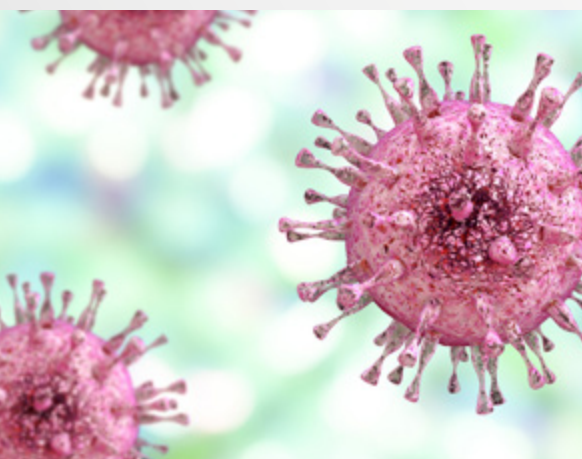


# GeneProof®



Immunocompromised  
Transplanted Panel

## GeneProof Human Herpesvirus 6/7 (HHV-6/7) PCR Kit



### MORE INFORMATION WITH LESS SAMPLES

- PCR Kit detects both viruses in a single reaction tube

### QUANTITATIVE DETECTION OF BOTH VIRUSES

- Precise quantification of the both viruses in two separate detection channels

### SIMPLE LABORATORY WORKFLOW

- Easily combinable with other GeneProof PCR kits in one workflow

### HIGH SENSITIVITY AND TRACEABILITY

- Sensitivity was established with WHO certified strain

### CONTAMINATION PREVENTION

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

#### ORDER INFORMATION

REF	PACKAGE
HHV/GP/025	25 reactions
HHV/GP/100	100 reactions



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



# GeneProof Human Herpesvirus 6/7 (HHV-6/7) 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 <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	U94 gene (HHV-6A/B), U57 gene (HHV-7)			
ANALYTICAL SPECIFICITY	Human Herpesvirus 6 (HHV-6), 100 % Human Herpesvirus 7 (HHV-7), 100 %			
ANALYTICAL SENSITIVITY (LoD with 95% probability)	<b>Sample processing</b>	<b>Plasma</b>	<b>Whole blood</b>	<b>CSF</b>
	GeneProof PathogenFree DNA Isolation Kit	134.89 IU/ml	169.02 IU/ml	152.27 IU/ml
	croBEE 201A Nucleic Acid Extraction Kit	312.85 IU/ml	448.41 IU/ml	793.35 IU/ml
	myCROBE/croBEE 2.0 Universal Extraction Kit	274.46 IU/ml	1132.02 IU/ml	904.58 IU/ml
DIAGNOSTIC SPECIFICITY	97.58 % (CI <sub>95%</sub> : 92.56 % - 99.37 %)			
DIAGNOSTIC SENSITIVITY	96.97 % (CI <sub>95%</sub> : 82.49 % - 99.84 %)			
POSITIVE PREDICTIVE VALUE	91.43 % (CI <sub>95%</sub> : 75.81 % - 97.76 %)			
NEGATIVE PREDICTIVE VALUE	99.18 % (CI <sub>95%</sub> : 94.85 % - 99.96 %)			
LINEAR RANGE [IU/ml]	<b>HHV-6:</b>	<b>Precision</b>	<b>Plasma</b>	<b>Whole blood</b>
	GeneProof PathogenFree DNA Isolation Kit		(10 <sup>8</sup> - 10 <sup>2.5</sup> )	(10 <sup>8</sup> - 10 <sup>2.5</sup> )
	croBEE 201A Nucleic Acid Extraction Kit	± 0.5 log	(10 <sup>8</sup> - 10 <sup>2.5</sup> )	(10 <sup>8</sup> - 10 <sup>3</sup> )
	myCROBE/croBEE 2.0 Universal Extraction Kit		(10 <sup>8</sup> - 10 <sup>3</sup> )	(10 <sup>8</sup> - 10 <sup>3</sup> )
	<b>HHV-7*:</b> 10 <sup>8</sup> - 10 <sup>2.5</sup> IU/ml with precision of ± 0.5 log (determined on positive control)			
DYNAMIC RANGE	10 <sup>8</sup> - LoD IU/ml (LoD varying according to the extraction and material used)			
TRUENESS	<b>Extraction Method</b>	<b>Plasma</b>	<b>Whole blood</b>	<b>CSF</b>
		CI <sub>95%</sub>	CI <sub>95%</sub>	CI <sub>95%</sub>
	GeneProof PathogenFree DNA Isolation Kit	0.005 log -0.05 - 0.06 log	-0.05 log -0.17 - 0.06 log	-0.09 log -0.22 - 0.05 log
	croBEE 201A Nucleic Acid Extraction Kit	-0.002 log -0.08 - 0.07 log	-0.05 log -0.14 - 0.04 log	-0.05 log -0.16 - 0.06 log
	myCROBE/croBEE 2.0 Universal Extraction Kit	-0.09 log -0.24 - 0.07 log	-0.02 log -0.11 - 0.07 log	-0.09 log -0.23 - 0.05 log
PRECISION - REPEATABILITY	Intra-assay	SD of log concentration (FAM) = 0.066 (CI <sub>95%</sub> : 0.053 - 0.086) SD of log concentration (Cy5) = 0.077 (CI <sub>95%</sub> : 0.062 - 0.101)		
PRECISION - REPRODUCIBILITY	Intra-assay	SD of log concentration (FAM) = 0.094 (CI <sub>95%</sub> : 0.061 - 0.208) SD of log concentration (Cy5) = 0.087 (CI <sub>95%</sub> : 0.056 - 0.191)		
	Inter-lot	SD of log concentration (FAM) = 0.073 (CI <sub>95%</sub> : 0.047 - 0.160) SD of log concentration (Cy5) = 0.074 (CI <sub>95%</sub> : 0.048 - 0.163)		
	Total	SD of log concentration (FAM) = 0.090 (CI <sub>95%</sub> : 0.058 - 0.199) SD of log concentration (Cy5) = 0.088 (CI <sub>95%</sub> : 0.057 - 0.194)		
REPORTING UNITS	IU/ml			
CONVERSION FACTOR	1 IU = 0.6 cp (FAM), 1 cp = 1.8 IU (FAM), 1 cp = 1 IU (Cy5)			
METROLOGICAL TRACEABILITY	1 <sup>st</sup> WHO International Standard for HHV-6B virus DNA, NIBSC code: 15/266			
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by the Internal Control (IC)			
VALIDATED SPECIMEN	DNA extracted from <b>CSF, plasma, whole blood (EDTA)</b>			
STORAGE	(-20 ± 5) °C			
VALIDATED EXTRACTION METHOD	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	LightCycler <sup>®</sup> 480		
	AMPLilab Real-Time PCR System	LineGene 9600 Plus		
	Applied Biosystems 7500 Real-Time PCR System	Mic qPCR Cycler		
	AriaMx Real-Time PCR System	QuantStudio <sup>™</sup> 5 Real-Time PCR System		
	BioQuant-96 Real-Time PCR System	Rotor-Gene Q		
	CFX96 <sup>™</sup> / Dx Real-Time PCR Detection System	SLAN <sup>®</sup> Real-Time PCR System		
	Gentier 96E/96R Real-Time PCR System			
DETECTION CHANNELS	FAM (HHV-6), HEX/JOE/VIC (IC), Cy5* (HHV-7)			
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>			

\*NOTE: Due to the availability of the international reference standard only for HHV-6, it is possible to monitor HHV-7 without metrological traceability.