Viral DNA and RNA Extraction Kit

User Guide

Version 6.0

Σ 64 T014H

Σ 20 T016H

Σ 32 T060H

CE IVD

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

REF T014H T016H T060H

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Contents

Intended Use

The ***Viral DNA and RNA Extraction Kit*** is designed to rapidly extract viral DNA and RNA from swab samples. 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 professionals, such as biotechnologists, microbiologists, clinical technicians, and physicians who are trained in molecular and biological techniques.

Product Performance Indicators

The ***Viral DNA and RNA Extraction kit*** can extract nucleic acids from swab samples in high-efficiency, particularly from low-copy complex samples. Both the intra and inter-batch variations of kit are less than 5%.

Special Notes

The ***Viral DNA and RNA Extraction Kit*** is worked with TIANLONG® automated nucleic acid extractors (Libex and GeneRotex 96) 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 mins. An automatic nucleic acid extractor automates the entire purification process and can process 1-96 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 a variety of liquid samples such as swab samples.

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 (Libex, GeneRotex 96 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 conduction of nucleic acid extraction and final adsorption of highly pure nucleic acids with the transfer of magnetic beads and nucleic acids.

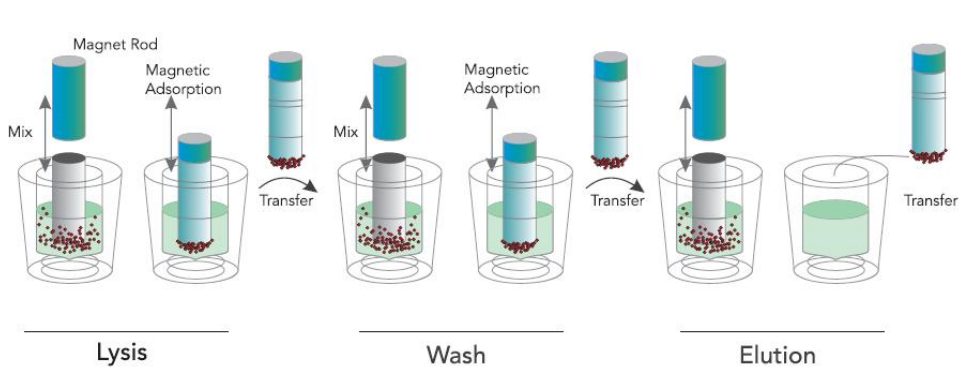

Figure 1. Schematic Diagram of Full-automatic Nucleic Acid Extractor

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

A magnetic rod protected by the mixing sleeve inserts into a well which contains sample. The mixing sleeve stirs rapidly and repeatedly in the liquid to ensure complete mixing of the liquid and magnetic beads. After cell lysis, nucleic acid adsorption, washing and elution, highly pure nucleic acid is obtained.

GeneRotex 96 equipped with an array of 96 magnetic rods, allowing it to process up to 96 samples simultaneously.

Kit Contents

Short Code / Name of Component		T016H	T014H	T060H
Pre-filled Reagent	Size	20T/Box (DT6)	64T/Box	32T/Box
	Component	Pre-filled 6 strip tube	Pre-filled 96-deep well plate	Pre-filled 96-deep well plate
	Quantity	20	4	4
	Component Specification	1 Test	16 Tests	8 Tests
Instructions for Use		1 Copy	1 Copy	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: 200μL or 1000μL
- Tip: 200μL or 1000μL
- Vortex mixer
- Sample holder
- 75% ethanol
- Single kit docking (matched with T016H (6 strip tube), could be purchased from Tianlong)

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 throughout the operation. The clinical samples should be collected on a clean bench or in a bio-safety cabin.

Before using TIANLONG® automated nucleic acid extractors (Libex and GeneRotex 96), 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, keep away from the source of heat, sparks, open flames, and smoking.

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 to UV light (e.g., for decontamination), which may result in accelerated 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 with in 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 (Libex and GeneRotex 96) enables nucleic acid extraction by magnetic beads. It uses magnetic rods to move the beads adsorbed with nucleic acid into different reagent wells. Magnetic rod protected by the mixing sleeve which stirs rapidly and repeatedly in the liquid to ensure complete mixing of the liquid and magnetic beads. After cell lysis, nucleic acid adsorption, washing, and elution, the highly pure nucleic acids are 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 1-96 samples concurrently.

The automatic nucleic acid extractor can extract and purify nucleic acids from human samples using a variety of magnetic bead 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 nucleic acid extraction reagents into the reaction consumables, the 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 and 3. Please refer to the user manual provided with an instrument for operating instructions.

Figure 2. Libex Automatic Nucleic Acid Extractor

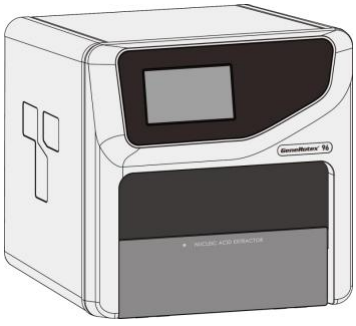

Figure 3. GeneRotex 96 Automatic Nucleic Acid Extractor

2. Operation Steps of Automated Extraction

2.1 Automatic NucleicAcid Extractor (model: Libex)

2.1.1 Start up

Turn on the power of instrument switch which is at the back side The buzzer will beep twice. After that, the LCD screen of instrument will light up and automatically show the self-test interface for self-test and initialization, which is shown in Figure 4.

Figure 4. Instrument system software

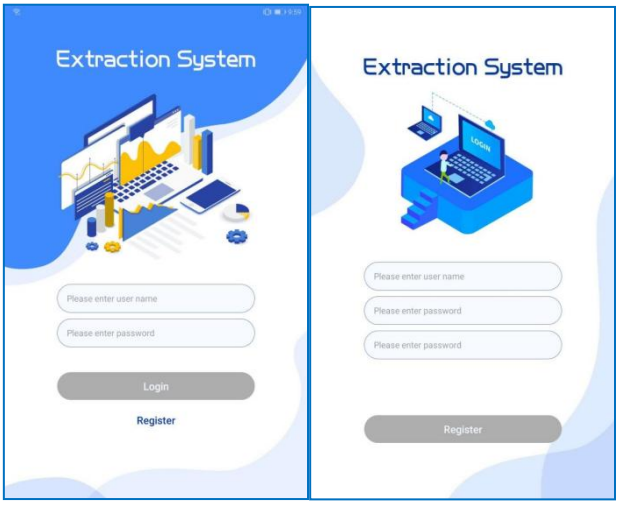

Figure 5. Application software - Login interface

Users can install the application software "**Extraction System**" on the tablet PC to operate the automatic nucleic acid extractor. Click < **Extraction System** > on the tablet PC, the application software will automatically enter login interface, where users can enter their user name and password for login or register as a new user, which is shown in Figure 5.

After login, the application software will enter the main interface, which is shown in Figure 6.

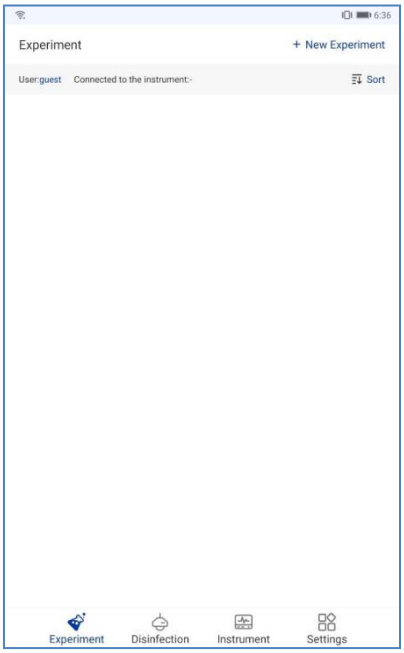

Figure 6. Main interface

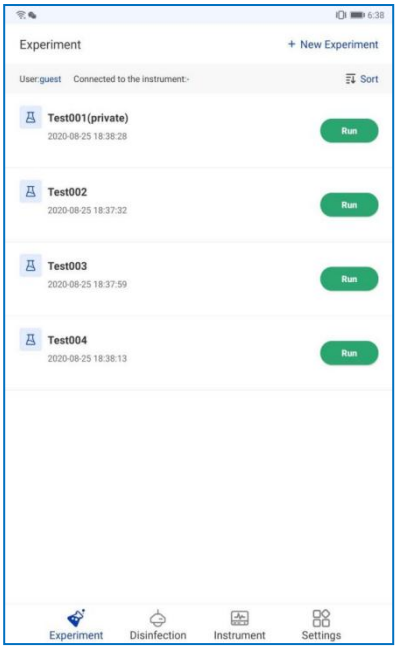

Figure 7. Experiment interface

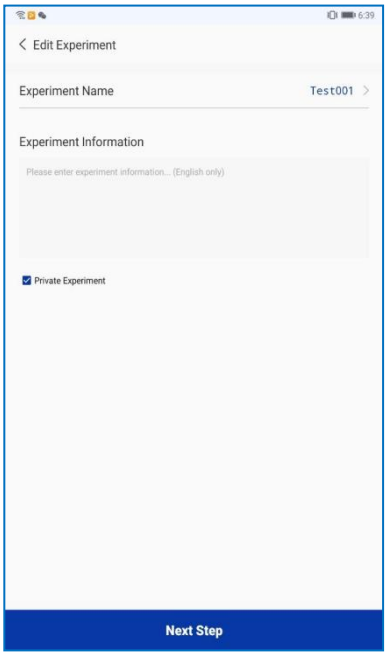

Figure 8. Experiment edit

Click < **Experiment** > and the icon will change into < **Experiment** >, the main interface will automatically switch to the Experiment interface, where users can add, delete, edit and run/stop experiment, which is shown in Figure 7.

Edit Experiment: select any experiment on the experiment interface and slide it to the left, click < **Edit** > to edit the current selected test experiment, which is shown in Figure 8.

The extraction procedure of Libex Nucleic Acid Extractors is as follows:

No.	Well	Name	Waiting (s)	Mixing (s)	Magnet (s)	Speed	Volume (μL)	Heating State	Temp (°C)
1	1	Lysis	0	240	45	7	800	Closed	0
2	2	Washing 1	0	60	30	7	700	Elution	90
3	3	Washing 2	0	60	30	7	800	Elution	90
4	6	Elution	60	300	30	7	80	Elution	90
5	2	Release bead	0	60	0	7	700	Closed	0

After finishing editing the experiment, users can click < **Save Experiment** > to save current experiment settings and return to Experiment interface, which is shown in Figure 7.

Long-press saved experiment on the experiment interface and click < **Synchronize to instrument** > to synchronize the current experiment from the application software to the instrument system, which is shown in Figure 9.

2.1.2 Reagent preparation

96-deep well plate:

Open the kit, take out the pre-filled reagent from the plastic package, slowly invert it several times to resuspend the magnetic beads, then remove the plastic package and gently shake the 96-well plate so that the reagent and magnetic beads are concentrated on the bottom of the 96-well plate (a 96-well plate horizontal centrifuge can also be used for centrifugation at 500rpm for 1min). carefully tear off the aluminum foil sealing film before use to avoid liquid splashing.

6 strip tube:

Open the kit, take out the pre-filled 6 strip tube, slowly invert it several times to resuspend the magnetic beads, then gently shake the 6 strip tube so that the reagent and magnetic beads are concentrated on the bottom of the tube. Put the reagent on the docking (Note the direction and make sure that the tube is placed at the lowest level), carefully tear off the aluminum foil sealing film before use to avoid splashing, which is shown in Figure 10.

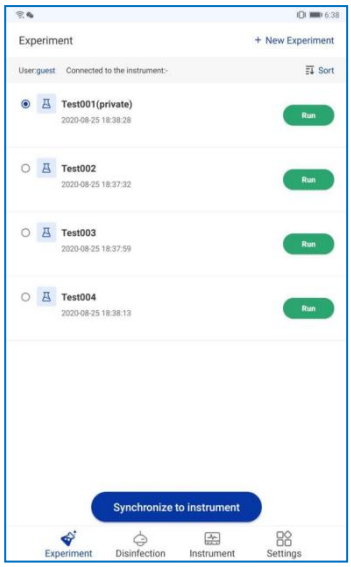

Figure 9. Synchronize to instrument

Figure 10. Put the 6 strip tube on the single kit docking

2.1.3 Adding Sample to the Reagent

96-deep well plate:

Add 200μL of the sample that has been equilibrated to room temperature to column 1 or column 7 of the pre-filled reagent (Be aware of that column No. is for effective wells.)

6 strip tube:

Add 200μL of the sample that has been equilibrated to room temperature to the first well of the pre-filled 6 strip tube.

⚠ **Caution: When pipetting the sample, avoid having substance than liquid adhere to the tip of the sample injector; do not add the sample too quickly to avoid contaminating the upper portion of the well wall; and do not splash air bubbles to avoid contaminating adjacent wells.**

Note: The following points should be taken into consideration when determining whether a samples is suitable for The Viral DNA and RNA Extraction Kit.

a. Type of sample: swab samples etc.

b. Short-term storage: Samples can be used immediately after collection for nucleic acid extraction or stored at 2~8°C for testing with a maximum storage period of 24 hours.

c. Long-term storage: If the user does not operate the sample temporarily, it should be kept sealed in a refrigerator at -20°C.

2.1.4 Loading in deep well plate

Place the 96-deep well plate or 6 strip tube in the Automatic Nucleic Acid Extractor, and ensure the marked notch of the plate faces front.

Insert the mixing sleeve into the sleeve holder and close the cabin door.

Note: As shown in Figure 11 and Figure 12, the user should ensure that the 96-deep well plate and the single kit docking is properly positioned with the notch facing outward.

Note: Place the 96-deep well plate into the experiment cabin and push the magnetic rod covers into the right position. Check the position of the magnetic rod covers. Otherwise, instrument dysfunction or malfunction may occur and affect the experiment results.

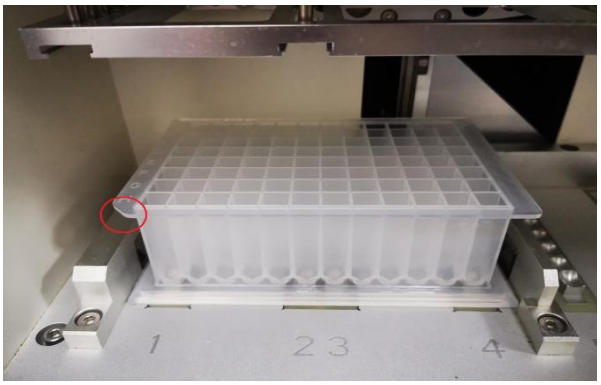

Figure 11. 96-deep well plate

Figure 12. Put the single kit docking into the instrument

2.1.5 Procedure run

On the main interface, click the < **Experiment Manage** > icon to access to the experiment manage interface. Choose the experimental program that is going to run. Click < **Run** >, the detailed information about the selected experiment will be displayed. Click < **Run** > again to resume the execution of the selected experimental program.

After the procedure is completed, the instrument will notice the user that the experiment has completed. Transfer the extracted product from well 6 and well 12 to a clean centrifuge tube free of nuclease.

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

⚠ **Caution: Any used deep well plate and mixing sleeve should be considered as biological contaminants and disposed of in accordance with relevant regulations.**

⚠ **Caution: Using expired reagents or those that are not compatible with this instrument does not guarantee the expected results.**

2.1.6 Cleaning and maintenance of the instrument

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

2.2 Full-Automatic Nucleic Acid Extractor (model: GeneRotex 96)

2.2.1 Edit Experiment Program

Please connect the power supply and turn on the power switch. The main interface of the instrument system 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 13.

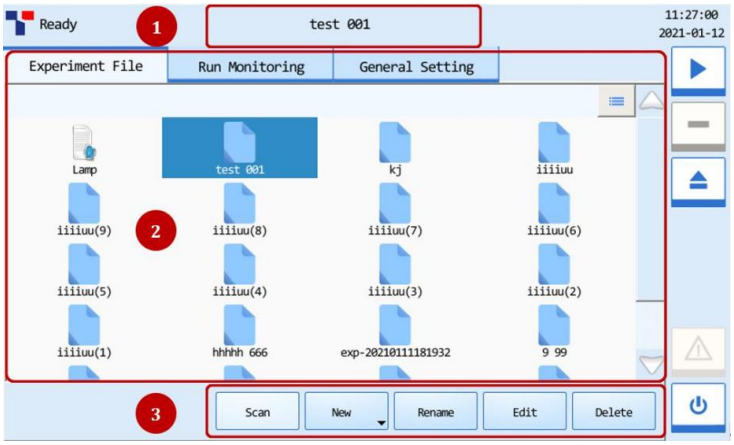

Figure 13. Main Interface of the System Software

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 14. Users can click < **Close** > to exit the keyboard.

Figure 14. Experiment File Interface - Keyboard

Select the new experiment file on the experiment file interface, click < **Edit** > to enter into the experiment file edit interface,which is shown in Figure 15. Edit the experiment steps and parameters according to the reagent kit specification, and then click < **Save** > to save the corresponding settings.

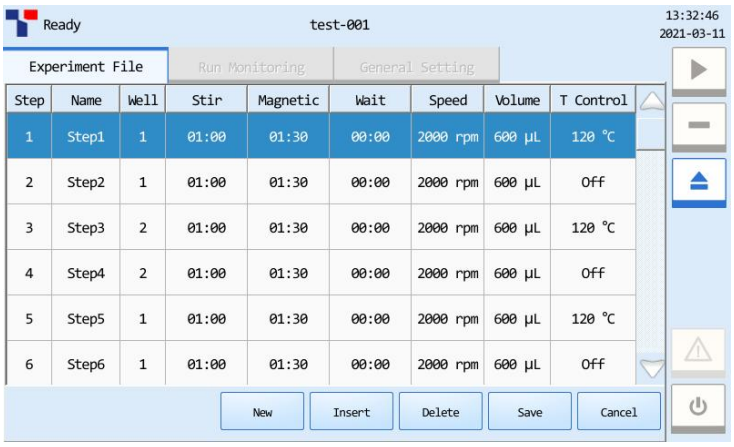

Figure 15. GeneRotex System Software - Experiment File Edit Interface

The extraction procedure of GeneRotex 96 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	Lysis	1	04:00	00:45	00:00	2500	800	0
2	Washing 1	2	01:00	00:30	00:00	3000	700	100
3	Washing 2	3	01:00	00:30	01:00	3000	800	100
4	Elution	6	05:00	00:30	00:00	2500	80	100

2.2.2 Reagent preparation

96-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 96-well plate so that the reagent and magnetic beads are concentrated on the bottom of the 96-well plate (A 96-well plate horizontal centrifuge can also be used for centrifugation at 500rpm for 1min). Carefully tear off the aluminum foil sealing film to avoid the liquid splashing.

6 strip tube:

Open the kit, take out the pre-filled 6 strip tube, slowly invert it several times to resuspend the magnetic beads. Gently shake the 6 strip tube so that the reagent and magnetic beads are concentrated on the bottom of the tube. Put the reagent on the docking (Note the direction and make sure that the tube is placed at the lowest level), carefully tear off the aluminum foil sealing film before use to avoid the liquid splashing, which is shown in Figure 16.

Figure 16. Put the 6 strip tube on the single kit docking

2.2.3 Adding Sample to the Reagent

96-deep well plate: Add 200μL of the sample that has been equilibrated to room temperature to column 1 or column 7 of the pre-filled reagent (Note the column No. is for effective wells.)

6 strip tube: Add 200μL of the sample that has been equilibrated to room temperature to the first well of the pre-filled 6 strip tube.

(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.)

2.2.4 Loading in the deep well plate

Properly position the 96-deep well plate or 6 strip tube containing the sample in the experimental cabin of the fully automated nucleic acid extractor (GeneRotex 96).

Note: The user should ensure the marked notch of the plate of the 96-deep well plate and 6 strip tube are on the left, which is shown in Figure 17 and Figure 18.

Insert the rotatory mixing sleeve into column 2 and/or column 8 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.**

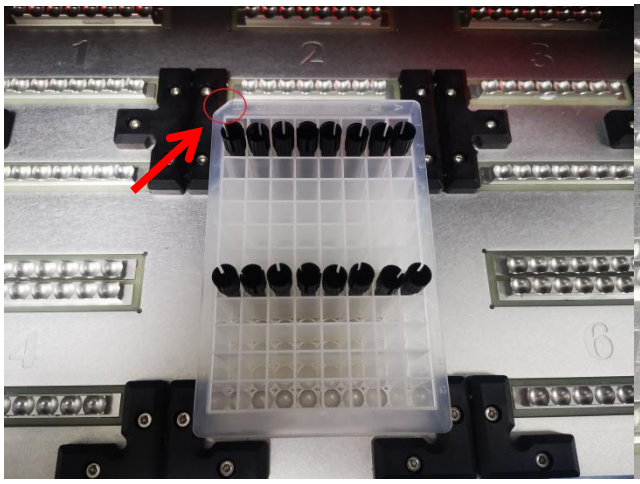

Figure 17. 96-deep well plate

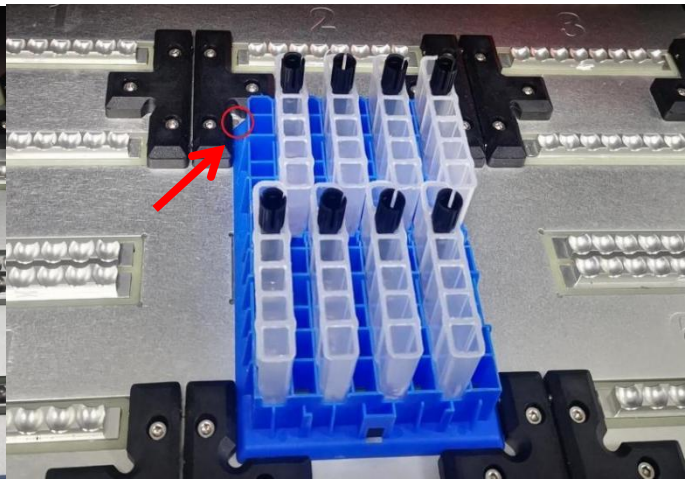

Figure 18. Put the single kit docking into the instrument

2.2.5 Experimental procedure run

Click the new experimental file in the experimental file interface, and click < **Run Experiment** > in the main control bar to run the current experimental file. Before the experiment begins, the instrument will automatically detect the position of the mixing sleeve and prompt the user to confirm the position, which is shown in Figures 19 and 20.

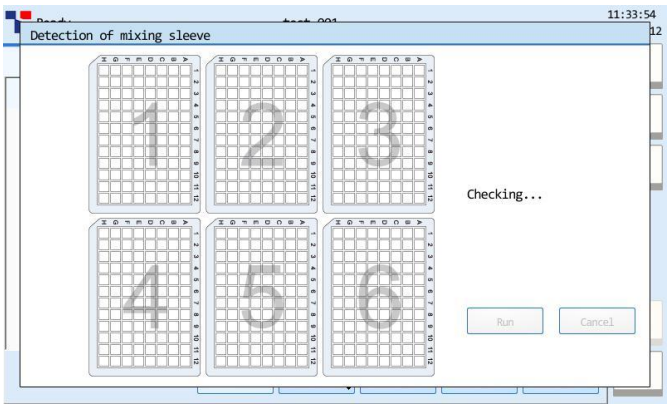

Figure 19. Check the mixing sleeve position

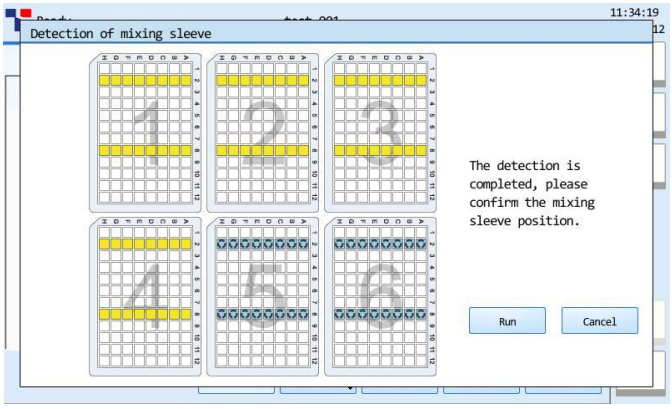

Figure 20. Confirm the mixing sleeve position

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 file run, which is shown in Figure 21.

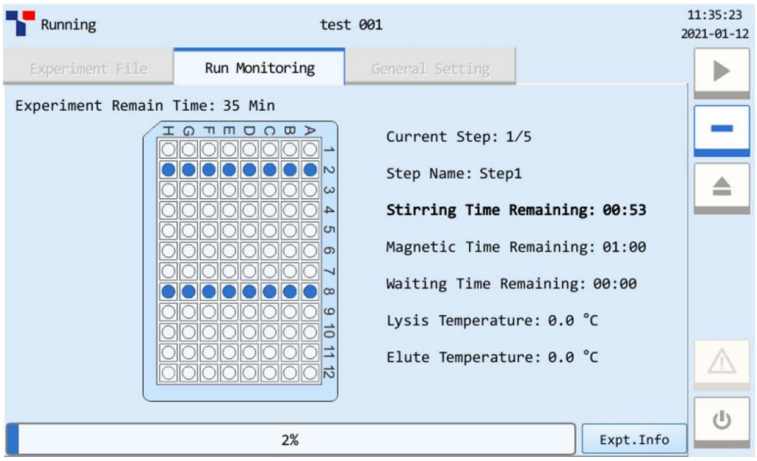

Figure 21. Tab for Monitoring Run

After an experiment starts running, the instrument will notice user when the experiment is completed. Transfer the eluate from column 6 and column 12 to a clean centrifuge tube free of nuclease.

Note: If the user is not going to use the extracted product immediately, please seal and store it in a refrigerator at -20°C.

2.2.6 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 cabin 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/stopped. 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.	Have you 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 correctly.	Conduct reposition of the deep well plate.
		The mixing sleeve may not be inserted in place.	Reinsert the mixing sleeve.
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 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.

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	REF	Catalogue number
2	LOT	Batch code
3	Σ <N>	Contains sufficient for <N> tests
4		Use by date
5		Caution
6		Temperature limit
7	IVD	In vitro diagnostic medical device
8		Reminder
9		Manufacturer
10		Do not re-use
11	CE	Conformed with EU standard
12	EC REP	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.

For up-to-date licensing information or product-specific disclaimers, please see the respective User Guide. Tianlong User Guides are available at www.medtl.net or can be requested from Tianlong Technical Services or the local distributor.