



# Nucleic Acid Extraction Kit

## (For HCMV/EB DNA Extraction-GeneFlex)

### User Guide

Version 2.0



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

**REF** T524H T525H T526H T527H



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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.....	3
Precautions for Safe Handling.....	4
Reagent Storage and Handling.....	4
Sample Handling and Storage.....	4
Operation Guide.....	4
1. Automated Extraction Process.....	4
2. Operation Steps of Automated Extraction.....	5
2.1 Automatic Nucleic Acid Extractor (model: GeneFlex).....	5
Troubleshooting Guide.....	7
Quality Control.....	7
Limitations of Test Methods.....	8
Safety Symbols and Signs.....	8
Contact Information.....	9

Kit Version	2.0		
Changes	Address of Manufacturer Address of EU Representative Chapter “Content of the kit” Chapter “Warnings and Precautions” Chapter “Automatic Nucleic Acid Extractor (model: Libex)” Chapter “Automatic Nucleic Acid Extractor (model: GeneRotex 96)” Chapter “Safety Symbols and Signs” Chapter “Contact Information”	Additions	Chapter “Precautions for Safe Handling”

## Intended Use

The **HCMV/EB DNA Extraction Kit (GeneFlex)** is intended for rapidly extracting HCMV/ EB DNA from serum, plasma, urine, whole blood and swab samples. The extracted HCMV/ EB DNA 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 **HCMV/EB DNA Extraction Kit (GeneFlex)** 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  $\geq 500$  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 (GeneFlex)** must be used in combination with the TIANLONG® automatic nucleic acid extractor (GeneFlex) 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 minutes. An automatic nucleic acid extractor automates the entire purification process and can process 1-96n samples in a single run.

The **HCMV/EB DNA Extraction Kit (GeneFlex)** is used to extract HCMV/EB DNA. Use exclusive-use utensils and sample injectors and use disposable centrifuge tubes and tips preprocessed by autoclaving before use. 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, whole blood 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 a 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 to the possible consequences.

## Testing Principle

The **HCMV/EB DNA Extraction Kit (GeneFlex)** is worked with the TIANLONG® automatic nucleic acid extractor (GeneFlex). 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.

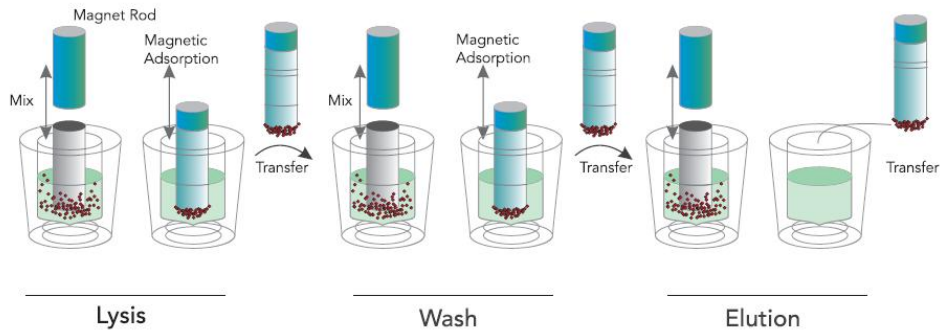


Figure 1. Schematic Diagram of Automatic Nucleic Acid Extractor

**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 the 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 purified nucleic acid is obtained.

GeneFlex 16 is equipped with an array of 16n magnetic rods, allowing it to process up to 16n samples simultaneously.

### Content of the Kit

Short Code		T524H	T525H	T526H	T527H
		Name of Component			
REAG1	Size	64 T/Box	32 T/Box	20 T/Box	20 T/Box
	Component	Pre-filled 96-deep well plate	Pre-filled 96-deep well plate	Pre-filled 96-deep well plate	Pre-filled 6 strip tube
	Quantity	4	4	4	20
	Component Specification	16 Tests	8 Tests	5 Tests	1 Test
REAG2	Component	Proteinase K Solution	Proteinase K Solution	Proteinase K Solution	Proteinase K Solution
	Component Specification	1.28 mL	1.28 mL	0.8 mL	0.8 mL
	Quantity	2	1	1	1
Corrugated Paper		1 Piece	1 Piece	1 Piece	1 Piece
White Board		1 Piece	1 Piece	1 Piece	1 Piece
Packaging Box		1	1	1	1
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, disposable powder-free gloves and protective goggles. For more information, please consult the Safety Data Sheets (SDSs) 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 T527H (6 strip tube), could be purchased from Tianlong)
- Extractor

## Warnings and Precautions

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

The extraction kit is particularly used for HCMV/ EB DNA from serum, plasma, urine, whole blood and swab samples. Use exclusive-use utensils and sample injectors and use disposable centrifuge tubes and tips processed by autoclaving before use. 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 the TIANLONG® automatic nucleic acid extractor (GeneFlex), 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.

Unless otherwise indicated, avoid mixing reagents from different batches and use the kit within the kit's shelf-life (expiry date).

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


The **HCMV/EB DNA Extraction Kit (GeneFlex)** is intended for *in vitro* diagnosis 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 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 solution 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		Acute toxicity (oral), Category 4 H302	<b>Hazard statements (CLP)</b> H302 - Harmful if swallowed. H315 - Causes skin irritation. H319 - Causes serious eye irritation <b>Precautionary statements (CLP)</b> 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).
	Washing Buffer A		Skin corrosion/irritation, Category 2 H315 Serious eye damage/eye irritation, Category 2	

				<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 Dilution Buffer Washing Buffer B Elution Buffer</p>	None	None	None
<b>REAG 2</b>	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 reagent and kit 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 detail information on sample pretreatment, please refer to 2.1.3.

## Operation Guide

### 1. Automated Extraction Process

Automatic nucleic acid extractor (GeneFlex) enables nucleic acid extraction by magnetic beads. It uses magnetic rods to move the beads adsorbed with nucleic acid into different reagent wells, and then rapidly and repeatedly stirs 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. They are compatible with special reaction consumables and can process up to 16n samples concurrently.

The user needs to load/put samples and magnetic bead-based nucleic acid extraction reagents into the reaction consumables, automatic nucleic acid extractors then perform all nucleic acid extraction operations according to the experimental procedures.

## 2. Operation Steps of Automated Extraction

### 2.1 Automatic Nucleic Acid Extractor (model: GeneFlex)

#### 2.1.1 Edit Experiment Program

The extraction procedure of GeneFlex Automatic Nucleic Acid Extractor is as follows:

Step	Name	Well	Stir (min: s)	Magnetic (min: s)	Wait (min: s)	Speed (rpm)	Volume ( $\mu$ L)	T Control ( $^{\circ}$ C)
1	Lysis	2	05:00	00:00	00:00	2000	1500	60
2	Remove bead	1	00:10	00:10	00:00	2000	600	0
3	Combine	2	05:00	00:45	00:00	2000	1500	60
4	Washing 1	3	01:00	00:00	00:00	1500	1100	95
5	Washing 1	3	01:00	00:00	00:00	1500	1100	95
6	Washing 1	3	01:00	00:20	00:00	2000	1100	95
7	Washing 2	4	01:00	00:00	00:00	1500	1500	95
8	Washing 2	4	01:00	00:20	02:00	2000	1500	95
9	Elution	5	05:00	00:45	00:00	2500	70	95

#### 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 plate vibration and liquid splashing.

6 strip tube: Open the kit and take out the REAG1, slowly invert it several times to resuspend the magnetic beads, then 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, as shown in Figure 2.

Please give priority to select the single base from Tianlong. Before extraction, the electronic label in the reagent needs to be attached to the left side of the base; each box is equipped with one electronic label, which can be used for 20 times. Before using the 20T reagent, do not tear it off or discard the label. After using a single 20T reagent, a new electronic label needs to be replaced. The electronic label pasting method is shown in Figure 3.



Figure 2. Put the 6 strip tube on the single kit docking

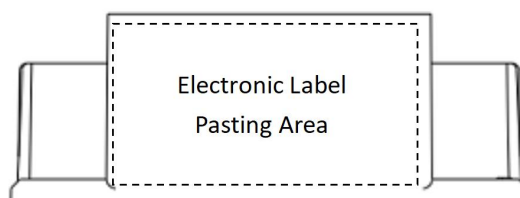


Figure 3. The electronic label pasting method

#### 2.1.3 Adding Sample to the Reagent

96-deep well plate: Add 40  $\mu$ L REAG2 and 500  $\mu$ L of the sample that has been equilibrated to room temperature to the 2<sup>nd</sup> and 8<sup>th</sup> columns of the pre-filled reagent (note the column no. is for effective wells).

6 strip tube: Add 40  $\mu$ L REAG2 and 500  $\mu$ L of the sample that has been equilibrated to room temperature to the 2<sup>nd</sup> column 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 (GeneFlex)*.

a. Type of sample: As stated in the intended use.

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 outward.

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

**ⓘ Note:** As shown in Figure 4 and Figure 5, the user should ensure that the 96-deep well plate and the single kit docking is properly positioned with the notch facing outward.

**ⓘ Note:** 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.

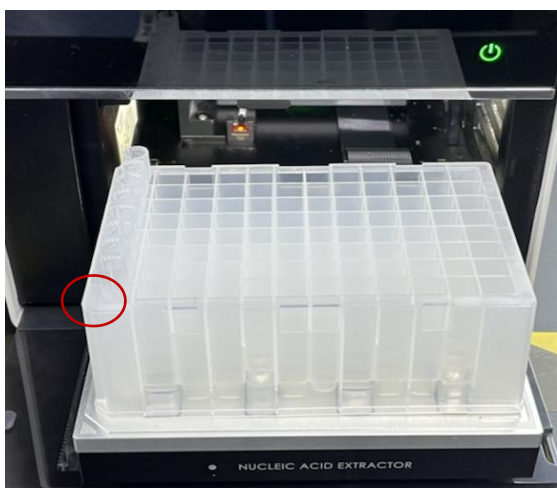


Figure 4. 96-deep well plate



Figure 5. Put the single kit docking into the instrument

### 2.1.5 Procedure Run

After the procedure is completed, the instrument will notice the user the experiment has been completed. Transfer the extracted product from column 5 and column 11 to a clean centrifuge tube which is free of nuclease.

**ⓘ Note:** If the user does not analyze the extracted product for the immediate use, please store and seal it in 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.



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	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.	Perform re-extraction of nucleic acid.
5	Abnormal noise from the instrument during extraction	The 96-deep well plate may be placed incorrectly.	Conduct reposition of the deep well plate.
		The mixing sleeves may be inserted in wrong place.	Reinsert the mixing sleeves.
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.

\* 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 the **HCMV/EB DNA Extraction Kit (GeneFlex)** is tested against predetermined specifications to ensure consistent product quality.















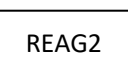

The system performance has been established through performance evaluation studies using serum, plasma, urine, whole blood and swab samples to extract HCMV/EB DNA.


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 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 may influence 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/6 strip tube
15		Proteinase K Solution
16		Warning

17		PAP21: Not-corrugated cardboard
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**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](mailto: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](http://www.medtl.net) or can be requested from Tianlong Technical Services or the local distributor.

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