



CE

NMPA

FSC



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

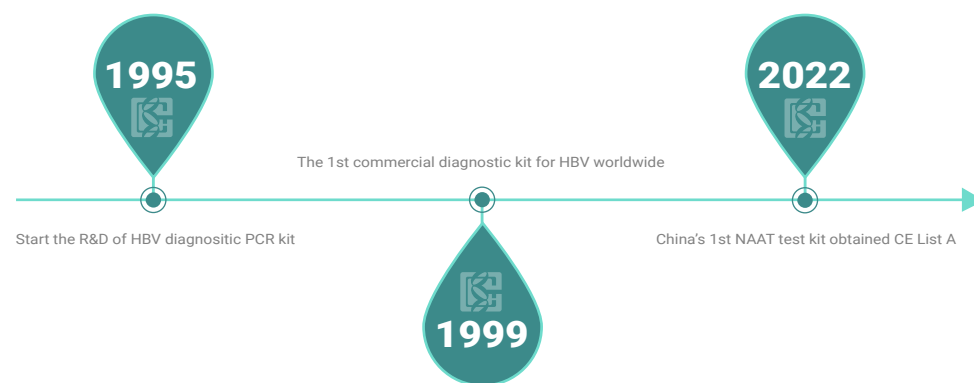
Decode Genetic Life. Assure Human Health.



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. 79, 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 device referred to in List A in Annex II

Diagnostic Kit for Quantification of Hepatitis B Virus DNA (PCR-Fluorescence Probing)
catalogue number: DA004

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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Validity date: 03.04.2022 - 04.03.2025

Issue date: 03.04.2022

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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.



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.



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

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