GeneProof

GeneProof Parvovirus B19 PCR Kit



HIGH SENSITIVITY AND TRACEABILITY

 Sensitivity was established with certified strain (NIBSC 3rd WHO International standard 12/208)

PRECISE QUANTITATIVE DETECTION

 Precise and fully traceable quantification according NIBSC 3rd WHO International standard 12/208

CONTAMINATION ELIMINATION

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





www.geneproof.com

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



Immunocompromised Transplanted

GeneProof Parvovirus B19 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 VP1 protein (capsid protein)			
ANALYTICAL SPECIFICITY	Parvovirus B19, 100 %			
ANALYTICAL SENSITIVITY (LOD)	reaches up to 90.29 IU/ml with the probability of 95 % (on Parvovirus B19 NIBSC 12/208 using manual extraction GeneProof PathogenFree DNA Isolation Kit) reaches up to 156.7 IU/ml with the probability of 95 % (on Parvovirus B19 NIBSC 12/208 using automatic extraction croBEE NA16 Nucleic Acid Extraction System)			
LINEAR RANGE	10 ⁸ - 10 ^{2.5} IU/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 ⁸ – 90.29 IU/ml (using manual extraction GeneProof PathogenFree DNA Isolation Kit) 10 ⁸ – 156.7 IU/ml (using automatic extraction croBEE NA16 Nucleic Acid Extraction System)			
REPORTING UNITS	IU/μl			
CONVERSION FACTOR	1 IU = 1.6 cp			
METROLOGICAL TRACEABILITY	Parvovirus B19 NIBSC 12/208			
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control (ISEX version)			
VALIDATED SPECIMEN	plasma, whole blood			
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 CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System LightCycler 480 LineGene 9600 Plus Mic qPCR Cycler Rotor-Gene 3000 / 6000 / Q SLAN* 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 IVD			

PRODUCT NAME	TECHNOLOGY	ORDER NO.		
		25 REACTIONS	50 REACTIONS	100 REACTIONS
GeneProof Parvovirus B19 PCR Kit	real-time PCR	B19/ISEX/025	B19/ISEX/050	B19/ISEX/100

GeneProof a.s.

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