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

<table>
<thead>
<tr>
<th>REF</th>
<th>PACKAGE</th>
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<tbody>
<tr>
<td>HCVD/ISEX/025</td>
<td>25 reactions</td>
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<tr>
<td>HCVD/ISEX/100</td>
<td>100 reactions</td>
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</tbody>
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COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CERTIFIED DIAGNOSTIC TEST

GUARANTEED CONTROL OVER THE COMPLETE PROCESS OF DEVELOPMENT, MANUFACTURING AND DISTRIBUTION OF ALL THE OFFERED GENEPROOF PRODUCTS
GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit

**+ GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit**

**INDICATION**
in vitro diagnostic medical device

**REGULATORY STATUS**
CE _med 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)

**DIAGNOSTIC SPECIFICITY**
100.00 % (CI 95%: 99.07 % – 100.00 %)

**DIAGNOSTIC SENSITIVITY**
100.00 % (CI 95%: 95.39 % – 100.00 %)

**LINEAR RANGE**
- $10^{3}$ – $10^{7}$ IU/ml with precision of ± 0.5 log (GeneProof PathogenFree RNA Isolation Kit)
- $10^{5}$ – 170.062 IU/ml with precision of ± 0.5 log (croBEE 201A Nucleic Acid Extraction System)
- $10^{6}$ – $10^{10}$ IU/ml with precision of ± 0.5 log (MagCore Automated NA Extractor)

**DYNAMIC RANGE**
- $10^{1}$ – 53.505 IU/ml (GeneProof PathogenFree RNA Isolation Kit)
- $10^{5}$ – 170.062 IU/ml (croBEE 201A Nucleic Acid Extraction System)
- $10^{6}$ – 33.473 IU/ml (MagCore Automated NA Extractor)

**STORAGE**
-20 ± 5 °C

**VALIDATED SPECIMEN**
Plasma (EDTA, citrate), serum

**REPORTING UNITS**
IU/ml

**METROLOGICAL TRACEABILITY**
HCV NIBSC 14/150

**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

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www.geneproof.com
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