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Kit Specifications

Product Name	Hepatitis C Virus (HCV) Nucleic Acid Detection Kit (Fluorescence PCR Method)	
Specimen	Human serum/plasma	
Analysis Method	Quantitative Analysis (Internal Standard Method)	
LoD	12.5 IU/mL	
LoQ	30 IU/mL	
Linear Range	$30 \sim 1 \times 10^8$ IU/mL	
Linear Correlation Coefficient	|r|≥0.980	
Precision	CV≤5%	
Genotype Coverage	HCV genotypes 1-6	
Anti-contamination Measures	UNG-dUTP	
Storage & Validity	$-20\,℃ \pm 5\,℃$ 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		
Option 2		Tianlong GeneRotex 96		Tianlong Gentier 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 PanaII 8000
Option 2	Tianlong PANA 3200S+(with Gentier96)

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Hepatitis C Virus (HCV) Nucleic Acid Detection Kit (Fluorescence PCR Method)

Hepatitis C Virus (HCV) Nucleic Acid Detection Kit (Fluorescence PCR Method)

KHB Hepatitis C Virus (HCV) Nucleic Acid Detection Kit applies to quantitative detection of Hepatitis C Virus (HCV) in human serum or plasma samples. It is used to assess the response to antiviral therapy and monitor the therapeutic effect by monitoring the baseline level and changes of HCV RNA in HCV patients. This kit should not be used for blood screening.

01
Broad genotype coverage
covering HCV genotypes 1-6

02
High sensitivity
LoD: 12.5 IU/mL

03
Wide linear range
30~1.0×10⁸IU/mL

04
Accurate quantification
internal standard-based quantification

Clinical Significance

Confirmation of active HCV infection

Baseline viral load analysis before antiviral therapy

Monitoring of antiviral treatment efficacy

Response assessment after completion of antiviral 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

Product Performance

Figure 1: Linear range validation amplification curve
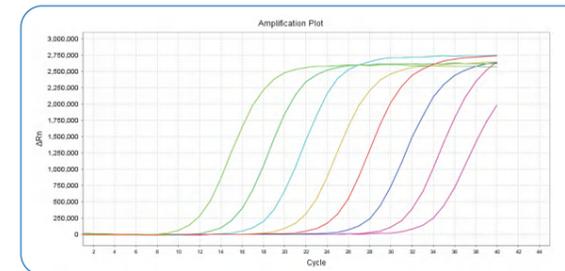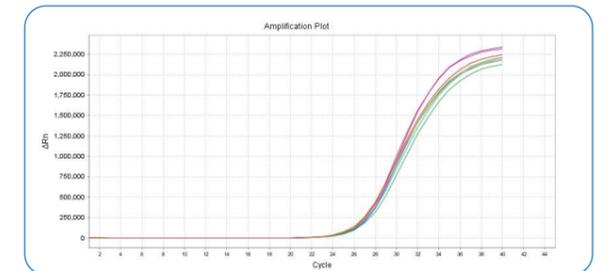

Figure 2: Non-competitive internal standard amplification curve

Clinical Evaluation

The product was subjected to clinical trials at three clinical trial institutions, with a total of 530 samples included for analysis. The positive, negative, and overall coincidence rates of the product with the reference reagents were 100.00%, 95.45%, and 99.43%, respectively. The results are accurate and reliable.

Kappa Test

KHB HCV reagent test results	Reference reagent test results		Total
	Positive	Negative	
Positive	464	3	467
Negative	0	63	63
Total	464	66	530

Regression Analysis

$Y = 0.224 + 1.003X$
$R^2 = 0.9761$