Viral DNA and RNA Extraction Kit

User Guide

Σ T041H
48

Version 3.0

CE IVD

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

REF T041H

Xi'an Tianlong Science and Technology Co., Ltd.

No.389, Zhuhong Road, Xi'an, 710018, Shaanxi, P.R. China;
2-3F, No. 2 Building, Yuanzheng Innovation Park, Caotan Ecological Zone, No.1258, Hongye Road, Economic & Technological Development Zone, Xi'an, 710018, Shaanxi, P.R. China.

EC REP **SUNGO Europe B.V.**

Olympisch Stadion 24, 1076 DE Amsterdam, Netherlands.

Contents

Intended Use

The ***Viral DNA and RNA Extraction Kit*** is designed to rapidly extract viral DNA and RNA from whole blood, serum, plasma, tissue fluid, urine, swab lotion, etc sample. The extracted viral DNA and RNA 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 professional, such as biotechnologists, microbiologists, clinical technicians, and physicians who are trained in molecular and biological techniques.

Product Performance Indicators

The extraction kit can extract nucleic acids from whole blood, serum, plasma, tissue fluid, urine, swab lotion samples in high-efficiency, especially from low-abundance samples.

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® automated nucleic acid extractors (GeneRotex 48) that have been disinfected by UV light before use. After an experiment, wipe the inside of the extractor with 75% ethanol and disinfect it with UV light for 15 minutes. An automatic nucleic acid extractor automates the entire purification process and can process 1-48 samples in a single run.

The kit is used to extract viral DNA and RNA targets. To avoid RNA degradation by RNase during operation, use exclusive-use utensils and sample injectors,and use disposable centrifuge tubes and tips processed by autoclave before using. The operator should wear powder-free gloves and a mask and a protective coverall.

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

Magnetic beads enables the purification of high-quality nucleic acids that are free of protein, nuclease, and other impurities. Purified nucleic acids can be widely used in variety of routine operations, including downstream experiments such as enzyme digestion, Polymerase Chain Reaction (PCR), DNA library construction, Southern hybridization and blotting.

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.

Testing Principle

The ***Viral DNA and RNA Extraction Kit*** is worked with TIANLONG® automated nucleic acid extractors (GeneRotex 48 and similar instruments 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.

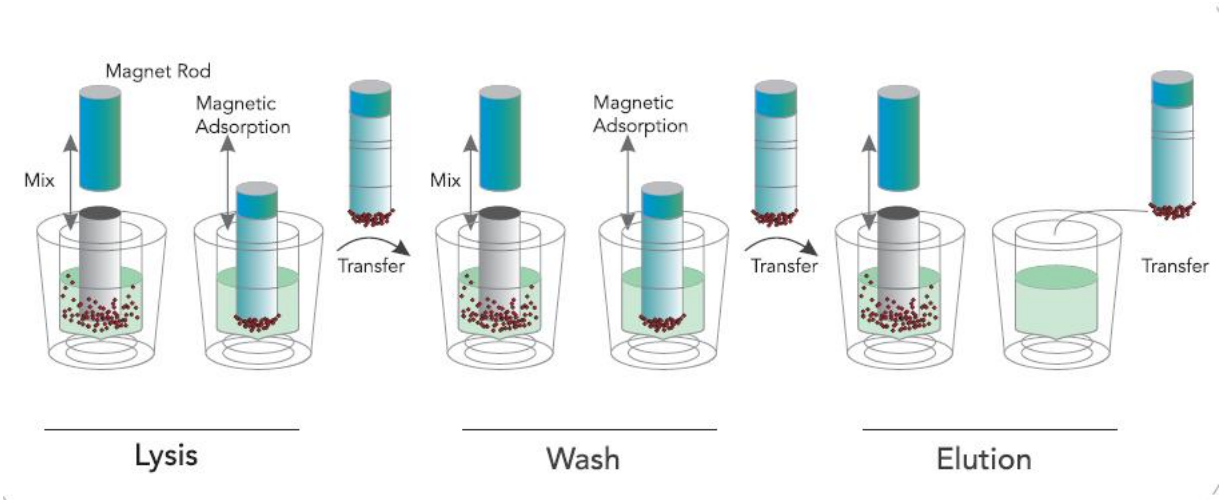

Figure 1. Schematic Diagram of Full-automatic Nucleic Acid Extractor

An automatic nucleic acid extractor performs the following steps on a sample containing magnetic particles:

A magnetic rod is inserted into a well containing the samples, protected by the mixing sleeve. The mixing sleeve rapidly and repeatedly stirs the liquid to ensure complete mixing of the liquid and magnetic beads. After cell lysis, nucleic acid adsorption, washing and elution, high-purity nucleic acid is obtained.

GeneRotex 48 equipped with an array of 48 magnetic rods, allowing it to process up to 48 samples simultaneously.

Kit Contents

Name of Component / Short Code		T041H
Pre-filled Reagent	Size	48T/Box
	Component	Pre-filled 48-deep well plate
	Quantity	6
	Component Specification	8 Tests
Proteinase K Solution	Component Specification	1.2mL
	Quantity	2
Rotatory Mixing Sleeve	Component Specification	8/ Package
	Quantity	6
Mixing Sleeve		1 Box
Corrugated Paper		1 Piece
White Board		1 Piece
Packaging Box		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.

- Pipettor: 50μL and 1000μL
- 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 kit is used to extract viral DNA and RNA targets. To avoid RNA degradation by RNase during operation, use exclusive-use utensils and sample injectors, and use disposable centrifuge tubes and tips processed by autoclave before using. The operator (researcher or clinical expert) should wear powder-free gloves and a mask.

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® automated nucleic acid extractors (GeneRotex 48), 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 minutes.

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 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*** come 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 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 nucleic acid extraction 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

Automatic nucleic acid extractor (GeneRotex 48) enables nucleic acid extraction by magnetic beads. It uses magnetic rods to move the beads adsorbed with nucleic acid into different reagent wells and then rapidly and repeatedly stirs the liquid through a mixing sleeve to mix the liquid and magnetic beads thoroughly. After cell lysis, nucleic acid adsorption, washing, and elution, the high-purity nucleic acid is obtained. Automatic nucleic acid extractors are characterized by high automation, rapid extraction speed, stable results, and ease of operation. They are compatible with special reaction consumables and can process up to 1-48 samples concurrently.

The automatic nucleic acid extractor can extract and purify nucleic acids from human samples using a variety of magnetic bead-based nucleic acid extraction reagents. Automatic nucleic acid extractors have a wide range of applications in scientific research, clinical practice, disease control, food safety, forensics and other fields. The user needs to load samples and magnetic bead-based nucleic acid extraction reagents into the reaction consumables, full-automatic nucleic acid extractors is going to perform all nucleic acid extraction operations according to the experimental procedures.

Automatic nucleic acid extractors are depicted in Figure 2 . Please refer to the user manual provided with an instrument for operating instructions.

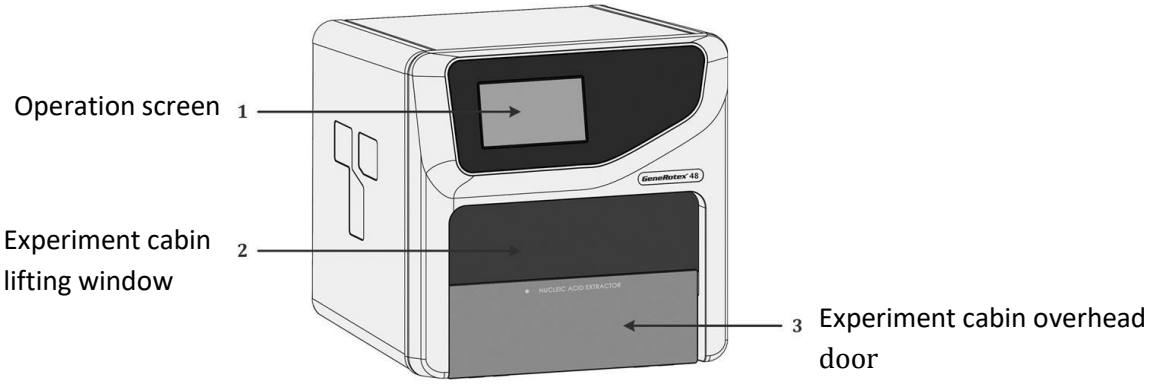

Figure 2. GeneRotex 48 Automatic Nucleic Acid Extractor

2. Operation Steps of Automated Extraction

2.1 Full-Automatic Nucleic Acid Extractor (model: GeneRotex 48)

2.1.1 Edit Experiment Program

Please connect the power supply and turn on the power switch. The main interface of the instrument system software displays experiment file tab by default. The experiment file interface will display file name, file icon and operation function buttons, which is shown in Figure 3.

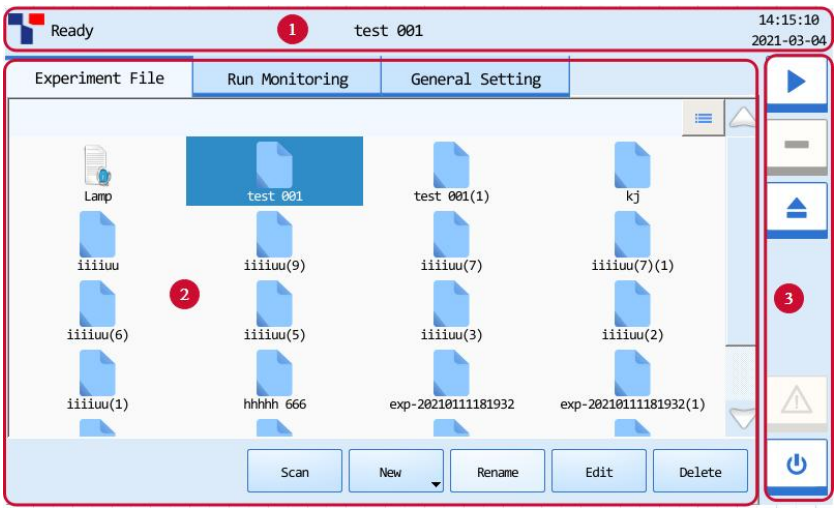

Figure 3. Main Interface of the System Software

Directly click < **New** > to create a new experiment file, enter the experiment file interface and create a new experiment file on the experiment file interface. The system will pop up a keyboard for users to name the new experiment file or file folder, which is shown in Figure 4. Users can click < **Close** > to exit the keyboard.

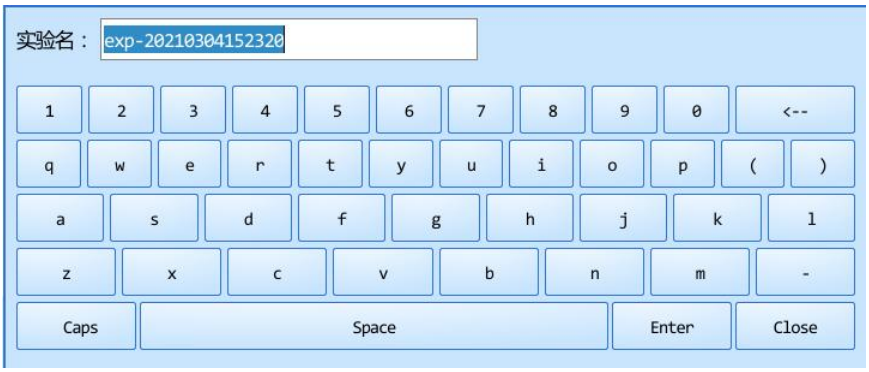

Figure 4. Experiment File Interface - Keyboard

Select the new experiment file on the experiment file interface, click < **Edit** > to enter the experiment file edit interface, and then the system software will automatically enter the experiment edit interface, which is shown in Figure 5. Edit the experiment program steps and parameters according to the reagent kit specification, and then click < **Save** > to save the corresponding settings.

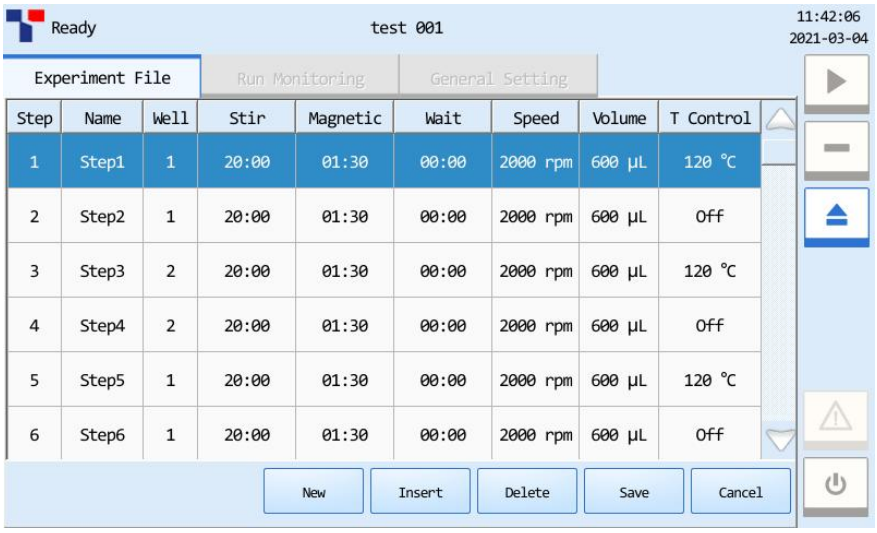

Figure 5. GeneRotex System Software - Experiment File Edit Interface

The extraction procedure of GeneRotex 48 Nucleic Acid Extractor is as follows:

Step	Name	Well	Stir (min:s)	Magnetic (min:s)	Wait (min:s)	Speed (rpm)	Volume (µL)	T Control (°C)
1	Remove Bead	2	00:10	00:20	00:00	1600	650	0
2	Lysis	1	05:00	00:45	00:00	2500	3000	100
3	Washing 1	3	02:00	00:30	00:00	2500	1000	0
4	Washing 2	4	02:00	00:30	00:00	2500	1500	0
5	Washing 3	5	01:00	00:30	02:00	2500	1500	80
6	Elution	6	04:00	00:30	00:00	2000	60	80
7	Release Bead	2	00:10	00:00	00:00	2500	650	0

2.1.2 Reagent preparation

48-deep well plate: Open the kit, remove the plastic package of pre-filled reagent, slowly invert it several times to resuspend the magnetic beads. Gently shake the 48-well plate so that the reagent and magnetic beads are concentrated on the bottom of the 48-well plate. Carefully tear off the aluminum foil sealing film to avoid the liquid splashing.

2.1.3 Adding Sample to the Reagent

48-deep well plate: Add 50µL Proteinase K solution and 1000µL sample to the column 1 of the Pre-filled reagent, respectively. (Note the column No. is for effective wells).

(Note: When pipetting the sample, avoid having more substance than liquid adhere to the tip of the sample injector; do not add the sample too quickly to avoid contaminating the upper part of the well wall; and avoid splashing air bubbles to avoid contamination of adjacent wells.)

2.1.4 Loading in the deep well plate

Properly position the 48-deep well plate the sample in the experimental chamber of the fully automated nucleic acid extractor (GeneRotex 48).

Note: The user should ensure that the notch of the deep well plate faces outward, which is shown in Figure 6.

Insert the rotatory mixing sleeve into column 2 of the deep well plate and close the experimental cabin door.

Caution: The user must ensure that the rotatory mixing sleeves are placed properly. Otherwise, the instrument may operate abnormally, or the magnetic rods may become contaminated.

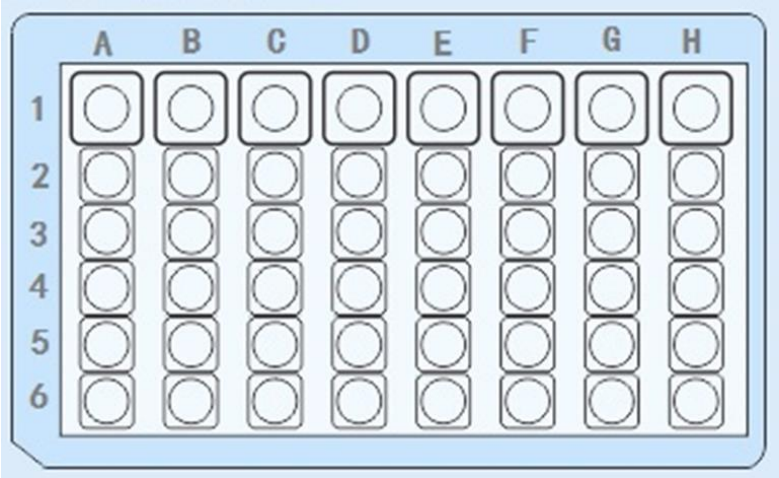

Figure 6. Put the single kit docking into the instrument

2.1.5 Experimental procedure run

Click the new experiment file in the experiment file interface, and click < **Run Experiment** > in the main control bar to run the current experiment file.

When an experimental file starts a run, the system software will automatically enter the run monitoring interface, which displays the real-time information about the current experimental running, which is shown in Figure 7.

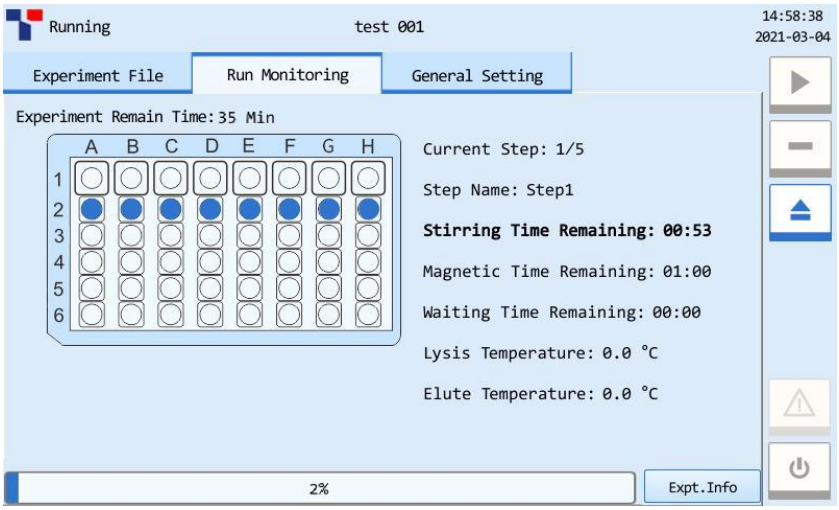

Figure 7. Tab for Monitoring Run

After an experiment stars run, the instrument will notify the user that the experiment is completed. Transfer the eluate from the wells in column 6 to a clean centrifuge tube free of nuclease.

Note: If the user does not analyse the extracted product for the moment, please store and seal it in a refrigerator at -20°C.

2.1.6 Cleaning and maintenance of the instrument

Follow the Cleaning and Maintenance of Instrument in accordance with the user manual provided with the equipment. Ensure that the experimental chamber is cleaned regularly to minimize the risk of cross-contamination.

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 48-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.

* **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, tissue fluid, urine, swab lotion samples to purify viral DNA and RNA.

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

Although the kit is intended for use in public health and scientific research, the purity and quality of extraction results are also affected by the testing instruments and personnel. Moreover, the kit uses a specially formulated eluent that can affect the absorbance value, so it is not recommended to use a UV rays spectrophotometer to measure the extraction effect directly.

The extraction kit is intended for use with clinical diagnostic samples, forensic materials, and scientific research samples. The instrument and operator have an effect on the concentration and purity of the extracted product. 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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