Viral DNA and RNA Extraction Kit

User Guide

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Version 3.0

IVD

In-Vitro Diagnostics / For Use with Automatic nucleic acid extractor compatible with Viral DNA and RNA Extraction Kit

REF T325H

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IFU_T325H_EN /Apr. 2022

Contents

Intended Use

The ***Viral DNA and RNA Extraction Kit*** is intended for rapidly extracting viral DNA/RNA from whole blood, serum, plasma, interstitial fluid, urine, swab samples. The extracted nucleic acids are of high purity and stability, and can be used in a variety of routine operations, including enzyme digestion, Polymerase Chain Reaction (PCR), DNA library constructions, Southern hybridization and blotting, Next-Generation Sequencing (NGS) and other experiments.

The ***Viral DNA and RNA Extraction Kit*** is intended to be used by professionals, such as biotechnologists, microbiologists, clinical technicians, and physicians who are trained in molecular and biological techniques.

Product Performance Indicators

The extraction kit can extract more than 10IU/mL viral DNA nucleic acid, and more than 30IU/mL viral RNA nucleic acid.

The coefficient of variation (CV) of intra-assay and inter-assay for the extraction kit is less than 5%.

Special Notes

The ***Viral DNA and RNA Extraction Kit*** must be used in combination with TIANLONG® Nucleic Acid Extraction Workstation (PANA 9600S) that have been disinfected by UV light before use. After the experiment, it is recommended to clean the instrument cabin using 75% ethanol and disinfecting it via UV light for about 15mins.

The extraction kit is particularly used for viral DNA/RNA isolation; therefore, all of experiment supplies, such as pipettes, tubes, and tips, must be processed by autoclave. Operator should wear powder-free gloves and a mask and a protective coverall.

The kit has magnetic beads with a unique separation function and buffer system to extract, separate and purify high-quality nucleic acids from whole blood, serum, plasma, interstitial fluid, urine, swab samples.

Magnetic beads enable the purification of high-quality nucleic acids that are free of protein, nuclease, and other impurities. Purified nucleic acids can be widely used in the fields of diagnostics,genomics research, disease detection, food safety and forensic identification, etc.

Please carefully read the manual of instructions before attempting to install or use the product for the first time. To consider all possible consequences of incorrect operation or non-recommended functions, pay special attention to the possible consequences.

In the absence of exceptional circumstances, it is prohibited to mix the reagents from different batches.

After the experiment, all of samples and reagents must be reasonably disposed of and other Instruments should be thoroughly cleaned and disinfected.

Testing Principle

The ***Viral DNA and RNA Extraction Kit*** is worked with TIANLONG® Nucleic Acid Extraction Workstation (PANA 9600S and similar apparatus designed by Xi'an Tianlong Science and Technology Co., Ltd). During the nucleic acid extraction process. Magnetic beads are adsorbed, transferred and released using special magnetic rods based on the principle of magnetic bead adsorption. The extraction process enables the transfer of magnetic beads/nucleic acids, the automatic completion of the nucleic acid extraction, and final isolation of high-purity nucleic acids.

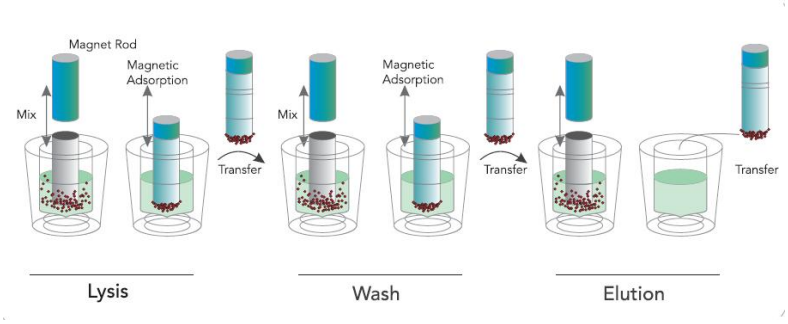


Figure 1. Schematic Diagram of Automatic Nucleic Acid Workstation

Kit Contents

Name of Component / Short Code		T325H
Pre-filled Reagent	Size	96T/Box
	Component	Pre-filled 96-deep well plate
	Component Specification	16 Tests
	Quantity	6
Proteinase K Solution	Component Specification	1.92mL
	Quantity	1
Instructions for Use		1 Copy

Materials Required but not Provided

When working in a laboratory, make sure to wear a proper lab coat, powder-free disposable gloves and protective goggles. For more information, please consult the Safety Data Sheet (SDS) available from the product supplier.

- Tip: 50µL and 1000µL
- Vortex mixer
- Sample holder
- 75% ethanol

Warnings and Precautions

Please be sure to read the precautions before using the kit.

The extraction kit is particularly used for viral DNA/RNA isolation; therefore, all of experiment supplies, such as pipettes, tubes, and tips, must be autoclaved. Operator should wear gloves and masks.

Please read the manual carefully before using the kit, and strictly follow the manual thoroughly during operation. The subjected clinical samples should be collected on a clean bench or in a bio-safety cabin.

Before using TIANLONG® Nucleic Acid Extraction Workstation (PANA 9600S), they must be disinfected by UV light. After an experiment, wipe the inside of the extractor with 75% ethanol and disinfect it with UV light for 15 mins.

Due to the possibility of residual magnetic beads in the eluate following extraction, every possible effort should be made to avoid suctioning of any magnetic beads during eluate absorption.

Do not mix reagents from different batches, and use the kit within expiry date.

Dispose of all samples and reagent materials used in an experiment, thoroughly clean and disinfect the experimental work bench.

The ***Viral DNA and RNA Kit*** is intended for in vitro diagnosis use.

When using kit, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate Material Safety Data Sheets (MSDSs). These documents are available online in a convenient and compact PDF format at https://www.ug-msds.com/MSDS1, where the operator can find, view and print the appropriate MSDSs.

⚠ **Caution: Do not add any bleach or acidic solution directly to the pre-filled reagent.**

The pre-filled reagent contains guanidinium salts, which, when combined with bleach can form highly reactive compounds. If any of these buffers are spilled, clean immediately with a suitable laboratory detergent and water. If the spilled liquid contains potentially infectious agents, clean the affected area first with laboratory detergent and water, and then with sodium hypochlorite at a concentration of 1% (v/v). The ***Viral DNA and RNA Extraction Kit*** comes with the following warnings and precautions.

- **Product contents**

Guanidine hydrochloride, sodium dodecyl sulfate, trihydroxymethyl aminomethane, isopropanol, absolute ethanol.

- **Toxicological information**

Skin corrosion/irritation
May irritate the skin.
Severe eye damage/eye irritation
May cause irreversible eye damage.
Respiratory or dermal sensitivity
No relevant data is available.
Germ cell mutagenesis
Do not conform with the classification criteria based on the existing data.
Carcinogenicity
Do not conform with the classification criteria based on the existing data.
Reproductive toxicity
Do not conform with the classification criteria based on the existing data.

Specific target organ toxicity - single exposure
May cause drowsiness or dizziness.
Specific target organ toxicity - repeated exposure
Do not conform with the classification criteria based on the existing data.
Potential health effects
Inhalation: Avoid inhalation of concentrated vapour. Inhaling a large amount of vapour may cause respiratory irritation. May cause drowsiness or dizziness.
Skin contact: May cause skin irritation.
Eye contact: Liquid contact may cause eye damage.
Ingestion: For any unexpected route of exposure, it may be harmful if ingested.

- **Ecological Information**

Ecotoxicity: Harmful to aquatic life with long-lasting effects.
Mobility: No relevant data is available.
Bioaccumulation potential: No relevant data is available.
Environmentally adverse effects: No relevant data is available.
Other adverse effects: Do not allow the product to enter drains or water sources.

- **First aid measures**

In case of eye contact: Immediately rinse the upper and lower eyelids with plenty of water.
In case of skin contact: Immediately remove contaminated clothing thoroughly, rinse the skin with soap and plenty of water. If irritation persists, immediately contact the nearest doctor/physician.
In case of inhalation: Keep away from exposure and transfer to a place with fresh air.
In case of ingestion: Do not give anything orally to an unconscious person. Rinse mouth thoroughly with water and seek immediate medical attention

for symptomatic treatment.

Reagent Storage and Handling

The ***Viral DNA and RNA Extraction Kit*** should be stored at room temperature in a cool, dry and well-ventilated area. All components of the kit can be adequately stored for up to 12 months.

The kit should be used in a well-ventilated area, away from the source of heat, sparks, open flames and smoking is not permitted.

To avoid evaporation, the pre-filled reagent should be used immediately upon opening and should not be placed open for a long period of time.

Avoid exposure of the kit to UV light (e.g., for decontamination), which may result in accelerated reagent and kit aging.

Sample Handling and Storage

Prevent foam formation inside or on the samples. Depending on the starting material, sample pre-treatment may be required. Samples should be stored at room temperature (15~25°C) before starting the experiment.

Samples should be used immediately after collection to extract nucleic acid or stored at 2~8°C for further experiment within 24 hours. While for long-term storage, the samples should be placed at -20°C.

Operation Guide

1. Automated Extraction Process

The intended use of PANA 9600S Automatic Nucleic Acid Workstation is to complete the automatic extraction and purification of nucleic acid in various samples and set up the PCR reagent system for the detection of the nucleic acids extracted. It is an automatic in vitro diagnostic instrument that can provide systematic solution for nucleic acid detection.

The PANA 9600S Automatic Nucleic Acid Workstation can precisely control the robot arm movement and drive the high-precision air displacement pipettor (ADP), provide accurate and reliable liquid transfer and sample adding operation. It greatly reduces the professional technology and time required for manual operation. The biological hazard of sample and reagent to the operator is reduced, and the automatic, safe and high-throughput PCR reagent system is set up for the the detection of the nucleic acids extracted. It can be used in clinical laboratory, CDC and medical institutions at all levels.

PANA 9600S Automatic Nucleic Acid Workstation is depicted in Figure 2 . Please refer to the user manual provided with an instrument for operating instructions.

Figure 2. PANA 9600S Automatic Nucleic Acid Workstation

2. Operation Steps of Automated Extraction

2.1 Automatic Nucleic Acid Workstation (model: PANA 9600S)

2.1.1 Experiment Preparation

Reagent Preparation

Please remove the PCR reagent from the refrigerator, thaw and balance to room temperature.

please remove the protease K solution from the refrigerator, thaw and balance to room temperature.

Instrument Preparation

- Please power on the PANA workstation.
- Please login the PANA system software, which is shown in figure 3.

Figure 3. PANA System Software-Login Interface

- After login the PANA system software, the touch screen of the master computer will display the main interface, which is shown in figure 4.

Figure 4. PANA System Software-Main Interface

▸ Please click the < ***Experiment Setting*** > tab in the menu bar of PANA system software, the system software will automatically enter the experiment setting interface, as shown in figure 4. The experiment setting interface consists of following three columns: ***Experiment Item,*** ***Sample Setting and Reagent/Consumable.***

Figure 5. PANA System Software-Experiment Setting Interface

▸ Please input the experiment information in the< ***Experiment Item*** > column and <***Sample Setting*** >column on the experiment setting interface of the PANA system software， as shown in figure 6 and 7.

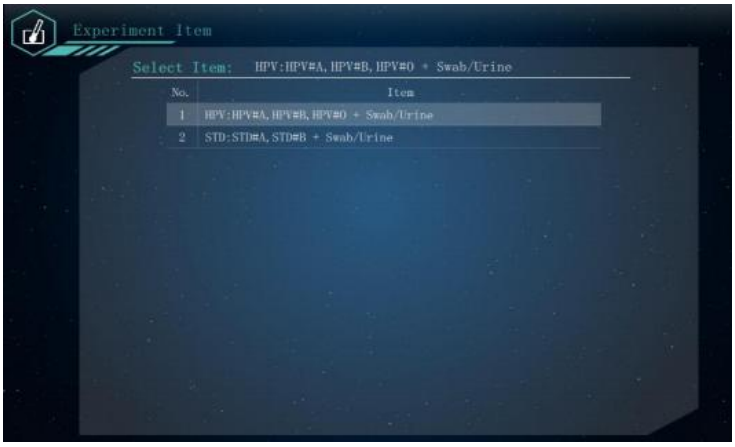


Figure 6. Experiment Setting Interface-Experiment Item Window

Figure 7. Experiment Setting Interface-Sample Quantity Setting

User can also click < Details >, the software will pop up the sample setting window, as shown in Figure 8. The sample setting window consists of Sample No., Sample Type, Test Item, Std/Control four options and sample area. The sample area is divided into six columns, 16 samples per column. It corresponds to the six sample holders in the sample cabin. User can select one or more sample(s) and perform the sample setting in the left options for the selected sample(s).

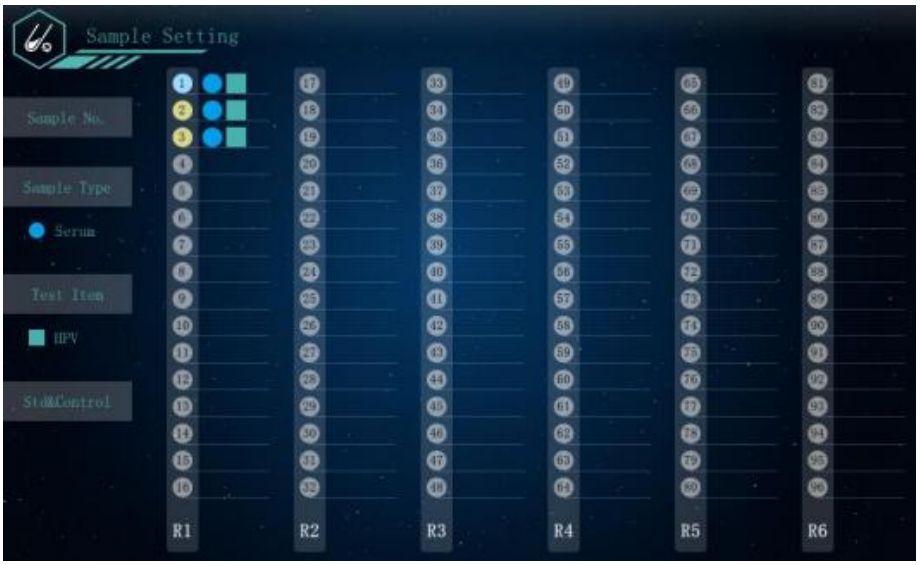


Figure 8. Experiment setting interface-Sample Setting Window

Sample Preparation

- **Please prepare the sample according to the input of <*Experiment Item*> and <*Sample Setting*>.**

- Please firstly record the sample information according to the requirements of laboratory operation and mark the special sample state such as hyperlipidemia, hyperbilirubin, hemolysis and so on.
- Please complete the sample centrifugation and other pre-processing operations according to the experimental requirements, and add or divide the prepared samples into sample tubes in the biosafety cabinet.
- Please insert the sample tubes into the sample holder and slowly push the sample holder along the track into the sample cabin.

Consumable Preparation

- The system software of PANA workstation can automatically analyze the requirement information of reagent and consumable according to the input of <***Experiment Item*** > and <***Sample Setting*** >. User can click ***<Details >*** in the <***Reagent/Consumable >*** column on the experiment setting interface to view these requirement information.
- User can prepare the corresponding reagent and consumables and load them in the right position according to the requirement information of reagent and consumable.

2.1.2 Experiment Running

User can click <***Start >*** on the system software to start running the experiment. Use can also click <***Pause >*** or <***Stop >*** to pause or stop the currently running experiment in case any exception occurs during the experiment process.

2.1.3 Experiment Complete

Product Transfer

- After the experiment, please add the PCR consumables and transfer the PCR reaction system established by the PANA workstation to the PCR equipment for follow-up experiment.
- After the experiment, please cover the sample reserve tubes and transfer the reserved sample or nucleic acid extracted from the PANA workstation to the -20°C refrigerator.

Reagent and Sample Recovery

- After the experiment, please cover the reagent bottles and recover the remaining reagents (including protease K) from the reagent cabin of the PANA workstation, and store them in -20°C refrigerator together with the code and the reagent holder.
- After the experiment, please take out the sample holders, cover the sample tubes, and store the sample in the refrigerator.

Instrument cleaning and maintenance

- After the experiment, please regard the used consumables such as deep well plates, rod covers, premix bottles as biological contaminants and comply with all applicable local or national regulations for processing.
- After the experiment, please comply with all applicable local or national regulations, dispose the biological pollutants in the waste bin within the waste cabin of the PANA workstation, and replace the waste bag in the waste bin.
- After the experiment, please enter the general setting interface of PANA system software, click < **Maintenance** > and click < **UV Lamp Setting** > function key, and click < **Start** > to start the UV disinfection process.
- After the UV disinfection process, please turn off the PANA workstation and unplug the power cord.

Reminding: Never open the experiment cabin door during the UV disinfection process.

Troubleshooting Guide

This troubleshooting guide should assist you in resolving any problems that arise during the experimental process. For more information, please visit our Technical Support Centre and Frequently Asked Questions, page at: http://www.medtl.net The scientists in our Tianlong company's Technical Services Department are always available to answer any questions you may have about the information and protocols contained in the manual, as well as sample and assay technologies (for contact information is included on the back cover or at: http://www.medtl.net).

When an exception or error occurs during the experiment, the current run step is terminated/stop. After resolving the error or exception, restart the run from the beginning. The troubleshooting guide is shown in the following table.

No.	Fault Symptom	Fault Cause	Handling Method
1	The well plate vibrates and the liquid splashes when tearing off the aluminum foil sealing film.	When tearing the film, please press the well plate to prevent it from rocking.	The reagent for this plate shall be scrapped, and re-extraction shall be performed.
2	Add the sample to unexpected wells.	Please read this manual carefully before adding samples.	The reagent for this plate shall be scrapped, and re-extraction shall be performed.
3	The amount of liquid in the reagent wells is insufficient.	/	Contact the after-sales service of our company.
4	Reuse of pre-filled components	Please read the precautions in this manual before using the kit.	Perform re-extraction of nucleic acid.
5	Abnormal noise from the instrument during extraction	The 96-deep well plate may be placed incorrectly.	Conduct reposition of the deep well plate.
		The mixing sleeve may be inserted in wrong place.	Reinsert the mixing sleeves.
6	Poor extraction performance	Please follow the operation requirements in the manual.	Contact the after-sales service of our company.
		The temperature control components of the instrument may be abnormal.	Contact the after-sales service of our company.
		Other	Contact the after-sales service of our company.
7	software running errors	Other	See Equipment Troubleshooting or Consult maintenance engineer.

* **Ensure that the reagents have been preserved and used according to the manufacturer's instructions.**

Quality Control

In accordance with Tianlong Company's ISO-certified Quality Management, each lot of ***Viral DNA and RNA Extraction Kit*** is tested against predetermined specifications to ensure consistent product quality.

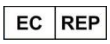
Limitations of Test Methods

The system performance has been established through performance evaluation studies using whole blood, serum, plasma, interstitial fluid, urine, swab samples to purify viral DNA and RNA.

It is the user's responsibility to validate system performance for any procedures used in their laboratory that are not covered by Xi'an Tianlong Science and Technology Co., Ltd performance evaluation studies.

The extraction kit is intended for clinical diagnostics, health system and scientific research only, whose usage can act as an ancillary step for molecular detection and should be matched with other molecular detection methods. The concentration and purity of its extraction product are affected by instruments and operators. Any generated diagnostic results must be interpreted in conjunction with the other clinical or laboratory findings.

Safety Symbols and Signs

No.	Symbol	Implication
1		Catalogue number
2		Batch code
3		Contains sufficient for <N> tests
4		Use by date
5		Caution
6		Temperature limit
7		In vitro diagnostic medical device
8		Reminder
9		Manufacturer
10		Do not re-use
11		Conformed with EU standard
12		Authorized representative in the European Community

Contact Information

For technical assistance and more information, please contact our Technical Support Center at +86-29-82218051 (Tel), +86-29-82216680 (Fax), www.medtl.net or contact your local distributor.

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