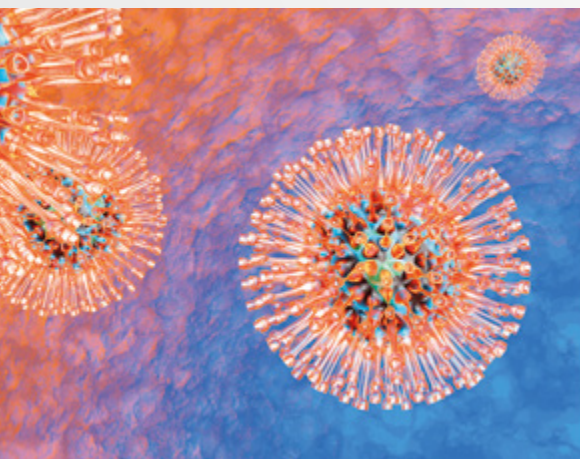


# GeneProof®



Immunocompromised  
Transplanted Panel

## GeneProof Cytomegalovirus (CMV) PCR Kit



### W.H.O STANDARD BASED QUANTIFICATION

- Precise and fully traceable quantification according to 1<sup>st</sup> 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



CERTIFIED  
DIAGNOSTIC TEST

GeneProof® ALPCO®

A GLOBAL  
DIAGNOSTICS COMPANY

[geneproof.com](http://geneproof.com) | [alpcos.com](http://alpcos.com)



# 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	<i>in vitro</i> diagnostic medical device					
REGULATORY STATUS	CE <sub>2797</sub> 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)	<b>Sample processing</b>	<b>CSF</b>	<b>Plasma</b>	<b>Serum</b>	<b>Urine</b>	<b>Whole blood</b>
	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 <sub>95%</sub> : 88.01 % - 97.44 %)					
DIAGNOSTIC SENSITIVITY	98.32 % (CI <sub>95%</sub> : 95.90 % - 99.38 %)					
POSITIVE PREDICTIVE VALUE	97.67 % (CI <sub>95%</sub> : 95.04 % - 98.97 %)					
NEGATIVE PREDICTIVE VALUE	95.80 % (CI <sub>95%</sub> : 89.98 % - 98.44 %)					
LINEAR RANGE [IU/ml]	<b>Extraction Method</b>	<b>CSF</b>	<b>Plasma</b>	<b>Serum</b>	<b>Urine</b>	<b>Whole blood</b>
	GeneProof PathogenFree DNA Isolation Kit	10 <sup>10</sup> - 10 <sup>2.5</sup>		10 <sup>10</sup> - 10 <sup>2</sup>	10 <sup>10</sup> - 10 <sup>3</sup>	10 <sup>10</sup> - 10 <sup>2.5</sup>
	croBEE 201A Nucleic Acid Extraction Kit	10 <sup>10</sup> - 10 <sup>3</sup>	10 <sup>10</sup> - 10 <sup>2.5</sup>	10 <sup>10</sup> - 10 <sup>2.5</sup>	10 <sup>10</sup> - 10 <sup>3</sup>	10 <sup>10</sup> - 10 <sup>3</sup>
	myCROBE/croBEE 2.0 Universal Extraction Kit	10 <sup>10</sup> - 10 <sup>3</sup>		10 <sup>10</sup> - 10 <sup>2.5</sup>	10 <sup>10</sup> - 10 <sup>2.5</sup>	10 <sup>10</sup> - 10 <sup>2.5</sup>
		with precision of ± 0.5 log				
DYNAMIC RANGE	10 <sup>10</sup> - LoD IU/ml (LoD varying according to the extraction and material used)					
TRUENESS	<b>Extraction Method</b>	<b>CSF</b> CI <sub>95%</sub>	<b>Plasma</b> CI <sub>95%</sub>	<b>Serum</b> CI <sub>95%</sub>	<b>Urine</b> CI <sub>95%</sub>	<b>Whole blood</b> CI <sub>95%</sub>
	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 <sub>95%</sub> : 0.043 - 0.070)					
PRECISION - REPRODUCIBILITY	Inter-assay SD of log concentration = 0.059 (CI <sub>95%</sub> : 0.038 - 0.130) Inter-lot SD of log concentration = 0.062 (CI <sub>95%</sub> : 0.040 - 0.136) Total SD of log concentration = 0.062 (CI <sub>95%</sub> : 0.040 - 0.137)					
REPORTING UNITS	IU/ml					
CONVERSION FACTOR	1 IU = 1 cp					
METROLOGICAL TRACEABILITY	CMV NIBSC 09/162 (1 <sup>st</sup> 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 <b>CSF, plasma, serum, urine, whole blood (EDTA)</b>					
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 Cyclcr 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 <a href="http://www.geneproof.com">www.geneproof.com</a>					