TIANLONG

Viral DNA and RNA Extraction Kit

User Guide

Σ 20 T049H

Σ 64 T050H

Σ 40 T051H

Σ 20 T052H

Version 4.0

CE IVD

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

REF T049H 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.

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

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.

IFU_T049H/T050H/T051H/T052H_EN /Jul. 2023

Contents

Intended Use....1
Product Performance Indicators....1
Special Notes....1
Testing Principle....1
Kit Contents....2
Materials Required but not Provided....2
Warnings and Precautions....2
Reagent Storage and Handling....4
Sample Handling and Storage....4
Operation Guide....4
1. Automated Extraction Process....4
2. Operation Steps of Automated Extraction....4
2.1 Automatic Nucleic Acid Extractor (model: Libex)....4
2.2 Full-Automatic Nucleic Acid Extractor (model: GeneRotex 96)....6
Troubleshooting Guide....8
Quality Control....9
Limitations of Test Methods....9
Safety Symbols and Signs....9
Contact Information....10

TIANLONG

Kit Version	4.0		
Changes	Small lexical corrections Chapter “Intended Use” Chapter “Kit Contents” Chapter “Operation Guide” Chapter “Contact Information”	Additions	Add Product Specification – short code: T049H

Intended Use

The ***Viral DNA and RNA Extraction Kit*** is intended for rapidly extracting 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), Southern hybridization and blotting 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 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 have 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. To avoid RNA degradation by RNase during operation, use exclusive-use utensils and sample injectors. Please note that all the disposable centrifuge tubes and tips should be processed by autoclave before using. The operator should wear powder-free gloves, a mask and a protective cover all.

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 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 a 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 working with TIANLONG® automatic nucleic acid extractors (Libex and GeneRotex 96) 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.

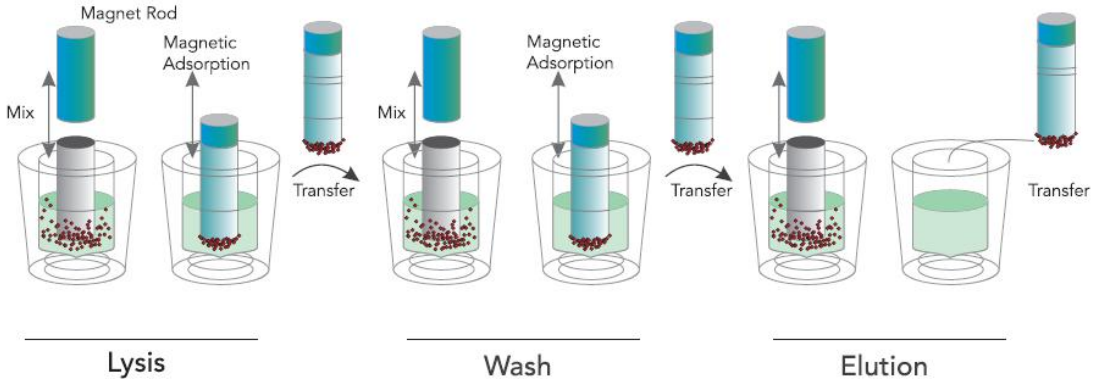

Figure 1. Schematic Diagram of Full-Automatic Nucleic Acid Extractor

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 an array of 96 magnetic rods which allow to process up to 96 samples simultaneously.

Kit Contents

Short Code / Name of Component		T049H	T051H	T052H	T050H
Pre-filled reagent	Size	20T/Box	40T/Box	20T/Box	64T/Box
	Component	Pre-filled 6 strip tube	Pre-filled 96-deep well plate	Pre-filled 96-deep well plate	Pre-filled 96-deep well plate
	Quantity	20	4	4	4
	Component specification	1 Test	10 Tests	5 Tests	16 Tests
Instructions for Use		1 copy	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: 200 µL or 1000 µL
- Tip: 200 µL or 1000 µL
- 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 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 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 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 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 for the kit.

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 extractors (Libex and GeneRotex 96) enable 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.

The user needs to load samples and magnetic bead nucleic acid extraction reagents into the reaction consumables, the nucleic acid extractors are going to perform all nucleic acid extraction operations according to the experimental procedures. Please refer to the user manual provided with an instrument for operating instructions.

2. Operation Steps of Automated Extraction

2.1 Automatic Nucleic Acid Extractor (model: Libex)

2.1.1 Edit Experiment Program

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 (℃)
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

2.1.2 Reagent Preparation

96-deep well plate:

Open the kit and take out the pre-filled reagent, 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 500 rpm for 1 min). carefully tear off the aluminum foil sealing film before use to avoid liquid splashing.

6 strip tube:

Open the kit and 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 plate vibration and liquid splashing, which is shown in Figure 2.

Figure 2. Put the 6 strip tube on the single kit docking

2.1.3 Adding Sample to the Reagent

96-deep well plate:

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

⚠ **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 the sample 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 3 and Figure 4 , 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 or the single kit docking into the experiment cabin and push the mixing sleeves into the right position. Check the position of the mixing sleeves. Otherwise, instrument dysfunction or malfunction may occur and affect the experiment results.

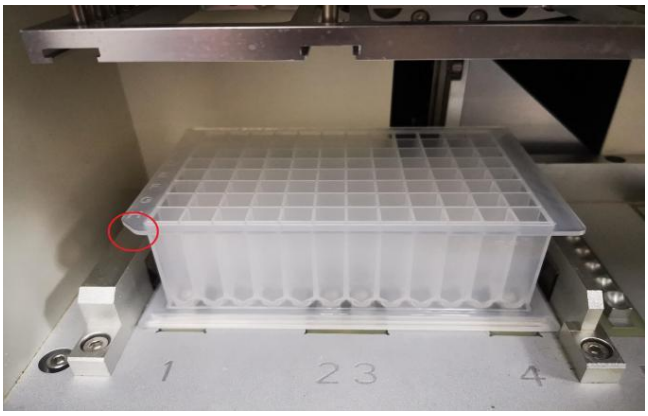

Figure 3. 96-deep well plate

Figure 4. Put the single kit docking into the instrument

2.1.5 Procedure Run

For special operations please refer to 2.1.1. After the procedure is completed, the instrument will notify the user that the experiment has been completed. Transfer the extracted product from well 6 and well 12 to a clean centrifuge tube that is 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 Automatic Nucleic Acid Extractor (model: GeneRotex 96)

2.2.1 Edit Experiment Program

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 500 rpm for 1 min). Carefully tear off the aluminum foil sealing film to avoid the liquid splashing.

6 strip tube:

Open the kit and 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 5.

Figure 5. Put the 6 strip tube on the single kit docking

2.2.3 Adding Sample to the Reagent

96-deep well plate: Add 200 µL 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 200 µL of the sample that has been equilibrated to room temperature to the first well of the pre-filled reagent.

⚠ **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.

2.2.4 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 that the 96-deep well plate should be placed with its notch at the upper left corner, as shown in Figure 6 and Figure 7.

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.**

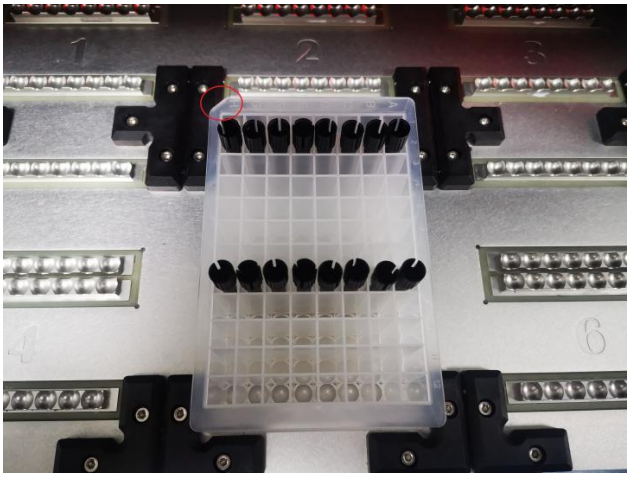

Figure 6. 96-deep well plate

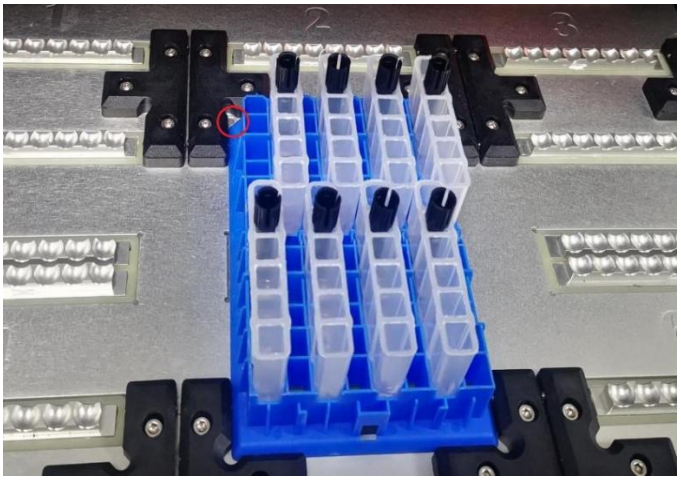

Figure 7. Put the single kit docking into the instrument

2.2.5 Experimental Procedure Run

For special operations please refer to 2.2.1. After the procedure is completed, the instrument will notify the user that the experiment has been completed. Transfer the extracted product from well 6 and well 12 to a clean centrifuge tube that is 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.	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 Sales Support team of Tianlong.

4	Reuse of pre-filled components	Please read the precautions in this manual before using the kit.	A re-extraction of nucleic acid should be performed.
5	Abnormal noise from the instrument during extraction	The 96-deep well plate may be placed correctly.	Reposition the deep well plate.
		The mixing sleeve may not be inserted in place.	Reinsert the stirring sleeve.
6	Poor extraction performance	Please follow the operation requirements in the manual.	Contact the Sales Support team of Tianlong.
		The temperature control components of the instrument may be abnormal.	Contact the Sales Support team of Tianlon.
		Others	Contact the Sales Support team of Tianlon.

***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 the performance evaluation studies of Xi'an Tianlong Science and Technology Co., Ltd.

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), inquiry@medtl.com or contact your local distributor.

For a patient/user/third party in the European Union and in countries with similar regulatory regime (Regulation 2017/746/EU on IVD Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national regulatory authority.

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.