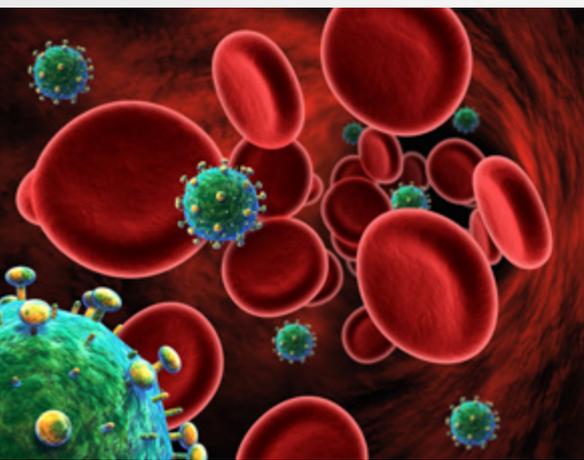




GeneProof[®]

GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit



DUAL TARGET DETECTION

- Protection against detection failures caused by virus mutations

QUALITATIVE AND QUANTITATIVE DETECTION

- Monitoring of pathogen level in time
- Full traceability to WHO standard

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
HIV1D/GP/025	25 reactions
HIV1D/GP/100	100 reactions



COMPATIBLE WITH A WIDE
RANGE OF REAL-TIME PCR
DEVICES



CERTIFIED
DIAGNOSTIC TEST



GeneProof HIV type 1 (HIV-1) Diagnostic PCR Kit

+ GeneProof Hepatitis C Virus
(HCV) Diagnostic PCR Kit

+ GeneProof Hepatitis B Virus
(HBV) PCR Kit

+ GeneProof HIV type 1 (HIV-1)
Diagnostic PCR Kit

INDICATION	<i>in vitro</i> diagnostic medical device			
REGULATORY STATUS	CE ₁₀₂₃ IVD / EU Directive 98/79/EC			
INTENDED USER	For professional use in laboratories with trained staff			
TECHNOLOGY	Real-time PCR			
TYPE OF ANALYSIS	Qualitative and quantitative			
TARGET SEQUENCE	LTR sequence, <i>gag/pol</i> gene boundary and <i>gag</i> gene			
ANALYTICAL SPECIFICITY	HIV subtypes A - D, AE, F, G, AG-GH, BF, H, K, CRF03_AB, Group N, Group O - 100 %			
ANALYTICAL SENSITIVITY (LoD with 95% probability)	Sample Processing	Sensitivity		
			Plasma	Serum
		GeneProof PathogenFree RNA Isolation Kit	129.6 IU/ml, i.e. 71.3 cp/ml	213.5 IU/ml, i.e. 117.4 cp/ml
		croBEE 201A Nucleic Acid Extraction Kit	404.5 IU/ml, i.e. 222.5 cp/ml	253.9 IU/ml, i.e. 139.65 cp/ml
	MagCore Automated NA Extractor	58.8 IU/ml, i.e. 32.4 cp/ml	70.6 IU/ml, i.e. 38.84 cp/ml	
DIAGNOSTIC SPECIFICITY	100.00% (CI _{95%} : 99.05% - 100.00%)			
DIAGNOSTIC SENSITIVITY	95.41% (CI _{95%} : 89.10% - 98.30%)			
POSITIVE PREDICTIVE VALUE	100.00% (CI _{95%} : 95.56% - 100.00%)			
NEGATIVE PREDICTIVE VALUE	100.00% (CI _{95%} : 99.05% - 100.00%)			
LINEAR RANGE	Extraction Method	Precision	Plasma	Serum
	GeneProof PathogenFree RNA Isolation Kit	± 0.5 log	10 ⁹ - 10 ^{2.5} IU/ml	10 ⁹ - 10 ³ IU/ml
	croBEE 201A Nucleic Acid Extraction Kit		10 ⁹ - 10 ³ IU/ml	10 ⁹ - 10 ³ IU/ml
	MagCore Automated NA Extractor		10 ⁹ - 10 ^{2.5} IU/ml	10 ⁹ - 10 ³ IU/ml
DYNAMIC RANGE	10 ⁹ IU/ml - LoD (LoD varying according to the extraction and material used)			
TRUENESS (of expected concentration)	Extraction Method	Plasma		Serum
	GeneProof PathogenFree RNA Isolation Kit	-0.02 log (CI _{95%} : -0.10 - 0.06)		-0.09 log (CI _{95%} : -0.22 - 0.04)
	croBEE 201A Nucleic Acid Extraction Kit	-0.09 log (CI _{95%} : -0.16 - -0.01)		-0.32 log (CI _{95%} : -0.42 - -0.21)
	MagCore Automated NA Extractor	-0.36 log (CI _{95%} : -0.42 - -0.29)		-0.36 log (CI _{95%} : -0.42 - -0.31)
PRECISION - REPEATABILITY	Intra-assay SD of log concentration = 0.065 (CI _{95%} : 0.052 - 0.085)			
PRECISION - REPRODUCIBILITY	Inter-assay SD of log concentration = 0.083 (CI _{95%} : 0.054 - 0.184)			
	Inter-lot SD of log concentration = 0.076 (CI _{95%} : 0.049 - 0.167)			
	Total SD of log concentration = 0.086 (CI _{95%} : 0.055 - 0.189)			
REPORTING UNITS	IU/ml			
CONVERSION FACTOR	1 IU = 0.55 cp			
METROLOGICAL TRACEABILITY	4 th HIV-1 International Standard NIBSC 16/194			
EXTRACTION/INHIBITION CONTROL	PCR inhibition, reverse-transcription efficiency and RNA extraction efficiency control by Internal Control			
VALIDATED SPECIMEN	Plasma (EDTA, citrate), serum			
STORAGE	(-20 ± 5) °C			
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree RNA Isolation Kit MagCore Automated NA Extractor			
APPLIED INSTRUMENTS	croBEE Real-Time PCR System Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96, Fluorescent Quantitative Detection PCR system CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System LineGene 9600 Plus Rotor-Gene 3000 / Q SLAN [®] Real-Time PCR System			
REQUIRED DETECTION CHANNELS	FAM, HEX/JOE			
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and INSTAND e.V. External Quality Assessment Panels - results at www.geneproof.com			