



Viral DNA and RNA Extraction Kit

User Guide

Version 3.0



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



T050H T051H T052H



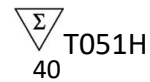
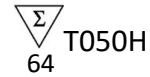
Xi'an Tianlong Science and Technology Co., Ltd.

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.



SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.



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Intended Use

The ***Viral DNA and RNA Extraction Kit*** is intended for rapidly extracting viral DNA/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 product is intended for scientific research only and should not be used for therapeutic or clinical purposes.

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 100 copies/mL viral DNA nucleic acid, and more than 100 copies/mL viral RNA nucleic acid. Both the intra and inter-batch variations of kit are less than 5%.

Special Notes

The Kit must be used in combination with TIANLONG® automated nucleic acid extractors (Libex and GeneRotex 96) that has been UV disinfected before use. After an experiment, wipe the inside of the extractor with 75% ethanol and disinfect 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. Precaution should be taken to avoid RNA degradation by RNase during operation. All utensils and the sample injector should be used extensively for that purposes and disposable consumables such as the centrifuge tube and the tip should be autoclaved before being used. The operator should wear powder-free gloves and a mask, among other protective measures.

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 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.

Before attempting to install or use the product for the first time, please carefully read the manual's instructions, consider all possible consequences of misoperations or non-recommended functions, and pay special attention to the possible consequences.

Testing Principle

The Kit is used in combination 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. This enables the transfer of magnetic beads/nucleic acids, the automatic completion of the nucleic acid extraction, and final isolation of high-purity nucleic acids.

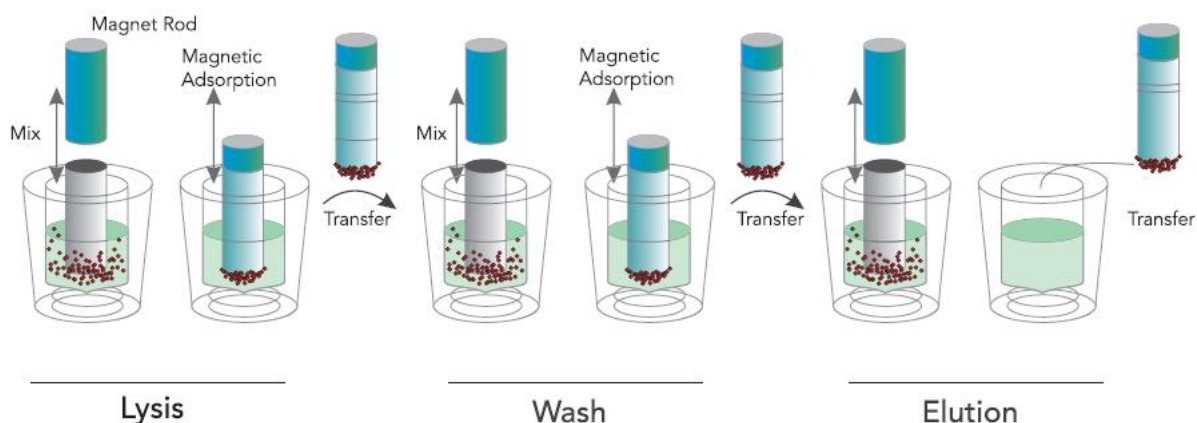


Figure 1. Schematic Diagram of Full-automatic Nucleic Acid Extractor

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 stirring sleeve. The stirring 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 96 equipped with a magnetic head that contains an array of 96 magnetic rods, allowing it to process up to 96 samples simultaneously.

Kit Contents

Short Code		T050H	T051H	T052H
Name of Component				
Pre-filled reagent	Size	64T/Box (Pre-filled)	40T/Box (Pre-filled)	20T/Box (Pre-filled)
	Component	Pre-filled 96-deep well plate	Pre-filled 96-deep well plate	Pre-filled 96-deep well plate
	Quantity	4	4	4
	Component specification	16 Tests	10 Tests	5 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

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. Precautions should be taken to avoid RNA degradation by RNase during experiment; all utensils and sample injector should be used exclusively for the purposes, and disposable consumables such as the centrifuge tubes and tips should be autoclaved before use. The operator (researcher or clinical expert) should wear powder-free gloves and a mask, among the protective equipments.

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 biosafety chamber.

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 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.

Unless otherwise indicated, avoid mixing reagents from different batches, and use the kit within the kit's shelf life (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 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 Kit should be stored at room temperature in a cool, dry and well-ventilated area. All components of the kit can be adequately store 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

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 and then rapidly and repeatedly stirs the liquid through a stirring 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 1~96 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/put samples and magnetic bead-based nucleic acid extraction reagents into the reaction consumables, full-automatic nucleic acid extractors then 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

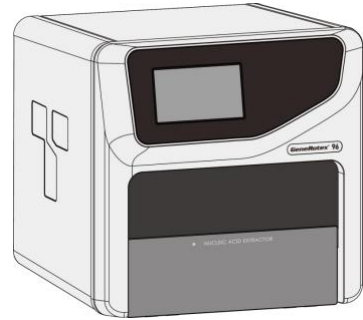


Figure 3. GeneRotex 96 Automatic Nucleic Acid Extractor

2. Operation Steps of Automated Extraction

2.1 Automatic Nucleic Acid Extractor (model: Libex)

2.1.1 Start up

Turn on the instrument's power switch at the back side, and the buzzer will beep twice. After that, the instrument will begin to start up (boot), with the LCD screen lighting up and automatically navigating to the self-test interface for self-test and initialization, as shown/illustrated in Figure 4.

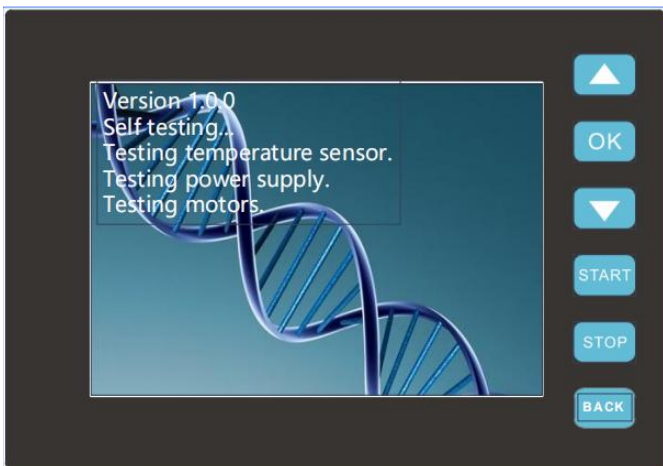


Figure 4. Instrument system software

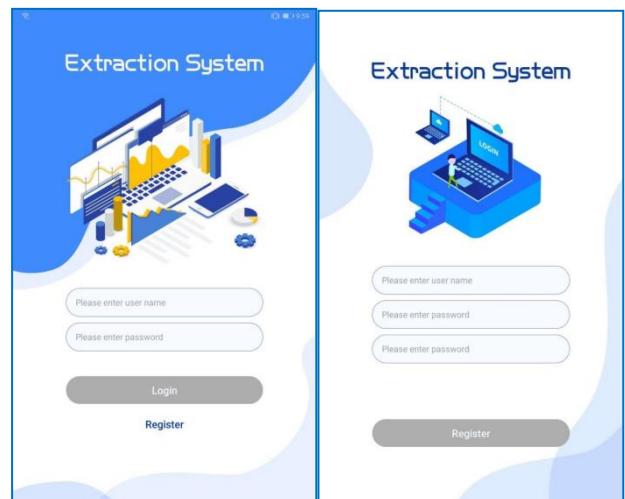


Figure 5. Application software - Login interface

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.

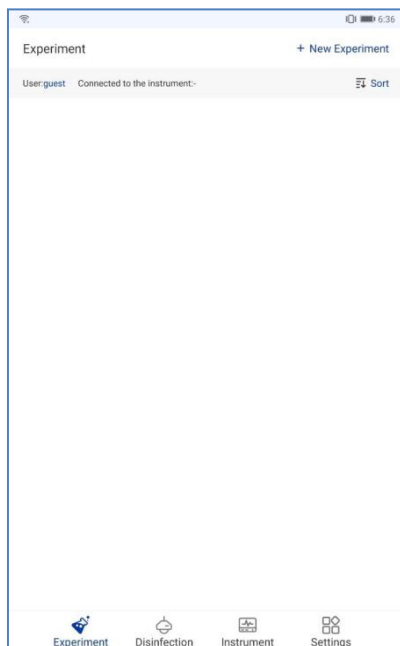


Figure 6. Main interface

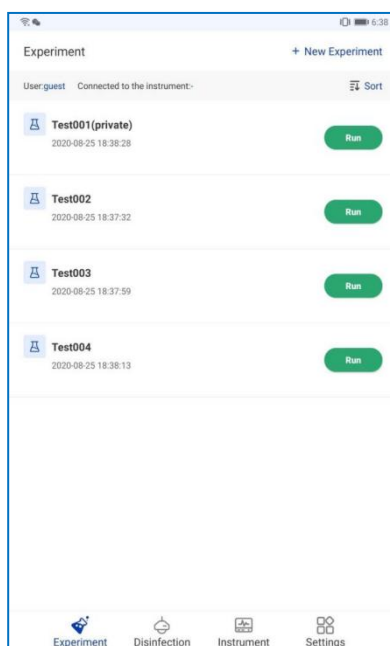


Figure 7. Experiment interface

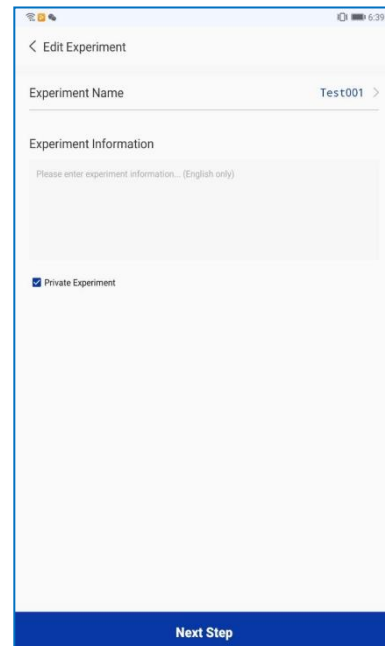


Figure 8. Experiment edit

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	2	Remove bead	0	60	10	8	300	Closed	0
2	1	Lysis	0	180	45	7	750	Lysis	90
3	3	Washing 1	0	60	30	7	700	Elution	90
4	4	Washing 2	0	60	30	7	800	Elution	90
5	6	Elution	60	120	30	7	80	Elution	90
6	2	Release bead	0	60	0	7	300	Closed	0

After finishing editing the experiment, users can click < Save Experiment > to save current experiment settings and return to Experiment interface, as 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, as 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 plate vibration and liquid splashing.

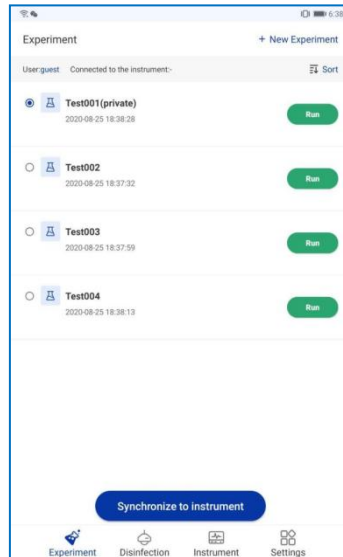


Figure 9. Synchronize to instrument

2.1.3 Adding Sample to the Reagent

96-deep well plate: Add 200 μ L of the sample that has been equilibrated to room temperature to column 1 or 7 of the pre-filled reagent, respectively. (note the column no. is for effective wells, which have been added with color indicators).

⚠ 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.

b. Short-term storage: Samples can be used immediately after collection for nucleic acid extraction or stored at 4°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 10, the user should ensure that the 96-deep well plate 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.

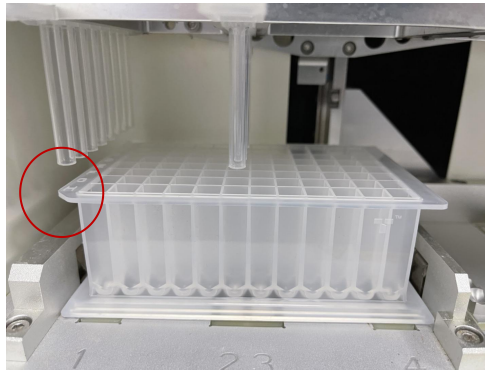



Figure 10. 96-deep well plate

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 11.

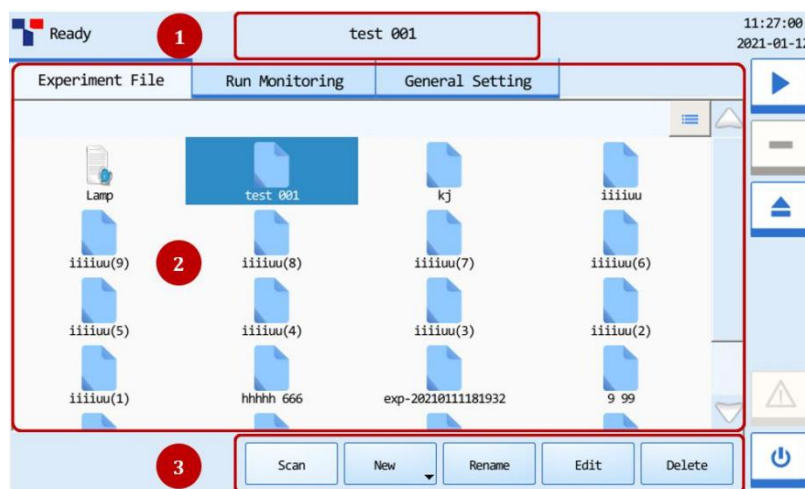


Figure 11. Main Interface of the System Software

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



Figure 12. 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 13. Edit the experiment steps and parameters according to the reagent kit specification, and then click < **Save** > to save the corresponding settings.

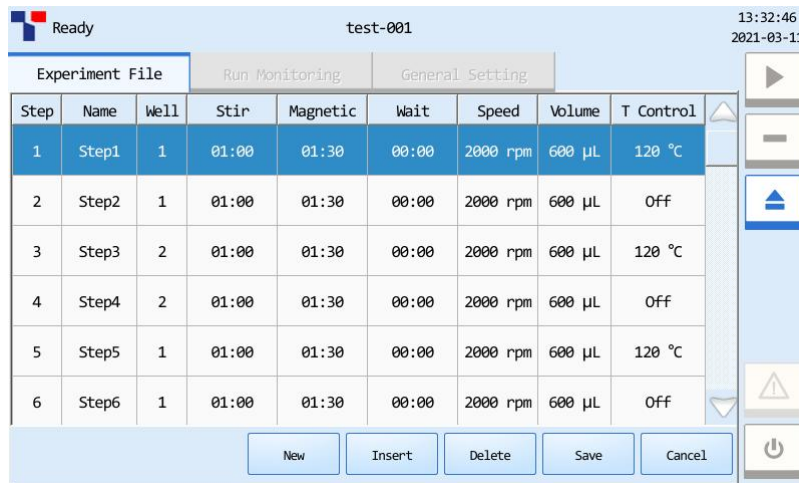


Figure 13. GeneRotex System Software - Experiment File Edit Interface

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	Remove bead	2	00:10	00:10	00:00	2500	300	0
2	Lysis	1	03:00	00:45	00:00	2500	750	120
3	Washing 1	3	01:00	00:20	00:00	3000	700	120
4	Washing 2	4	01:00	00:20	01:00	3000	800	120
5	Elution	6	02:00	00:30	00:00	2500	80	120

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.

2.2.3 Adding Sample to the Reagent

96-deep well plate: Add 200 μ L 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.)

(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 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 are on the left, which is shown in Figure 14.

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.

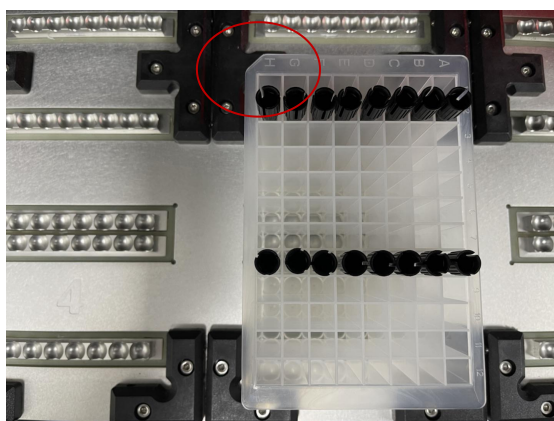


Figure 14. 96-deep well plate

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 15 and 16.

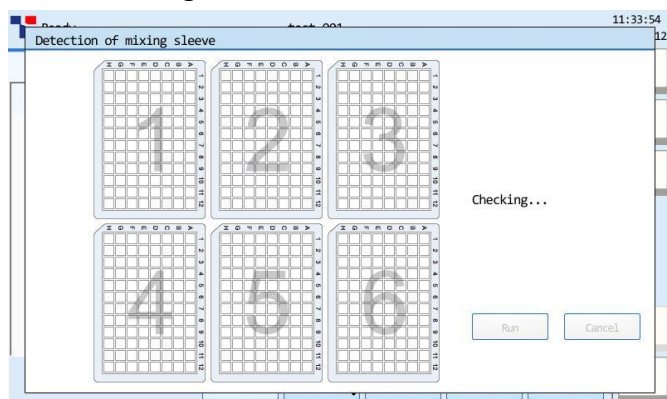


Figure 15. Check the mixing sleeve position

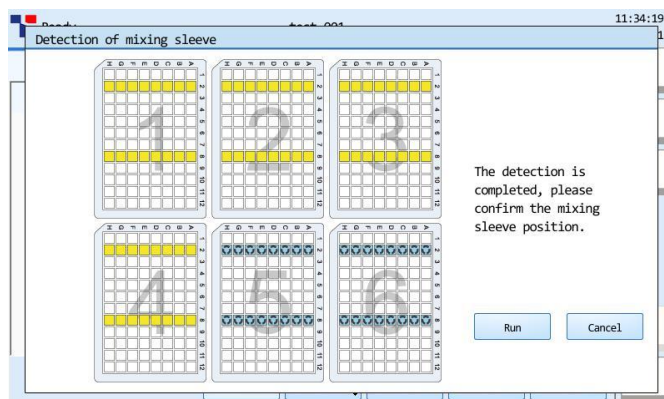


Figure 16. Confirm the mixing sleeve position

When an experiment starts a run, the system will enter operation monitoring interface automatically, which displays the real-time information about the current experimental running, which is shown in Figure 17.

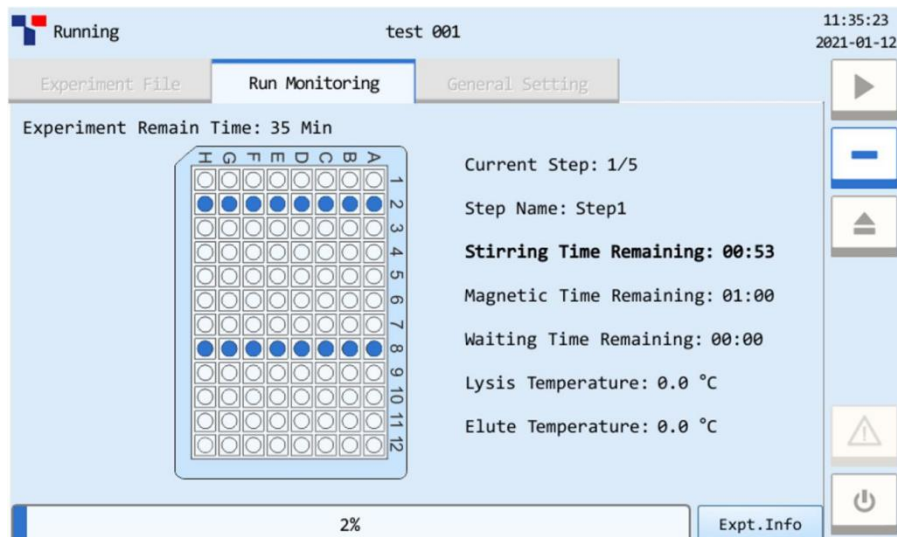


Figure 17. Tab for Monitoring Run

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, do you 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	Have you read the precautions in this manual before using the kit.	re-extraction of nucleic acid is performed.
5	Abnormal noise from the instrument during extraction	Is the 96-deep well plate placed correctly.	Reposition the deep well plate.
		Is the stirring sleeve inserted in place.	Reinsert the stirring sleeve.
6	Poor extraction performance	Have you follow the operation requirements in the manual.	Contact the after-sales service of our company.
		Is the temperature control item of the instrument 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		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.

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.

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