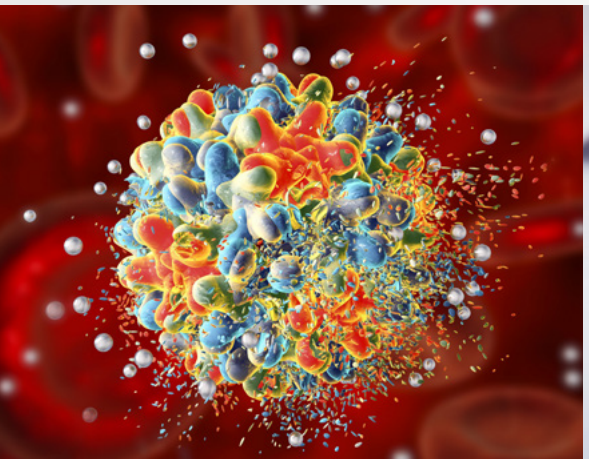
GeneProof®

Bloodborne Infections

GeneProof Hepatitis B Virus (HBV) PCR Kit



HIGH SPECIFICITY

- Secured by targeting specific conservative DNA sequence of *P* gene
- Prevents detection failure caused by the occurrence of mutations (including safe detection of core and pre-core mutants)
- Detection of all HBV genotypes A – H
- 100% diagnostic specificity

HIGH SENSITIVITY

- Ensures excellent sensitivity up to 13.9 IU/ml
- 100% diagnostic sensitivity

EASY-TO-USE CONCEPT

- Single tube Ready-to-Use Master Mix contains all components for PCR amplification
- No additional PCR reagents pipetting necessary

W.H.O. STANDARD BASED QUANTIFICATION

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

CONTAMINATION PREVENTION

- Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating carryover contamination

ORDER INFORMATION

REF	PACKAGE
HBV/ISEX/025	25 reactions
HBV/ISEX/100	100 reactions

COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CE 1023 IVD CERTIFIED DIAGNOSTIC TEST

www.geneproof.com

GUARANTEED CONTROL OVER THE COMPLETE PROCESS OF DEVELOPMENT, MANUFACTURING AND DISTRIBUTION OF ALL THE OFFERED GENEPROOF PRODUCTS

Bloodborne Infections

GeneProof Hepatitis B Virus (HBV) 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	*in vitro* 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	specific conservative DNA sequence of *P* gene
ANALYTICAL SPECIFICITY	HBV genotype A-H, precore mutants HBV (HBeAg negative), 100 %
ANALYTICAL SENSITIVITY (LoD with probability 95 %)	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 % ($CI_{95\%}$: 99.06 % – 100.00 %)
DIAGNOSTIC SENSITIVITY	100.00 % ($CI_{95\%}$: 95.90 % – 100.00 %)
LINEAR RANGE	10^{10} – 10^{2} IU/ml with precision of ± 0.5 log
DYNAMIC RANGE	10^{10} – 36.9792 IU/ml (using GeneProof PathogenFree DNA Isolation Kit) 10^{10} – 64.067 IU/ml (using croBEE 201A Nucleic Acid Extraction Kit)
REPORTING UNITS	IU/ml
METROLOGICAL TRACEABILITY	HBV NIBSC 10/266 (4th WHO International Standard)
VALIDATED SPECIMEN	**Plasma, serum**
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHOD	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree DNA Isolation Kit
INSTRUMENTS	croBEE Real-Time PCR System AMPLilab Real-Time PCR System Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96 Real-Time PCR System CFX Connect™ / CFX96™/ Dx Real-Time PCR Detection System DT lite Real-Time PCR System Gentier 96E/96R Real-Time PCR System LightCycler® 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cycler QuantStudioTM 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System StepOneTM/StepOne PlusTM 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

GeneProof a.s. / 08-2022

www.geneproof.com

GeneProof a.s.
Vídeňská 101/119 / Dolní Heršpice / 619 00 Brno / Czech Republic
+420 543 211 679 PHONE / info@geneproof.com E-MAIL