TIANLONG

Nucleic Acid Extraction Kit

(For HCMV/EB DNA Extraction)

User Guide

Σ 20 T111H

Σ 64 T112H

Σ 20 T123H

Version 6.0

CE IVD

In-Vitro Diagnostics / For use with Automatic nucleic acid extractor compatible with HCMV/EB DNA Extraction Kit

REF T111H T112H T123H

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Intended Use

The ***HCMV/EB DNA Extraction Kit*** is intended for rapidly extracting HCMV/ EB DNA from serum, plasma, urine and whole blood. The extracted HCMV/ EB DNA is of high purity and stability, which 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 ***HCMV/EB DNA 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 that can extract HCMV/EB samples is able to extract at a nucleic acid concentration of ≥ 500 copies/mL. Both the coefficient of variation (CV) of intra-assay and inter-assay for the extraction kit is less than 5%.

Special Notes

The ***HCMV/EB DNA Extraction Kit*** must be used in combination with TIANLONG® automatic nucleic acid extractors (Libex and GeneRotex 96) 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 1-96 samples in a single run.

The ***HCMV/EB DNA Extraction Kit*** is used to extract HCMV/EB DNA. Use exclusive-use utensils, sample injectors and disposable centrifuge tubes and tips processed by autoclave before using. The operator should wear powder-free gloves, 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 serum, plasma, urine and whole blood.

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 variety of routine operations, including downstream experiments, such as enzyme digestion, polymerase chain reaction (PCR), DNA library construction and 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 on the possible consequences.

Testing Principle

The ***HCMV/EB DNA Extraction Kit*** is worked with TIANLONG® automatic nucleic acid extractors (Libex, GeneRotex 96 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 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.

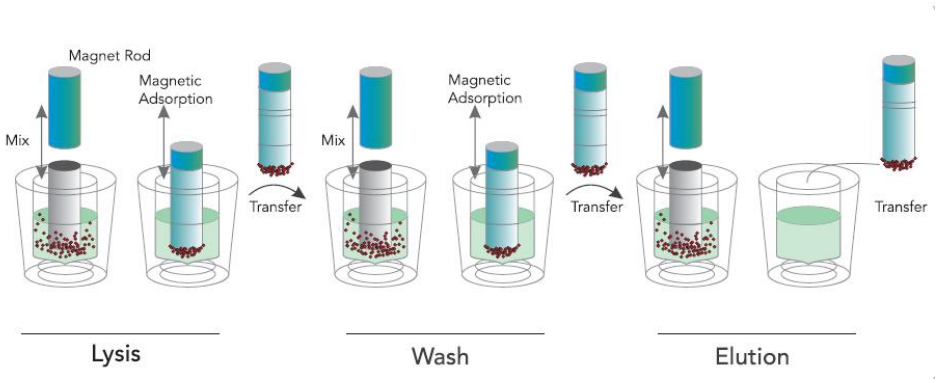

Figure 1. Schematic Diagram of Automatic Nucleic Acid Extractor

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

A magnetic rod protected by the mixing sleeve inserts into a well which contains samples. 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

Name of Component \ Short Code		T111H	T112H	T123H
REAG1	Size	20 T/Box	64 T/Box	20 T/Box
	Component	Pre-filled 96-deep well plate	Pre-filled 96-deep well plate	Pre-filled 6 strip tube
	Quantity	4	4	20
	Component Specification	5 Tests	16 Tests	1 Test
REAG2	Component	Proteinase K Solution	Proteinase K Solution	Proteinase K Solution
	Component Specification	1 mL	1.5 mL	1 mL
	Quantity	1	2	1
Corrugated Paper		1 Piece	1 Piece	1 Piece
White Board		1 Piece	1 Piece	1 Piece
Packaging Box		1	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: 50 µL or 1000 µL
- Tip: 50 µL or 1000 µL
- Vortex mixer
- Sample holder

- 75% ethanol
- Single kit docking (matched with T123H (6 strip tube), could be purchased from Tianlong)
- Extractor

Warnings and Precautions

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

The extraction kit is particularly used for HCMV/ EB DNA from serum, plasma, urine and whole blood. Use exclusive-use utensils, sample injectors and 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. 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 extractors (Libex and 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 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 before the expiry date.

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

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 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 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		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 Washing Buffer B 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 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 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 collection to extract nucleic acid 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 extractors (Libex and GeneRotex 96) enable nucleic acid extraction by magnetic beads. They use magnetic rods to move the beads adsorbed with nucleic acid into different reagent wells and then rapidly and repeatedly stir 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.

The user needs to load/put samples and magnetic bead-based nucleic acid extraction reagents into the reaction consumables, full-automatic nucleic acid extractors then 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 Extractor is as follows:

No.	Column	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	1	Lysis	0	600	45	7	670	Lysis	80
3	3	Lysis	0	600	45	7	670	Closed	0
4	4	Washing1	0	180	20	7	670	Elution	90
5	2	Washing2	0	180	10	7	600	Elution	90
6	5	Washing3	0	120	20	8	800	Elution	90
7	5	Washing3	0	120	20	8	800	Elution	90
8	5	Washing3	0	120	20	8	800	Elution	90
9	6	Elution	60	300	45	7	80	Elution	90
10	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. 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: Add 20 µL of REAG2 and 250 µL of the sample that has been equilibrated to room temperature to the 1st and 3rd columns, 7th and 9th columns of the pre-filled reagent (note the column no. is for effective wells).

6-strip tube: Add 20 µL of REAG2 and 250 µL of the sample that has been equilibrated to room temperature to the 1st and 3rd columns 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 is suitable for the *HCMV/EB DNA Extraction Kit*.

a. Type of sample: serum, plasma, urine and whole blood, etc.

b. Short-term storage: samples can be used immediately after collection for nucleic acid extraction or stored at 2 ~ 8°C for testing with a maximum storage period of 24 hours.

c. Long-term storage: if the user does not operate the sample temporarily, it should be kept sealed in a refrigerator at -20°C.

2.1.4 Loading in Deep Well Plate

Place the 96-deep well plate or 6-strip tube in the Automatic Nucleic Acid Extractor, ensuring that the plate gap faces outwards.

Insert the mixing sleeves into the mixing sleeve holder and close the cabin door.

Note: As shown in Figure 3 and Figure 4, the user should ensure that the 96-deep well plate and the single kit docking is properly positioned with the notch facing outward.

Note: Insert/Place the 96-deep well plate or the single kit docking into the experiment cabin and push the magnetic rod covers into the right position. Check the position of the magnetic rod covers; otherwise, instrument dysfunction or malfunction may occur and affect the experiment results.

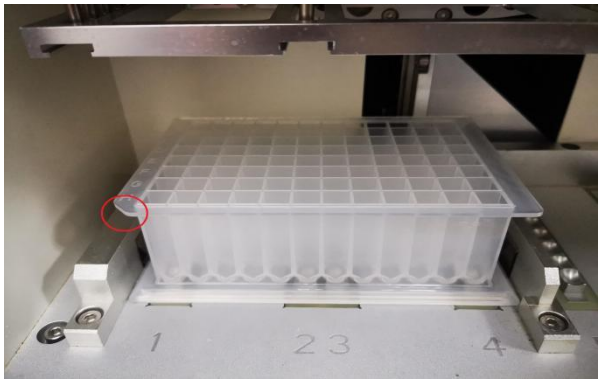

Figure3. 96-deep well plate

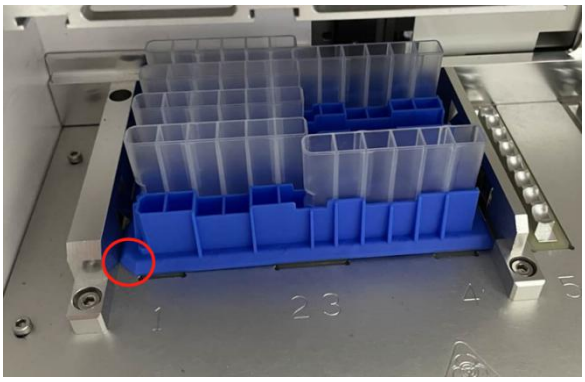

Figure 4. Put the single kit docking into the instrument

2.1.5 Procedure Run

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

Note: If the user does not analyse the extracted product for immediate use, please store and seal it a refrigerator at -20°C.

Caution: Any used deep well plate and mixing sleeves 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 that the expected results will be obtained.

2.1.6 Cleaning and Maintenance of the Instrument

Follow the Cleaning and Maintenance of the 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	Lysis1	1	05:00	00:00	00:00	2000	720	110
2	Lysis2	3	05:00	00:00	00:00	2000	720	0
3	Remove bead	2	00:10	00:10	00:00	1600	600	0
4	Lysis1	1	05:00	00:45	00:00	2000	670	110
5	Lysis2	3	05:00	00:45	00:00	2000	670	0
6	Washing 1	4	03:00	00:20	00:00	1500	670	90
7	Washing 2	5	02:00	00:20	01:00	1500	800	120
8	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. 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 to avoid the 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 the liquid splashing, which is shown in Figure 2.

2.2.3 Adding Sample to the Reagent

96-deep well plate: Add 20 µL of REAG2 and 250 µL of the sample that has been equilibrated to room temperature to the 1st and 3rd columns, 7th and 9th columns of the pre-filled reagent (note the column no. is for effective wells).

6 strip tube: Add 20 µL of REAG2 and 250 µL of the sample that has been equilibrated to room temperature to the 1st and 3rd columns of the pre-filled 6-strip tube.

⚠ **Caution: When pipetting the sample, avoid having substance other 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 *HCMV/EB DNA Extraction Kit*.

a. Type of sample: serum, plasma, urine and whole blood, etc.

b. Short-term storage: samples can be used immediately after collection for nucleic acid extraction or stored at 2 ~ 8°C for testing with a maximum storage period of 24 hours.

c. Long-term storage: if the user does not operate the sample temporarily, it should be kept sealed in a refrigerator at -20°C.

2.2.4 Loading in the Deep Well Plate

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

Note: The user should ensure that the 96-deep well plate should be placed with its notch at the upper left corner, as shown in Figure 5 and Figure 6.

Insert the rotatory mixing sleeves into row 2 and/or row 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.**

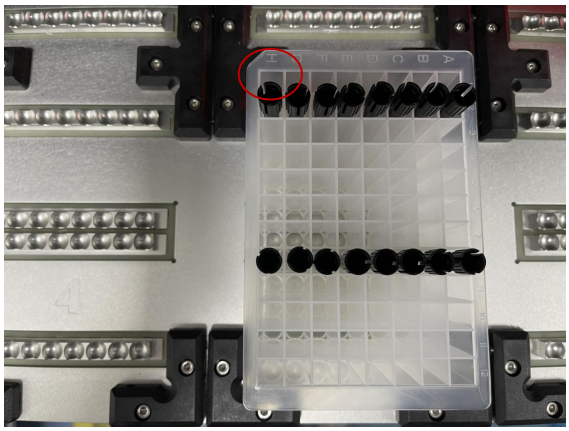

Figure 5. 96-deep well plate

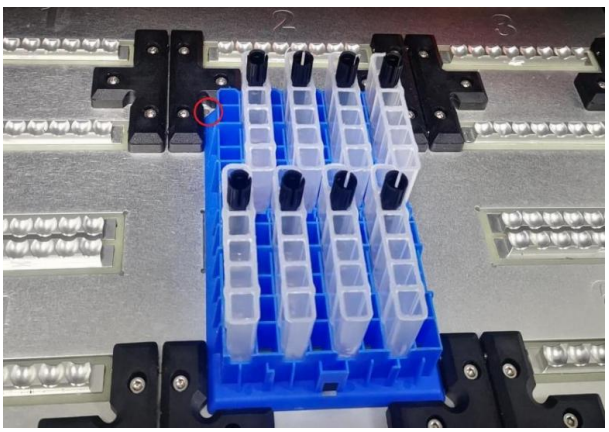

Figure 6. Put the single kit docking into the instrument

2.2.5 Experimental Procedure Run

For special operations please see 2.2.1. After the procedure is completed, the instrument will notify the user that the experiment has been completed. Transfer the extracted product from well 6 and well 12 to a clean centrifuge tube that is free of nuclease.

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

2.2.6 Cleaning and Maintenance of the Instrument

Follow the Cleaning and Maintenance of 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, 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 that you may have about the information and protocols contained in the manual, as well as sample and assay technologies (the 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.	Re-extraction of nucleic acid is performed.
5	Abnormal noise from the instrument during extraction	The 96-deep well plate may be placed correctly.	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	Contact the after-sales service of Tianlong.

		may be abnormal.	
		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 ***HCMV/EB DNA 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, plasma, urine and whole blood to extract HCMV/EB DNA.

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 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	CONT	Content of the kit
14	REAG1	Pre-filled 96-deep well plate/6 strip tube
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.