



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](http://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)	<b>Sample processing</b>	<b>Type</b>	<b>Plasma</b>	<b>Serum</b>	<b>Whole blood</b>	<b>CSV</b>
	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 <sub>95%</sub> : 93.63 % - 99.23 %)					
DIAGNOSTIC SENSITIVITY	100.00 % (CI <sub>95%</sub> : 98.24 % - 100.00 %)					
POSITIVE PREDICTIVE VALUE	98.53 % (CI <sub>95%</sub> : 96.04 % - 99.53 %)					
NEGATIVE PREDICTIVE VALUE	100.00 % (CI <sub>95%</sub> : 97.15 % - 100.00 %)					
LINEAR RANGE	10 <sup>10</sup> - 10 <sup>2</sup> cp/ml with precision of ± 0.5 log (GeneProof PathogenFree DNA Isolation Kit) 10 <sup>10</sup> - 10 <sup>2.5</sup> cp/ml with precision of ± 0.5 log (croBEE 201A Nucleic Acid Extraction Kit)					
DYNAMIC RANGE	10 <sup>10</sup> - 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	<b>CSF, plasma, serum, urine, swab</b> (genital, vesicular), <b>whole blood</b> (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 <a href="http://www.geneproof.com">www.geneproof.com</a>					