TIANLONG

Viral DNA and RNA Extraction Kit

User Guide

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Version 5.0

CE IVD

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Intended Use

The ***Viral DNA and RNA Extraction Kit*** is designed to extract viral DNA and RNA from serum and swab. The extracted Viral DNA and RNA is 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 30 IU/ mL viral RNA nucleic acid. Both the intra and inter-batch variations of kit are less than 5%.

Special Notes

The extraction kit is particularly used for viral DNA and RNA isolation; therefore, all of experiment supplies, such as pipettes, tubes, tips, must be autoclaved. Operator should wear gloves and masks. Before using the kit, please read the manual and strictly follow the protocol. Clinical samples should be processed on clean bench or in biosafety cabinet.

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, and thoroughly clean and disinfect the experimental workbench.

Testing Principle

During the process of nucleic acid extraction, using silicagel column principle to conduct adsorption and washing of nucleic acid, which can achieve the transfer of nucleic acid and complete the extraction and purification of nucleic acid.

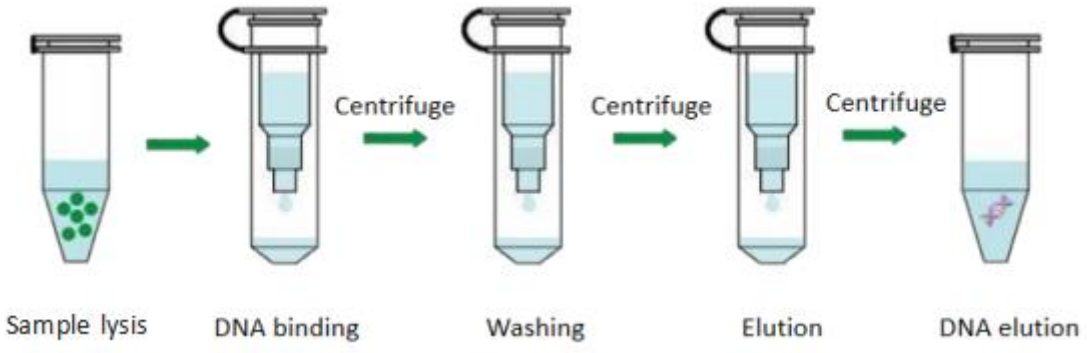

Figure 1. Schematic Diagram of Spin-Column Method

Content of the Kit

NO.	Name of Component	Components	Specification	Quantity
1	REAG1	Lysis Buffer	16 mL	1 bottle
2	REAG2	Washing Buffer 1	22.4 mL	1 bottle
3	REAG3	Washing Buffer 2	22.4 mL	1 bottle
4	REAG4	Elution Buffer	1.6 mL	1 bottle
5	REAG5	Proteinase K Solution	0.64 mL	1 bottle
6	REAG6	Adsorption Column	/	32
7	REAG7	Collection Tube	/	64
8	Sponge Inner Support	/	/	1
9	Packaging Box	/	/	1
10	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.

- Pipettor: 50 µL, 200 µL, 1000 µL
- Tip: 50 µL, 200 µL, 1000 µL
- 1.5 mL nuclease-free centrifuge tube
- Vortex mixer
- High-speed centrifuge
- Water bath
- Sample holder
- 75% ethanol
- EtOH (to be ordered separately)

Warnings and Precautions

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

The extraction kit is particularly used for viral DNA and RNA isolation. Therefore, all of experiment supplies, such as pipettes, tubes, tips, must be processed by autoclave. Operator should wear gloves and masks.

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

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

After the experiment, dispose of all samples and reagent materials used in an experiment, and clean and disinfect the experimental workbench thoroughly.

The ***Viral DNA and RNA Extraction 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 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). The kit comes with the following warnings and precautions.

Name of Component		Hazard pictograms (CLP)	Classification according to Regulation	Labelling according to Regulation
REAG 1	Lysis Buffer		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.
REAG 2	Washing Buffer 1			
REAG 3	Washing Buffer 2			
REAG 4	Elution Buffer	None	None	None
REAG 5	Proteinase K Solution	None	None	None

Please see MSDS for more details.

Precautions for Safe Handling

Do not dispose of the preparations or of 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, keep away from the source of heat, sparks, open flames, and smoking.

To avoid evaporation, the pre-filled reagent should be used immediately after opening and should not be placed for a long period of time.

Avoid exposure 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.

Detail information on sample pretreatment, please refer to 2.1.3.

Operation Guide

Extraction Steps

a. Add 20 µL REAG5, 500 µL REAG1 and 200 µL samples into 1.5 mL nuclease-free centrifuge tube then vortex mixing for 15 s. (Note: please do not use the solution which combines REAG5 with REAG1).

b. 50 °C water bath for 5 mins, during the period, vortex and mix about once every 2 min, and mix well 2 times.

c. Place the solution at room temperature for 3-5 mins, instantly centrifuge to remove residual liquid from the top lid after the solution has reached room temperature.

d. Add 300 µL absolute ethyl alcohol (self-contained) into centrifuge tube, and Instantly centrifuge to remove residual liquid from the top lid after mixing completely.

e. Pipette 510 µL solution from the above centrifuge, then add that into REAG6; cover the lid and centrifuge at 8000 rpm for 1 min; discard the waste liquid and put REAG6 into the REAG7.

f. Repeat Step e once.

g. Open the tube lid slowly, add 700 µL REAG2, centrifuge at 12000 rpm for 1 min, then discard the waste liquid and put REAG6 into the REAG7.

h. Open the tube lid slowly, add 700 µL REAG3, centrifuge at 12000 rpm for 1 min, then discard the waste liquid and put REAG6 into the REAG7, after that centrifuge at 12000 rpm for 2 mins.

i. After centrifugation, the REAG6 placed in a new 1.5 mL nuclease-free centrifuge tube, then open the tube lid and place them at room temperature for 3-5 mins.

j. Add 50 µL REAG4 (should be heated to 60 °C) into adsorption, placed it at room temperature for 2-5 mins, centrifuge at 12000 rpm for 1 min; then collect the solution to 1.5 mL centrifuge tube (self-contained), and stored it at -20 °C.

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 (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	Poor extraction performance	The operations of sample pretreatment is incorrect	Please follow the operation requirements in the manual.
		The sample lysis may be incomplete.	Please follow the operation requirements in the manual.
		Others	contact the Sales Support Service team 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 serum and swab samples to isolate viral DNA and RNA.

The user's responsibility is to validate system performance for any procedures performed 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	Lysis Buffer
15	REAG2	Washing Buffer 1
16	REAG3	Washing Buffer 2
17	REAG4	Elution Buffer

18	REAG5	Proteinase K Solution
19	REAG6	Adsorption Column
20	REAG7	Collection Tube
21		Warning
22		PAP21: Not-corrugated cardboard

Contact Information

For technical assistance and more information, please contact our Technical Support Center at +86-29-826 82132 (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.