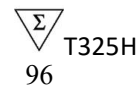




Viral DNA and RNA Extraction Kit

User Guide



Version 4.0



In-Vitro Diagnostics / For Use with Automatic Nucleic Acid Workstation compatible with
Viral DNA and RNA Extraction Kit



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Contents

Intended Use.....	1
Product Performance Indicators.....	1
Special Notes.....	1
Testing Principle.....	1
Content of the Kit.....	2
Materials Required but not Provided.....	2
Warnings and Precautions.....	2
Precautions for Safe Handling.....	3
Reagent Storage and Handling.....	3
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 Workstation (model: PANA 9600S).....	4
Troubleshooting Guide.....	5
Quality Control.....	6
Limitations of Test Methods.....	6
Safety Symbols and Signs.....	6
Contact Information.....	7

Changes	Logo Address of Manufacturer Address of EU Representative Chapter "Intended Use" Chapter "Content of the Kit" Chapter "Materials Required but not Provided" Chapter "Warnings and Precautions" Chapter "Sample Handling and Storage" Chapter "1. Automated Extraction Process" Chapter "2. Operation Steps of Automated Extraction" Chapter "Troubleshooting Guide" Chapter "Limitations of Test Methods" Chapter "Safety Symbols and Signs" Chapter "Contact Information" Small lexical corrections.	Additions	Chapter "Precautions for Safe Handling"
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Intended Use

The ***Viral DNA and RNA Extraction Kit*** is intended for rapidly extracting viral DNA/RNA from whole blood, serum, plasma, interstitial fluid, urine and swab samples. The extracted nucleic acids 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 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 10 IU/mL viral DNA nucleic acid, and more than 30IU/mL viral RNA nucleic acid.

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*** is worked with TIANLONG® automatic nucleic acid workstation (PANA 9600S) that have been disinfected by UV light before use. After the experiment, it is recommended to clean the instrument cabin using 75% ethanol and disinfecting it via UV light for about 15 mins.

The extraction kit is particularly used for viral DNA/RNA isolation; therefore, all of experiment supplies, such as pipettes, tubes, and tips, must be processed by autoclave. Operator should wear powder-free gloves and a mask and a protective coverall.

The kit has magnetic beads with a unique separation function and buffer system to extract, separate and purify high-quality nucleic acids from whole blood, serum, plasma, interstitial fluid, urine and 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 the fields of diagnostics, genomics research, disease detection, food safety and forensic identification, etc.

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.

In the absence of exceptional circumstances, it is prohibited to mix the reagents from different batches.

After the experiment, all of samples and reagents must be reasonably disposed of and other Instruments should be thoroughly cleaned and disinfected.

Testing Principle

The ***Viral DNA and RNA Extraction Kit*** is worked with TIANLONG® automatic nucleic acid workstation (PANA 9600S). During the nucleic acid extraction process. Magnetic beads are adsorbed, transferred and

Viral DNA and RNA Extraction Kit (T325H) –User Guide **Page 1 of 7**

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.

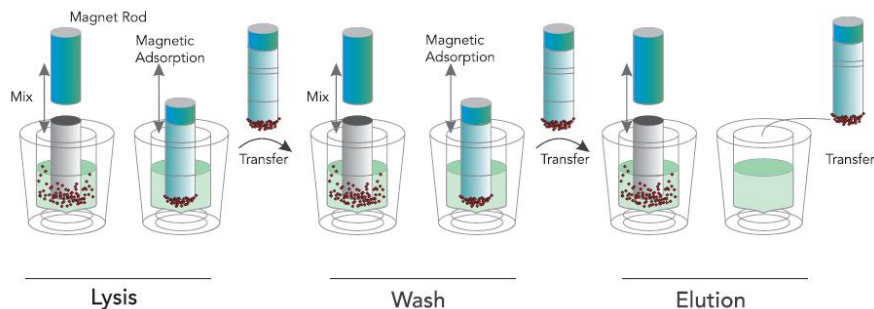


Figure 1. Schematic Diagram of Automatic Nucleic Acid Workstation

Content of the Kit

Name of Component		Short Code	T325H
REAG1	Size		96 T/Box
	Component		Pre-filled 96-deep well plate
	Component Specification		16 Tests
	Quantity		6
REAG2	Component		Proteinase K Solution
	Component Specification		1.92 mL
	Quantity		1
Instructions for Use			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.

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

Warnings and Precautions

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

The extraction kit is particularly used for viral DNA/RNA isolation. To avoid RNA degradation by RNase during operation, use exclusive-use utensils and sample injectors, and use disposable centrifuge tubes and tips processed by autoclave before using. The operator (researcher or clinical expert) should wear powder-free gloves and a mask.

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

Before using TIANLONG® automatic nucleic acid workstation (PANA 9600S), it must be disinfected by UV light. After an experiment, wipe the inside of the workstation with 75% ethanol and disinfect it with UV light for 15 mins.

Due to the possibility of residual magnetic beads in the eluate following extraction, every possible effort should be made to avoid suctioning of any magnetic beads during eluate absorption.

Do not mix reagents from different batches and use the kit within expiry date.

Dispose of all samples and reagent materials used in an experiment, thoroughly clean and disinfect the experimental work bench.


The **Viral DNA and RNA Kit** is intended for in vitro diagnosis use.

When using kit, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate Material Safety Data Sheets (MSDSs). These documents are available online in a convenient and compact PDF format at

<https://www.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 of these buffers are spilled, clean immediately with a suitable laboratory detergent and water. If the spilled liquid contains potentially infectious agents, clean the affected area first with laboratory detergent and water, and then with sodium hypochlorite at a concentration of 1% (v/v). The **Viral DNA and RNA Extraction Kit** comes with the following warnings and precautions.

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 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

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 workstation (PANA 9600S) enables nucleic acid extraction by magnetic beads. They use 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, highly pure nucleic acids are obtained. Automatic nucleic acid workstations is 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 workstation is 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 Workstation (model: PANA 9600S)

2.1.1 Experiment Preparation

Reagent Preparation

Please remove the PCR reagent from the refrigerator, thaw and balance to room temperature.

Sample Preparation

- ▶ Please firstly record the sample information according to the requirements of laboratory operation.
- ▶ Please complete the sample centrifugation and other pre-processing operations according to the experimental requirements and add or divide the prepared samples into sample tubes in the biosafety cabinet.
- ▶ Please insert the sample tubes into the sample holder and slowly push the sample holder along the track into the sample cabin.

⚠ 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.

Consumable Preparation

- ▶ User can prepare the corresponding reagent and consumables and load them in the right position according to the requirement information of reagent and consumable.

2.1.2 Experiment Running

- a. Pre-filled 96 deep well plate: Take out the plates from the kit box, turn it up and down to suspend the magnetic beads. Then remove the vacuum package, gently swing the plates to make the magnetic beads are gathered at the bottom of the wells. Please carefully tear down the aluminum foil sealing membrane to avoid liquid splash.
- b. Please follow the manual to set the protocols.

2.1.3 Experiment Complete

Product Transfer

- ▶ After the experiment, please add the PCR consumables and transfer the PCR reaction system established by the PANA workstation to the PCR equipment for follow-up experiment.
- ▶ After the experiment, please cover the sample reserve tubes and transfer the reserved sample or nucleic acid extracted from the PANA workstation to the -20°C refrigerator.

Reagent and Sample Recovery

- ▶ After the experiment, please cover the reagent bottles and recover the remaining reagents from the reagent cabin of the PANA workstation and store them in -20°C refrigerator together with the code and the reagent holder.
- ▶ After the experiment, please take out the sample holders, cover the sample tubes, and store the sample in the refrigerator.

Instrument cleaning and maintenance

- ▶ After the experiment, consider the used consumables such as deep well plates, rod covers, premix bottles as biological contaminated and comply with all applicable local or national regulations for the disposal of potentially infected waste.
- ▶ After the experiment, please comply with all applicable local or national regulations, dispose the biological waste in the waste bin within the waste cabin of the PANA workstation, and replace the waste bag in the waste bin.

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/stop. 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 96-deep well plate may be placed incorrectly.	Reposition the deep well plate.
		The mixing sleeve may not be inserted in place.	Reinsert the mixing sleeve.
6	Poor extraction performance.	Please follow the operation requirements in the manual.	Contact the after-sales service of 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.
7	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.

* 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, interstitial fluid, urine and swab 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.

The extraction kit is intended for clinical diagnostics, health system and scientific research only, whose usage can act as an ancillary step for molecular detection and should be matched with other molecular detection methods. The concentration and purity of its extraction product are affected by instruments and operators. 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 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.

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