

Gold Immunochromatography Analyzer

User Manual

Ringbio

Ring Biotechnology Co., Ltd.

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Chapter I Introduction

Thank you for selecting GIC-H1W Gold Immunochromatography Analyzer of Ring Biotechnology Co., Ltd. The product is a Gold Immunochromatography strip test system based on photoelectric detection principle which should support the use of reagent based on Gold Immunochromatography principle. Please thoroughly read this User Manual before use so that you can refer to it when necessary.

This User Manual is applicable to GIC-H1W Gold Immunochromatography Analyzer. For details, refer to actual interface operation.

1.1 Instrument Introduction

【Product name】 Gold Immunochromatography Analyzer

【Product model】 GIC-H1W

【overall dimensions】 220mm×100mm×75mm (L×W×H)

【Weight】 0.5kg

【Software version】 V1

【Date of manufacture】 See the label at the bottom

1.2 Scope of Application

With the suitable paper strip based on the principle of colloidal gold immunochromatography, it is used for the detection of colloidal gold in dairy product or other samples.

Chapter II Configuration List and Main Structure

After the product is unpacked, please check whether there are missing or damaged parts according to configuration list.

2.1 Configuration List

No.	Item	Qty.	Unit
1	GIC-H1W host	1	Set
2	USB cable	1	Pcs.
3	Specification	1	Pcs.
4	Warranty Card	1	Pcs.
5	Certificate of Quality	1	Pcs.
6	Packing List	1	Pcs.
7	Scanner gun (optional)	1	Pcs.
8	ID card	1	Pcs.

Table 1 Configuration list



Attention:

Please check Configuration List as per Packing List. In case of missing or damaged parts, please contact our company and local agent timely.

2.2 Main Structure

Note: Appearance of the instrument and accessories should apply to material objects.

- 1) Main structures on the front side of instrument (Fig. 1)



Fig. 1

1) Side view (Fig. 2)

There are ID card slot and USB port on a side of the instrument.



Fig. 2

2) USB cable (Fig. 3)



Fig. 3

2.3 Explanation of Medical Equipment Label



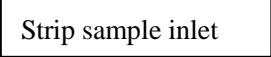




Label	Description
	Biohazard. Wear gloves before contacting tested specimen, calibration product and quality control product
	IVD (in vitro diagnosis) device
	Strip sample inlet
	ID card slot
	RS232 port
	USB port
	Double insulated or reinforced insulated equipment

Table 2 Explanation of medical equipment label

Chapter III Parameter Performance and Service Conditions

3.1 Parameter Performance

- Instrument interface: RS232, USB、wifi、bluetooth
- Display: 24-digit 4.3 inch color LCD
- Power supply parameter: 18650 lithium battery pack DC 7.2V 3300mAh
- Repeatability: $CV \leq 10\%$
- Stability: $\sigma \leq 10\%$ (relative deviation is no greater than $\pm 10\%$)
- Accuracy: $\Delta n \leq 10\%$
- Linearity: $|r| \geq 0.99$
- Measurement range: 100 times

3.2 Transportation and Storage Conditions

After packaging, the product should be stored at the ambient temperature of $-40^{\circ}\text{C} \sim 55^{\circ}\text{C}$, the relative humidity of no greater than 93% and the barometric pressure of $700\text{hPa} \sim 1060\text{hPa}$ and should be free from toxic gases, inflammables, explosives and corrosive gases. Measures should be adopted against moisture, impact and violent vibration during transportation.

3.3 Service Conditions

1 Location and placement requirements

- 1) The instrument should be placed steadily and horizontally and free from heavy dust, direct sunlight and corrosive gas indoors. The working table can bear the weight of above 0.5kg;
- 2) There should be no strong vibration source and strong electromagnetic field around;
- 3) The product should be placed in a well-ventilated place and there should be a space of above 10cm around the instrument so as to ensure a sufficient space for operation and maintenance.

2 Normal working conditions

- 1) Ambient temperature range: 5°C-40°C;
- 2) Relative humidity range: 10%~80%;
- 3) Barometric pressure range: 700hpa~1060hpa.
- 4) Power supply parameter: 18650 lithium battery pack DC 7.2V 3300mAh

3 Electromagnetic compatibility requirements

1) The product conforms to electromagnetic compatibility requirements of IEC61326-1/IEC326-2-6, including emission and noise immunity requirements.

2) User should evaluate the electromagnetic environment before using the product, so as to ensure normal operation.

3) When the product is used in a dry environment, especially in a dry environment containing artificial materials (fabric and carpet, etc.), destructive electrostatic discharge may be caused and wrong conclusions may be drawn.

4) The product cannot be used near strong radiation source (such as unshielded radio source); otherwise normal operation of the instrument may be disturbed.

5) The product may cause radio disturbance in domestic situations, so protective measures should be adopted.

Chapter IV Installation

4.1 Installation Requirements

Please install and use the instrument under normal working conditions.



Attention: (See Chapter III “Normal Working Conditions” for details)

4.2 Installation Method



Attention:

Please check Configuration List as per Packing List. In case of missing or damaged parts, please contact our company and local agent timely.

1 Charging

Connect an end of GIC-H1W USB cable to USB port on the top of the analyzer and the other end to computer USB port to charge it. The electric quantity is displayed on the screen.

2 Power on

Press Power on to turn on the instrument and enter the initial interface.



Fig. 4

3 Power off

Keep pressing Power on to turn off the instrument.

Chapter V Instructions

The product is designed with different operation procedures specific to different customer demands. Generally, the instrument should be set as per the following operation procedure before delivery. See *Test Flow Chart* for details.

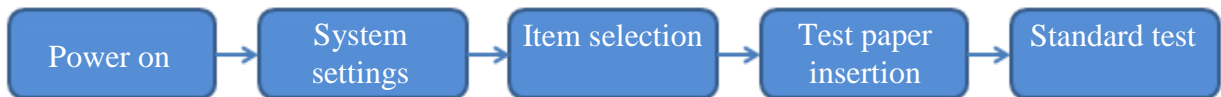


Fig. 5

5.1 Power on

Press the front button to turn on the instrument. The instrument undergoes initialization and self-inspection and the interface is displayed after passing self-inspection.

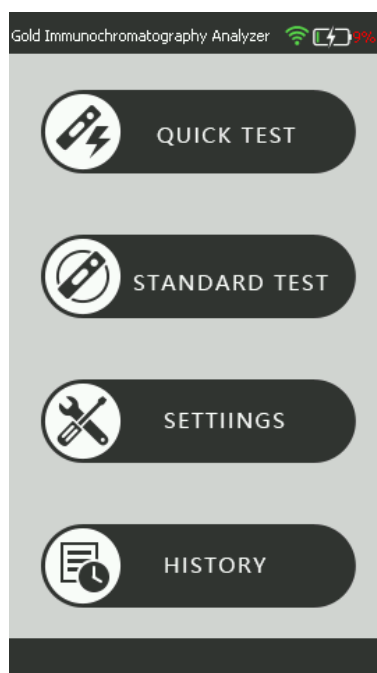


Fig. 6

Set up the system according to actual operation need before use and then conduct quick test, standard test and record operation.

5.2 System Settings

Click on [Settings] to enter the interface and a secondary menu is shown below:

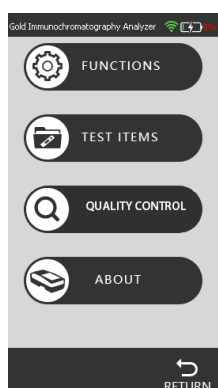



Fig. 7

5.2.1 System Function Settings

Click on [Functions] to enter the following interface. Click on  to set up corresponding items.

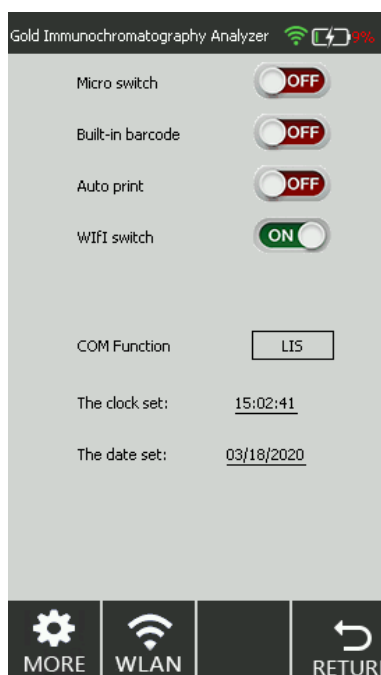


Fig. 8

- 1 Turn on microswitch: On-Detection is started automatically after strip is inserted
Off-Click on the detection button manually to start detection
- 2 Start built-in bar code: On-Scan bar code on the strip and start detection
Off-Not scan bar code on the strip but start detection directly
- 3 Print the result automatically: On-Print the result automatically after inspection
Off-Not print the result automatically
- 4 WIFI switch: On-Turn on WIFI switch
Off-Turn off WIFI switch

[MORE] Enter the password for settings by professionals only.



Attention:

Advanced settings are used for manufacturer's debugging and test only and cannot be modified by unauthorized user.

WLAN :

Click on [WLAN] to enter the following interface,GIC-H1Wcan connect to wifi and connect to network servers.

Click  turn on or turn off WIFI,Click  Automatically searches nearby wlangs and updates the list. Select nearby WLAN, enter the password, you can reconnect WLAN, connected to the WLAN after the instrument automatically connected to the server.



5.2.2 Test Item

Click on [Test Item] to enter the following interface. Click on item number to select test information.

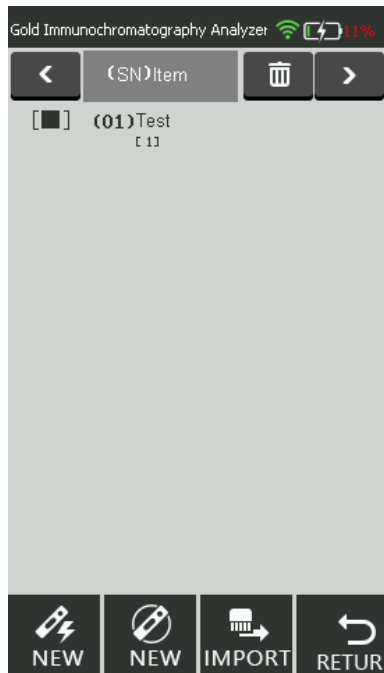




Fig. 9

Click on  and  to enter the previous page and the next page.

Select a test item and click on  or  to switch to the test interface.

Select a test item and click on  to delete corresponding standard curve.

ID card is imported as below:

Step 1 Insert ID Card into ID Card slot in the front part of the instrument.

Step 2 Click on  in System Settings-> Test Item Management interface to import test information



Attention:

Each item number and each batch number have the unique test data. Reset it and original settings will be covered.

5.2.3 Quality CONTROL

Turn on the instrument and insert ID Card into ID Card slot and standard quality control card into the strip slot.

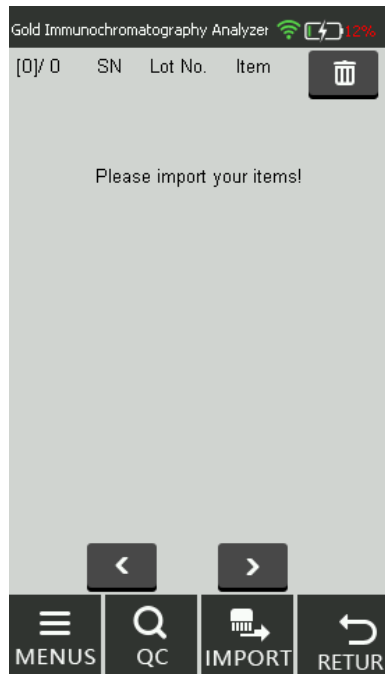



Fig. 10

Select an item and click on , the interface gives a prompt message

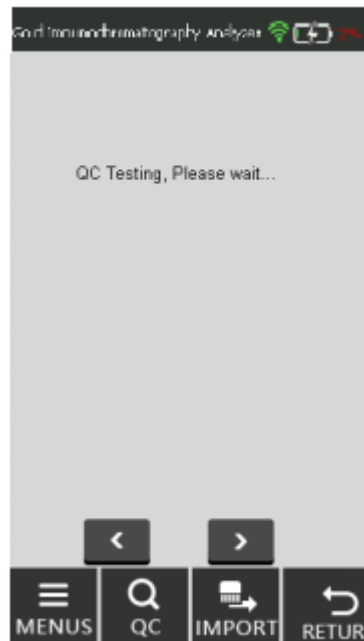


Fig. 11

After quality inspection, the instrument works normally and the interface gives a prompt message

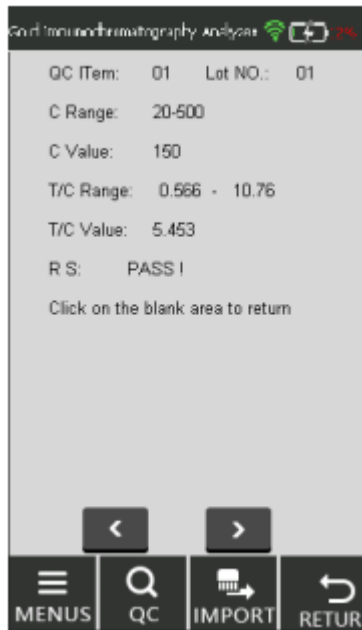


Fig. 12

Click on the blank area in the screen to return to the quality control interface.
If quality inspection fails, the test result is invalid. Return the product for repair.

5.2.4 Instrument Information

Click on [ABOUT] to enter the following interface. Mode and version of handheld Gold Immunochromatography Analyzer will be displayed.



Fig. 13

1 Factory reset



Click on **FACTORY RESET** to clear all data and recover factory settings.

The instrument will be restarted automatically after factory reset.

2 Parameter calibration



Click on **CALIBRATION** to enter the following interface

This function is intended for debugging by professionals only and the correct password should be entered.



Attention:

Factory reset will cause history loss, so please ensure data has been exported and backed up before operation.

5.3 Quick Test

Step 1 Press the power switch on the front side to turn on the instrument

Step 2 Click on [Quick Test] to switch to the following interface

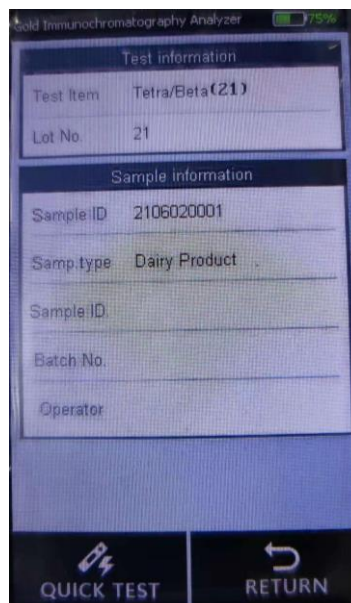


Fig. 14



Step 3 Click on

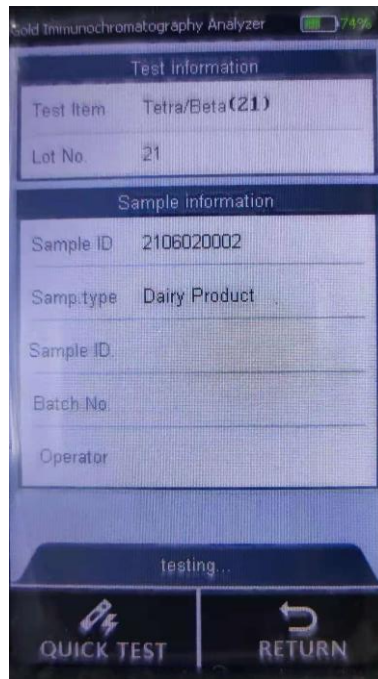


Fig. 15


Step 4 The result will be displayed after test





Fig. 16

Step 6 Operation of test result

1 Click on  to start a new test.

2 Click on  to upload test result to cloud server.

3 Click on  to print test result using miniprinter.

4 Click on  to return to the main menu interface.

5.4 Standard Test

Step 1 Press the power switch on the front side to turn on the instrument

Step 2 Click on [Standard Test] to switch to the following interface

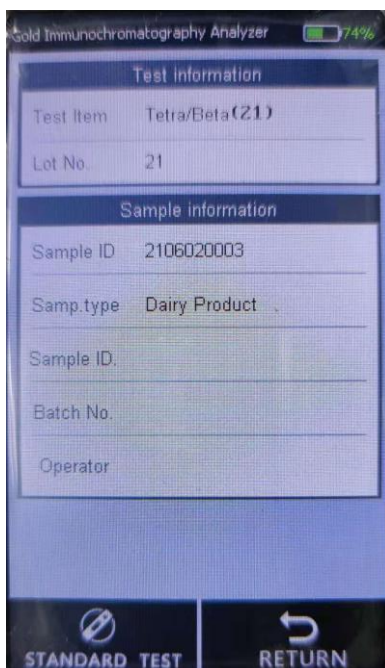


Fig. 17

Step 3 Click on Standard Test



Fig. 18


Step 4 The result will be displayed after test





Fig. 19

Step 5 Operation of test result

1 Click on  to start a new test.

2 Click on  to upload test result to Lis system.

3 Click on  to print test result using miniprinter.

4 Click on  to return to the main menu interface.

5.5 History

Click on [History] in the main menu to switch to the following interface, which displays History Review and Management.



Fig. 20

5.5.1 Record Review

Click on [History Review] to switch to the following interface, in which all inspection records can be viewed.

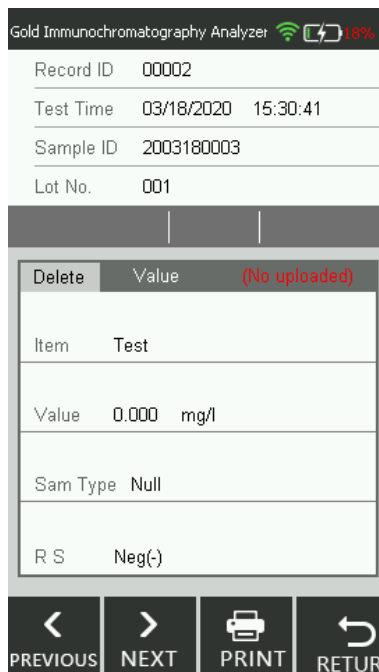


Fig. 21

The record interface displays test information:

- 1) Record ID: Test serial No., record ID increases by 1 after each test;
- 2) Test time: System time during each test
- 3) Sample ID: Sample serial No.
- 4) Lot No.: Strip batch No.



Click on **PREVIOUS** or **NEXT** to view test record;



Click on **PRINT** to print current test result using miniprinter;



Click on **RETURN** to return to the parent directory.

5.5.2 Management

Click on [Management] to switch to the following interface, in which records can be transmitted and cleared.

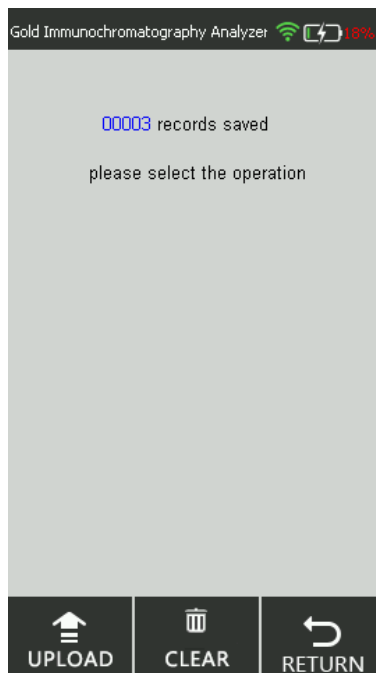


Fig. 22

Count the number of test records in the interface.

1 Upload



Click on **UPLOAD** to upload all records to Lis system.

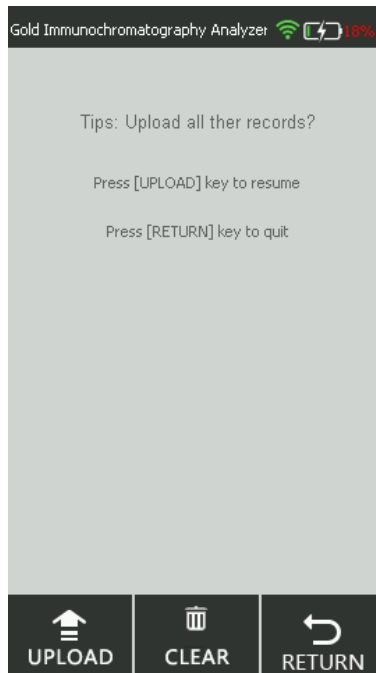


Fig. 23

Click on [Return] to cancel data upload and return to the record interface according to prompts.

2 Clear

Click on [Clear] to clear all inspection records.

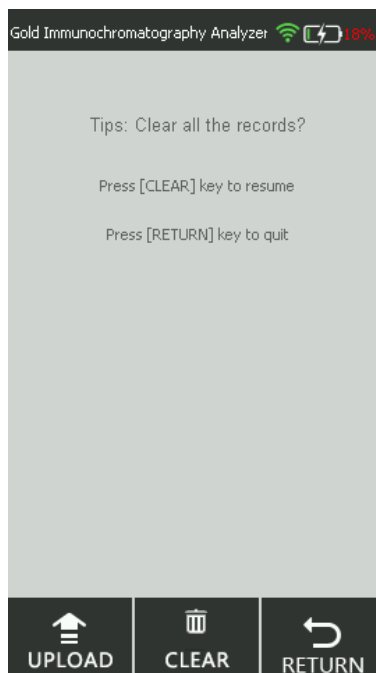


Fig. 24

Click on [Clear] to clear all test records according to prompts.

Click on [Return] to cancel clear operation according to prompts.

Chapter VI Quality Control

Upon first power on or each power on, test quality control product from reagent to control the quality. For quality control method, please refer to Chapter V 【System Settings】 - 【Quality Inspection】 .



Attention:

The instrument can be tested after passing quality inspection. If quality control conditions are dissatisfied or quality control fails, the use of the instrument is prohibited! Contact after-sales service engineer timely and return the instrument for calibration or repair. If the instrument is tested upon failed quality inspection and consequently an improper diagnosis is caused, the Company assumes no liability.

Chapter VII Repair and Maintenance

7.1 Repair

- 1) Managerial personnel must inspect the instrument and parts regularly.
- 2) Inspect whether power line is deformed or broken visually. If any, a fire may be caused by electric leakage. Please contact service engineer about replacement of power line immediately.

7.2 Maintenance

- 1) The product just requires external cleaning and dust removal instead of special maintenance in daily use
- 2) Before cleaning and dust removal, turn off the power switch and disconnect USB cable.
- 3) While cleaning the product, clean the external surface using wet cloth and 70% ethyl alcohol instead of strong decolorizer ($\geq 0.5\%$ solution), because oxidizer and solvent may damage casing and touch screen of the instrument. Do not clean any internal part or internal surface.



Attention:

Before cleaning the instrument, turn off the power switch and disconnect USB cable so as to avoid short circuit and electric shock!

7.3 Common Fault and Elimination Method

Fault Phenomenon	Possible Cause	Elimination Method
The instrument cannot be powered on	Dead battery	Charge the battery
	Battery failure	Contact after-sales engineer
The screen fails to display	The screen connecting line is loose	Contact after-sales engineer
Test result is invalid	Transmission part of the reagent card is invalid	Contact after-sales engineer
	The reagent card is invalid	Contact after-sales engineer
	Test part of the instrument is invalid	Contact after-sales engineer
The motor makes abnormal sound	Mechanical movement failure	Contact after-sales engineer

and gets stuck during test		
Other faults	Other faults	Please contact after-sales engineer timely

Chapter VIII Precautions

1) User;

- a. Professionals of medical institutions
- b. People trained by manufacturer



Attention

Other people than the above mentioned are not allowed to operate the instrument; otherwise the Company assumes no liability for faults thus incurred.

2) Limits of toxic and harmful substances;

The content of toxic and harmful substances in all homogeneous materials of the parts should be below the specified limits of SJ/T 11363-2006 *Requirements for concentration limits for certain hazardous substances in electronic information products*.

3) Potential safety maintenance and use restrictions;

Potential biohazards which exist when the sample is tested using the product should be disposed of according to safety requirements for test species of hospitals when the sample is disposed of and operated. Please do not put hand or any article into a moving part during test.

4) If an accident occurs when the product is used correctly, adopt protective measures for operator and user and appropriate emergency and corrective measures;

The probability that an accident occurs when the product is used correctly is very low. If an accident occurs, please cut off the power immediately.

5) Necessary monitoring, evaluation and control methods;

Please inspect the quality of the instrument using quality control card every month so as to evaluate whether the instrument works normally. User may reduce the quality control cycle according to actual service condition.

6) Potential mutual interference with other products and potential hazards;



Attention

1. Whereas the product may be affected by electromagnetic interference during operation and consequently the test result may be invalid, please keep the product far away from strong electromagnetic interference in use.

2. Whereas the product may emit electromagnetic wave during operation, please keep the product

far away from electromagnetic sensitive equipment in use.

7) Potential adverse events

The product is an in vitro diagnostic device and adverse events have not been observed yet. Whereas the tested specimen may be biologically infective, please avoid direct skin contact with the reagent card and the sample inlet.

The instrument should be cleaned and disinfected in use or before transportation, maintenance and storage, so as to prevent pollution and potential biohazard.

8) Other notices

a. Diagnosis and treatment cannot be based on the test result only, please consider clinical history and other test results simultaneously.

b. Be sure to use the kit provided by the manufacturer and attached to the instrument and confirm the applicability before use.

c. Be sure to import the standard curve using ID Card attached to the reagent and conduct a test.

d. Normal use of the instrument will be automatically saved in the instrument in the form of at most 10000 records. Data will not be lost in case of power failure and can be cleared by “Factory Reset”.

Chapter IX Service, Maintenance and Destruction

The product just requires cleaning instead of special maintenance. When necessary, please consult 0512-66806823 for service or maintenance.

Key parts of the product such as circuit board, optical detection model and display screen must be detected and replaced by our company and cannot be maintained by third parties.

If the product breaks down and consequently works abnormally, please consult 0512-66806823. We will provide technical support and guide customers to eliminate faults. If recall is needed, please post the product back. If obsolescence is needed during the warranty period, we will provide a new product.

If destruction is needed for some reason, user may destruct the product according to regulation on class B electronic instrument.

Hereby we declare that the aforesaid service guarantees are available only for full compliance with the User Manual. The Company assumes no liability for other damages.