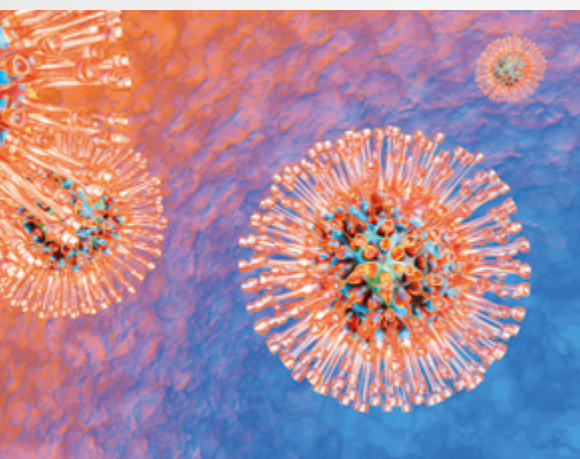




Immunocompromised  
Transplanted

# GeneProof®

## 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

### 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



CERTIFIED  
DIAGNOSTIC TEST

[www.geneproof.com](http://www.geneproof.com)

ISO 13485

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



# 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 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	<i>in vitro</i> 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 <sub>95%</sub> : 81.15 % - 95.85 %)	
DIAGNOSTIC SENSITIVITY	92.86 % (CI <sub>95%</sub> : 64.17 % - 99.63 %)	
LINEAR RANGE	10 <sup>10</sup> - 10 <sup>2.5</sup> IU/ml with precision of ± 0.5 log	
DYNAMIC RANGE	10 <sup>10</sup> - 122.594 cp/ml (using manual extraction GeneProof PathogenFree DNA Isolation Kit) 10 <sup>10</sup> - 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 Cyclser 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 <a href="http://www.geneproof.com">www.geneproof.com</a>	

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