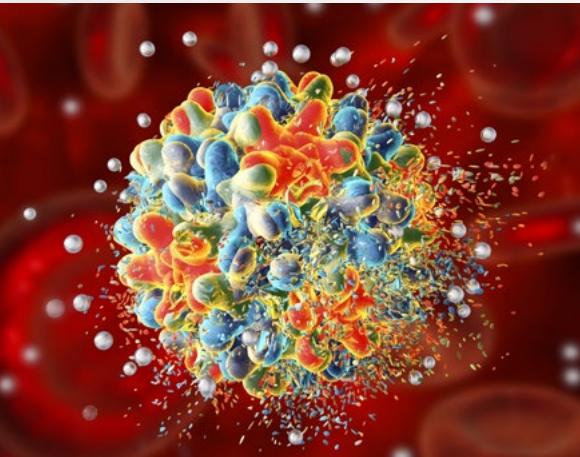




GeneProof

GeneProof Hepatitis B Virus (HBV) PCR Kit



HIGH SPECIFICITY

- Secured by targeting the DNA conservative sequence of ORF_x
- Prevents analysis failure caused by the occurrence of mutations (including safe detection of core and pre-core mutants)
- Detection of all HBV genotypes A - H

SINGLE TUBE READY-TO-USE MASTERMIX

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

HIGH SENSITIVITY

- Sensitivity was established with certified strain (HBV NIBSC 10/266)
- Ensures excellent sensitivity reaches up to 13.9 IU/ml

PRECISE QUANTITATIVE DETECTION

- Precise and fully traceable quantification according to WHO International HBV DNA Standard NIBSC 10/266
- Excellent results in EQA panel testing (QCMD, INSTAND)

CONTAMINATION ELIMINATION

- Ready-to-Use Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating possible contamination with amplification products



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof Hepatitis B Virus (HBV) PCR Kit

+ GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit

+ Hepatitis C Virus (HCV) PCR Kit
+ HIV type 1 (HIV-1) PCR Kit

+ Hepatitis B Virus (HBV) PCR Kit

TECHNOLOGY	real-time PCR
TYPE OF ANALYSIS	qualitative and quantitative
TARGET SEQUENCE	DNA conservative sequence of open reading frame X (ORF _X)
ANALYTICAL SPECIFICITY	HBV genotype A-H, pre-core mutants HBV (HBeAg negative), 100%
ANALYTICAL SENSITIVITY (LOD)	reaches up to 36.9792 IU/ml with the probability of 95% (on HBV NIBSC 05/148 using manual extraction GeneProof PathogenFree DNA Isolation Kit) reaches up to 64.067 IU/ml with the probability of 95% (on HBV NIBSC 10/266 using automatic extractor croBEE NA16 Nucleic Acid Extraction System) reaches up to 13.9 IU/ml with the probability of 95% (on HBV NIBSC 10/266 using manual extraction SpinStar Viral Nucleic Acid Kit 1.0 with SpinStar Pretreatment Solution)
DIAGNOSTIC SPECIFICITY	100% (CI _{95%} : 99.06% - 100%)
DIAGNOSTIC SENSITIVITY	100% (CI _{95%} : 95.90% - 100%)
LINEAR RANGE	10 ¹⁰ - 10 ² IU/ml with precision of ± 0.5 log (using manual extraction GeneProof PathogenFree DNA Isolation Kit or automatic extractor croBEE NA16 Nucleic Acid Extraction System)
DYNAMIC RANGE	10 ¹⁰ - 36.9792 IU/ml (using manual extraction GeneProof PathogenFree DNA Isolation Kit) 10 ¹⁰ - 64.067 IU/ml (using automatic extractor croBEE NA16 Nucleic Acid Extraction System)
REPORTING UNITS	IU/μl
CONVERSION FACTOR	Not applicable
METROLOGICAL TRACEABILITY	HBV NIBSC 10/264
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control (ISEX version)
VALIDATED SPECIMEN	plasma, serum
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE NA16 Nucleic Acid Extraction System GeneProof PathogenFree DNA 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 DT lite Real-Time PCR System LightCycler® 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cyclers QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System StepOne™/StepOne Plus™ 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	CE ₁₀₂₃ IVD

* Validated instruments

PRODUCT NAME	TECHNOLOGY	ORDER NO.		
		25 REACTIONS	50 REACTIONS	100 REACTIONS
GeneProof Hepatitis B Virus (HBV) PCR Kit	real-time PCR	HBV/ISEX/025	HBV/ISEX/050	HBV/ISEX/100