

GeneProof®



Sexually
Transmitted
Infections



Neuroinfections



Immunocompromised
Transplanted Panel

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

- Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating 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 (96.08%)

ORDER INFORMATION

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



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



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 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 ₂₇₉₂ 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	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 with 95% probability] [cp/ml]	Sample processing	Type	Plasma	Serum	Whole blood	CSF	Urine	
	GeneProof PathogenFree DNA Isolation Kit	HSV-1	122.1	196.2	272.6	82.8	65.9	
		HSV-2	194.5	70.0	160.9	60.2	80.4	
	croBEE 201A Nucleic Acid Extraction Kit	HSV-1	673.7	302.6	219.2	642.7	342.0	
		HSV-2	440.4	308.4	219.6	432.6	257.4	
	myCROBE/croBEE 2.0 Universal Extraction Kit	HSV-1	436.0	303.1	332.4	641.8	193.0	
		HSV-2	214.3	123.6	431.8	193.1	464.8	
DIAGNOSTIC SPECIFICITY	96.08 % (CI _{95%} : 89.69 % - 98.74 %)							
DIAGNOSTIC SENSITIVITY	100 % (CI _{95%} : 98.38 % - 100 %)							
POSITIVE PREDICTIVE VALUE	98.65 % (CI _{95%} : 96.34 % - 99.57 %)							
NEGATIVE PREDICTIVE VALUE	100 % (CI _{95%} : 95.30 % - 100 %)							
LINEAR RANGE [cp/ml]	Extraction Method	Type	Plasma	Serum	Whole blood	CSF	Urine	
	GeneProof PathogenFree DNA Isolation Kit	HSV-1	10 ¹⁰ - 10 ²	10 ¹⁰ - 10 ²	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ²	10 ¹⁰ - 10 ²	
		HSV-2	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	
	croBEE 201A Nucleic Acid Extraction Kit	HSV-1	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	
		HSV-2	10 ¹⁰ - 10 ³	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	
	myCROBE/croBEE 2.0 Universal Extraction Kit	HSV-1	10 ¹⁰ - 10 ³	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	
		HSV-2	10 ¹⁰ - 10 ³	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	10 ¹⁰ - 10 ^{2.5}	
DYNAMIC RANGE	10 ¹⁰ - LoD cp/ml (LoD varying according to the extraction, material and channel used)							
TRUENESS	Extraction Method	Type	Plasma CI _{95%}	Serum CI _{95%}	Whole blood CI _{95%}	CSF CI _{95%}	Urine CI _{95%}	
	GeneProof PathogenFree DNA Isolation Kit	HSV-1	0.01 log -0.03 - 0.04 log	0.10 log 0.00 - 0.20 log	0.06 log 0.00 - 0.12 log	0.08 log -0.01 - 0.17 log	0.11 log 0.00 - 0.22 log	
		HSV-2	0.03 log -0.05 - 0.11 log	0.22 log 0.01 - 0.42 log	0.13 log -0.04 - 0.30 log	0.18 log 0.01 - 0.35 log	0.20 log 0.00 - 0.40 log	
	croBEE 201A Nucleic Acid Extraction Kit	HSV-1	-0.01 log -0.06 - 0.04 log	0.13 log 0.00 - 0.25 log	0.09 log 0.00 - 0.17 log	0.16 log 0.00 - 0.33 log	0.09 log -0.01 - 0.19 log	
		HSV-2	0.03 log -0.06 - 0.12 log	0.16 log -0.04 - 0.37 log	0.12 log -0.04 - 0.29 log	0.12 log -0.04 - 0.27 log	0.14 log -0.04 - 0.32 log	
	myCROBE/croBEE 2.0 Universal Extraction Kit	HSV-1	-0.02 log -0.08 - 0.04 log	0.09 log 0.00 - 0.19 log	0.05 log -0.03 - 0.12 log	0.08 log -0.01 - 0.17 log	0.08 log 0.00 - 0.17 log	
		HSV-2	0.07 log -0.10 - 0.25 log	0.17 log -0.04 - 0.38 log	0.11 log -0.04 - 0.27 log	0.15 log -0.04 - 0.34 log	0.19 log -0.07 - 0.44 log	
PRECISION - REPEATABILITY	Intra-assay	SD of log concentration (FAM) = 0.083 (CI _{95%} : 0.067 - 0.108) SD of log concentration (Cy5) = 0.069 (CI _{95%} : 0.056 - 0.090)						
PRECISION - REPRODUCIBILITY	Intra-assay	SD of log concentration (FAM) = 0.097 (CI _{95%} : 0.062 - 0.213) SD of log concentration (Cy5) = 0.132 (CI _{95%} : 0.085 - 0.291)						
	Inter-lot	SD of log concentration (FAM) = 0.071 (CI _{95%} : 0.046 - 0.157) SD of log concentration (Cy5) = 0.113 (CI _{95%} : 0.073 - 0.249)						
	Total	SD of log concentration (FAM) = 0.089 (CI _{95%} : 0.057 - 0.196) SD of log concentration (Cy5) = 0.125 (CI _{95%} : 0.081 - 0.275)						
REPORTING UNITS	cp/ml							
CONVERSION FACTOR	Not applicable							
METROLOGICAL TRACEABILITY	AcroMatrix™ HSV-1 Plasma Panel (AcroMatrix HSV-1) AcroMatrix™ HSV-2 Plasma Panel (AcroMatrix HSV-2)							
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control (IC)							
VALIDATED SPECIMEN	DNA extracted from CSF, plasma, serum, urine, swab (genital, vesicular)*, whole blood (EDTA)							
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 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 CFX Opus 96 Real-Time PCR System			Gentier 96E/96R Real-Time PCR System LightCycler 480 LineGene 9600 / 9600 Plus Mic qPCR Cyclor QuantStudio™ 5 Real-Time PCR System Rotor-Gene 3000 / Q SLAN® Real-Time PCR System				
DETECTION CHANNELS	FAM (HSV-1), HEX/JOE/VIC (IC), Cy5 (HSV-2)							
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com							

*NOTE: Qualitative evaluation only.