



Sexually
Transmitted
Infections



Neuroinfections



Immunocompromised
Transplanted

GeneProof®

GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit



MORE INFORMATION FROM ONE REACTION

- PCR kit detects and distinguishes Herpes Simplex Virus 1 and Herpes Simplex Virus 2 in a single reaction tube

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

SIMPLE LABORATORY WORKFLOW

- Easily combinable with other GeneProof PCR kits in one workflow

EXCELLENT QUALITY

- The highest possible diagnostic sensitivity (100.00%) and diagnostic specificity (97.62%)

ORDER INFORMATION

REF	PACKAGE
HSV/ISEX/025	25 reactions
HSV/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 Herpes Simplex Virus (HSV-1/2) 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	Gene encoding B glycoprotein (gB)					
ANALYTICAL SPECIFICITY	Herpes simplex virus type 1 (HSV-1), 100 % Herpes simplex virus type 2 (HSV-2), 100 %					
ANALYTICAL SENSITIVITY (LoD)	Sample processing	Type	Plasma	Serum	Whole blood	CSV
	GeneProof PathogenFree DNA Isolation Kit	HSV-1	122,1 cp/ml	196,2 cp/ml	272,6 cp/ml	82,8 cp/ml
	GeneProof PathogenFree DNA Isolation Kit	HSV-2	194,5 cp/ml	70,0 cp/ml	160,9 cp/ml	60,2 cp/ml
	croBEE 201A Nucleic Acid Extraction Kit	HSV-1	673,7 cp/ml	302,6 cp/ml	219,2 cp/ml	642,7 cp/ml
	croBEE 201A Nucleic Acid Extraction Kit	HSV-2	440,4 cp/ml	308,4 cp/ml	219,6 cp/ml	432,6 cp/ml
DIAGNOSTIC SPECIFICITY	97.62 % (CI _{95%} : 93.63 % - 99.23 %)					
DIAGNOSTIC SENSITIVITY	100.00 % (CI _{95%} : 98.24 % - 100.00 %)					
POSITIVE PREDICTIVE VALUE	98.53 % (CI _{95%} : 96.04 % - 99.53 %)					
NEGATIVE PREDICTIVE VALUE	100.00 % (CI _{95%} : 97.15 % - 100.00 %)					
LINEAR RANGE	10 ¹⁰ - 10 ² cp/ml with precision of ± 0.5 log (GeneProof PathogenFree DNA Isolation Kit) 10 ¹⁰ - 10 ^{2.5} cp/ml with precision of ± 0.5 log (croBEE 201A Nucleic Acid Extraction Kit)					
DYNAMIC RANGE	10 ¹⁰ - LoD cp/ml (LoD varying according to the extraction, material and channel used)					
REPORTING UNITS	cp/ml					
METROLOGICAL TRACEABILITY	AcroMetrix™ HSV-1 Plasma Panel (AcroMetrix HSV-1) AcroMetrix™ HSV-2 Plasma Panel (AcroMetrix HSV-2)					
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Standard (IS)					
VALIDATED SPECIMEN	CSF, plasma, serum, urine, swab (genital, vesicular), 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 QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System		
REQUIRED DETECTION CHANNELS	FAM (HSV-1), HEX/JOE/VIC (IS), Cy5 (HSV-2)					
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com					