TIANLONG

Viral DNA and RNA Extraction Kit

User Guide

Σ 20 T508H

Σ 20 T507H

Σ 48 T506H

Σ 96 T505H

Version 4.0

CE IVD

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

REF T508H T507H T506H T508H

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Changes	Address of Manufacturer Address of EU Representative Chapter “Content of the Kit” Chapter “Materials Required but not Provided” Chapter “Warnings and Precautions” Chapter “Sample Handling and Storage” Chapter “Safety Symbols and Signs” Small lexical corrections.	Additions	/

Intended Use

The ***Viral DNA and RNA Extraction Kit*** is designed to rapidly extract HBV DNA and HCV RNA from serum and plasma samples. The extracted HBV DNA and HCV 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 professionals, such as biotechnologists, microbiologists, clinical technicians, and physicians who are trained in molecular and biological techniques.

Product Performance Indicators

The ***Viral DNA and RNA Extraction Kit*** can extract more than 5 IU/mL HBV DNA nucleic acid, and more than 15 IU/mL HCV RNA nucleic acid. Both the intra and inter-batch variations of the kit are less than 5%.

Special Notes

The ***Viral DNA and RNA Extraction Kit*** is worked with TIANLONG® automatic nucleic acid extractors (Libex, GeneRotex 96 and PANA 9600S) 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 mins. An automatic nucleic acid extractor automates the entire purification process and can process 1-96 samples in a single run.

The ***Viral DNA and RNA Extraction Kit*** is used to extract HBV DNA and HCV 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 buffer system to extract, separate 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 widely used in a variety of routine operations, including 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 (Libex, GeneRotex 96 and PANA 9600S). 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 the final adsorption of highly pure nucleic acids with the transfer of magnetic beads and nucleic acids.

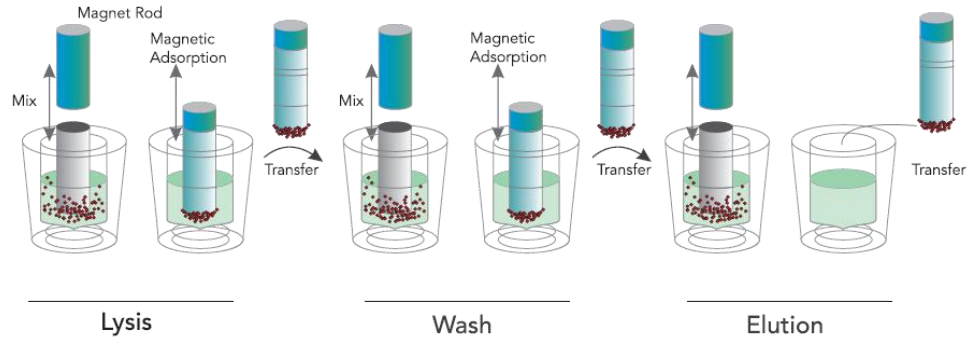

Figure 1. Schematic Diagram of Automatic Nucleic Acid Extractor

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

A magnetic rod protected by the mixing sleeve inserts into a well which contains sample. The mixing sleeve stirs rapidly and repeatedly in the liquid to ensure the complete mixing of the liquid and magnetic beads. After cell lysis, nucleic acid adsorption, washing and elution, the 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

Name of Component \ Short Code		T508H	T507H	T506H	T505H
REAG1	Size	20 T/Box	20 T/Box	48 T/Box	96T /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
	Component Specification	20	4	3	6
	Quantity	1 Test	5 Tests	16 Tests	16 Tests
REAG2	Component	Proteinase K Solution	Proteinase K Solution	Proteinase K Solution	Proteinase K Solution
	Component Specification	0. 6 mL	0.6 mL	1.44 mL	1.44 mL
	Quantity	1	1	1	2
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: 10 µL, 20 µL, 200 µL
- Tip: 10 µL, 20 µL, 200 µL
- Vortex mixer
- Sample holder
- 75% ethanol
- Single kit docking (matched with T508H (6 strip tube), can be purchased from Tianlong)
- Extractor

Warnings and Precautions

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

The ***Viral DNA and RNA Extraction Kit*** is used to extract HBV DNA and HCV 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, and strictly follow the manual throughout the operation. The clinical samples should be collected on a clean bench or in a bio-safety cabin.

Before using TIANLONG® automatic nucleic acid extractors (Libex, GeneRotex 96 and PANA 9600S), 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 the expiry date.

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

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

When using the 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 the buffers are spilled, clean them 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 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, inaccordance with local, regional, national and/or international regulation.
	Magnetic Beads Dilution Buffer 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 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.

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

Operation Guide

1. Automated Extraction Process

Automatic nucleic acid extractors (Libex, GeneRotex 96 and PANA 9600S) enable 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 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 Automatic Nucleic Acid Extractors is as follows:

No.	Well	Name	Waiting (s)	Mixing (s)	Magnet (s)	Speed	Volume (μL)	Heating State	Temp (°C)
1	2	Remove Bead	0	60	10	7	600	Closed	0
2	3	Lysis	0	300	45	7	670	Closed	0
3	1	Lysis	0	300	45	7	670	Lysis	90
4	4	Washing 1	0	180	20	7	670	Elution	90
5	5	Washing 2	0	120	20	7	700	Elution	90

6	6	Elution	60	300	45	7	60	Elution	90
7	2	Release Bead	0	60	0	7	600	Closed	0

2.1.2 Reagent Preparation

96-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 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 REAG1, 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:

a. Extraction of HBV DNA: Add 15 µL 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).

b. Extraction of HCV RNA: Add 15 µL 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).

6 strip tube:

a. Extraction of HBV DNA: Add 15 µL REAG2 and 200 µL sample to column 1/3 of the pre-filled 6 strip tube.

b. Extraction of HCV RNA: Add 15 µL REAG2 and 200 µL sample to column 1/3 of the pre-filled 6 strip tube.

⚠ **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 *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 deep well plate

Place the 96-deep well plate or the single kit docking in the Automatic Nucleic Acid Extractor (Libex), and ensure the marked notch of the plate faces the front. Insert the mixing sleeve into the mixing sleeve holder

and close the cabin door.

Note: As shown in Figure 3 and Figure 4, ensure that the 96-deep well plate or the single kit docking is properly positioned, and the marked notch of the plate faces front.

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.

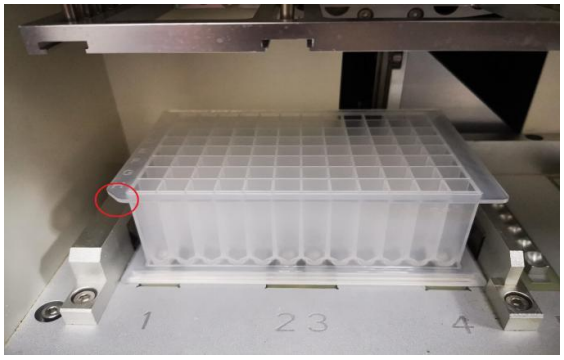

Figure 3. 96-deep well plate

Figure 4. Put the single kit docking into the instrument

2.1.5 Experimental Procedure Run

For special operations please see 2.1.1. After the procedure is completed, the instrument will notify the user the experiment has been completed. Transfer the extracted product from column 6 and column 12 to a clean centrifuge tube that is free of nuclease.

Note: If the user does not analyse the extracted product immediately, 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 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 cabin 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 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	00:10	00:00	1600	600	0
2	Lysis	3	05:00	00:45	00:00	2000	670	0
3	Lysis	1	05:00	00:45	00:00	2000	670	120
4	Washing 1	4	03:00	00:20	00:00	1500	670	90
5	Washing2	5	02:00	00:20	01:00	1500	700	120
6	Elution	6	05:00	00:45	00:00	2500	80	120

2.2.2 Reagent Preparation

96-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 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 REAG1, 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.

2.2.3 Adding Sample to the Reagent

96-deep well plate:

a. Extraction of HBV DNA: Add 15 µL 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).

b. Extraction of HCV RNA: Add 15 µL 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).

6 strip tube:

a. Extraction of HBV DNA: Add 15 µL REAG2 and 200 µL sample to column 1/3 of the pre-filled 6 strip tube.

b. Extraction of HCV RNA: Add 15 µL REAG2 and 200 µL sample to column 1/3 of the pre-filled 6 strip tube.

⚠ **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 *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.

2.2.4 Loading in Deep Well Plate

Properly position the 96-deep well plate or 6 strip tube containing the sample in the experimental cabin of the fully automatic nucleic acid extractor (GeneRotex 96).

Note: The user should ensure the marked notch of the plate of the 96-deep well plate and 6 strip tube is on the left, which is shown in Figure 5 and Figure 6.

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.**

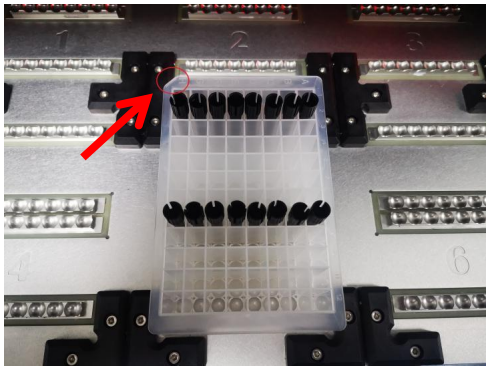

Figure 5. 96-deep well plate

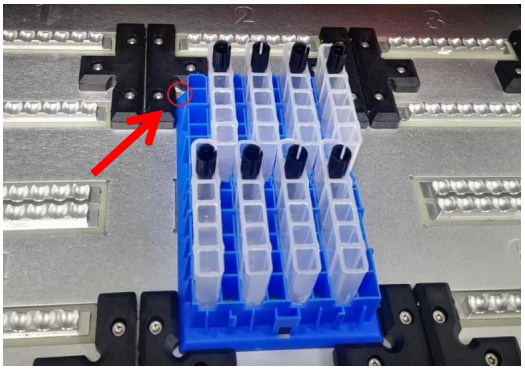

Figure 6. Put the single kit docking into the instrument

2.2.5 Experimental Procedure Run

For special operations please see 2.2.1. After the procedure is completed, the instrument will notice the user the experiment has been completed. Transfer the extracted product from 6 and column 12 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 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 expected results.

2.2.6 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 laboratory and equipment are cleaned regularly to minimize the risk of cross-contamination.

2.3 Automatic Nucleic Acid Workstation (model: PANA 9600S)

2.3.1 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.

2.3.2 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 protocol.

2.3.3 Experiment Complete

Product Transfer

- After the experiment, please add the PCR consumables and transfer the PCR reaction systemestablished 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 thebiological 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/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 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 our 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 serum and plasma samples to rapidly extract HBV DNA and HCV 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 ***Viral DNA and RNA 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 ***Viral DNA and RNA Extraction Kit*** can be applied to clinical diagnostic samples, forensic materials and scientific research samples. The concentration and purity of its extraction product is affected by instruments and operators.

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Safety Symbols and Signs

No.	Symbol	Implication
1	REF	Catalogue number
2	LOT	Batch code
3	Σ <N>	Contain 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 96-deep well plate/6 strip tube
15	REAG2	Proteinase K Solution
16		Warning
17	21 PAP	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.