Kit Specifications

Product Name	Human Immunodeficiency Virus Type 1 (HIV-1) Nucleic Acid Detection Kit (Fluorescence PCR Method)	
Specimen	Human serum/plasma	
Analysis Method	Quantitative Analysis (Internal Standard Method)	
Target Gene	pol, gag, LTR	
LoD	20 IU/mL	
LoQ	40 IU/mL	
Linear Range	40~1.0×10^8 IU/mL	
Linear Correlation Coefficient	|r|≥0.980	
Precision	CV≤5%	
Genotype Coverage	HIV-1 group M, N and O	
Anti-contamination Measures	UNG-dUTP	
Storage & Validity	-20℃±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		 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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Molecular Diagnosis

Human Immunodeficiency Virus Type 1 (HIV-1) Nucleic Acid Detection Kit (Fluorescence PCR Method)

Human Immunodeficiency Virus Type 1 (HIV-1) Nucleic Acid Detection Kit (Fluorescence PCR Method)

This kit is intended for quantitative detection of HIV-1 RNA in human serum or plasma samples. It is indicated for patients with acquired immunodeficiency syndrome (AIDS) receiving antiviral therapy. It is used to assess the response to antiviral therapy and monitor the therapeutic effect by monitoring the baseline level and changes of HIV-1 RNA in AIDS patients. This kit should not be used for blood screening.

01 **Broad subtype coverage**
covering HIV-1 group M, N, O

04 **Accurate quantification**
internal standard-based quantification

02 **High sensitivity**
LoD: 20 IU/mL

05 **Wide linear range**
40~1.0×10⁸IU/mL

03 **Highly Reliable**
triple targets design:pol, gag, LTR

06 **High Flexibility**
compatible with multiple instruments to meet diverse needs

Clinical Significance

Confirmation of active HIV-1 infection

Early diagnosis of HIV-1 Mother-to-Child transmission in infants

Monitoring of antiviral treatment efficacy

Baseline viral load analysis before antiviral therapy

Detection Principle

Full-process internal control for reliable results

No run-specific standard curve required for simplified workflow

Internal standard quantification

Minimize inter-tube variation and ensure batch reliability

Reduced contamination risk and reagent consumption

HIV-1 Viral Load Testing Frequency[1,2]

Acute phase, window period	Before starting therapy	After therapy or after adjustment of therapy	Long-term therapy				
		4-8 weeks	8-12 weeks	Every 3-4 months	Every 3 months	Every 3 months	Every 6 months
Early detection and diagnosis	Determine baseline viral load	Determine treatment response effectiveness and efficacy	Antiviral therapy until below the lower limit of detection	Within 2 years of therapy	HIV viral load > 200 copies/mL	Patients on glucocor-ticoids or chemother-apeutic agents	After 2 years of therapy

Product Performance

Figure 1: Linear range validation amplification curve

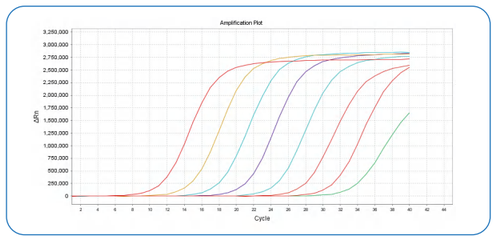
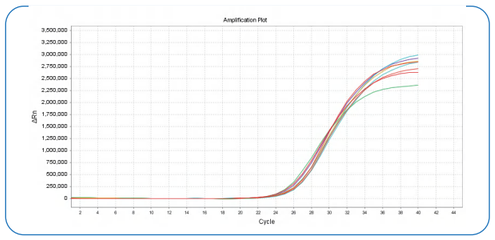


Figure 2: Non-competitive internal standard amplification curve



References:
1.National Technical Specifications for HIV Testing (2020)
2.China AIDS Diagnosis and Treatment Guidelines (2024)