TIANLONG

Viral DNA and RNA Extraction Kit

User Guide

Σ T041H
48

Σ T392H
96

Version 5.0

CE IVD

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

REF T041H T392H

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

No.4266, Shanglin Road, Weiyang District, Xi'an, 710021, Shaanxi, P.R. China

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

Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den lJssel, The Netherlands

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Kit Version	5.0		
Changes	/	Additions	Added T392H specification

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 and swab lotion samples, etc. 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 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® automatic 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 and swab lotion samples, etc.

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.

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® automatic 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.

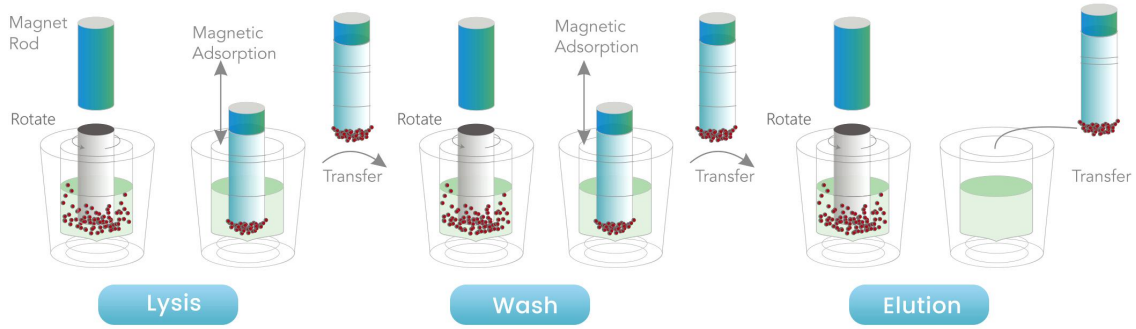

Figure 1. Schematic Diagram of Automatic Nucleic Acid Extractor

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.

Content of the Kit

Name of Component \ Short Code		T041H	T392H
REAG1	Size	48 T/Box	96 T/Box
	Component	Pre-filled 48-deep well plate	Pre-filled 48-deep well plate
	Quantity	6	12
	Component Specification	8 Tests	8 Tests
REAG2	Component	Proteinase K Solution	Proteinase K Solution
	Component Specification	1.2 mL	1.2 mL
	Quantity	2	4

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

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. Follow the manual strictly during the operation. The subjected clinical samples should be collected on a clean bench or in a biosafety cabin.

Before using TIANLONG® automatic 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 diagnostic 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.medtl.net/resources/download/catalogue-all/catalogue, 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*** comes with the following warnings and precautions.

Name of Component		Hazard pictograms (CLP)	Classification under CLP:	H- and P-statements
REAG 1	Lysis Buffer Washing Buffer A Washing Buffer B		Acute toxicity (oral), Category 4 Skin corrosion/irritation, Category 2 Serious eye damage/eye irritation, Category 2	**Hazard statements (CLP)** H302: Harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation. **Precautionary statements (CLP)** P264 ： Wash hands, forearms and face thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P321: Specific treatment (see supplemental first aid instruction on this label). P337+P313: If eye irritation persists: Get medical advice/attention. P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
	Magnetic Beads Dilution Buffer Washing Buffer C Elution Buffer	None	None	None
REAG 2	Proteinase K Solution	None	None	None

Please see MSDS for more details.

Precautions for Safe Handling

Do not dispose of the preparations or the packaging waste in drains leading to the sewage system or in

the drainage system for waste not produced by industrial processing/analysis waste.

Any material in contact with reagents should be treated as a biological contaminant and treated in accordance with relevant local regulations.

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 any source of heat, sparks, or 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.

For detailed information on sample pretreatment, please refer to 2.1.3.

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 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: GeneRotex 48)

2.1.1 Edit Experiment Program

The extraction procedure of GeneRotex 48 Automatic 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 and take out the REAG1, slowly invert it several times to resuspend the magnetic beads, then remove the plastic package and gently shake the 48-well plate so that the reagent and magnetic beads are concentrated on the bottom of the 48-well plate. Please carefully tear down the aluminum foil sealing membrane to avoid liquid splash.

2.1.3 Adding Sample to the Reagent

48-deep well plate: Add 50 µL REAG2 and 1000 µL of the sample that has been equilibrated to room temperature to row 1 of the pre-filled reagents.

⚠ **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 sample is suitable for the *Viral DNA and RNA Extraction Kit*.

a. Type of sample: As stated in the intended use.

b. Sample Storage: Immediate extraction or keep at 2~8°C for later use, the storage period should not exceed 24 hours. Long-term storage should be under -20°C.

2.1.4 Loading in the Deep Well Plate

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

Note: The user should ensure the marked notch of the plate of the 48-deep well plate is on the left, which is shown in Figure 2.

Insert the rotatory mixing sleeve into rank 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.**

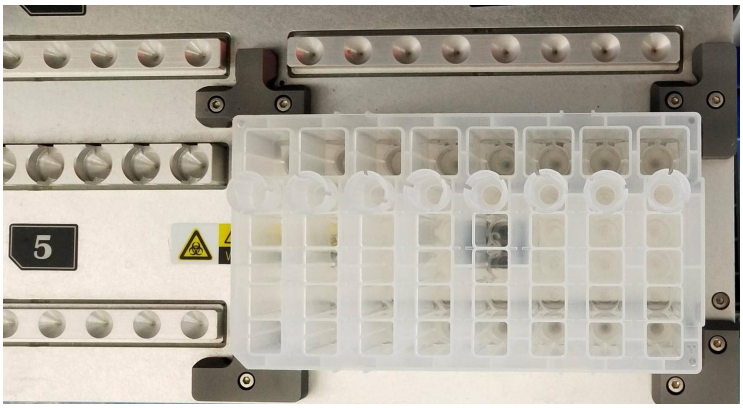

Figure 2. 48-deep well plate

2.1.5 Experimental Procedure Run

Program operation see 2.1.1 for specific programs. After the procedure is completed, the instrument will notice the user the experiment has been completed. Transfer the extracted product from row 6 to a clean centrifuge tube which is free of nuclease.

Note: If the user does not analyse the extracted product immediately, please seal and store 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 expected results.**

2.1.6 Cleaning and Maintenance of the Instrument

Follow the Cleaning and Maintenance of the 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 and Frequently Asked Questions, please visit our Technical Support Center 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, sample and assay technologies (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 after-sales service of Tianlong.
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 Tianlong.
		The temperature control components of the instrument may be abnormal.	Contact the after-sales service of Tianlong.
		Other	Contact the after-sales service of Tianlong.

* **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 and swab lotion samples to purify viral DNA and RNA.

It is users' 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	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
13	CONT	Content of the kit
14	REAG1	Pre-filled 48-deep well plate
15	REAG2	Proteinase K Solution

16		Warning
17		PAP21: Not-corrugated cardboard

Contact Information

For technical assistance and more information, please contact our Technical Support Center at +86-29-82682132 (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 authorised 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.