

# Case Study

## Clinical Evaluation of Daan Gene HBV DNA Quantitative Assay

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# Case Study: Clinical Evaluation of Daan Gene HBV DNA Quantitative Assay

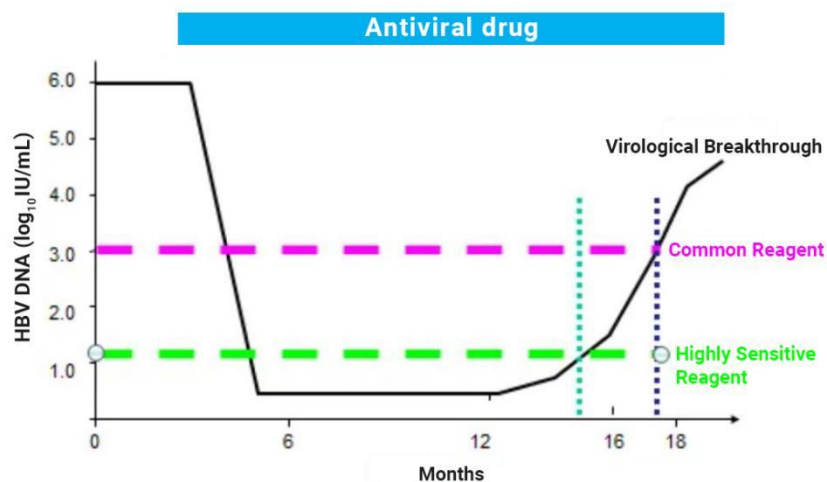
Precise diagnosis is crucial to stop the progression of chronic hepatitis b, HBV DNA quantitative PCR test plays a significant part in measuring HBV infectivity and prescribing antiviral treatment for hepatitis b.

## Why HBV DNA Quantitative Test Important?

As nucleic acid-based technology has enabled more precise quantification of HBV DNA detection, hepatitis B virus PCR detection assay is vital for the evaluation of the hepatitis b development stage and efficacy of antiviral treatment. In this article, we discuss the importance of the HBV DNA quantitative PCR test in assessing HBV infectivity and prescribing antiviral treatment for hepatitis b.

## Evaluating the Infectivity and Phases of hepatitis B

Chronic hepatitis B is a dynamic disease, patients may experience several disease phases from disease activity to inactivity. Hepatitis B virus (HBV) infection develops through several stages. The immune activation phase of chronic hepatitis B is characterized by moderate to high levels of HBV replication and infectivity. While an inactive carrier state, marked by low levels of HBV replication and infectivity. The Hepatitis B virus (HBV) DNA quantitative test can help evaluate the infection phases and infectivity of the disease, which can provide better treatment to the patient.



# Making Hepatitis B Antiviral Treatment Decision Based on HBV DNA Quantitative Test

Before prescribing hepatitis b antiviral treatment, quantitative detection of HBV DNA should conduct to confirm the level of the virus, alanine aminotransferase (ALT), and the severity of the liver disease.

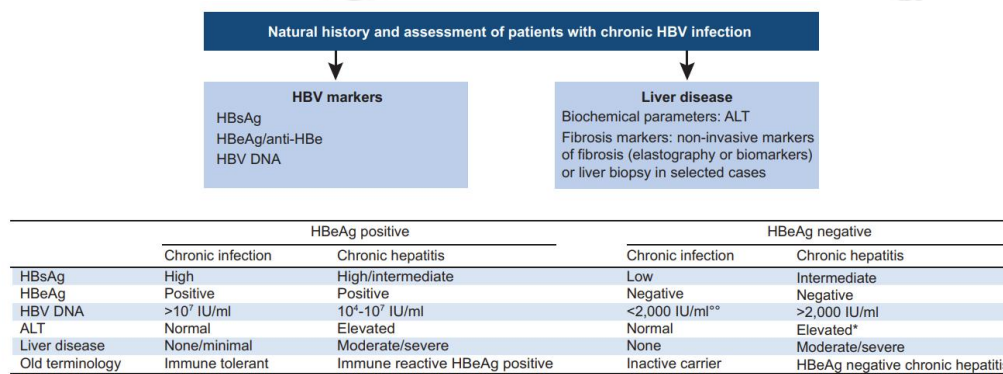


Fig. 1. Natural history and assessment of patients with chronic HBV infection based upon HBV and liver disease markers. \*Persistently or intermittently. \*\*HBV DNA levels can be between 2,000 and 20,000 IU/ml in some patients without signs of chronic hepatitis.

Source: <https://easl.eu/wp-content/uploads/2018/10/HepB-English-report.pdf>

Antiviral therapy for hepatitis B is to reduce the risks of long-term complications such as cirrhosis and HCC. Since the HBV replication and elevation of ALT levels indicate a critical risk of disease progression. Conducting antiviral therapy is aim to decrease the HBV viral load and the replication ability of the virus, so HBV DNA detection is important during hepatitis B antiviral therapy because it can evaluate the possibility of antiviral resistance.

To eliminate viral hepatitis, it is necessary to improve the public's awareness of viral hepatitis and increase the diagnosis and treatment efficiency of viral hepatitis. Advanced viral hepatitis diagnostic assays are essential to tackle HBV and HCV.

## Guidelines for Viral Hepatitis Detection

Hepatitis B is liver inflammation caused by the hepatitis B virus (HBV). Hepatitis B antiviral therapy is aiming to inhibit the replication of the hepatitis B virus and reduce the HBV DNA copies level, to decrease the risk of liver cancer. High-sensitivity HBV DNA diagnostic assays are of great importance in clinical diagnosing. Currently, improving criteria of HBV DNA PCR diagnostic assay from different hepatitis academic association reflects the rising attention towards eliminating HBV from all over the world.

Guidelines	Sensitivity	
2015	Guidelines of Asia Pacific Society of Hepatology (APASL)	≤12 IU/ml
	Guidelines of World Health Organization (WHO) Hepatitis B	≤15 IU/ml
2017	The European Society of Hepatology (EASL)	The lower the better, Recommend ≤10 IU/ml
2018	Guidelines of American Academy of Hepatology (AASLD)	≤10 IU/ml

## Case Study on Daan Gene High Sensitivity HBV Test Kit

An investigation conducted by Wang Yajie's team at Beijing Ditan Hospital affiliated with Capital Medical University collected plasma from 514 outpatients and inpatients with hepatitis B who visited the hospital from February to June 2019. Professor Wang's team conduct parallel testing on the Daan Gene high-sensitivity HBV virus nucleic acid quantitative testing kit and other international mainstream HBV detection assays, to test the viral load in the plasma of hepatitis B patients and then conducted a comparative analysis of the correlation and consistency of the two testing results.

Table 1 Characterization comparison of 2 reagents

Item	Daan Gene HBV Detection Kit	Other International Mainstream HBV Detection Kit
Sample Type	Serum or plasma	Serum or plasma
Sensitivity	HBV: 10 IU/mL	HBV: 9 (serum)/ 19 (plasma) IU/mL
Liner Range	HBV: 20~1x10 <sup>9</sup> IU/mL	HBV: 20~1.7x10 <sup>8</sup> IU/mL

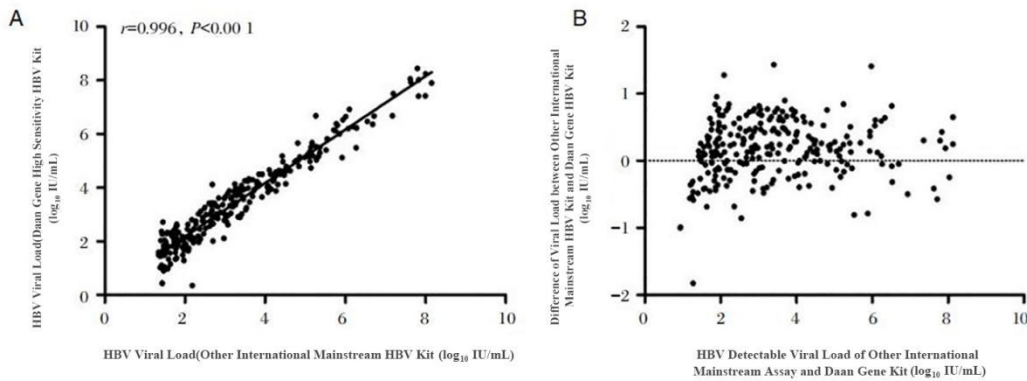


Figure 1 The Correlation and consistency analysis between 2 reagents

The results prove that Daan Gene's high-sensitivity HBV reagent increased the linear range to  $10^9$  IU/ml, and reduced the detection limit to 10 IU/ml. The detection result shows that the effective values of the two reagents had good correlation and consistency.

## High Sensitivity Hepatitis B Test Kit Application

HBV tends to mutate quite more easily than other DNA virus due to the unstable structure of the HBV genome. The mutation of HBV changes the biological behavior of the virus and decrease the efficacy of antiviral drugs, affecting the therapeutic effect and the progress of the disease. Hepatitis b virus DNA quantitative test can help identify occult HBV infection (OBI) and occult chronic hepatitis B. In addition, high sensitivity test assay of HBV DNA is crucial for the diagnosis of serologically atypical chronic HBV infection, and it is of great significance for the confirmation of inactive HBsAg carrying status (serum HBV DNA $<2000$ IU/ml).

High-sensitivity HBV detection assay not only can screen the occult HBV infection, but also serve as an important indicator for preoperative examination, risk assessment of HBV reactivation after radiotherapy and chemotherapy in tumor patients, efficacy and end-point evaluation of antiviral therapy, and prediction of HBV resistance mutations in HBeAg-negative patients.

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## Daan Gene High Sensitivity HBV DNA Quantitative Test Kit

Daan Gene's HBV PCR test kit has obtained **CE List A** approval, performing high sensitivity and specificity in HBV DNA quantitative test.

In the Daan Gene HBV DNA Quantitative PCR assay, a specific primer and a fluorescence probe are designed by adopting the fluorescence PCR technology and selecting a relatively conserved region in the HBV genome as a target region. After the sample nucleic acid is purified, the HBV DNA is quickly quantitatively detected by PCR. In addition, the Daan Gene HBV test kit also contains an internal standard substance for monitoring the whole process of nucleic acid extraction, to reduce false-negative results.

### Features of DaAn Gene HBV Test Kit

- Wide liner range: 20 IU/mL- $1.0 \times 10^9$  IU/mL.
- Internal control: monitor the whole extraction process.
- Reliable: UNG enzyme to prevent contamination.
- High Sensitivity: LOD 10 IU/mL
- Genotype: Cover HBV genotype A-G

[>> Learn More about DaAn Gene Hepatitis B Test Kit](#)

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