

# HBV PCR Fluorescence Quantitative Detection Kit



Hepatitis B Virus (HBV) is the causative agent of hepatitis B (HB), belonging to the Hepadnaviridae family. This family includes the Orthohepadnavirus genus and the Avihepadnavirus genus. The virus that infects humans is from the Orthohepadnavirus genus. HBV is characterized by high replication levels and mutation rates. At least eight genotypes (A-H) of HBV have been identified, each of which can be further divided into subgenotypes, and recombination between genotypes has been observed. In the United States and Europe, the predominant HBV genotypes are typically genotype A and genotype D. Genotype A is common in North America and Europe, while genotype D is prevalent in Southern Europe and parts of the Middle East.

HBV DNA quantification is used to assess the viral load and replication activity in patients. It is currently considered the "gold standard" for evaluating HBV replication and is a critical laboratory diagnostic tool for confirming occult HBV infection and chronic hepatitis B. This test is also a valuable indicator for monitoring disease progression. Nucleic acid amplification testing (NAT) is highly sensitive for detecting low levels of HBV virus in the body, enabling the detection of low viral loads. This allows clinicians to understand the viral quantity, replication level, infectivity, drug treatment efficacy, and guide treatment strategies. NAT is the only laboratory diagnostic tool that can help confirm occult HBV infection and latent chronic HBV infection.

## Specifications

Parameter Name	Description
Sample Type	Plasma, Serum
Genotype Coverage	Genotypes A-H (8 genotypes)
LOD	5 IU /mL
LOQ	20 IU/mL
Linear Range	20 IU /mL ~2x10 <sup>9</sup> IU /mL
Specificity	No cross-reactivity with pathogens like Hepatitis C virus
Compatible Instruments	LineGene, QuantGene Fluorescent Quantitative Detection System
Recommended Extraction Kits	BSC86 MagaBio plus Virus DNA/RNA Purification Kit III BSC71 MagaBio plus Virus DNA/RNA Purification Kit II BSC110 MagaBio plus Virus DNA/RNA Purification Kit VI
Detection Time	Pre-mixed reagents, detection can be completed within 1 hour

## Principle

This kit is designed based on the conserved regions of the Hepatitis B virus genome, utilizing specific primers and fluorescence-labeled probes for enhanced specificity. Compared to conventional PCR methods, this approach offers higher automation, faster processing, greater sensitivity, and higher specificity. The kit uses a fully pre-mixed reagent system, optimized through the refinement of the reaction buffer and hot-start DNA polymerase, which reduces the need for user preparation of reagents. Additionally, an external internal control is introduced during the extraction process to monitor both the extraction and detection stages, ensuring more accurate and reliable results.

## Product Features

- ✓ **Applicable Samples:** Plasma, Serum.
- ✓ **High Accuracy:** Effectively quantifies the Hepatitis B virus content in samples, with results that meet expectations.
- ✓ **Good Specificity:** No cross-reactivity with pathogens such as Hepatitis C virus.
- ✓ **Real-time Monitoring:** An external internal control is introduced to monitor the entire extraction and PCR detection process.
- ✓ **Simple Operation:** Fully pre-mixed reagents, ready for use with direct dispensing. The process is fully closed-tube, preventing aerosol contamination during amplification and detection.

## Application Cases

### Case 1:

Hepatitis B virus, Human Immunodeficiency Virus (HIV), Hepatitis C Virus, Herpes Simplex Virus Type 1, Herpes Simplex Virus Type 2, Influenza A Virus, and Staphylococcus aureus were tested using this kit. No amplification signals were detected for any pathogens other than Hepatitis B virus, indicating that the kit has no cross-reactivity with other pathogens and exhibits good specificity.

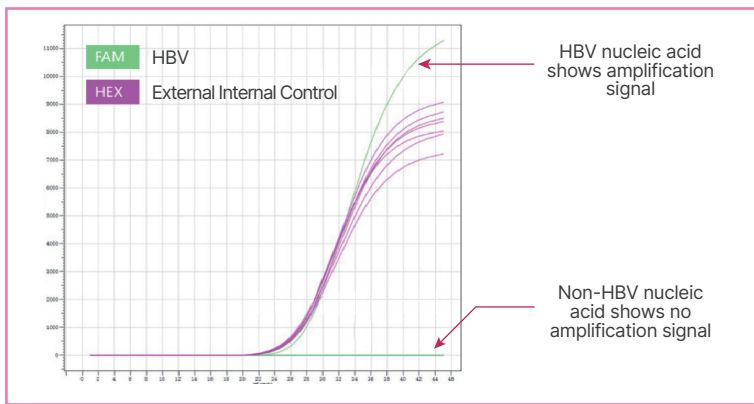


Figure 1: Fluorescence Quantitative PCR Amplification Curve of Hepatitis B Virus and Other Viral Strains

### Case 2:

The Hepatitis B virus was detected using this kit, and a standard curve was generated. The correlation coefficient of the Ct value of the target gene reached above 0.995, indicating a good linear relationship and high PCR efficiency. The results are shown in the figure below:

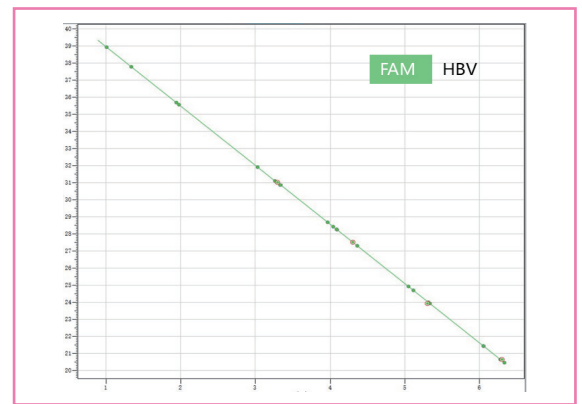


Figure 2: Standard Curve of Hepatitis B Virus Quantification Detection Kit

### Case 3:

The Hepatitis B virus was detected using this kit with nucleic acid samples of known concentration. The logarithmic deviation between the measured and theoretical values was  $\leq 0.5$ , indicating high accuracy in the kit's quantification. The results are shown in the figure below:

Sample	Theoretical Value IU/mL	Measured Value IU/mL	Logarithmic Deviation
S1	100000	1.12E+05	0.05
S2	10000	1.21E+04	0.08
S3	1000	1.08E+03	0.03
S4	100	9.55E+01	0.02
S5	20	2.19E+01	0.14
S6	5	8.02E+00	0.01
Negative	\	\	\

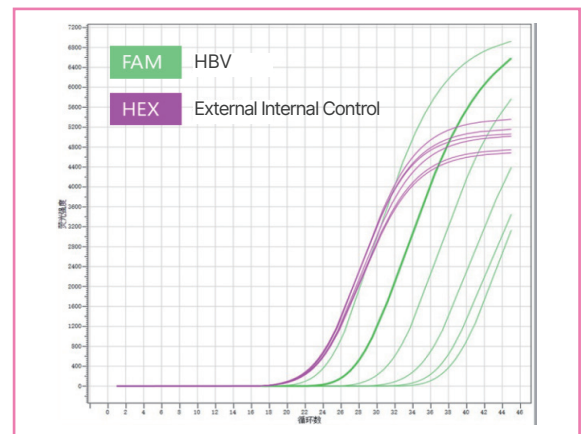


Figure 3: qPCR Amplification Curve of Hepatitis B Virus Quantification Detection Kit

## Ordering Information

Product Name	Cat.No.	Package	Storage Condition
HBV PCR Fluorescence Quantitative Detection Kit	BSB01M1	48T	-20 ± 5°C



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Add: 1192 Bin An Rd., Hi-tech (Binjiang) District, Hangzhou, 310053, P.R.China Web: [www.bioer.com](http://www.bioer.com)  
Tel: +86-571-87774513 Fax: +86-571-87774553 E-Mail: [reagent@bioer.com](mailto:reagent@bioer.com) E-Date: 2024.12