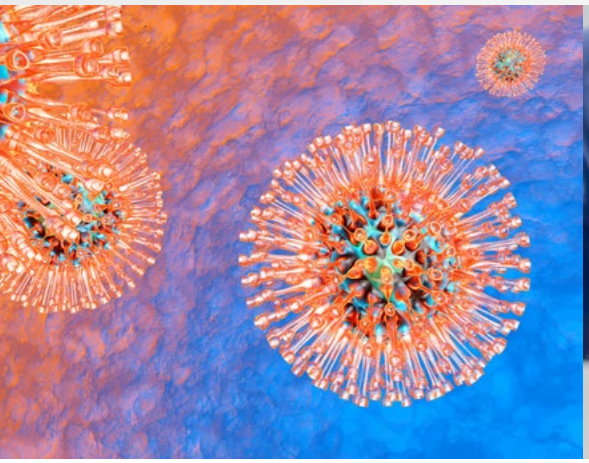
Immunocompromised
Transplanted

GeneProof

GeneProof Cytomegalovirus (CMV) PCR Kit



DETECTION OF ALL CMV GENOTYPES

- The kit detects all genotypes of *Cytomegalovirus* including genotypes GB1-GB4

FULL TRACEABILITY WITH WHO STANDARDS

- Sensitivity was established with WHO certified strain (1st WHO International Standard NIBSC 09/162)
- Precise and fully traceable quantification according to NIBSC 09/162

CONTAMINATION ELIMINATION

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

EXCELLENT EQA PANEL RESULTS

- Very high diagnostic sensitivity (up to 99.5% on core samples) and specificity (100%) confirmed by analysis of QCMD panel reports from 2008 to present

UNIVERSAL PCR PROFILE

- Easily combinable with other PCR kits from the Immunocompromised / Transplanted group
- Simplifies laboratory workflow

COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CE 1023 IVD **CERTIFIED DIAGNOSTIC TEST**

www.geneproof.com

GUARANTEED CONTROL OVER THE COMPLETE PROCESS OF DEVELOPMENT, MANUFACTURING AND DISTRIBUTION OF ALL THE OFFERED GENEPROOF PRODUCTS

Immunocompromised
Transplanted

GeneProof Cytomegalovirus (CMV) PCR Kit

+ Human Herpesvirus 6/7 (HHV-6/7) PCR Kit
+ Herpes Simplex Virus 1 (HSV-1) PCR Kit
+ Aspergillus PCR Kit
+ Cytomegalovirus (CMV) PCR Kit
+ Herpes Simplex Virus 2 (HSV-2) PCR Kit
+ BK/JC Virus (BK/JC) PCR Kit
+ Epstein-Barr Virus (EBV) PCR Kit
+ Herpes Simplex Virus (HSV-1/2) PCR Kit
+ Parvovirus B19 PCR Kit
+ Varicella Zoster Virus (VZV) PCR Kit
+ Human Herpesvirus 8 (HHV-8) PCR Kit

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)	reaches up to 122.594 IU/ml with the probability of 95 % (on CMV NIBSC 09/162 using manual extraction GeneProof PathogenFree DNA Isolation Kit) reaches up to 165.237 IU/ml with the probability of 95 % (on CMV NIBSC 09/162 using automatic extraction croBEE NA16 Nucleic Acid Extraction System)
DIAGNOSTIC SPECIFICITY	90.67 % (CI95 % : 81.15 % – 95.85 %)
DIAGNOSTIC SENSITIVITY	92.86 % (CI95 % : 64.17 % – 99.63 %)
LINEAR RANGE	10^{10} – $10^{2.5}$ cp/ml with precision of ± 0.5 log (using manual extraction GeneProof PathogenFree DNA Isolation Kit or automatic extraction croBEE NA16 Nucleic Acid Extraction System)
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 NA16 Nucleic Acid Extraction System)
REPORTING UNITS	cp/µl
CONVERSION FACTOR	1 IU = 1 cp
METROLOGICAL TRACEABILITY	CMV NIBSC 09/162
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control (ISEX version)
VALIDATED SPECIMEN	plasma, serum, whole blood, urine* *validated only on manual extraction GeneProof PathogenFree DNA Isolation Kit
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE NA16 Nucleic Acid Extraction System GeneProof PathogenFree DNA Isolation Kit
INSTRUMENTS	croBEE Real-Time PCR System* Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx 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 / 5 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 by QCMD and Instand e.V. External Quality Assessment Panels -results at www.geneproof.com
REGULATORY STATUS	CE_{1023} IVD

*Validated instruments

PRODUCT NAME	TECHNOLOGY	ORDER NO.		
		25 REACTIONS	50 REACTIONS	100 REACTIONS
GeneProof Cytomegalovirus (CMV) PCR Kit	real-time PCR	CMV/ISEX/025	CMV/ISEX/050	CMV/ISEX/100

GeneProof a.s. / 08-2019

www.geneproof.com

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