

CE-IVD

TaqPath Menu GeneProof HIV Type 1 (HIV-1) Diagnostic PCR Kit

Molecular diagnostic for bloodborne infections

Broad range of reliable and simple PCR-based testing to help diagnosis

Prompt and early diagnosis of bloodborne infection is important to enable appropriate treatment and help prevent further transmission. Clinical testing labs require testing solutions that help provide confidence, fast turnaround time, and accurate results. This helps give confidence in diagnostic and treatment monitoring decisions.

Applied Biosystems™ TaqPath™ Menu | GeneProof™ HIV Type 1 (HIV-1) Diagnostic PCR Kit features:



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



Compatible with a wide range of real-time PCR devices



Contamination reduction

- Ready-to-use Master Mix contains uracil-DNA glycosylase (UNG) and dUTPs reducing possible carryover contamination



Easy-to-use concept

- Single tube ready-to-use Master Mix contains all components for PCR amplification
- No additional pipetting of PCR reagents is necessary

Product details for the TaqPath Menu | GeneProof HIV Type 1 (HIV-1) Diagnostic PCR Kit

| | | | |
|--|---|-------------------------------|--------------------------------|
| Technology | Qualitative and quantitative real-time PCR | | |
| Target sequence | LTR sequence, <i>gag/pol</i> gene boundary and <i>gag</i> gene | | |
| Sample type | Plasma (EDTA, citrate), serum | | |
| 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 | Plasma | Serum |
| | GeneProof PathogenFree RNA | 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%) | | |
| Reporting units | IU/mL, 1 IU = 0.55 cp | | |
| Metrological traceability | 4th HIV-1 International Standard NIBSC 16/194 | | |
| Extraction/inhibition control | PCR inhibition, reverse-transcription efficiency and RNA extraction efficiency control by internal control | | |
| Instruments | Applied Biosystems™ 7300 and Applied Biosystems™ 7500 Real-Time PCR Systems croBEE 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 | | |
| Validated extraction methods | Refer to the instructions for use (IFU) | | |
| Detection channel | FAM, HEX/JOE | | |
| External quality assessment | Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels | | |

Ordering information

| Description | Quantity | Cat. No. |
|--|---------------|----------|
| TaqPath Menu GeneProof HIV Type 1 (HIV-1) Diagnostic PCR Kit | 100 reactions | A58119 |


 Learn more at thermofisher.com/hivdr-ivd
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For *In Vitro* Diagnostic Use. Intended use and regulatory statements of products vary. For specific intended use and regulatory statements, please refer to the Instructions for Use (IFU). Product availability by country varies. For product availability in your country, check the associated product webpages. TaqPath Menu | GeneProof assays are manufactured by GeneProof and distributed by Thermo Fisher Scientific. © 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. GeneProof™ and croBEE are the property of GeneProof. CFX96, CFX Connect, and CFX DX™ are the property of BioRad. AriaMx is the property of Agilent. LineGene is the property of Appolon Biotech. Rotor-Gene is the property of Qiagen®, SLAN® is the property of Sansure Biotech. MagCORE® is the property of Bioscience. BioQuant-96 is the property of Biosan. **COL23334 0423**