TIANLONG

Whole Blood Genomic DNA Extraction Kit (For SMA Detection Use)

User Guide

Σ 64 T372H

Σ 32 T376H

Σ 20 T516H

Version 4.0

CE IVD

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

REF T372H T376H T516H

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Version	4.0		
Changes	Logo Address of Manufacturer Address of EU Representative Chapter “Contents of 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”	Additions	Chapter “Precautions for Safe Handling ”

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 in stability, can be widely 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 200 µL, whole blood sample ≥ 1.5 µg.
Both the Extraction Purity: OD260/OD280 ≥1.5.

Special Notes

The ***Whole Blood Genomic 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 mins. An automatic nucleic acid extractor automates the entire purification process and can process 1-96 samples in a single run.

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, 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 misoperation 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 extractors (Libex and GeneRotex 96). 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.

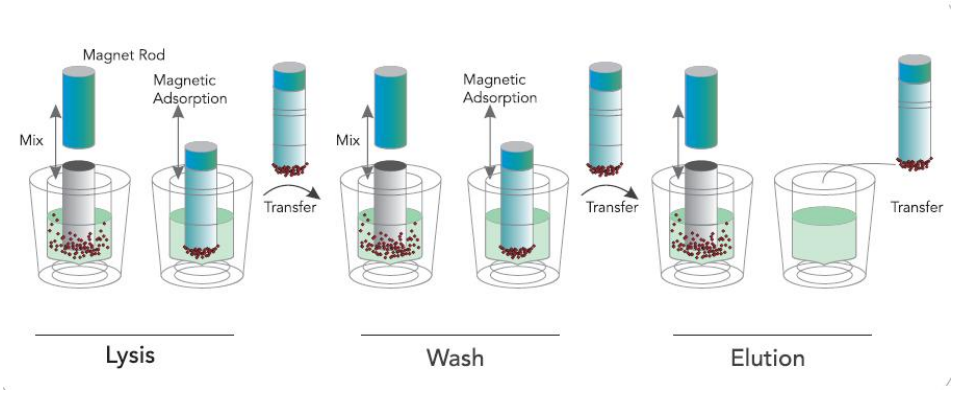

Figure 1. Schematic Diagram of Automatic Nucleic Acid Extractor

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, 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

Short Code / Name of Component		T372H	T376H	T516H
REAG1	Size	64 T/Box (Pre-filled)	32 T/Box (Pre-filled)	20 T/Box (Pre-filled)
	Component	Pre-filled 96-deep well plate	Pre-filled 96-deep well plate	Pre-filled 6 strip tube
	Quantity	4	4	20
	Component Specification	16 Tests	8 Tests	1 Test
REAG2	Component	Proteinase K Solution	Proteinase K Solution	Proteinase K Solution
	Component Specification	0.96 mL	0.48 mL	0.30 mL
	Quantity	1	1	1
	Component	Nucleic Acid Releaser	Nucleic Acid Releaser	Nucleic Acid Releaser
REAG3	Component Specification	1.28 mL	0.96 mL	1.20 mL
	Quantity	3	2	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: 20 µL, 100 µL, 200 µL or 1000 µL
- Tip: 20 µL, 100 µL, 200 µL or 1000 µL
- Vortex Mixer
- Sample Holder
- 75% Ethanol
- Single kit docking (matched with T516H (6 strip tube), could be purchased from Tianlong)
- Extractor

Warnings and Precautions

The ***Whole Blood Genomic DNA Extraction Kit*** is particularly used for whole blood genomic DNA isolation. Therefore, all of experiment supplies such as pipettes, tubes, tips, must be processed by autoclave before using. Operators should wear gloves and masks.

Please read the manual carefully before using the kit, and strictly follow the manual thoroughly during operations. The subjected clinical samples should be collected on a clean bench or in a biosafety 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 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 clean and disinfect the experimental work bench thoroughly.

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). Be aware of following warnings and precautions while using the ***Whole Blood Genomic DNA Extraction Kit***.

Name of Component		Hazard pictograms (CLP)	Classification according to Regulation	Labelling according to Regulation
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, 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
REAG3	Protein Digestive Buffer		Serious eye damage/eye irritation, Category 2 H319 Full text of H- and EUH-statements: see section 16	**Hazard statements (CLP)** H319 - Causes serious eye irritation. **Precautionary statements (CLP)** P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P337+P313 - If eye irritation persists: Get medical advice/attention.

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 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.

To avoid evaporation, the pre-filled reagent should be used immediately after 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

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 nucleic acid extraction 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 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. 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 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 1~96 samples concurrently.

The user needs to load samples and magnetic bead-based nucleic acid extraction reagents into the reaction consumables. The extractors are going to perform all nucleic acid extraction operations according to the experimental procedures.

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.	Well	Name	Waiting (s)	Mixing (s)	Magnet (s)	Speed	Volume (μL)	Heating State	Temp (°C)
1	2	Remove Bead	0	60	90	8	600	Closed	0
2	1	Lysis	0	1200	90	7	750	Lysis	75
3	3	Washing 1	0	180	90	7	600	Closed	0
4	4	Washing 2	0	120	90	7	600	Elution	75
5	5	Washing 3	0	0	30	7	600	Elution	75
6	6	Elution	0	300	300	7	150	Closed	0
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. 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, 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, which is shown in Figure 2.

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

2.1.3 Adding Sample to the Reagent

Add 15 µL REAG2, 60 µL REAG3 and 200 µL of the sample that has been equilibrated to room temperature to column 1 or column 7 of the pre-filled reagent (be aware of the column No. is for effective wells).

⚠ **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 Whole Blood Genomic DNA Extraction Kit.

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 use the sample immediately, 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 in the Automatic Nucleic Acid Extractor, ensuring that the marked notch of the plate faces front.

Insert the mixing sleeve into the chamber mixing sleeve holder and close the chamber safety 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 and the marked notch of the plate faces front.

Note: Place the 96-deep well plate 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.

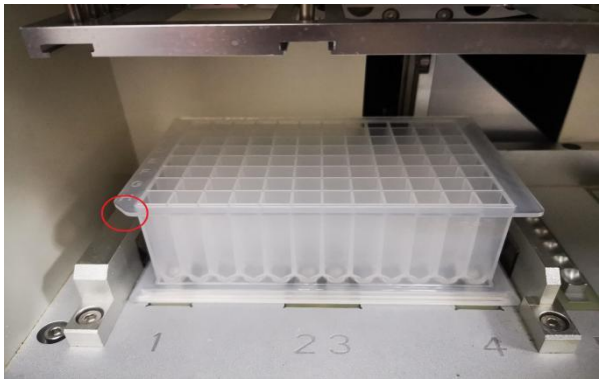

Figure 3. 96-deep well plate

Figure 4. Put the single kit docking into the instrument

2.1.5 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 completed. Transfer the extracted product from column 6 and column 12 to a clean centrifuge tube free of nuclease.

Note: If the user does not analyse the extracted product for the immediate use, 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 that the expected results will be obtained.

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	01:00	01:30	00:00	1500	630	0
2	Lysis	1	20:00	02:00	00:00	2500	750	80
3	Washing 1	3	03:00	01:30	00:00	2500	600	0
4	Washing 2	4	02:00	01:30	00:00	2500	600	80
5	Washing 3	5	00:00	00:30	00:00	100	600	80
6	Elution	6	07:00	02:00	00:00	1200	150	0

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

Add 15 μL REAG2, 60 μL REAG3 and 200 μL of the sample that has been equilibrated to room temperature to column 1 or column 7 of the pre-filled reagent (Note the column No. is for effective wells).

(Note: When pipetting the sample, avoid having more substance than liquid adhere to the tip of the sample injector; do not add the sample too quickly to avoid contaminating the upper part of the well wall; and avoid splashing air bubbles to avoid contamination of adjacent wells.)

2.2.4 Loading in the deep well plate

Properly position the 96-deep well plate containing the sample in the experimental chamber of the fully 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 sleeve into column 2 or column 8 of the deep well plate and close the experimental chamber cabin door.

Caution: The user must ensure that the rotatory mixing sleeve is placed properly. Otherwise, the instrument may operate abnormally, or the magnetic rods may become contaminated.

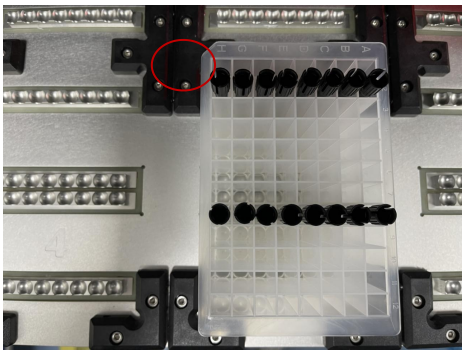

Figure 5. 96-deep well plate

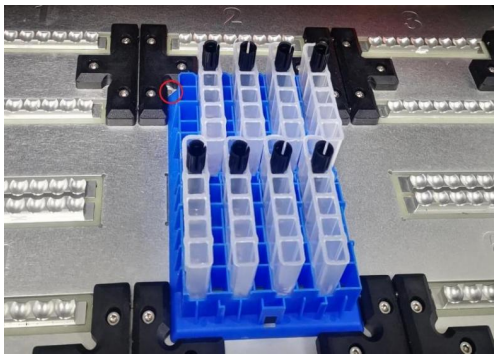

Figure 6. Put the single kit docking into the instrument

2.2.5 Experimental Procedure Run

Program operations see 2.2.1 for specific programs. After an experiment starts running, the instrument will notice user when the experiment is complete. Transfer the eluate from column 6 and column 12 to a clean centrifuge tube free of nuclease.

Note: If the user does not analyse the extracted product immediately, 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 the 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 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 Sales Support service team 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.
		Please ensure the mixing sleeve is inserted in place.	Reinsert the mixing sleeve.
6	Poor extraction performance	Please follow the operation requirements in the manual.	Contact the Sales Support service team of Tianlong.
		The temperature control components of the instrument may be abnormal.	Contact the Sales Support service team of Tianlong.
		Others	Contact the Sales Support service team of Tianlong.

* **Ensure that the reagents have been preserved and used according to the manufacturer's instructions.**

Quality Control

In accordance with Tianlong Company's ISO-certified Quality Management, each lot of ***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 to purify genomic 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 Technology Co., Ltd.

Although the kit is intended for use in public health and scientific research, the purity and quality of extraction results are also affected by the testing instruments and personnel. Moreover, the kit uses a

specially formulated eluent that can affect the absorbance value, so it is not recommended to use a UV rays' spectrophotometer to measure the extraction effect directly.

The extraction kit is intended for use with clinical diagnostic samples, forensic materials, and scientific research samples. The instrument and operator have an effect on the concentration and purity of the extracted product. Any generated diagnostic results must be interpreted in conjunction with the other clinical or laboratory findings.

Safety Symbols and Signs

No.	Symbol	Implication
1	REF	Catalogue number
2	LOT	Batch code
3	Σ <N>	Contains sufficient for <N> tests
4		Use by date
5		Caution
6		Temperature limit
7	IVD	In vitro diagnostic medical device
8		Reminder
9		Manufacturer
10		Do not re-use
11	CE	Conformed with EU standard
12	EC REP	Authorized representative in the European Community
13	CONT	Content of the kit
14	REAG1	Pre-filled 96-deep well plate/6 strip tube
15	REAG2	Proteinase K Solution
16	REAG3	Nucleic Acid Releaser
17		Warning
18	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.