.25) log	-0.07 log (-0.20 - 0.06) log	0.12 log (-0.15 - 0.39) log
PRECISION - REPEATABILITY	Intra-assay SD of log concentration = 0.063 (CI _{95%} : 0.050 - 0.084)				
PRECISION - REPRODUCIBILITY	Inter-assay SD of log concentration = 0.078 (CI _{95%} : 0.049 - 0.191) Inter-lot SD of log concentration = 0.088 (CI _{95%} : 0.055 - 0.216) Total SD of log concentration = 0.084 (CI _{95%} : 0.052 - 0.205)				
REPORTING UNITS	cp/ml				
CONVERSION FACTOR	Not applicable				
METROLOGICAL TRACEABILITY	Not applicable				
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control (IC)				
VALIDATED SPECIMEN	DNA extracted from CSF, plasma, whole blood (EDTA), saliva*				
STORAGE	(-20 ± 5) °C				
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit myCROBE/croBEE 2.0 Universal Extraction Kit GeneProof PathogenFree DNA Isolation Kit				
APPLIED 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® 2.0 / 480		LineGene 9600 / 9600 Plus Montania 4896 Real-Time PCR thermocycler Mic qPCR Cycler QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System StepOne™ / StepOne Plus™ Real-Time PCR System		
DETECTION CHANNELS	FAM (HHV-8), HEX/JOE/VIC (IC)				
EXTERNAL QUALITY ASSESSMENT	Regularly tested in Instand e.V. External Quality Assessment Panels - results at www.geneproof.com				

* NOTE: Qualitative detection only.