





Nucleic Acid Extraction Kit (For Viral DNA and RNA) User Guide

 T550H
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 T549H
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 T548H
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Version 1.0



In-Vitro Diagnostics / For use with automatic nucleic acid extractor compatible with
Nucleic Acid Extraction Kit



T548H T549H T550H



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

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



SUNGO Europe B.V.

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

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Intended Use

Nucleic Acid Extraction Kit (For Viral DNA and RNA) is designed to rapidly extract pathogen DNA/RNA from serum and plasma samples. The extracted pathogen DNA and RNA are of high purity and stability, and can be used for clinical in vitro detection.

Nucleic Acid Extraction Kit (For Viral DNA and RNA) 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

Nucleic Acid Extraction Kit (For Viral DNA and RNA) can extract more than 5IU/ml DNA nucleic acid, and more than 12.5 IU/ml RNA nucleic acid. Both the intra and inter-batch variations of the kit are less than 5%. With instrument extraction, 1-96 samples can be operated at the same time, keeping the results stable and reproducible.

Special Notes

Nucleic Acid Extraction Kit (For Viral DNA and RNA) is worked with TIANLONG® automatic nucleic acid extractor (GeneRotex 96) that has 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 pathogen 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 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 serum and plasma 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 used for clinical in vitro detection.

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

Nucleic Acid Extraction Kit (For Viral DNA and RNA) is worked with TIANLONG® automatic nucleic acid extractor (GeneRotex 96). During the nucleic acid extraction process, magnetic beads are adsorbed, transferred and released by 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.

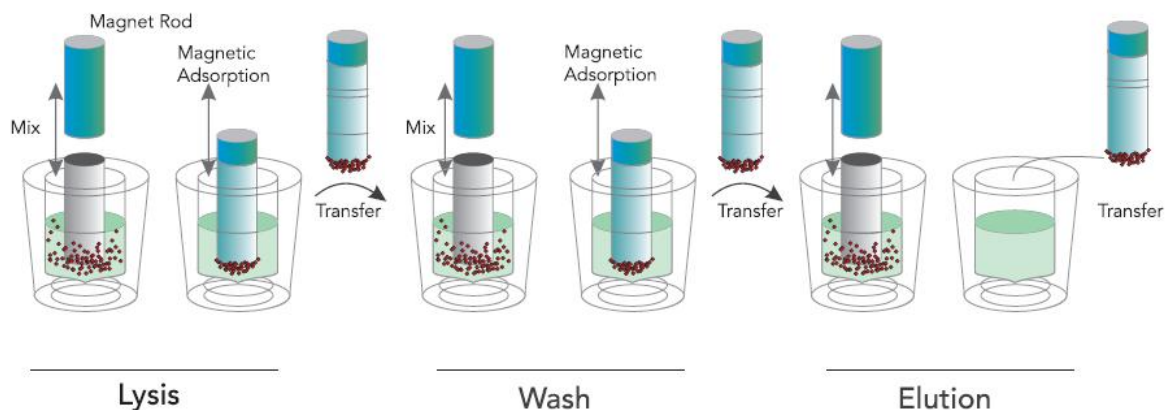


Figure 1. Schematic Diagram of Automatic Nucleic Acid Extractor

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

A magnetic rod protected by the mixing sleeve is inserted 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 is equipped with an array of 96 magnetic rods, allowing it to process up to 96 samples simultaneously.

Content of the Kit

| Short Code Name of Component | | T548H | T549H | T550H |
|---------------------------------|----------------------------|----------------------------------|----------------------------------|----------------------------------|
| | | Size | 64 T/Box | 32 T/Box |
| REAG1 | Component | Pre-filled 96-deep well plate | Pre-filled 96-deep well plate | Pre-filled 96-deep well plate |
| | Quantity | 4 | 4 | 4 |
| | Specification | 16 Tests | 8 Tests | 5 Tests |
| | Component | Proteinase K Solution | Proteinase K Solution | Proteinase K Solution |
| REAG2 | Component Specification | 0.96 mL | 0.96 mL | 0.6 mL |
| | Quantity | 2 | 1 | 1 |
| 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: 10 µL, 20 µL, 1000 µL
- Tip: 10 µL, 20 µL, 1000 µL
- Vortex mixer
- High-speed centrifuge
- Sample holder
- 75% ethanol
- Extractor

Warnings and Precautions

Please be sure to read the precautions before using the kit.

Nucleic Acid Extraction Kit (For Viral DNA and RNA) is used to extract pathogen 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 and protective coverall.

Please read the manual carefully before using the kit and strictly follow the manual throughout operation. The clinical samples should be collected on a clean bench or in a bio-safety cabin.

Before using TIANLONG® automatic nucleic acid extractors (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.

Nucleic Acid Extraction Kit (For Viral DNA and RNA) 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

⚠ 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 first. Then clean with sodium hypochlorite at a concentration of 1% (v/v). Be aware of following warnings and precautions while using *the Nucleic Acid Extraction Kit (For Viral DNA and RNA)*.

| Name of Component | | Hazard pictograms (CLP) | Classification according to Regulation | Labelling according to Regulation |
|-------------------|------------------|---|---|--|
| REAG1 | Lysis Buffer |  | Acute toxicity (oral), Category 4 Skin corrosion/irritation, Category 2 Serious eye damage/eye irritation, Category 2 | <p>Hazard statements (CLP)</p> <p>H302 - Harmful if swallowed. H315 - Causes skin irritation. H319 - Causes serious eye irritation.</p> <p>Precautionary statements (CLP)</p> <p>P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P302+P352 - IF ON SKIN: Wash with plenty of water. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P362+P364 - Take off contaminated clothing and wash it before reuse. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.</p> |
| | Washing Buffer A |  | Acute toxicity (oral), Category 4 Skin corrosion/irritation, Category 2 Serious eye damage/eye irritation, Category 2 | <p>Hazard statements (CLP)</p> <p>H302 - Harmful if swallowed. H315 - Causes skin irritation. H319 - Causes serious eye irritation.</p> <p>Precautionary statements (CLP)</p> <p>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</p> |

| | | | | |
|--------------|--|------|------|---|
| | | | | <p>first aid instruction on this label).</p> <p>P337+P313 - If eye irritation persists: Get medical advice/attention.</p> <p>P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.</p> |
| | <p>Magnetic Beads</p> <p>Dilution Buffer</p> <p>Washing Buffer B</p> <p>Elution Buffer</p> | None | None | None |
| REAG2 | Proteinase K | 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

Nucleic Acid Extraction Kit (For Viral DNA and RNA) should be stored at room temperature in a cool, dry and well-ventilated area. All components of the kit can be adequately stored for up to 12 months.

The kit should be used in a well-ventilated area, away from the source of heat, sparks, open flames and smoking is not permitted.

To avoid evaporation, the pre-filled reagent should be used immediately after 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 aging.

Sample Handling and Storage

Avoid foam 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. 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 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.

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 96)

2.1.1 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 | 1600 | 600 | 0 |
| 2 | Lysis | 1 | 05:00 | 00:45 | 00:00 | 2000 | 750 | 0 |
| 3 | Lysis | 3 | 05:00 | 00:45 | 00:00 | 2000 | 750 | 0 |
| 4 | Washing 1 | 4 | 03:00 | 00:20 | 00:00 | 1500 | 670 | 90 |
| 5 | Washing 2 | 5 | 02:00 | 00:20 | 01:00 | 1500 | 750 | 120 |
| 6 | Elution | 6 | 05:00 | 00:45 | 00:00 | 2500 | 80 | 120 |
| 7 | Release bead | 2 | 00:10 | 00:00 | 00:00 | 2500 | 600 | 0 |

2.1.2 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 1min). Carefully tear off the aluminum foil sealing film to avoid the liquid splashing.

2.1.3 Adding Sample to the Reagent

96-deep well plate:

Add 15μL REAG2 and 200 μL sample to column 1/3 or column 7/9 of the pre-filled reagent respectively. (Be aware of the column No. is for effective wells).

⚠ 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 suitable for the *Nucleic Acid Extraction Kit (For Viral DNA and RNA)*.

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 96-deep well plate containing the sample in the experimental cabin of the automatic nucleic acid extractor.

⚠ 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 2.

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

⚠ Caution: The user must ensure that the rotatory mixing sleeve is placed properly. Otherwise, the instrument may operate abnormally, or the magnetic rods may be contaminated.

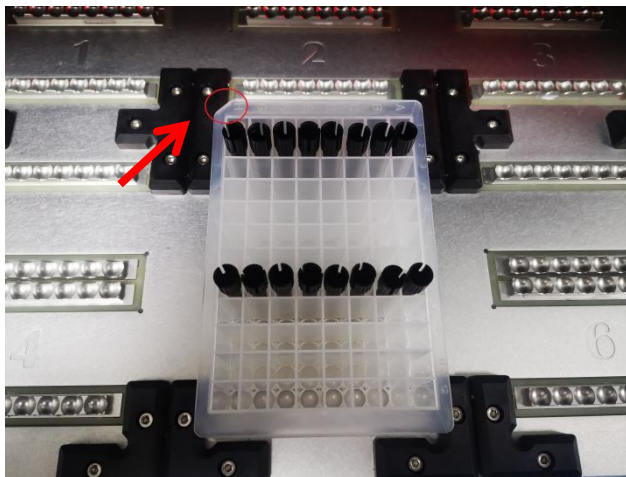


Figure 2. 96-deep well plate

2.1.5 Experimental Procedure Run

For special operations please see 2.1.1. After an experiment starts running, the instrument will notice user when the experiment is complete. Transfer the eluate from column 6 to a clean centrifuge tube free of nuclease.

⚠ Note: If the user does not analyse the extracted product immediately, please store it sealed in a refrigerator at -20°C.

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 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 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 aluminium 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. | 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 incorrectly. | Reposition the deep well plate. |
| | | The mixing sleeve may not be inserted in place. | Reinsert the stirring sleeve. |
| 6 | Poor extraction performance | Please follow operation requirements from 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 **Nucleic Acid 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 serum and plasma samples to purify targeted DNA and RNA.









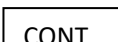
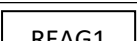
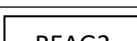


It is the user's responsibility to validate system performance for any procedures used in their laboratory that are not covered by the performance evaluation studies of Xi'an Tianlong Science and Technology Co., Ltd.

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 |
| 13 |  | Content of the kit |
| 14 |  | Pre-filled 96-deep well plate |
| 15 |  | 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.

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