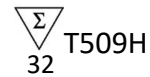




# Whole Blood Genomic DNA Extraction Kit (SMA-GeneFlex)

## User Guide



Version 2.0



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



T509H



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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.....	6
Quality Control.....	7
Limitations of Test Methods.....	7
Safety Symbols and Signs.....	8
Contact Information.....	8

Kit Version	2.0		
Changes	Address of Manufacturer Address of EU Representative Chapter “Intended Use” Chapter “Kit Contents” Chapter “Warnings and Precautions ” Chapter “Materials Required but not Provided ” Chapter “Automatic Nucleic Acid Extractor (model: GeneFlex)” Chapter “Limitations of Test Methods ” Chapter “Safety Symbols and Signs ” Small lexical corrections.	Additions	/

### Intended Use

The **Whole Blood Genomic DNA Extraction Kit (SMA-GeneFlex)** 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 (SMA-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 can extract total yield of DNA extracted from 200µL whole blood sample  $\geq 1.5\mu\text{g}$ . Both the Extraction Purity: OD260/OD280  $\geq 1.5$ .

### Special Notes

The **Whole Blood Genomic DNA Extraction Kit (SMA-GeneFlex)** must be used in combination with 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 mins. An automatic nucleic acid extractor automates the entire purification process and can process 1-16n 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, 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 (SMA-GeneFlex)** is worked with 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.

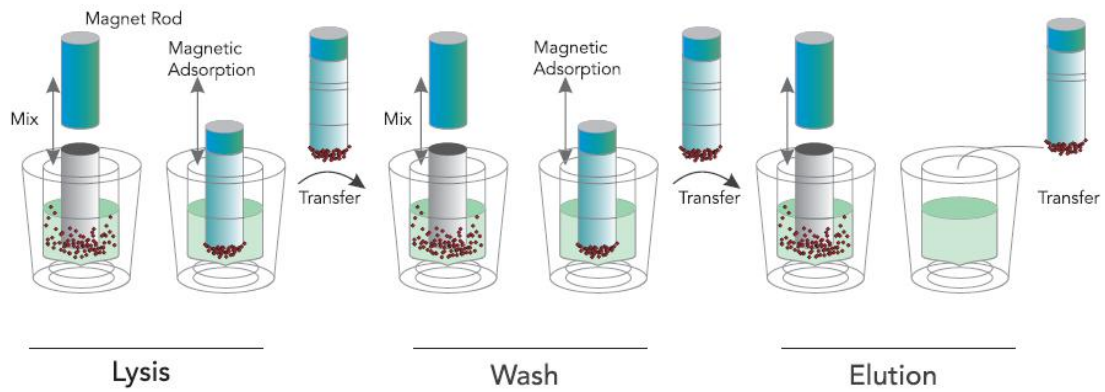


Figure 1. Schematic Diagram of Automatic Nucleic Acid Extractor

**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 pure 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

Name of Component		Short Code	T509H
REAG1	Size		32 T/Box (Pre-filled)
	Component		Pre-filled 96-deep well plate
	Quantity		4
	Component Specification		8 Tests
REAG2	Component		Proteinase K Solution
	Component Specification		0.48 mL
	Quantity		1
REAG3	Component		Nucleic Acid Releaser
	Component Specification		0.96 mL
	Quantity		2
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: 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
- Extractor

## Warnings and Precautions

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

The **Whole Blood Genomic DNA Extraction Kit (SMA-GeneFlex)** 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. Operator should wear gloves and masks.

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 biosafety cabin.

Before using TIANLONG® automatic nucleic acid extractor (GeneFlex), it 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 (SMA-GeneFlex)** is intended for in vitro diagnostic use.


When using the kit, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate Material Safety Data Sheets (MSDSs). These documents are available online in a convenient and compact PDF format at

<https://www.medtl.net/resources/download/catalogue-all/catalogue>, where the operator can find, view and print the appropriate MSDSs.

 **Caution: Do not add any bleach or acidic solution directly to the pre-filled reagent.**

The pre-filled reagent contains guanidinium salts, which, when combined with bleach can form highly reactive compounds. If any of 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 **Whole Blood Genomic DNA Extraction Kit (SMA-GeneFlex)** comes with the following warnings and precautions.

Name of Component		Hazard pictograms (CLP)	Classification according to Regulation	Labelling according to Regulation
<b>REAG 1</b>	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
<b>REAG 2</b>	Proteinase K Solution	None	None	None
<b>REAG 3</b>	Nucleic Acid Releaser		Serious eye damage/eye irritation, Category 2 H319 Full text of H- and EUH-statements: see section 16	Precautionary statements (CLP) H319 - Causes serious eye irritation. 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 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.

*Detail information for sample pretreatment, please refer to 2.1.3.*

## Operation Guide

### 1. Automated Extraction Process

Automatic nucleic acid extractor 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 extractors are characterized by high automation, rapid extraction speed, stable results, and ease of operation.

The user needs to load samples and magnetic bead-based nucleic acid extraction reagents into the reaction consumables, the 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: GeneFlex)

#### 2.1.1 Edit Experiment Program

The extraction procedure of GeneFlex 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	1	01:00	00:30	00:00	2000	630	0
2	Lysis	2	15:00	01:00	00:00	2500	750	55
3	Washing 1	3	03:00	00:45	00:00	2500	600	0
4	Washing 2	4	02:00	00:45	00:00	2500	600	70
5	Washing 3	6	00:00	00:30	00:00	100	600	70
6	Elution	5	07:00	00:45	00:00	1200	140	0

#### 2.1.2 Reagent preparation


96-deep well plate:

Open the kit and take out the **REAG 1** from the plastic package, 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.

#### 2.1.3 Adding Sample to the Reagent

96-deep well plate:

Add 15  $\mu$ L **REAG 2** solution, 60  $\mu$ L **REAG 3** and 200  $\mu$ L of the sample that has been equilibrated to room temperature to column 2 of the pre-filled reagent.

 **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 (SMA-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  $^{\circ}$ 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  $^{\circ}$ C.

### 2.1.4 Loading in the deep well plate

Properly position the 96-deep well plate containing the sample in the experimental chamber of the fully automated nucleic acid extractor.

**⚠ 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 2.

Insert the rotatory mixing sleeve into column 1 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.

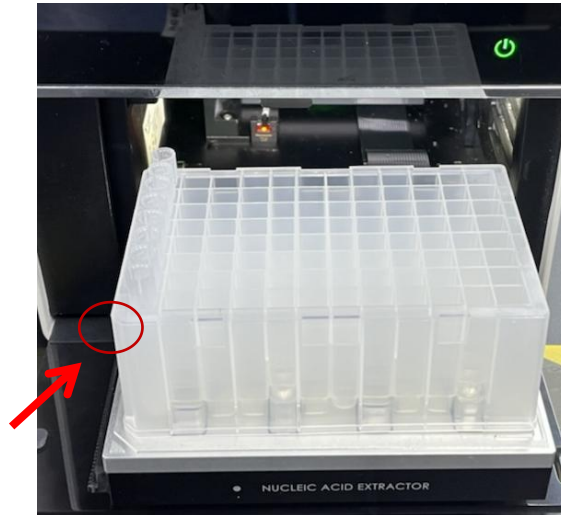


Figure 2. 96-deep well plate

### 2.1.5 Experimental Procedure Run

For special operations please see 2.1.1. After an experiment starts running, the instrument will notice user when the experiment is complete. Transfer the eluate from column 5 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.

**⚠ 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 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 after-sales service of our company.
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 after-sales service of our company.
		The temperature control components of the instrument may be abnormal.	Contact the after-sales service of our company.
		Other	Contact the after-sales service of our company.

\* 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 (SMA-GeneFlex)** 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 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 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		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

### 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](http://www.medtl.net) or can be requested from Tianlong Technical Services or the local distributor.

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