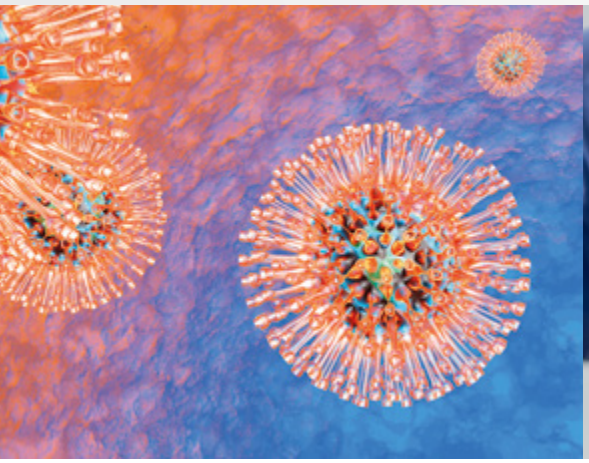
GeneProof®

IVDR

Immunocompromised Transplanted Panel

GeneProof Cytomegalovirus (CMV) PCR Kit



W.H.O STANDARD BASED QUANTIFICATION

- Precise and fully traceable quantification according to 1st WHO International Standard NIBSC 09/162
- Enables reliable viral load monitoring

SIMPLE LABORATORY WORKFLOW

- Easily combinable with other GeneProof PCR kits in one workflow

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

ORDER INFORMATION

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

COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CE 2797 IVD CERTIFIED DIAGNOSTIC TEST

Immunocompromised Transplanted Panel

GeneProof Cytomegalovirus (CMV) 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	*in vitro* diagnostic medical device					
REGULATORY STATUS	CE_{2797} 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 the IE1 protein					
ANALYTICAL SPECIFICITY	Human Cytomegalovirus (CMV), 100 %					
ANALYTICAL SENSITIVITY (LoD with 95% probability)	**Sample processing**	**CSF**	**Plasma**	**Serum**	**Urine**	**Whole blood**
	GeneProof PathogenFree DNA Isolation Kit	134.28 IU/ml	122.59 IU/ml	87.52 IU/ml	255.48 IU/ml	172.44 IU/ml
	croBEE 201A Nucleic Acid Extraction Kit	411.43 IU/ml	165.24 IU/ml	228.15 IU/ml	745.68 IU/ml	117.70 IU/ml
	myCROBE/croBEE 2.0 Universal Extraction Kit	630.34 IU/ml	281.37 IU/ml	82.49 IU/ml	287.95 IU/ml	431.21 IU/ml
DIAGNOSTIC SPECIFICITY	94.21 % ($CI_{95\%}$: 88.01 % – 97.44 %)					
DIAGNOSTIC SENSITIVITY	98.32 % ($CI_{95\%}$: 95.90 % – 99.38 %)					
POSITIVE PREDICTIVE VALUE	97.67 % ($CI_{95\%}$: 95.04 % – 98.97 %)					
NEGATIVE PREDICTIVE VALUE	95.80 % ($CI_{95\%}$: 89.98 % – 98.44 %)					
LINEAR RANGE [IU/ml]	**Extraction Method**		**CSF**	**Plasma**	**Serum**	**Urine**	**Whole blood**
	GeneProof PathogenFree DNA Isolation Kit	with precision of ± 0.5 log	10^{10} – $10^{2.5}$	10^{10} – $10^{2.5}$	10^{10} – 10^{2}	10^{10} – 10^{3}	10^{10} – $10^{2.5}$
	croBEE 201A Nucleic Acid Extraction Kit		10^{10} – 10^{3}		10^{10} – $10^{2.5}$	10^{10} – 10^{3}	10^{10} – 10^{3}
	myCROBE/croBEE 2.0 Universal Extraction Kit		10^{10} – 10^{3}		10^{10} – $10^{2.5}$	10^{10} – $10^{2.5}$	10^{10} – $10^{2.5}$
DYNAMIC RANGE	10^{10} – LoD IU/ml (LoD varying according to the extraction and material used)					
TRUENESS	**Extraction Method**	**CSF** $CI_{95\%}$	**Plasma** $CI_{95\%}$	**Serum** $CI_{95\%}$	**Urine** $CI_{95\%}$	**Whole blood** $CI_{95\%}$
	GeneProof PathogenFree DNA Isolation Kit	-0.06 log -0.12 – 0.01 log	-0.03 log -0.12 – 0.05 log	0.10 log -0.05 – 0.24 log	-0.15 log -0.28 – -0.02 log	-0.09 log -0.16 – -0.01 log
	croBEE 201A Nucleic Acid Extraction Kit	-0.06 log -0.13 – 0.02 log	-0.02 log -0.09 – 0.05 log	-0.06 log -0.08 – 0.20 log	-0.14 log -0.26 – -0.02 log	-0.06 log -0.14 – 0.02 log
	myCROBE/croBEE 2.0 Universal Extraction Kit	-0.09 log -0.17 – 0.00 log	-0.04 log -0.11 – 0.02 log	0.06 log -0.08 – 0.19 log	-0.11 log -0.22 – -0.01 log	-0.10 log -0.19 – -0.01 log
PRECISION – REPEATABILITY	Intra-assay SD of log concentration = 0.054 ($CI_{95\%}$: 0.043 – 0.070)					
PRECISION – REPRODUCIBILITY	Inter-assay SD of log concentration = 0.059 ($CI_{95\%}$: 0.038 – 0.130) Inter-lot SD of log concentration = 0.062 ($CI_{95\%}$: 0.040 – 0.136) Total SD of log concentration = 0.062 ($CI_{95\%}$: 0.040 – 0.137)					
REPORTING UNITS	IU/ml					
CONVERSION FACTOR	1 IU = 1 cp					
METROLOGICAL TRACEABILITY	CMV NIBSC 09/162 (1st WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification Techniques)					
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control (IC)					
VALIDATED SPECIMEN	DNA extracted from **CSF, plasma, serum, urine, 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 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 CFX Opus 96 Real-Time PCR System Gentier 96E/96 R Real-Time PCR System			LightCycler® 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cycler QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System StepOne™ / StepOne Plus™ Real-Time PCR System		
DETECTION CHANNELS	FAM (CMV), HEX/JOE/VIC (IC)					
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels – results at www.geneproof.com					

GeneProof a.s. / 10-2022

GeneProof a.s. Manufacturer and Global Distribution
Vídeňská 101/119 / Dolní Heršpice / 619 00 Brno / Czech Republic
+420 543 211 679 PHONE / info@geneproof.com E-MAIL / **www.geneproof.com**

ALPCO Distribution in North America
26 Keewaydin Drive / Salem, NH / 03110 / USA
800 592 5726 PHONE / sales@alpco.com E-MAIL / **www.alpco.com**