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

DETECTS A BROAD SPECTRUM OF HIV-1 SUBTYPES


SINGLE TUBE READY-TO-USE MASTER MIX

- Contains all components for PCR amplification
- No additional PCR reagents pipetting necessary
- Reduces the need for qualified laboratory staff
- Ensures reproducibility of the result

CONTROL OF THE WHOLE DIAGNOSTIC PROCESS

- RNA extraction, reverse transcription and PCR amplification

COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CERTIFIED DIAGNOSTIC TEST

www.geneproof.com

GUARANTEED CONTROL OVER THE COMPLETE PROCESS OF DEVELOPMENT, MANUFACTURING AND DISTRIBUTION OF ALL THE OFFERED GENEPROOF PRODUCTS
GeneProof HIV type 1 (HIV-1) PCR Kit

**PRODUCT NAME** | TECHNOLOGY | ORDER NO. |
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<tr>
<td>GeneProof HIV type 1 (HIV-1) PCR Kit</td>
<td>real-time PCR</td>
<td>HIV1/ISEX/025 / HIV1/ISEX/050 / HIV1/ISEX/100</td>
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**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)**
- reaches up to 273.971 IU/ml i.e. 153.424 cp/ml with the probability of 95 % (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 with the probability of 95 % (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 with the probability of 95 % (on Acrometrix HIV-1 Panel IU/ml using manual extraction SpinStar Viral Nucleic Acid Kit 1.0 with SpinStar Pretreatment Solution)

**DIAGNOSTIC SPECIFICITY**
100 % (CI95 % : 99.10 % - 100 %)

**DIAGNOSTIC SENSITIVITY**
93.66 % (CI95 % : 87.96 % - 96.88 %)

**LINEAR RANGE**
10^-1 - 10^2.5 IU/ml with precision of ± 0.5 log (using manual extraction GeneProof PathogenFree RNA Isolation Kit)
10^-1 - 10^3 IU/ml with precision of ± 0.5 log (using automatic extractor croBEE NA16 Nucleic Acid Extraction System)

**DYNAMIC RANGE**
10^0 - 273.971 IU/ml (using manual extraction GeneProof PathogenFree RNA Isolation Kit)
10^0 - 548.121 IU/ml (using automatic extractor croBEE NA16 Nucleic Acid Extraction System)

**REPORTING UNITS**
IU/µl

**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 NA16 Nucleic Acid Extraction System
GeneProof PathogenFree RNA 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
QuantStudio™ 3 / 5 Real-Time PCR System
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**
CE19271VD

* Validated instruments