



DA-TF/Hepa-100 V1/3



Polymerase chain reaction (PCR) Diagnostic Kit for **Hepatitis Virus**

Features



Quality control

Internal control to monitor the whole NAT procedure



High sensitivity

LOD: 10 IU/mL (HBV)
and 20 IU/mL (HCV)



Shorter window period

Shorter window period (diagnostic period) owing to the adoption of PCR-based technology



Wide linear range

Wide linear range from 20 to more than 1.0×10^9 IU/mL (HBV)
and from 50 to more than 1.0×10^8 IU/mL (HCV)



Fully automatic nucleic acid extraction

Compatible with automated extraction platform for nucleic acid purification



No cross-reactivity

Accuracy can be guaranteed as the kits are free of cross-reactivity with other viruses

Decode Genetic Life. Assure Human Health.

Polymerase chain reaction (PCR) Diagnostic Kit for **Hepatitis Virus**

Since 1995, Daan gene has been engaged in the R&D and clinical practice of hepatitis virus nucleic acid reagent. In 1999, The PCR detection kit for Hepatitis B Virus has been launched and became the first commercial HBV PCR kit in China and in the world. **On April 12, 2022**, Daan Gene's nucleic acid testing kits for **Hepatitis B Virus** (PCR-fluorescent probe method) and **Hepatitis C Virus** nucleic acid testing kits (PCR-fluorescent probe method) obtained **CE List A** product certification, becoming China's **FIRST** manufacturer to obtain the highest level of NAAT kit certification in the European Union.

Years of Daan Gene's Combat with the Hepatitis Virus



Background

Hepatitis B and C are viral infections that attack the liver and can cause both acute and chronic hepatitis, ranging in severity from a mild illness to a serious, lifelong illness including liver cirrhosis and cancer. Hepatitis B and C can also be transmitted through unsafe injections, sexual contact and sharing equipment for injecting drug use, etc.

WHO estimates that 354 million people worldwide live with hepatitis B or C, with about 3 million new infections occurring per year.

WHO's Global hepatitis strategy aims to reduce new hepatitis infections by 90% and deaths by 65% between 2016 and 2030.

Clinical Significance

- Used in early diagnosis of at-risk individuals
- Used to monitor response to therapy and as a marker of infectivity
- The WHO "Guidelines on hepatitis B and C testing" made a strong recommendation for the use of a **nucleic acid testing assay (e. g. PCR)** as the preferred strategy for diagnosis of viraemic infection.



Ce Cert.

CERTIFICATE

DIRECTIVE 98/79/EC
FULL QUALITY ASSURANCE SYSTEM

CeCert Sp. z o.o. hereby confirms that
the quality assurance system in the organization

Daan Gene Co., Ltd.
No. 19, Xiangshan Road, Science Park,
High & New Technology Development District,
Guangzhou, Guangdong, P.R. China

with regard to the design, manufacture and final inspection
of in vitro diagnostic medical devices referred to in List A in Annex II

Diagnostic Kit for Quantification
of Hepatitis B Virus DNA
(PCR- Fluorescence Probing)
catalogue number: DA0041

conforms to the requirements of Annex IV (excluding section 4 and 6)
to Directive 98/79/EC (as amended) implemented into Polish Law,
as evidenced by the audit conducted by CeCert Sp. z o.o.



2934



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Diagnostic Kit for Quantification
of Hepatitis C Virus RNA
(PCR- Fluorescence Probing)
catalogue number: DA0082

conforms to the requirements of Annex IV (excluding section 4 and 6)
to Directive 98/79/EC (as amended) implemented into Polish Law,
as evidenced by the audit conducted by CeCert Sp. z o.o.



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The 1st company
in China to obtain
CE List A
approval for
HBV/HCV
PCR kit.





DA0041

Diagnostic Kit for Quantification of Hepatitis B Virus DNA (PCR-Fluorescence Probing)

Diagnostic Kit for Quantification of Hepatitis B Virus DNA (PCR-Fluorescence Probing) is intended for the quantitative detection of HBV DNA in human serum or plasma specimens. This kit is based on the real-time fluorescent PCR technique and designs specific primers and fluorescence probes that take relatively conserved regions in the HBV genome as target regions.



CE

NMPA

FSC

Parameter

Test Principle	Quantitative real-time fluorescent PCR
Specimen type	Serum or plasma
Fluorescence channel	FAM, VIC
LOD	10 IU/mL
linear range	20 IU/mL-1.0×10 ⁹ IU/mL
Storage and shelf life	-20±5°C, 9 months
Applicable Instruments	ABI Prism 7500
Certificate	CE, NMPA, FSC



DA0182

Diagnostic Kit for Quantification of Hepatitis C Virus RNA (PCR-Fluorescence Probing)

Diagnostic Kit for Quantification of Hepatitis C Virus RNA (PCR-Fluorescence Probing) is intended for the quantitative detection of hepatitis C virus (HCV) RNA in human serum or plasma specimens. This kit is based on the real-time fluorescent PCR technique and designs specific primers and fluorescence probes that take relatively conserved regions in the HCV genome as target regions.



CE

NMPA

FSC

Parameter

Test Principle	Quantitative real-time fluorescent PCR
Specimen type	Serum or plasma
Fluorescence channel	FAM, VIC
LOD	20 IU/mL
linear range	50 IU/mL-1.0×10 ⁸ IU/mL
Storage and shelf life	-20±5°C, 9 months
Applicable Instruments	ABI Prism 7500
Certificate	CE, NMPA, FSC



DA003X

Diagnostic Kit for Quantification of Hepatitis B Virus DNA (PCR-Fluorescence Probing)

Diagnostic Kit for Quantification of Hepatitis B Virus DNA (PCR-Fluorescence Probing) is intended for the quantitative detection of hepatitis B virus (HBV) DNA in human serum or plasma specimens. This kit is based on the real-time fluorescent PCR technique and designs specific primers and fluorescence probes that take relatively conserved regions in the HBV genome as target regions.



Parameter

Test Principle	Quantitative real-time fluorescent PCR
Specimen type	Serum or plasma
Fluorescence channel	FAM, VIC
LOD	30 IU/mL
linear range	100 IU/mL-5.0×10 ⁸ IU/mL
Storage and shelf life	-20±5°C, 9 months
Applicable Instruments	ABI Prism 7300, ABI Prism 7500, LightCycler480
Certificate	NMPA, FSC



Order Information

Description	Cat. No.	Package
Diagnostic Kit for Quantification of Hepatitis B Virus DNA (PCR-Fluorescence Probing)	DA0041	Large package, 48 tests/kit
Diagnostic Kit for Quantification of Hepatitis C Virus RNA (PCR-Fluorescence Probing)	DA0182	Large package, 48 tests/kit
Diagnostic Kit for Quantification of Hepatitis B Virus DNA (PCR-Fluorescence Probing)	DA0030	Single tube for single test: 20 tests/kit
	DA0032	Large package, 20 tests/kit

Daan Gene Co., Ltd.

CHINA (Headquarters)

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