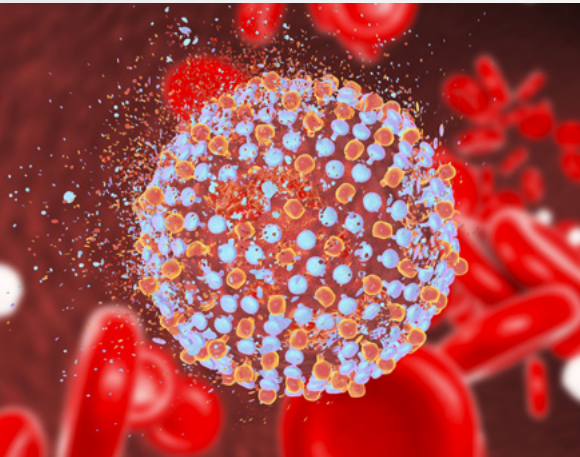




GeneProof®

GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit



RELIABLE DIAGNOSTICS

- Dual targeting prevents detection failures caused by the occurrence of mutations
- 100% diagnostic sensitivity

W.H.O. STANDARD BASED QUANTIFICATION

- Precise and fully traceable quantification according to 5th WHO International Standard NIBSC 14/150

UNIQUE FALSE-NEGATIVE RESULTS CONTROL

- Unique Internal RNA control construction
- Controls the whole diagnostic process, including RNA extraction, reverse transcription, and PCR amplification

HIGH SPECIFICITY

- The kit detects all known HCV genotypes 1-8
- 100% diagnostic specificity

EASY-TO-USE CONCEPT

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

CONTAMINATION PREVENTION

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

ORDER INFORMATION

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



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof Hepatitis C Virus (HCV) Diagnostic 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	<i>in vitro</i> 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	Conservative region of 5' UTR sequence	
ANALYTICAL SPECIFICITY	HCV genotype 1-8, 100 %	
ANALYTICAL SENSITIVITY (LoD with probability 95 %)	53.505 IU/ml (on HCV NIBSC 14/150 using GeneProof PathogenFree RNA Isolation Kit) 170.062 IU/ml (on HCV NIBSC 14/150 using croBEE 201A Nucleic Acid Extraction Kit) 33.473 IU/ml (on Acrometrix HCV-S Panel using MagCore Automated NA Extractor) 7.95 IU/ml (on Acrometrix HCV-S Panel using 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 %)	
LINEAR RANGE	10 ^{8.5} - 10 ² IU/ml with precision of ± 0.5 log (GeneProof PathogenFree RNA Isolation Kit) 10 ^{8.5} - 170.062 IU/ml with precision of ± 0.5 log (croBEE 201A Nucleic Acid Extraction System) 10 ^{8.5} - 10 ^{1.7} IU/ml with precision of ± 0.5 log (MagCore Automated NA Extractor)	
DYNAMIC RANGE	10 ^{8.5} - 53.505 IU/ml (GeneProof PathogenFree RNA Isolation Kit) 10 ^{8.5} - 170.062 IU/ml (croBEE 201A Nucleic Acid Extraction System) 10 ^{8.5} - 33.473 IU/ml (MagCore Automated NA Extractor)	
REPORTING UNITS	IU/ml	
METROLOGICAL TRACEABILITY	HCV NIBSC 14/150	
VALIDATED SPECIMEN	Plasma (EDTA, citrate), serum	
STORAGE	-20 ± 5 °C	
VALIDATED EXTRACTION METHOD	croBEE 201A Nucleic Acid Extraction System GeneProof PathogenFree RNA Isolation Kit MagCore Automated NA Extractor	
INSTRUMENTS	croBEE Real-Time PCR System Applied Biosystems 7300 / 7500 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	Gentier 96E/96R Real-Time PCR System LightCycler® 480 LineGene 9600 Plus Mic qPCR Cycler QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q
REQUIRED DETECTION CHANNELS	FAM, HEX	
QUALITY CONTROL	Quality management system is certified in compliance with the requirements of the standard ISO 13485	
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com	