

CE-IVD

TaqPath Menu GeneProof Hepatitis B Virus (HBV) PCR Kit

Molecular diagnostic for hepatitis

Applied Biosystems™ TaqPath™ Menu | GeneProof™ Hepatitis B Virus (HBV) PCR Kit features:*



High specificity

- Secured by targeting the DNA conservative sequence of ORF_x
- Reduces detection failure caused by the occurrence of mutations (including safe detection of core and precore mutants)
- Detection of HBV genotypes A–H
- 100% diagnostic specificity



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



Contamination reduction

- Master Mix contains uracil-DNA glycosylase (UNG) and dUTPs reducing carryover contamination



WHO standard-based quantification

- Precise and fully traceable quantification according to the 4th HBV International Standard NIBSC, 10/266



Compatible with a wide range of real-time PCR devices



High sensitivity

- Facilitates excellent sensitivity up to 13.9 IU/mL
- 100% diagnostic sensitivity*

* Refer to the Instructions for Use.

Product details for the TaqPath Menu | GeneProof Hepatitis B Virus (HBV) PCR Kit

Technology	Qualitative and quantitative real-time PCR
Target sequence	P gene
Sample type	Plasma, serum
Analytical specificity	HBV genotype A–H, precore mutants HBV (HBeAg-negative), 100%
Analytical sensitivity (LoD)	36.9792 IU/mL (on HBV NIBSC 05/148 using GeneProof PathogenFree DNA Isolation Kit), 64.067 IU/mL (on HBV NIBSC 10/266 using croBEE 201A Nucleic Acid Extraction Kit), 13.9 IU/mL (on HBV NIBSC 10/266 using manual extraction SpinStar Viral Nucleic Acid Kit 1.0 with SpinStar Pretreatment Solution)
Diagnostic specificity	100.00% (CI _{95%} : 99.07%–100.00%)
Diagnostic sensitivity	100.00% (CI _{95%} : 95.39%–100.00%)
Extraction/inhibition control	PCR inhibition and DNA extraction efficiency control
Instruments	Applied Biosystems™ 7300 and 7500 Real-Time PCR Systems Applied Biosystems™ QuantStudio™ 3 and QuantStudio™ 5 Real-Time PCR Systems StepOne™/StepOne Plus™ Real-Time PCR Systems croBEE Real-Time PCR System AMPLilab Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96 Real-Time PCR System CFX Connect/CFX96/Dx Real-Time PCR Detection System DTlite Real-Time PCR System Gentier 96E/96R Real-Time PCR System LightCycler 2.0/480 LineGene 9600/9600 Plus Mic qPCR Cyclers Rotor-Gene 3000/6000/Q SLAN Real-Time PCR System
Validated extraction methods	Refer to the Instructions for Use (IFU)
Detection channel	FAM, HEX
External quality assessment	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels

Ordering information

Description	Quantity	Cat. No.
TaqPath Menu GeneProof Hepatitis B Virus (HBV) PCR Kit	100 reactions	A58426

Add a second Applied Biosystems™ TaqPath™ Menu | GeneProof™ Kit for comprehensive detection of HBV and HCV to help meet your lab's clinical testing needs

TaqPath Menu | GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit



Learn more at thermofisher.com/hepatitis-taqpath-menu

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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. QIAamp and Rotor-Gene are the property of Qiagen. AMPLilab is the property of Adaltis. CFX96 and CFX DX are the property of BioRad. Mic qPCR is the property of bms. LineGene is the property of Appolon Biotech. SLAN is the property of Sansure Biotech. LightCycler 480 is the property of Roche. Gentier is the property of Tianlong Technology. AriaMX is the property of Agilent. BioQuant is the property of Biosan. **COL120398 0523**