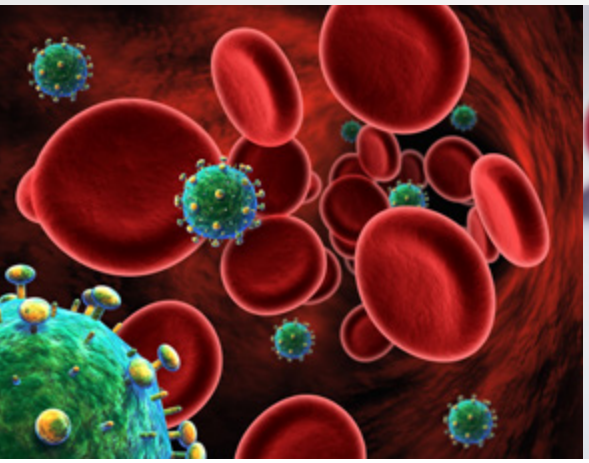
GeneProof®

Bloodborne Infections

GeneProof HIV type 1 (HIV-1) PCR Kit



HIGH DIAGNOSTIC SPECIFICITY AND SENSITIVITY

- Diagnostic sensitivity was verified on 128 HIV positive plasma samples acquired from Centre for AIDS Reagents (CFAR), National Institute for Biological Standards and Control (NIBSC)
- Diagnostic specificity was verified on 500 HIV negative samples

DUAL TARGET DETECTION

- Dual targeting prevents detection failure caused by possible mutations inside the HIV-1 genome

EASY-TO-USE CONCEPT

- Single tube Ready-to-Use Master Mix contains all components for PCR amplification
- No additional PCR reagents pipetting necessary

DETECTS A BROAD SPECTRUM OF HIV-1 SUBTYPES

- HIV genotypes A - D, AE, F, AG-GH, Group N, Group O, BF, H, K, CRF03_AB

CONTROL OF THE WHOLE DIAGNOSTIC PROCESS

- RNA extraction, reverse transcription and PCR amplification

ORDER INFORMATION

REF	PACKAGE
HIV1/ISEX/025	25 reactions
HIV1/ISEX/100	100 reactions

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

Bloodborne Infections

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

INDICATION	*in vitro* diagnostic medical device
REGULATORY STATUS	CE_{1023} IVD
INTENDED USER	For professional use in laboratories with trained staff
TECHNOLOGY	Real-time PCR
TYPE OF ANALYSIS	Qualitative and quantitative
TARGET SEQUENCE	LTR sequence and *GaG* gene
ANALYTICAL SPECIFICITY	HIV genotypes A – D, AE, F, AG-GH, Group N, Group O, BF, H, K, CRF03_AB, 100%
ANALYTICAL SENSITIVITY (LoD with 95% probability)	Reaches up to 273.971 IU/ml i.e. 153.424 cp/ml (on HIV-1 NIBSC 16/194 using manual extraction GeneProof PathogenFree RNA Isolation Kit) Reaches up to 548.121 IU/ml i.e. 306.948 cp/ml (on HIV-1 NIBSC 16/194 using automatic extractor croBEE NA16 Nucleic Acid Extraction System) Reaches up to 98.59 IU/ml i.e. 55.21 cp/ml (on Acrometrix HIV-1 Panel IU/ml using manual extraction SpinStar Viral Nucleic Acid Kit 1.0 with SpinStar Pretreatment Solution)
DIAGNOSTIC SPECIFICITY	100 % ($CI_{95\%}$: 99.10 % – 100 %)
DIAGNOSTIC SENSITIVITY	93.66 % ($CI_{95\%}$: 87.96 % – 96.88 %)
LINEAR RANGE	10^9– $10^{2.5}$ IU/ml with precision of ± 0.5 log (using manual extraction GeneProof PathogenFree RNA Isolation Kit) 10^9– 10^3 IU/ml with precision of ± 0.5 log (using automatic extractor croBEE NA16 Nucleic Acid Extraction System)
DYNAMIC RANGE	10^9 – 273.971 IU/ml (using manual extraction GeneProof PathogenFree RNA Isolation Kit) 10^9 – 548.121 IU/ml (using automatic extractor croBEE NA16 Nucleic Acid Extraction System)
REPORTING UNITS	IU/ml
CONVERSION FACTOR	1 IU = 0.56 cp
METROLOGICAL TRACEABILITY	HIV NIBSC 16/194
EXTRACTION/INHIBITION CONTROL	PCR inhibition and RNA extraction efficiency control (ISEX version)
VALIDATED SPECIMEN	**Plasma**
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction System GeneProof PathogenFree RNA 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 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® 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 www.geneproof.com

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