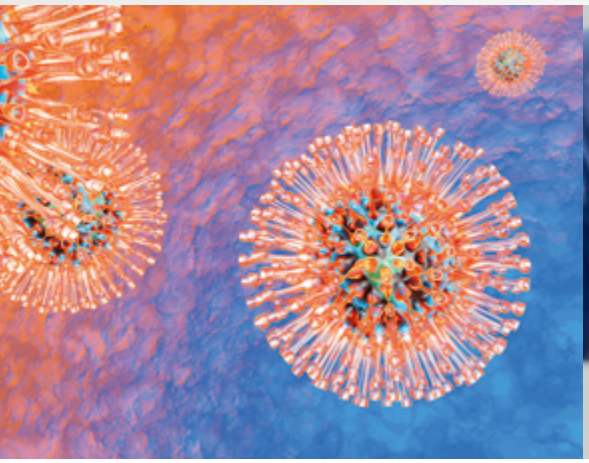
GeneProof®

GeneProof Cytomegalovirus (CMV) PCR Kit

Immunocompromised
Transplanted



W.H.O STANDARD BASED QUANTIFICATION

- Precise and fully traceable quantification according to 1st WHO International Standard NIBSC 09/162

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

- Ready-to-Use Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating possible carryover contamination

ORDER INFORMATION

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

COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CE 1023 IVD 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

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+ 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	*in vitro* 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	Specific conservative DNA sequence of a single copy gene encoding the 4 IE antigen
ANALYTICAL SPECIFICITY	Human Cytomegalovirus (CMV), 100 %
ANALYTICAL SENSITIVITY (LoD with the probability of 95 %)	122.594 IU/ml (on CMV NIBSC 09/162, manual extraction GeneProof PathogenFree DNA Isolation Kit) 165.237 IU/ml (on CMV NIBSC 09/162, automatic extraction croBEE 201A Nucleic Acid Extraction Kit)
DIAGNOSTIC SPECIFICITY	90.67 % ($CI_{95\%}$: 81.15 % – 95.85 %)
DIAGNOSTIC SENSITIVITY	92.86 % ($CI_{95\%}$: 64.17 % – 99.63 %)
LINEAR RANGE	10^{10} – $10^{2.5}$ IU/ml with precision of ± 0.5 log
DYNAMIC RANGE	10^{10} – 122.594 cp/ml (using manual extraction GeneProof PathogenFree DNA Isolation Kit) 10^{10} – 165.237 cp/ml (using automatic extraction croBEE 201A Nucleic Acid Extraction Kit)
REPORTING UNITS	IU/ml
VALIDATED SPECIMEN	**plasma, serum, urine*, whole blood**
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 LightCycler® 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cycler QuantStudio™ 3 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System StepOne™ / StepOnePlus™ Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM, HEX
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels – results at www.geneproof.com

*Validated only on manual extraction GeneProof PathogenFree DNA Isolation Kit.

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