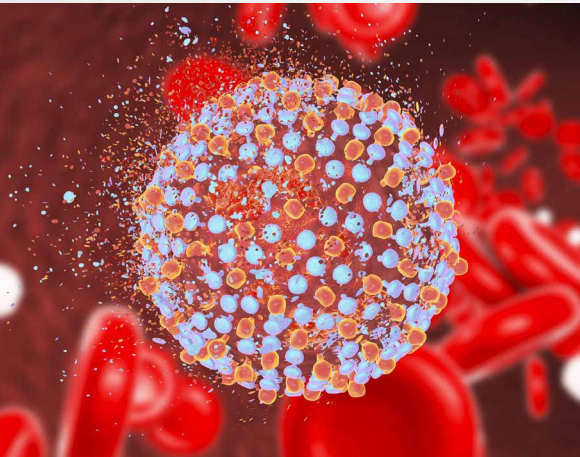




# GeneProof

## GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit



### UNIQUE DUAL TARGET DETECTION

- Prevents analysis failure caused by the appearance of mutants
- Ensures maximum sensitivity, reaches up to 7.95 IU/ml
- Ensures maximum specificity

### CONTAMINATION ELIMINATION

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

### INTERNAL RNA CONTROL

- Controls the whole diagnostic process, i.e. efficiency
- RNA extraction, reverse transcription and PCR amplification
- IC is included in the PCR kit



**COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES**

### DETECTS THE NEWLY DESCRIBED GENOTYPES 7 AND 8

- The Kit detects all known HCV genotypes 1-8

### SINGLE TUBE READY-TO-USE MASTERMIX

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



**CERTIFIED DIAGNOSTIC TEST**



# GeneProof Hepatitis C Virus (HCV) Diagnostic 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
TARGET ANALYSIS	qualitative and quantitative
TARGET SEQUENCE	conservative region of 5' UTR sequence
ANALYTICAL SPECIFICITY	HCV genotype 1-8, 100%
ANALYTICAL SENSITIVITY (LOD)	reaches up to 53.505 IU/ml with the probability of 95% (on HCV NIBSC 14/150 using manual extraction GeneProof PathogenFree RNA Isolation Kit) reaches up to 170.062 IU/ml with the probability of 95% (on HCV NIBSC 14/150 using automatic extractor croBEE NA16 Nucleic Acid Extraction System) reaches up to 33.473 IU/ml with the probability of 95% (on Acrometrix HCV-S Panel using automatic extractor MagCore Automated NA Extractor) reaches up to 7.95 IU/ml with the probability of 95% (on Acrometrix HCV-S Panel using manual extraction SpinStar Viral Nucleic Acid Kit 1.0 with SpinStar Pretreatment Solution)
DIAGNOSTIC SPECIFICITY	100% (CI <sub>95%</sub> : 99.07% - 100%)
DIAGNOSTIC SENSITIVITY	100% (CI <sub>95%</sub> : 95.39% - 100%)
LINEAR RANGE	10 <sup>8.5</sup> - 10 <sup>2</sup> IU/ml with precision of ± 0.5 log (using manual extraction GeneProof PathogenFree RNA Isolation Kit) 10 <sup>8.5</sup> - 170.062 IU/ml with precision of ± 0.5 log (using automatic extractor croBEE NA16 Nucleic Acid Extraction System) 10 <sup>8.5</sup> - 10 <sup>1.7</sup> IU/ml with precision of ± 0.5 log (using automatic extractor MagCore Automated NA Extractor)
DYNAMIC RANGE	10 <sup>8.5</sup> - 53.505 IU/ml (using manual extraction GeneProof PathogenFree RNA Isolation Kit) 10 <sup>8.5</sup> - 170.062 IU/ml (using automatic extractor croBEE NA16 Nucleic Acid Extraction System) 10 <sup>8.5</sup> - 33.473 IU/ml (using automatic extractor MagCore Automated NA Extractor)
REPORTING UNITS	IU/μl
CONVERSION FACTOR	Not applicable
METROLOGICAL TRACEABILITY	HCV NIBSC 14/150
EXTRACTION/INHIBITION CONTROL	PCR inhibition and RNA extraction efficiency control (ISEX version)
VALIDATED SPECIMEN	plasma (EDTA), serum
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE NA16 Nucleic Acid Extraction System GeneProof PathogenFree RNA Isolation Kit MagCore Automated NA Extractor
INSTRUMENTS	croBEE NA16 Nucleic Acid Extraction System* Applied Biosystems 7300 / 7500 Real-Time PCR System CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System LineGene 9600 Plus Mic qPCR Cyclers Rotor-Gene 3000 / 6000 / Q
REQUIRED DETECTION CHANNELS	FAM, HEX
EXTERNAL QUALITY ASSESSMENT	Regularly tested by QCMD and INSTAND e.V. External Quality Assessment panels - results at <a href="http://www.geneproof.com">www.geneproof.com</a>
REGULATORY STATUS	CE <sub>1023</sub> IVD

\* Validated instruments

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