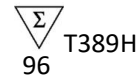




# Whole Blood Genomic DNA Extraction Kit

## User Guide



Version 3.0



In-Vitro Diagnostics / For use with Automatic nucleic acid extractor compatible with  
Whole Blood Genomic DNA Extraction Kit



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Version	3.0		
Changes	Logo Address of Manufacturer Address of EU Representative Chapter "Contents of Kit" Chapter "Warnings and Precautions" Chapter "Automatic Nucleic Acid Extractor (model: GeneRotex 48)" Chapter "Safety Symbols and Signs" Chapter "Contact Information"	Additions	/

## Intended Use

The **Whole Blood Genomic DNA Extraction Kit** is intended for rapidly extracting high-quality genomic DNA (gDNA) from whole blood sample. The extracted genomic 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 **Whole Blood Genomic 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 can extract total yield of DNA extracted from 1000  $\mu$ L whole blood sample  $\geq 20$   $\mu$ g. Both the Extraction Purity: OD260/OD280  $\geq 1.5$ .

## Special Notes

The **Whole Blood Genomic DNA Extraction Kit** must be used in combination with TIANLONG® automatic nucleic acid extractor (GeneRotex 48) 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 1-48 samples in a single run.

The extraction kit is particularly used for targeted genomic DNA isolation; therefore, all of experiment supplies, such as tubes, and tips, must be processed by autoclave. Operator should wear gloves and masks.

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 whole blood sample.

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 misoperations or non-recommended functions, pay special attention to the possible consequences.

## Testing Principle

The **Whole Blood Genomic DNA Extraction Kit** is worked with TIANLONG® automatic nucleic acid extractor (GeneRotex 48). 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.

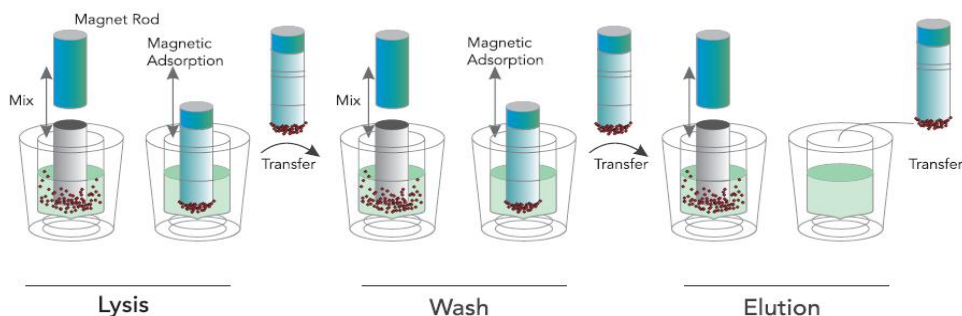


Figure 1. Schematic Diagram of Automatic Nucleic Acid Extractor

**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 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, the highly pure nucleic acid is obtained.

GeneRotex 48 is equipped with an array of 48 magnetic rods, allowing it to process up to 48 samples simultaneously.

### Content of the Kit

Short Code		T389H
Name of Component		
REAG1	Size	96 T/Box (Pre-filled)
	Component	Pre-filled 48-deep well plate
	Quantity	12
	Component Specification	8 Tests
REAG2	Component	Proteinase K Solution
	Component Specification	1.2 mL
	Quantity	4
REAG3	Component	Nucleic Acid Releaser
	Component Specification	1.44 mL
	Quantity	4
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: 100 µL, 1000 µL
- Tip: 100 µL, 1000 µL
- 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 targeted genomic DNA isolation; therefore, all of experiment supplies, such as tubes, and 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.

Before using TIANLONG® automatic nucleic acid extractor (GeneRotex 48), 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 expiry date.

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


The **Whole Blood Genomic DNA 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 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	<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). 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 B Washing Buffer C Elution Buffer	None	None	None
REAG 2	Proteinase K Solution	None	None	None
REAG 3	Nucleic Acid Releasing Reagent		Serious eye damage/eye irritation, Category 2	<p><b>Hazard statements (CLP)</b> H319: Causes serious eye irritation.</p> <p><b>Precautionary statements (CLP)</b> P280 :Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P337+P313: If eye irritation persists: Get medical advice/attention.</p>

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 Whole Blood Genomic DNA 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.

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 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.

### Operation Guide

#### 1. Automated Extraction Process

Automatic nucleic acid extractor (GeneRotex 48) enables nucleic acid extraction by magnetic beads. It uses 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, the highly pure nucleic acids are obtained. Automatic nucleic acid extractor 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 extractor 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 Extractor (model: GeneRotex 48)

#### 2.1.1 Edit Experiment Program

The extraction procedure of GeneRotex 48 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	Remove Bead	2	00:10	00:20	00:00	2500	650	0
2	Lysis	1	20:00	00:45	00:00	2500	3000	100
3	Washing 1	3	03:00	00:30	00:00	3000	1000	0
4	Washing 2	4	02:00	00:30	00:00	3000	1000	0
5	Washing 3	5	02:00	00:30	02:00	3000	1500	100
6	Elution	6	06:00	00:30	00:00	2000	60	100

#### 2.1.2 Reagent Preparation

48-deep well plate:

Open the kit and take out the REAG1, turn them up and down to suspend the magnetic beads. Then remove the package, gently swing the plates to make sure that the magnetic beads are gathered at the bottom of the wells. Please carefully tear down the aluminum foil sealing membrane to avoid liquid splash.

#### 2.1.3 Adding Sample to the Reagent

48-deep well plate: Add 50  $\mu$ L REAG2, 60  $\mu$ L REAG3 and 1000  $\mu$ L of the sample that has been equilibrated to room temperature to row 1 of the pre-filled reagents.

**⚠ 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 contamination adjacent wells.

**ⓘ Note:** The following points should be taken into consideration when determining whether a sample is suitable for the *Whole Blood Genomic DNA Extraction Kit*.

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

b. **Sample Storage:** Immediate extraction or keep at 2~8 $^{\circ}$ C for later use, the storage period should not exceed 24 hours. Long-term storage should be under -20 $^{\circ}$ C.

#### 2.1.4 Loading in Deep well plate

Properly position the 48-deep well plate containing the sample in the experimental cabin of the fully automatic nucleic acid extractor (GeneRotex 48).

**ⓘ Note:** The user should ensure the marked notch of the plate of the 48-deep well plate is on the left, which is shown in Figure 2.

Insert the rotatory mixing sleeve into rank 2 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.

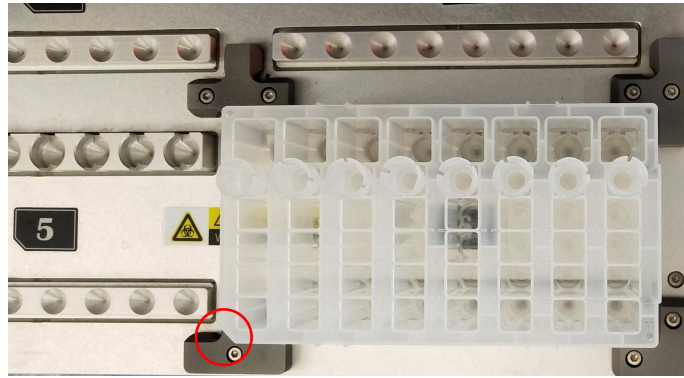


Figure 2. 48-deep well plate

### 2.1.5 Experimental Procedure Run

Program operation see 2.1.1 for specific programs. After the procedure is completed, the instrument will notice the user the experiment has been completed. Transfer the extracted product from row 6 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 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 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.

### 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 48-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.

\* 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 **Whole Blood Genomic 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 whole blood samples to purify genomic 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.

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 extraction kit can be applied to clinical diagnostic samples, forensic materials and scientific research samples. The concentration and purity of its extraction product are affected by instruments and operators.

## 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 48-deep well plate
15		Proteinase K Solution
16		Nucleic Acid Releaser
17		Warning
18		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](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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