

Kit Specifications

Product Name	Hepatitis B Virus (HBV) Nucleic Acid Detection Kit (Fluorescence PCR Method)	
Specimen	Human serum/plasma	
Analysis Method	Quantitative Analysis (Internal Standard Method)	
LoD	5 IU/mL	
LoQ	10 IU/mL	
Linear Range	10~1.0×10 ⁹ IU/mL	
Linear Correlation Coefficient	r >0.980	
Precision	CV≤5%	
Genotype Coverage	HBV genotypes A, B, C, D, E, F, G and H	
Anti-contamination Measures	UNG-dUTP	
Storage & Validity	-20 C ±5 C for 12 months	
Specification	96T/Kit	32T/Kit

Providing Integrated Solution

Flexible solutions to meet diverse customer needs

Comprehensive Solution	Sample Processing	Nucleic Acid Extraction	PCR Setup	PCR Detection
Option 1		 Tianlong Libex		 Tianlong Gentier 96
Option 2		 Tianlong GeneRotex 96		
Option 3	 Tianlong PANA9600S			
Option 4	 Tianlong PANA9600X			
All-in-one Solution	Sample Processing&Nucleic Acid Extraction&PCR Setup&PCR Detection			
Option 1		 Tianlong Panall 8000		
Option 2		 Tianlong PANA 3200S+ (with Gentier96)		

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Rev.: V3 Rel.: March 4, 2026

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Molecular Diagnosis

Hepatitis B Virus (HBV) Nucleic Acid Detection Kit (Fluorescence PCR Method)

Hepatitis B Virus (HBV) Nucleic Acid Detection Kit (Fluorescence PCR Method)

KHB Hepatitis B Virus (HBV) Nucleic Acid Detection Kit is intended for quantitative detection of HBV DNA in human serum or plasma samples. This is used for assessment of response to antiviral therapy and monitoring of therapeutic effect. This kit is not used for blood screening.



Clinical Significance

- Accurately assess antiviral treatment response
- Reliable monitoring of low-level viremia
- Supports detection of occult HBV infection (OBI)
- Early warning of HBV reactivation risk in immunosuppressed patients
- Helps identify virological breakthrough during therapy

Detection Principle

Full-process internal control for reliable results

Minimize inter-tube variation and ensure batch reliability

Internal standard quantification

No run-specific standard curve required for simplified workflow

Reduced contamination risk and reagent consumption

Reference Guideline

Sensitivity requirements for HBV DNA testing in authoritative guidelines

American Association for the Study of Liver Diseases (AASLD) 2018	5–10 IU/mL
European Association for the Study of the Liver (EASL) 2017	< 10 IU/mL
World Health Organization (WHO) 2015 Chronic Hepatitis B Prevention Guidelines	< 15 IU/mL
Asian Pacific Association for the Study of the Liver (APASL) 2015	< 12 IU/mL

Product Performance

Figure 1: Linear range validation amplification curve

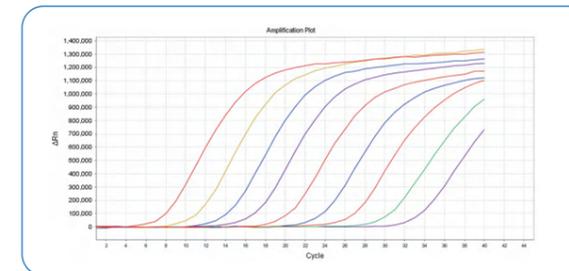
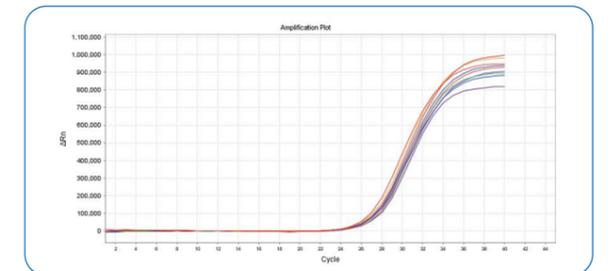


Figure 2: Non-competitive internal standard amplification curve



Clinical Evaluation

The product was subjected to clinical trials at three clinical trial institutions, with a total of 509 samples included. The positive, negative, and overall coincidence rates of the product with the reference reagents were 100.00%, 95.00%, and 99.41%, respectively. The results are accurate and reliable.

Kappa Test

KHB HBV reagent test results	Reference reagent test results		Total
	Positive	Negative	
Positive	449	3	452
Negative	0	57	57
Total	449	60	509

Regression Analysis

