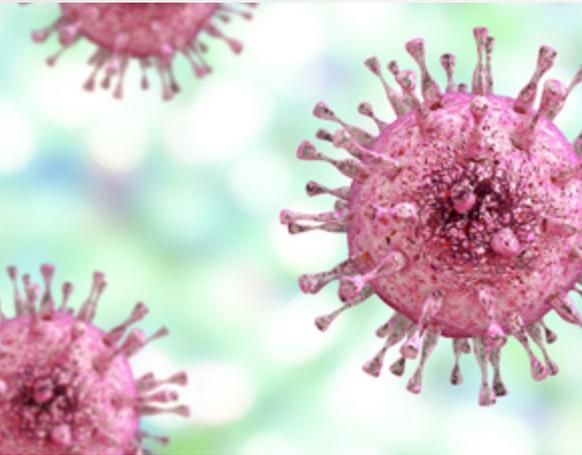




GeneProof®

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/ISEX/025	25 reactions
HHV/ISEX/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 IVD			
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 6/7 (HHV-6/7), 100%			
ANALYTICAL SENSITIVITY (LoD with 95% probability)	Sample Processing	Plasma	Whole blood	CSF
	GeneProof PathogenFree DNA Isolation Kit	134.9 IU/ml	169.0 IU/ml	152.3 IU/ml
	croBEE 201A Nucleic Acid Extraction Kit	312.9 IU/ml	448.4 IU/ml	793.4 IU/ml
DIAGNOSTIC SPECIFICITY	97.73 % (CI _{95%} : 92.99 % - 99.41 %)			
DIAGNOSTIC SENSITIVITY	98.72 % (CI _{95%} : 92.09 % - 99.93 %)			
POSITIVE PREDICTIVE VALUE	96.25 % (CI _{95%} : 88.68 % - 99.03 %)			
NEGATIVE PREDICTIVE VALUE	99.23 % (CI _{95%} : 95.16 % - 99.96 %)			
LINEAR RANGE	10 ⁸ - 10 ^{2.5} IU/ml with precision of ± 0.5 log			
DYNAMIC RANGE	10 ⁸ - LoD IU/ml (LoD varying according to the extraction and material used)			
TRUENESS (of expected concentration)	0.005 log (CI _{95%} : -0.05 - 0.06) using manual extraction GeneProof PathogenFree DNA Isolation Kit -0.002 log (CI _{95%} : -0.08 - 0.07) using automatic extraction croBEE 201A Nucleic Acid Extraction Kit			
REPORTING UNITS	IU/ml			
CONVERSION FACTOR	IU = 0.6 cp / 1 cp = 1.8 IU			
METROLOGICAL TRACEABILITY	NIBSC HHV6B 15/266			
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Standard (IS)			
VALIDATED SPECIMEN	CSF, plasma, whole blood (EDTA)*			
STORAGE	-20 ± 5 °C			
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree DNA Isolation Kit			
INSTRUMENTS	croBEE Real-Time PCR System AMPLilab Real-Time PCR System Applied Biosystems 7500 Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96 Real-Time PCR System CFX96™/ Dx Real-Time PCR Detection System Gentier 96E/96R Real-Time PCR System LightCycler 480 LineGene 9600 Plus Mic qPCR Cyclers QuantStudio TM 5 Real Time PCR System Rotor-Gene Q SLAN® Real Time PCR System			
DETECTION CHANNELS	FAM (HHV-6), HEX/JOE/VIC (IS), Cy5* (HHV-7)			
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com			

* Due to the availability of international reference standard only for HHV-6, it is possible to monitor HHV-7 in cp/ml reporting units.