DA-TF/BVCVIV-100 V2/1

DaAnGene

Blood Screening

Automatic Blood Screening System For Nucleic Acid Testing

Intended use

Blood transfusion is a life-saving intervention that has an essential role in patient management within health care systems, but many patients requiring transfusion do not have timely access to safe blood. WHO recommends that all blood donations should be screened for infections prior to use. Screening for HIV, hepatitis B and hepatitis C should be mandatory. According to the WHO report on blood safety (2018), 12 countries are not able to screen all donated blood for one or more of the above infections.

Nucleic Acid Test Kit for HBV HCV HIV (Real-time PCR)

Daan designed this kit based on fluorescent PCR/RT-PCR amplification detection technology for the qualitative detection of hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus type 1 (HIV-1) nucleic acids in pooled/separated serum and plasma specimens.

Features

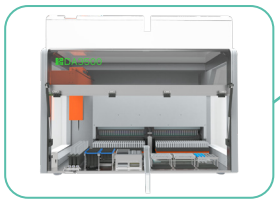
- HBV/HCV/HIV-1 triple independent amplification.
- UNG enzyme contamination prevention system.
- Internal control is set to monitor the whole process.

Procedure

Sample — Barcode Identification — Automatic Sample Loading — Automatic Extraction — PCR Set-up — RT-PCR

Workflow

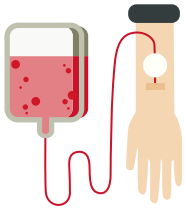
Nucleic Acid Test Kit for
HBV/HCV/HIV-1



DA3500
Nucleic Acid Extraction Instrument

Lava 96
Real-time PCR System

Automatic Blood Screening System For Nucleic Acid Testing



- **Integrated**
  Fully automatic sample preparation and nucleic acidextraction in one module to build up a integrated reaction system.
- **Flexible**
  HBV, HCV and HIV triple independent amplification.
- **No contamination**
  Rotation technology avoids contamination caused bythe violent oscillation. Air filtration system, UV lamp, aswell as independent sample pooling and extraction zone prevent cross contamination.
- **Zero waste**
  Individual cartridge-based extraction consumable meets 1-48 tests per run.

Result interpretation

If internal control, positive quality control and negative quality control meet quality control requirements, result can be interpreted as following:

Positive result: There is S-shaped amplification curve for FAM detection channel and Ct value is lower than 40.

Negative result: There is no S-shaped amplification curve for FAM detection channel.

Grey area: There is S-shaped amplification curve for FAM detection channel and Ct value is higher than 40. The whole test should be repeated.

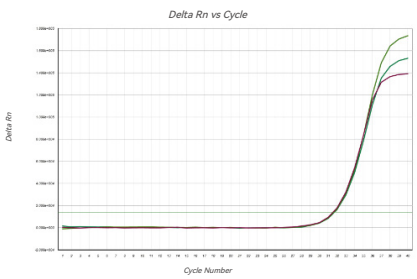


Fig.1. Sensitivity of HBV Blood Screening Real-time PCR Kit

Fig.2. Sensitivity of HCV Blood Screening Real-time PCR Kit

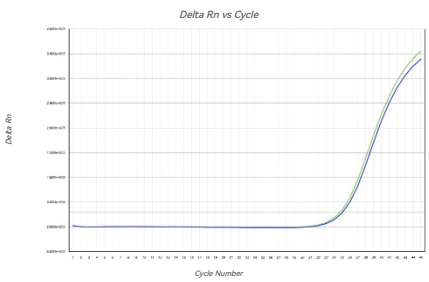


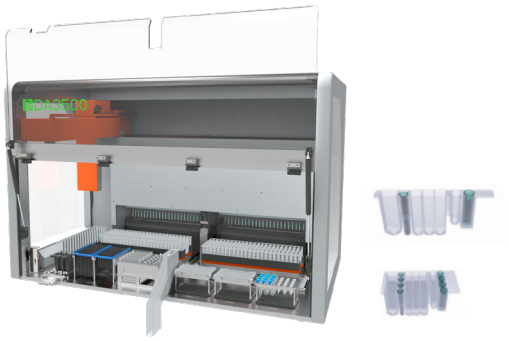
Fig.3. Sensitivity of HIV Blood Screening Real-time PCR Kit

Nucleic Acid Test Kit for HBV/HCV/HIV-1

Methodology	RT-PCR
Quality control	Internal control and UNG enzyme anti-contamination
LOD	1mL single sample: 100 IU/mL, Mixed sample: 500 IU/mL
Quantitative/qualitative	Qualitative
Storage and shelf life	-20±5℃, 12 months

DA3500 Nucleic Acid Extraction Instrument

Ready-to-use reagents simplify the extraction process. While individual and '4-in-1'cartridges satisfy different number of samples.



Method	Magnetic beads
Sample volume	20~2000uL
Sample capacity	48 samples
Running time	60 min/48samples (45 min only for extraction)
Anti-contamination	HEPA filter, UV light
Mixing method	Rotation

Lava 96 Real-time PCR System

It combines advanced optical system with precise temperature control to provide stable, reliable analysis of 1 to 96 samples.

Through-put	1-96 samples
Fluorescence channels	FAM,VIC,TEXAS-Red,CY5; 2extend channels
Temperature range	0-100℃
Temperature uniformity	±0.5℃
Heating rate	≥4.5℃/s
Cooling rate	≥3.0℃/s
Excitation light source	LED (maintenance-free)
Display	12.1 inches color touch screen

WHO data

99.8% of the donations in high-income countries and 99.9% in upper-middle-income countries are screened following basic quality procedures, as compared to 83% in lower-middle-income countries and 76 % in low-income countries. The prevalence of transfusion-transmissible infections in blood donations in high-income countries is considerably lower than in low- and middle-income countries.

Prevalence of transfusion-transmissible infections in blood donations

	HBV	HCV	HIV
High-income countries	0.02%	0.007%	0.002%
Upper middle-income countries	0.29%	0.19%	0.10%
Lower middle-income countries	1.70%	0.38%	0.19%
Low-income countries	2.81%	1.00%	0.70%

Daan Gene Co., Ltd.

CHINA (Headquarters)

Add: No.19, Xiangshan Road, Science Park, High & New Technology Development District, Guangzhou, Guangdong, P.R. China
Tel.: +86-20-32290789-5225
Fax: +86-20-32068352
Email: marketing@daangene.com

CANADA office

Add.: #413-4538 Kingsway, Burnaby, BC V5H 4T9, Canada
Tel.: +16044517588
Fax: +604451.7587
Email: gbai@daangene.net

COLOMBIA office

Add.: Cl 93 No.16 46 of 702, Bogotá D.C.
Tel.: +57 3103940417
Email: alonso.zheng@daangene.net

Website: https://en.daangene.com/