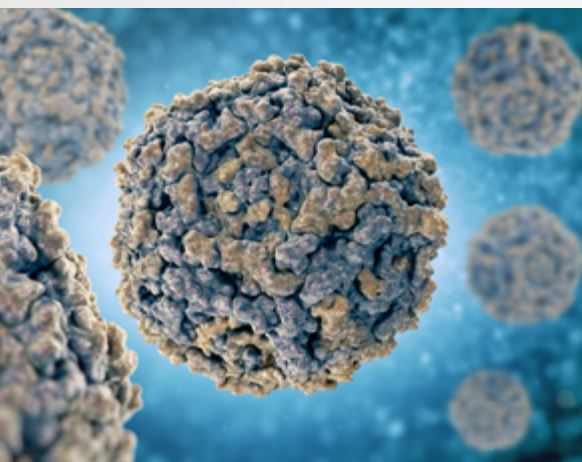




Immunocompromised  
Transplanted

# GeneProof®

## GeneProof Parvovirus B19 PCR Kit



### W.H.O. STANDARD BASED QUANTIFICATION

- Precise and fully traceable quantification according to WHO International Standard NIBSC 12/208
- Enables reliable viral load monitoring

### SIMPLE LABORATORY WORKFLOW

- Easily combinable with other GeneProof PCR kits in one run standard 12/208

### 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
B19/ISEX/025	25 reactions
B19/ISEX/100	100 reactions



COMPATIBLE WITH A WIDE  
RANGE OF REAL-TIME PCR  
DEVICES



CERTIFIED  
DIAGNOSTIC TEST

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

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



# GeneProof Parvovirus B19 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 IVD	
INTENDED USER	For professional use in laboratories with trained staff	
TEST PRINCIPLE	Real-time polymerase chain reaction (PCR) – amplification of the specific Target Sequence and detection using TaqMan probes with fluorophore-based detection	
TYPE OF ANALYSIS	Qualitative and quantitative	
TARGET SEQUENCE	Gene encoding VP1 protein (capsid protein)	
ANALYTICAL SPECIFICITY	Parvovirus B19, 100%	
ANALYTICAL SENSITIVITY (LoD with 95% probability)	<b>Sample Processing</b>	<b>Plasma</b>
	GeneProof PathogenFree DNA Isolation Kit	90.29 IU/ml
	croBEE 201A Nucleic Acid Extraction Kit	156.7 IU/ml
DIAGNOSTIC SPECIFICITY	100.00 % (CI <sub>95%</sub> : 90.40 % - 100.00 %)	
DIAGNOSTIC SENSITIVITY	100.00 % (CI <sub>95%</sub> : 90.77 % - 100.00 %)	
POSITIVE PREDICTIVE VALUE	100.00 % (CI <sub>95%</sub> : 90.77 % - 100.00 %)	
NEGATIVE PREDICTIVE VALUE	100.00 % (CI <sub>95%</sub> : 90.40 % - 100.00 %)	
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control (IC)	
REPORTING UNITS	IU/ml	
CONVERSION FACTOR	IU = 1 cp	
METROLOGICAL TRACEABILITY	Parvovirus B19 NIBSC 12/208	
VALIDATED SPECIMEN	<b>Plasma, whole blood (EDTA)</b>	
STORAGE	-20 ± 5 °C	
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree DNA Isolation Kit	
INSTRUMENTS	croBEE Real-Time PCR System	LightCycler <sup>®</sup> 480
	AMPLilab Real-Time PCR System	LineGene 9600 Plus
	Applied Biosystems 7300 / 7500 Real-Time PCR System	Mic qPCR Cyclers
	AriaMx Real-Time PCR System	QuantStudioTM 3 / 5 Real-Time PCR System
	BioQuant-96 Real-Time PCR System	Rotor-Gene 3000 / 6000 / Q
	CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System	SLAN <sup>®</sup> Real-Time PCR System
	Gentier 96E/96R Real-Time PCR System	StepOneTM / StepOne PlusTM Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM (B19), HEX/JOE/VIC (IS)	
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>	