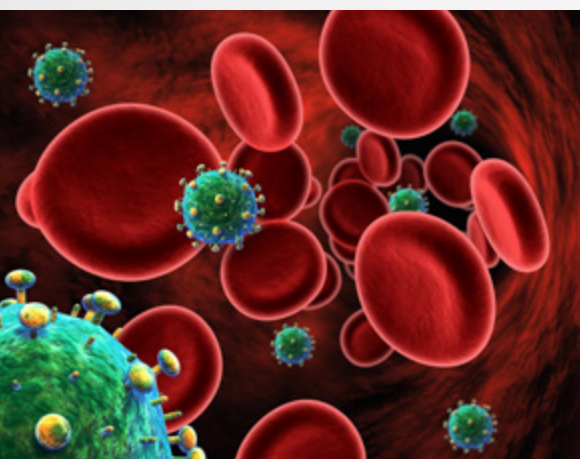




GeneProof[®]

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



COMPATIBLE WITH A WIDE
RANGE OF REAL-TIME PCR
DEVICES

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



CERTIFIED
DIAGNOSTIC TEST



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	<i>in vitro</i> 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 <i>Gag</i> 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 Cyclers 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