Dry Fluorescence Immunoassay Analyzer

Instruction Manual

Dezhou Guoke Medical Technology Co.,Ltd.

Catalog

Product instruction

Thank you for choosing Dry Fluorescence Immunoassay Analyzer (Hereinafter referred to as the instrument) of Dezhou Guoke Medical Technology Co.,Ltd.. This instrument is an immunofluorescence automatic detection system based on the principle of photoelectric detection, which needs to be used with special fluorescent immunoreagents. It is widely used in many fields such as disease detection, medical care, epidemic monitoring, food inspection and quarantine. To reduce the risk of fire, electric shock and personal injury, please read and understand all instructions, follow the warnings and instructions indicated on the instrument itself, and always follow basic safety precautions. The protection provided by the equipment may be impaired if the equipment is used in a manner not specified by the manufacturer. In all cases marked with a warning sign, the instruction manual should be consulted to clarify the nature of the potential hazard and any countermeasures that must be taken.

This instruction manual is applicable to the model GKYG-500, and the actual interface operation shall prevail.

Date of preparation/revision of the manual: Dec., 2024

Manual version number: V1.3

EC Declaration of Conformity

This medical device has been assigned to class A according to Annex II + Annex III + Article 17 of IVDR (EU) 2017/746. It bears the mark

CE

Whose single Authorized EU-Representative

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Intellectual property rights

The intellectual property rights of this instruction manual and its corresponding products belong to Dezhou Guoke Medical Technology Co.,Ltd.

If the contents of this manual or the design of product are changed, the user will not be notified separately.

Statement

Dezhou Guoke Medical Technology Co.,Ltd. has the final right to interpret this instruction manual.

The company believes that it is responsible for the safety, reliability and performance of the product only when all the following requirements are met, namely:

- Assembly operation, expansion, readjustment, improvement, maintenance and replacement of parts are all carried out by professionals recognized by the company;
- All repairs involve the replacement of parts and the accessories and consumables used for them are the original equipment (original) of the company or approved by the company;
- The relevant electrical equipment conforms to the national standards and the requirements of this instruction manual;
- The operation of the product is carried out in accordance with this instruction manual.

Use objects

The audience of this instruction manual is the following:

Personnel who carry out the daily operation of the system;

Personnel who perform system maintenance and troubleshooting;

Personnel who learn system operation.

Before using the product, please read the contents of this instruction manual carefully and use the product correctly. Please keep this instruction manual in a safe place for reference at any time. Warranty is voided if the precautions described in this instruction manual are not followed during use.

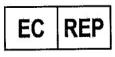
In order to keep the protection provided by the equipment effective, the experimenter or operator should consult and operate according to the requirements of this instruction manual.

WARNING:

This instrument is limited to the operation and use of inspection professionals, doctors or laboratory personnel trained by the company or its agents.

Safety symbols

Various safety symbols are used in this manual and the analyzer to remind you of matters needing attention during operation. As shown in the table below:

No.	Symbol	Signs	Explain
1.		WARNING	Documentation must be consulted in all cases marked with this symbol in order to ascertain the nature of the potential hazard and any countermeasures that must be taken. If you do not use the instrument in accordance with the instructions in this manual, the protective measures provided by this instrument may become invalid.
2.		IVD	Used in the nameplate position; indicates that the medical device is an in vitro diagnostic medical device.
3.		Risk of biological infection	Used in the card carrier to indicate a biological contamination hazard, which may be present if instructions are not followed.
4.		This way up	It indicates that the correct position of the transport package is vertical upward.
5.		Fragile	It indicates that the transport package contains fragile items, so it should be handled with care.
6.		Keep away from rain	It indicates that the transport package should be protected from rain.
7.		Do not roll	It indicates that the transport package cannot be rolled over.
8.		Stacking layer limit	Indicates that the maximum number of layers that can be stacked for the same shipping package is 3.
9.		CE mark	At the nameplate position. Indicates this medical device has been assigned to class A according to Annex II + Annex III + Article 17 of IVDR (EU) 2017/746.
10.		European authorized representative	At the nameplate position. Represents the authorized representative of the European Union.
11.		Marking of WEEE	Indicates the waste electrical and electronic equipment (WEEE), which designed for use with a voltage rating not exceeding 1000V for alternating current and 1500V for direct current, when marked with this marking the waste management should be in accordance with Directive 2002/96/EC(WEEE).

The user uses this product voluntarily, and the operation, maintenance, repair and transportation of this product must strictly follow the safety precautions listed below. The design

of this product fully considers biological pollution protection, electrical safety protection and mechanical movement protection. Any operation that does not comply with the safety precautions or other prompts in this manual may cause protection failure, or may Can undermine the safety standards of design and manufacture and the intended range of use of the instrument.

Safety notes

Dezhou Guoke Medical Technology Co.,Ltd. does not assume any responsibility for any loss caused by the user not reading this manual or operating in accordance with the contents of this manual! To use this instrument safely, please read the following safety precautions carefully. Any operation that violates the following safety precautions may cause personal injury or damage to the instrument.

WARNING:

In all cases marked with this warning sign, the instruction manual should be consulted in order to clarify the nature of the potential hazard and any countermeasures that must be taken. If you do not use the instrument in accordance with the instructions in this manual, the protective measures provided by this instrument may become invalid.

Biological Protection

Risk of biological infection

Improper use of samples can lead to infection. Do not touch reagent cards, samples, quality controls, and waste cards with bare hands. Be sure to wear gloves, work clothes to prevent infection, and protective glasses if necessary.

-
- If the sample accidentally comes into contact with the skin, please handle it according to the user's work standards immediately and consult a doctor.

Protection against chemical hazards

In order to prevent personal injury caused by dangerous chemicals, please observe the following precautions.

WARNING:

Some reagents may damage the skin. Please use reagents carefully to prevent direct contact between hands and clothes. In case of contact with hands or clothes, wash immediately with soap and water. In case of eye contact, rinse immediately with plenty of water and consult an ophthalmologist.

Waste liquid treatment

To prevent the waste liquid from causing environmental pollution and personal injury, please observe the following precautions when disposing of the waste liquid.

Risk of biological infection：

Some substances in the reagent are regulated by pollution regulations and discharge standards. Please comply with local emission standards and consult the relevant reagent manufacturer or distributor. Please dispose of used reagent cards in accordance with the "Medical Waste Management Regulations" to avoid biological hazards.

When handling waste liquid, be sure to wear gloves, work clothes to prevent infection, and protective glasses if necessary.

Prevent Fire And Explosion

To prevent fire and explosion, please observe the following precautions.

WARNING：

Alcohol is flammable and must be handled with great care.

Disposal of waste immunoassay analyzer

Please dispose of the discarded immunoassay analyzer according to the following requirements.

WARNING：

Some of the substances in the discarded immunoassay analyzer are subject to pollution regulations. Please comply with the local waste disposal standard to dispose of the abandoned immunoassay analyzer.

Instrument out of use

To reduce or eliminate the risks involved in taking the equipment out of service, such as during service, transportation, or disposal, observe the following precautions.

WARNING:

During equipment maintenance, transportation, or processing, please clean and disinfect the surface of the instrument and other components with biological risks, and remind relevant personnel of the risks of the instrument to avoid biological risks or other hazards during transportation or maintenance.

Operation precautions

In order to use the immunoassay analyzer correctly and effectively, please read the following notes carefully.

Instrument use

WARNING:

The instrument is used in conjunction with fluorescent immunochromatography reagents labeled with fluorescent microspheres, and is used for in vitro quantitative detection of analytes in human samples.

When making clinical judgments based on analytical results, please also consider clinical symptoms or other test results.

Instrument installation

WARNING：

Please place the instrument firmly in a stable and safe place to prevent the instrument from falling.

Please operate the instrument in an environment where the ambient temperature is within the range of 10℃~30℃, the humidity is within the range of ≤70%RH, and the atmospheric pressure is within the range of 86kPa~106kPa.

Do not place anything on the power cord, and place the instrument in a place where the power cord will not be stepped on or tripped over.

Do not place the device in a location where it is difficult to access the disconnect device.

Please keep the instrument away from the source of fire, otherwise the instrument may be deformed and there is a risk of fire.

Use environment

Be careful：

- Please install the instrument correctly according to the installation environment specified in the instruction manual. Installation and use of this instrument outside the specified conditions may give unreliable results and may result in damage to the instrument.
- At least 5cm of space should be left around the instrument to ensure air circulation and facilitate the heat dissipation of the instrument.
- Please keep the environment where the instrument is used clean and avoid dust, otherwise there will be a danger of destroying the instrument.
- Electromagnetic environment should be assessed before operating equipment.
- If you need to change the system status, please contact the company customer service center or the distributor in your area.

Protection against electromagnetic waves and noise

Be careful:

- Do not place equipment that emits abnormal noise near the instrument. Keep the instrument away from other electrical equipment, such as stereos; speakers in stereos may generate strong magnetic fields, and open magnetic fields may cause damage to data or displays.
- Do not use other medical equipment near this instrument. Electromagnetic waves emitted by this instrument may cause malfunctions of other medical instruments in its vicinity.

Electromagnetic Compatibility Related Precautions

Be careful:

- This instrument is designed and tested according to Group 1 Class A equipment in GB 4824. In a domestic environment, this equipment may cause radio interference, requiring precautions.
- Do not use this device near strong radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the normal operation of the device.
- Users are responsible for ensuring the electromagnetic compatibility environment of the equipment so that the equipment can work normally.
- It is recommended to evaluate the electromagnetic environment before using the equipment.
- This instrument complies with the immunity and emission requirements specified in this part of GB/T 18268.26.

Instrument use

Be careful:

- Please use the instrument according to the relevant instructions in the instruction manual. Improper use may result in inaccurate test results and may even cause instrument damage or personal injury.
- Please unplug the power cord on the instrument during thunderstorms, otherwise there is a danger of electric shock or fire.
- If your instrument falls, please unplug the power cord and seek help from the company's customer service center, otherwise there will be a risk of electric shock or fire.
- Please do not put lit cigarettes or candles on the instrument, otherwise there will be a risk of fire or damage to the instrument.
- Please do not block foreign objects in the fan exhaust port of the instrument, otherwise it will cause the risk of fire or damage to the instrument.
- Please do not scratch the display with sharp objects, otherwise the display may be damaged.
- This instrument is designed and tested according to the Class A equipment in CISPR 11. In a domestic environment, this equipment may cause radio interference, requiring precautions.
- Non-professional medical laboratory personnel of medical institutions should not operate it. This product must be operated by inspection professionals, doctors or laboratory professionals who have studied this manual and have been trained by our company or our agents.

Instrument maintenance

Be careful:

- Please maintain the instrument according to the relevant instructions in the instruction manual. Improper maintenance measures may result in incorrect analytical results and may even result in instrument damage or personal injury.
- If the instrument is placed for a long time, dust may accumulate on the surface. When cleaning, please use a clean soft cloth soaked in water and wring it out, gently wipe the surface, and dip a small amount of 75% ethanol if necessary. After cleaning, dry the surface with a dry cloth. Please use mild instrument-specific products to clean the instrument, and do not use the instrument until the instrument is completely dry, otherwise there will be a risk of electric shock or fire. If in doubt about the compatibility of disinfectants or cleaning agents with equipment parts or materials contained within the equipment, the manufacturer should be consulted.
- Before cleaning, please turn off all power of the instrument and unplug the power cord; during the cleaning process, please take necessary measures to prevent water droplets from entering the instrument, otherwise it may cause damage to the instrument or personal injury.
- If the instrument needs to be repaired due to failure, please contact the company's customer service center. When repairing or suspending use, please confirm that there is no reagent card left in the instrument; before the instrument is repaired, please carry out routine sterilization and disinfection.
- During the maintenance period, the instrument may need to be stopped or transported. Please operate with care to avoid the risk of biological infection, electric shock, and moving parts due to maintenance.
- After completing any inspection or repair, ask a technical service engineer to perform a safety test. Neglecting the safety test may result in electric shock or fire.

Sample

Be careful:

- Please use the correct sample storage measures. Improper sample storage practices may alter the composition of the sample and lead to incorrect analytical results.
- To prevent the sample from volatilizing, do not leave the sample open for a long time. If the sample volatilizes, it may lead to incorrect analytical results.
- Some samples may not be analyzed based on test parameters and reagents used. For these samples, please consult the relevant reagent manufacturer or distributor.

Other Notes:

a. Please do not use loose or damaged power sockets, otherwise there will be danger of electric shock and fire.

b. Use the correct grounding. If the socket is not properly grounded, there is a danger of electric shock and damage to the instrument.

c. Do not touch the power socket when your hands are wet, otherwise there will be a risk of electric shock

d. Please use your instrument under the appropriate voltage/current standard. Working under the unsuitable voltage/current will result in the danger of electric shock, fire or damage to the instrument.

e. If you hear noise from the power cord and power interface, please unplug the power cord immediately and seek help from your company's customer service center, otherwise there will be a risk of fire or electric shock.

f. Please keep the power socket and power interface in close contact, loose contact may cause fire hazard.

g. Do not bend the power cord or place heavy objects on the power cord to avoid damage to the power cord by persons and animals. Damaged power cords may cause electric shock or fire.

h. Please keep the power cord and plug clean, otherwise there will be a risk of fire.

i. If foreign objects or liquids enter the instrument, please remove the power cord and any other

cables from the instrument, and seek help from the company's customer service center, otherwise there will be danger of electric shock, fire and damage to the instrument.

j. Limit requirements for toxic and hazardous substances

k. This instrument complies with the limit requirements of toxic and hazardous substances stipulated in SJ/T11363-2006.

NOTE: In all cases marked with a warning sign ⚠, the instruction manual should be consulted to clarify the nature of the potential hazard and any countermeasures that must be taken.

Warranty and maintenance services

The warranty period of the purchased instrument is subject to the sales contract. Consumables: Refers to disposable consumable materials that need to be replaced after each use or fragile materials that need to be replaced regularly. Consumables have no warranty service.

Please note that the following situations will not be covered under warranty:

- The factory number of the instrument provided by the customer is incorrect (our company confirms whether the warranty is guaranteed by the factory number of the instrument);
- The company is not responsible for the failure and damage of the instrument in the following circumstances, or for direct or indirect damage during use:
- Failure and damage caused by violation of the method of use, precautions and purpose of use described in this instruction manual;
- Failure and damage caused by the operation of inspection professionals, doctors or laboratory personnel not trained by the company or the agent designated by the company;
- Failure and damage caused by maintenance or modification by companies other than those designated by the company;
- Failure and damage caused by the use of instruments other than those designated by the company;
- Failure and damage caused by the inconsistent operating environment and the operating environment (power conditions, installation environment, etc.) specified by the company;
- Failure and damage caused by irresistible natural disasters;
- Failure and damage caused by the company's unknowing movement or transfer (transportation) after the instrument is installed;
- Instrument failure caused by the use of reagents and other consumables not approved by the company does not belong to the scope of maintenance services provided by the company;
- Other faults not caused by the instrument itself.

During the warranty period, if the fault is caused by the design and manufacturing defects of our company, it will be repaired free of charge, and our company will take corresponding countermeasures according to the fault content.

After the expiration of the warranty period, the company can continue to provide fee based maintenance services.

After-sales service and contact details

After-sales service

Please contact our after-sales service department.

Repair

- Confirm failure and repair method： First, contact the company's after-sales service department to confirm the fault situation and confirm whether the repair method is on-site repair or return to the factory for repair.
- Repair fees：Negotiate with the company according to the specific situation.
- Freight：If the immunoassay analyzer is shipped to the company for repair, the user shall bear the freight (including customs fees).

Return

- Get permission to return goods. Contact after-sales service department of the company and inform product serial number (see the nameplate of immunoassay analyzer for details), explain the reason for return. If the product serial number cannot be clearly identified, the company will not return the goods.
- On the premise of obtaining the right to return goods, please go through the relevant procedures according to the requirements of the company.

Contact details

See the nameplate.

Foreword

Welcome to the "Dry Fluorescence Immunoassay Analyzer Instruction Manual", this instruction manual introduces the structure, function, installation, software interface, quality control, maintenance, troubleshooting, precautions and other aspects of the instrument in detail.Optimum performance of the instrument can only be guaranteed if the manufacturer's published instructions for use are fully followed, and must therefore be operated and maintained in accordance with the contents of these instructions. If you have any questions, please contact our company.

Before using this instrument, please read and understand the contents of this instruction manual carefully to ensure that this instrument can be used correctly.

The pictures in this instruction manual are for illustration or example only, not for other purposes. The actual picture please refer to the instrument.

1. Product overview

1.1. Instrument introduction

(1) Instrument Name：Dry Fluorescence Immunoassay Analyzer

(2) Model：GKYG-500

(3) Specification: 1 unit/box

(4) Software Name：Dry Fluorescence Immunoassay Analyzer Software

(5) Software release version: V1

(6) Software complete version: V1.0.4

(7) Production date: See the nameplate

(8) Service life: The service life of the immune analyzer is 8 years from the date of installation of the instrument (NOTE: excluding man-made damage). The expected service life of the instrument is determined according to the high temperature and high humidity accelerated life test. The instrument should be maintained, serviced and repaired in accordance with the instructions. Instruments that have been confirmed to maintain their basic safety and effectiveness after maintenance, upkeep and repair can be used normally.

1.2. Main structural composition

Dry Fluorescence Immunoassay Analyzer consists of host (including optical detection module (fluorescence), scanning module, data processing module, liquid crystal display module, information acquisition module, printer, shell), embedded software (software release version V1), power adapter, and power cord. Its structure diagram is shown in Figure 1.1 --- Figure 1.3.

The main component of the optical detection module is an optical path box, which is mainly composed of a light source, an optical path platform, and a detection component.

The scanning module is mainly composed of a code scanner, a scanning head connecting plate, a scanning head mounting seat and its fixing parts.

The data processing module is mainly composed of the measurement circuit board and its fixing parts.

The LCD module is mainly composed of LCD screen and control board.

The information collection module mainly refers to the ID card reader.

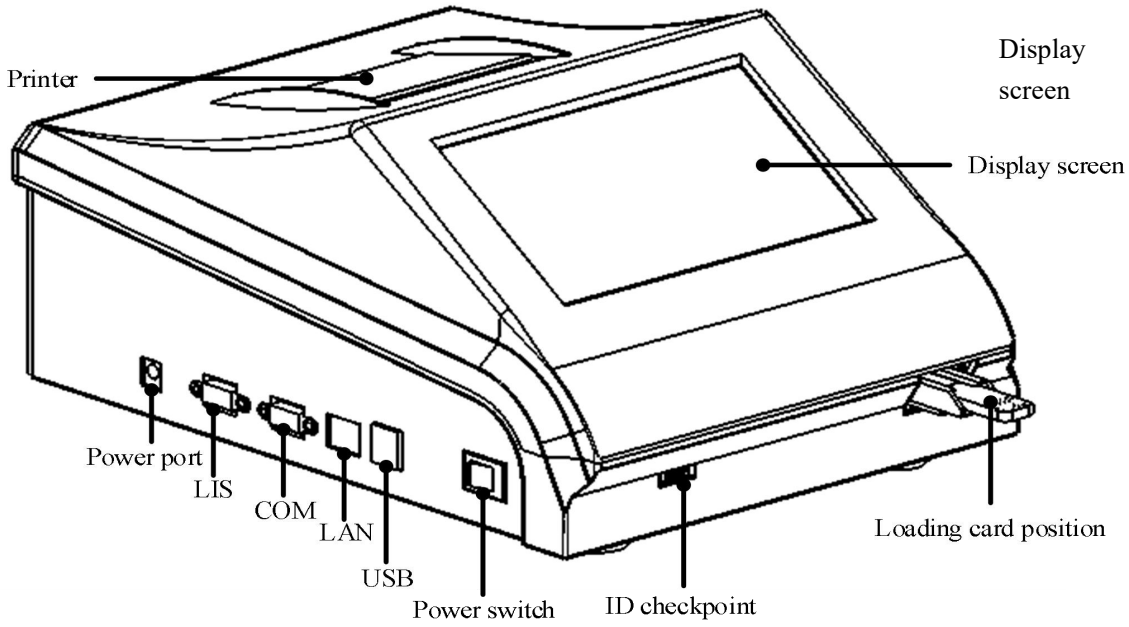


Fig. 1.1

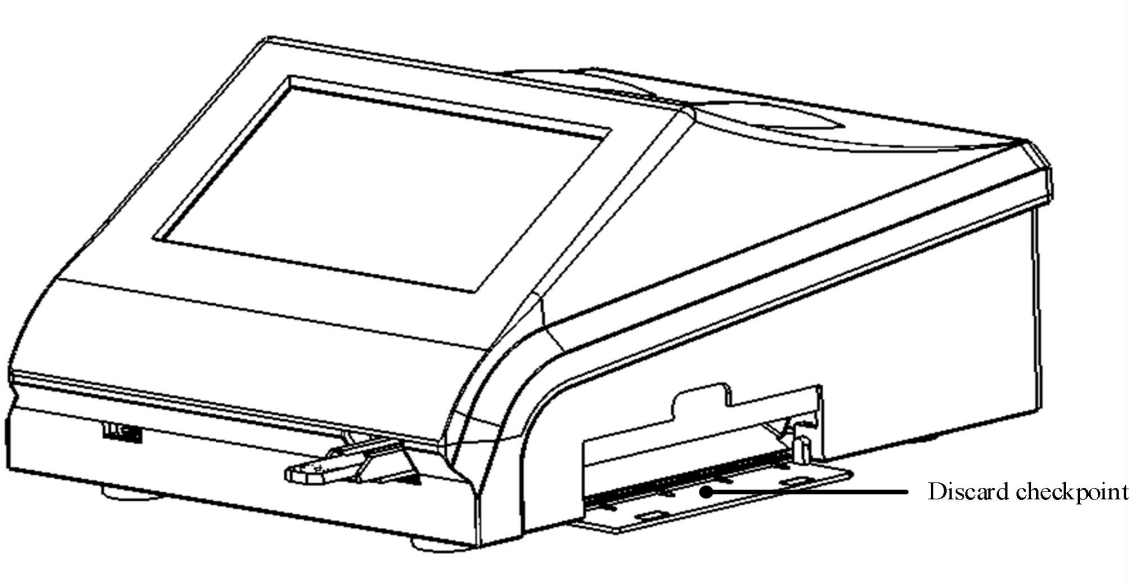


Fig. 1.2

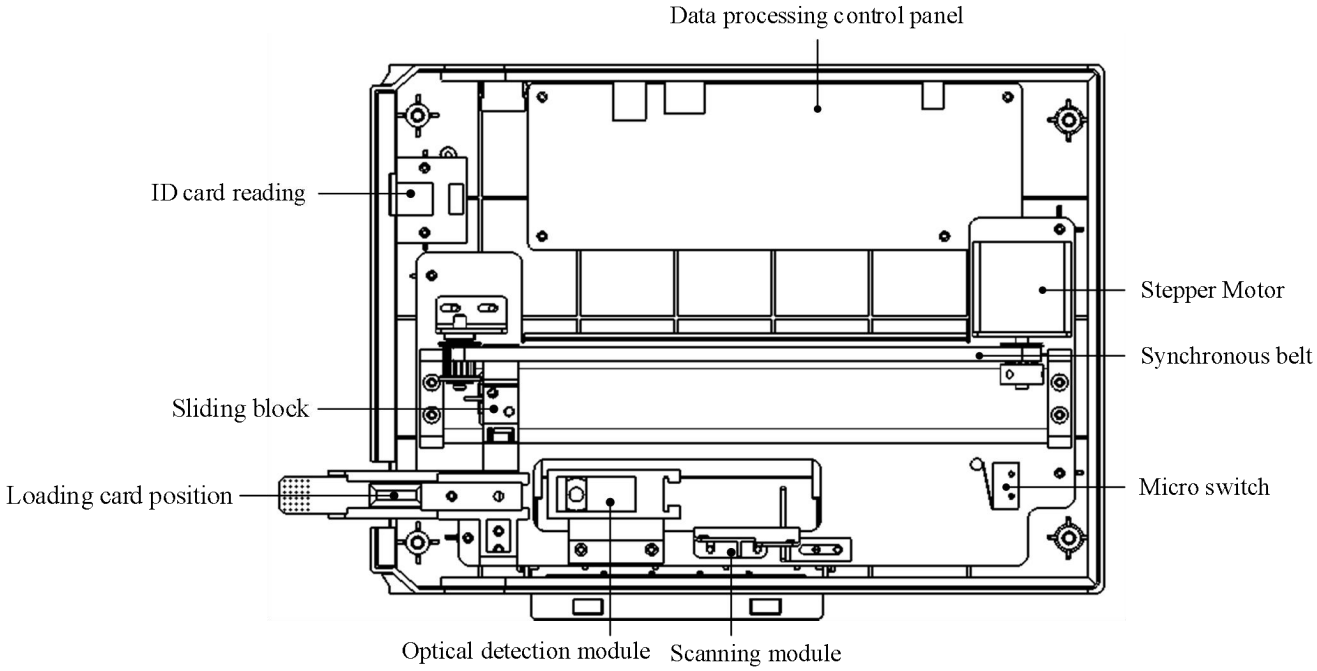


Fig. 1.3

Note: The appearance of the instrument is subject to the actual product.

1.3. Scope of application

1.3.1. Intended uses

Dry Fluorescence Immunoassay Analyzer is used in conjunction with fluorescent immunochromatography reagents labeled with fluorescent microspheres for in vitro quantitative detection of analytes in human samples.

1.3.2. Applicable items

Including pathogenic pathogen antigens/antibodies, proteins, carbohydrate, vitamins, kidney disease, myocardial disease, immune function and other items.

1.3.3. Intended use environment

It can be applied to central laboratories, outpatient/emergency laboratories, clinical departments and other medical service points (such as community medical points), physical examination centers, etc. in medical institutions, as well as scientific research laboratories. For laboratory medicine professionals to perform in vitro diagnostic experiments only.

1.4. Basic principle

(1) Principles of immune response：

① Competition method：

The detection area (T line) on the NC membrane of the detection card is coated with antigen, and the quality control area (C line) is coated with goat anti-mouse IgG.After the sample is added to the sample well, the liquid is chromatographed upward under the capillary effect.The analyte (antigen) in the sample competes with the antigen in the detection area (T line) on the NC membrane to bind the antibody labeled with fluorescent microspheres during the chromatography process, and then continues to be chromatographed upward,at the C line, a solid-phase goat anti-mouse IgG-fluorescent microsphere-labeled antibody complex is formedFluorescent microspheres emit visible light signals under excitation light. The more analytes in the sample, the less complexes accumulate on the T line. The signal intensity of the fluorescently labeled antibody on the T line is inversely proportional to the content of the analyte in the sample.

② Sandwich method：

The detection area (T line) on the NC membrane of the detection card is coated with coating antibody, and the quality control area (C line) is coated with goat anti-mouse IgG.After the sample is added to the sample well, the liquid is chromatographed upward under the capillary effect. During the chromatography process, the analyte in the sample is first combined with the labeled antibody labeled with fluorescent microspheres to form the analyte-fluorescent microsphere labeled labeled antibody complex, and then continue to be chromatographed upwards.Then the complex will be bound by the coated antibody coated on the T line, and a solid-phase coated antibody-antigen to be tested-fluorescent microsphere-labeled labeled antibody complex will be formed at the position of the T line.At the position of the C line, a solid-phase anti-mouse IgG-fluorescent microsphere-labeled labeled antibody complex was formed.The fluorescent microspheres emit fluorescent signals under excitation light. The more analytes in the sample, the more complexes accumulate on the T line. The signal intensity of the fluorescently labeled antibody reflects the amount of the analytes captured.

(2) Working principle：

Drop the sample containing the antigen (antibody) to be tested in the sample application

area. If you use the fast mode, you need to wait for the antigen and antibody to react completely before putting it into the instrument, and the instrument will directly read the data;If you choose the normal mode, you need to directly put the reagent card that has just added the sample on the loading card position. When the instrument detects that a card is inserted, it will start the countdown. After the predetermined time is over, the instrument will read the data.The read procedure is as follows:The instrument automatically turns on the LED light source and scans the reaction area of the reagent card horizontally.The LED will gradually irradiate the detection area, and then irradiate to the quality control area, and the fluorescent immune complexes solidified on the reagent card will be excited under the specific wavelength of the LED.The excited light is collected by the silicon photocell and converted into an electrical signal. The strength of the electrical signal is strictly related to the number of fluorescent molecules. The fluorescence signal of the reagent card will be converted to the corresponding voltage signal, and the software calculates the signal value of the reagent card by the highest peak area method.Substitute this value into the calibration curve to calculate the concentration, and the reading process ends. Finally, discard the reagent card after the test is completed.

1.5. Software

Software interface: wizard-style interface, intuitive layout and program settings, easier to operate and edit.

Language support: Chinese or English.

Data storage: The instrument can store experimental data files.

Data transmission: The experimental data can be printed out through the printer, or the experimental data can be exported to the U disk through USB.

1.6. Network security

Software operating environment requirements:

Embedded software, its operating environment requirements are as follows:

Android platform: PowerVR SGX544MPI, 8G (EMMC), android6.0 or above.

Motherboard hardware configuration:

Control board main control chip: GDF205VCT6

Memory: AT24C64

Network type: none

Security software: none

Data interface: LIS port, LAN port, USB port.

LIS port and LAN port are used to connect LIS.

The USB port is used for keyboard and mouse access, data export and system upgrade.

The LIS port transmission protocol is the RS232 communication protocol. The LAN port transmission protocol is TCP/IP or UDP/IP protocol, and the USB interface protocol is USB protocol.

Data type: export data through USB data interface, the storage medium is U disk, and the exported test data is in .xls format.

Access Control: Deny any unauthorized external access. The software can log in to the software after the user enters the user name and password for verification.

It is divided into two levels: administrator and ordinary user. Ordinary user authority: can only access the test data of this user; administrator authority: can access the test data of all users.

1.7. Contraindications

No.

2. Instrument basic parameters and conditions of use

2.1. Basic parameters of the instrument

Host size and weight	215mm*310mm*158mm（L*W*H）；3KG；
Sample type	Whole Blood, Serum, Plasma, Urine
Detection speed	Single detection time <10s
Detection method	Supports multiple items in one card
Printer	Built-in thermal printer，57mm
Display screen	7 inch touch screen
Interface Language	Chinese and English, other languages can be expanded
Data storage	Unlimited
Reaction channel (Card Carrier)	1
Detection channel	1
Excitation light source	LED
Working wavelength range	Excitation spectrum Center wavelengthλ0=365nm； Receive spectrum Center wavelengthλ1=615nm；
Power-on warm-up time	No preheating required
Power consumption	60VA
Normal working conditions	Indoor use; The altitude is below 2000m; Ambient temperature: 10℃～30℃; Relative humidity: ≤70%; Atmospheric pressure: 86.0kPa～106.0kPa The power supply voltage fluctuation should not exceed ±10% of the nominal voltage; Transient overvoltage is category II of facility category (overvoltage category); The rated pollution degree is 2.
Storage and transportation environment	The ambient temperature is -40℃～55℃, and the relative humidity is not more than 70%
Performance indicators	Repeatability: CV≤5%. Stability: σ≤±8%. Linear correlation: (r) ≥ 0.98. Accuracy: Δn≤±8%.

2.2. Function

(1) The analyzer should have ID card information reading function.

(2) The analyzer has a data display function: after testing with the analyzer, the test results can be inquired.

(3) The analyzer has touch operation function.

(4) The analyzer has the function of automatic printing. After the test is over, it can automatically print the test results.

(5) The analyzer has a self-checking function.

(6) The analyzer has a fault prompt: the analyzer has corresponding prompts for operation errors.

(7) The analyzer has a LIS data interface.

(8) The analyzer has user access control: it is divided into two levels: administrator and common user. Common user authority: can only access the test data of this user; administrator authority: can access the test data of all users.

2.3. Transport and storage conditions of the instrument

Transport

The instrument under the packaging condition is suitable for road, railway, air and water transportation. During loading, unloading and transportation, it should prevent severe vibration and shock, and should not be affected by moisture, and should not be mixed with flammable and corrosive substances. Requirements according to the order contract.

Storage

When storing the instrument, it should be placed in the original packaging box, placed in a well-ventilated room, the packaging box should be padded, the ambient temperature should be -40°C ~ 55°C, and the relative humidity should not be greater than 70%.Harmful gases, flammable, explosive substances and corrosive gases are not allowed.

3. Instrument installation

Please use this instrument under conditions that meet the environmental requirements of the instrument.

3.1. Package

If the package is damaged after receiving the instrument, or the instrument is obviously damaged, please contact the carrier immediately and file a claim according to the degree of damage. At the same time, please contact your supplier to confirm that the instrument is well packaged, and then follow the steps below to remove the packaging materials and install the instrument.

3.2. Unpack

Carefully remove the instrument and accessories from the box, saving the packing material for future shipping or storage.

(1) Count the random accessories item by item according to the packing list.

(2) Check the instrument and accessories for mechanical damage.

(3) When handling the instrument, it should be handled with care, and it is strictly forbidden to force the front case directly to avoid damage to the instrument.

(4) Place the instrument main body on a stable flat operating table.

If there are any problems please restore the packaging and contact your supplier immediately.

3.3. Packing list

No.	Name	Unit	Qty	P.S
1	Dry Fluorescence Immunoassay Analyzer	Set	1	
2.1	Instruction Manual	PCS	1	
2.2	Certification	PCS	1	
2.3	Customer Satisfaction Survery	PCS	3	

No.	Name	Unit	Qty	P.S
3	Network Cable	PCS	1	
4.1	Power Adapter	Set	1	Adapting instrument
4.2	Replaceable AC plug	Set	1	
5	Clean cloth	PCS	1	
6	Printing paper	PCS	1	Adapting instrument

3.4. Installation requirements

3.4.1. Installation environment

1) The instrument should be placed in a stable and level room with no serious dust, no direct sunlight and no corrosive gas, and the work surface can carry a weight of more than 5kg;

2) There are no strong vibration sources and strong electromagnetic fields around;

3) Do not place the instrument in a position where it is difficult to operate the disconnect device, with a clearance of at least 5 cm around the instrument;

4) Do not cover the instrument with anything to prevent the vents from being blocked;

5) Please try not to use parallel sockets to avoid fire caused by overload;

6) A 24V/2.5A power adapter and an effectively grounded socket must be used;

7) The instrument should be placed in a clean and ventilated room with a temperature of 10°C to 30°C and a relative humidity of not more than 70%.

8) To ensure the normal operation of the instrument, do not place objects on the instrument at any time.

3.4.2. Power supply voltage requirements

Power supply: AC 100-240V, 50Hz/60Hz, Rated input power: 60VA.

During use, be careful to avoid short circuit and risk of electric shock!

Note:The documentation must be consulted in all cases marked with a symbol  .

3.4.3. Accessories connection

Install the related accessories configured with the machine to the corresponding interface of the instrument.

3.4.4. Connect the power cord

Make sure that the power switch of the analyzer is in the off (O) state, insert one end of the power adapter cable provided with the instrument into the power socket of the instrument (there is a corresponding power mark on the body), and the other end into a standard well-grounded power socket; If you need to connect HIS/LIS, please connect the network cable to the LIS port of the instrument.

3.4.5. Thermal printing paper installation procedures

Open the printer compartment door, then place the thermal printer paper configured with the printer into the printer compartment and close the door.

⚠ Notes

Thermal printing paper size (width 57mm±0.05mm, outer diameter ≤30mm).

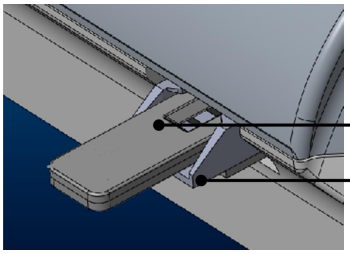
The paper is installed with the thermally coated side facing up.

Before closing the door, please extend the printing paper 2-5cm outwards.

3.4.6. Start-up operation procedures

Power on the instrument, then turn on the power switch, enter the user name and password after the instrument is turned on, enter the software experiment operation interface and enter the equipment self-check program, and the loading card reciprocates once. The test software starts automatically, and the main interface appears automatically.

The user name:admin Password:admin.



4. Software interface operation introduction

4.1. Main interface

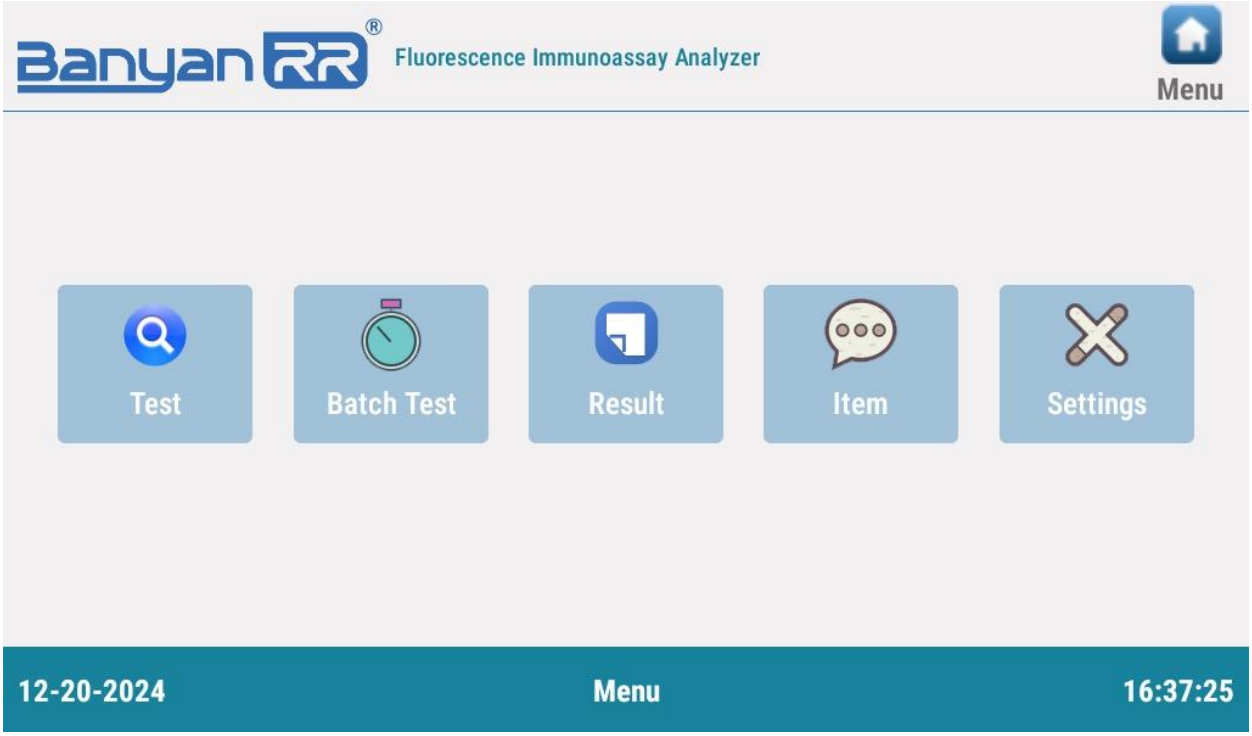


Fig. 4.1

As shown in Fig. 4.1, there is a main menu button at the bottom of all display interfaces, after clicking, it will return to the interface of Fig. 4.1. From left to right are the [Test], [Batch Test], [Result], [Item], and [Settings] buttons. Click one of the buttons to enter the corresponding function operation interface.

4.2. Test interface

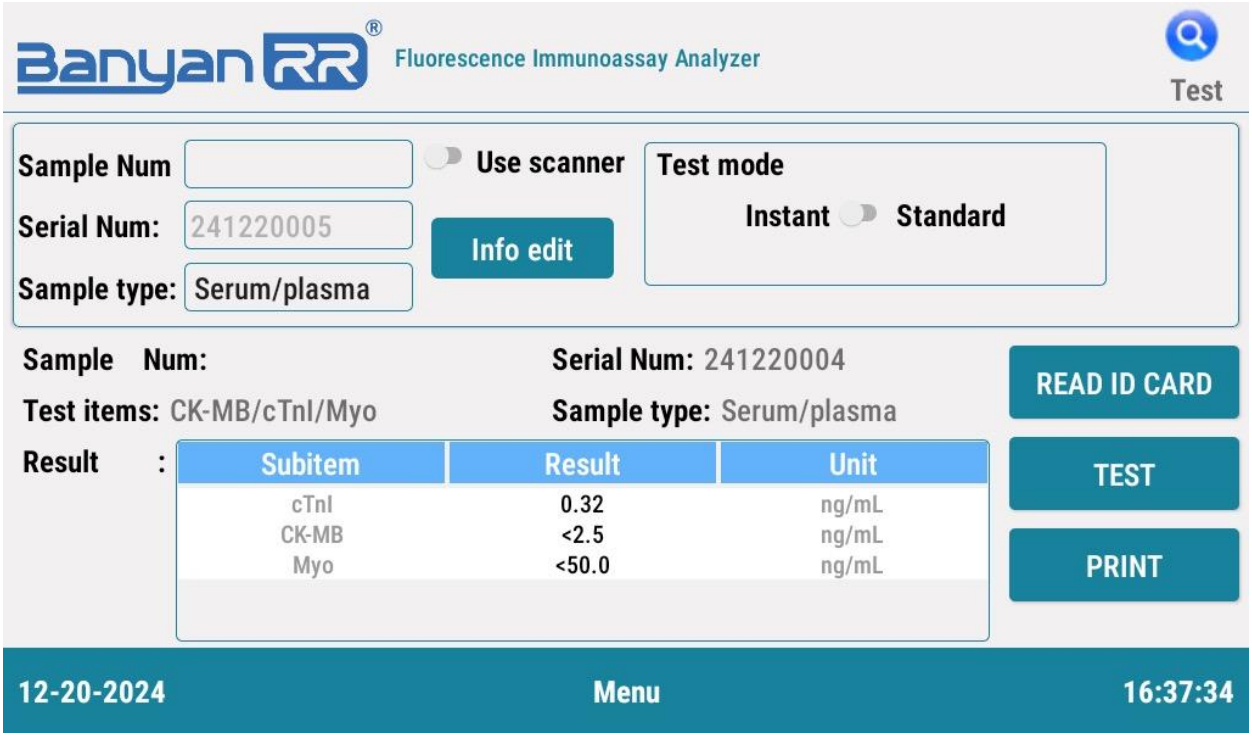


Fig. 4.2

1.First select [Test] on the main interface, after selecting, as shown in Fig. 4.2;

2.Before each batch of reagent cards is tested, there is no corresponding test item in the system, so the ID card needs to be inserted to read; the user can manually select the [READ ID CARD] button in Fig. 4.2 to read the data;

3.When the ID card data has been read, the sample type can be selected, and the sample number can be manually entered as needed;

4.Users can also click [Info edit] to enter detailed patient information;

5.After all the information is entered, the user can select [standard test] or [Instant test] to test.Standard test refers to scanning the reagent card and calculating the result after the reaction time of the item is counted down.The instant test refers to the instant test scan and the result calculation;

6.The user code is used to count the number of user tests and the distribution of test items.

7.After the corresponding information is input, the user can select the [TEST] button in Fig. 4.2 to test, and the test value result will be displayed in the corresponding value box in Fig. 4.2.

8.After testing each reagent card, the user can select the [PRINT] function in Fig. 4.2 to print the test report.

4.3. Batch test

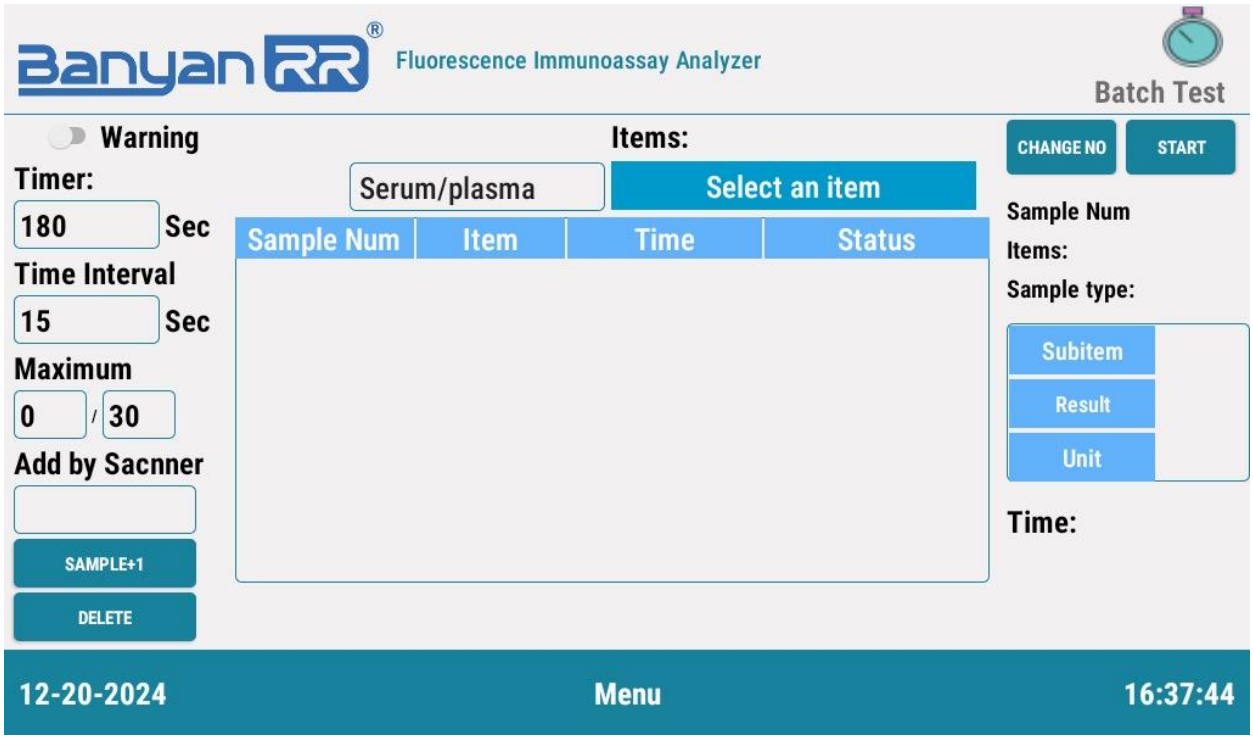


Fig. 4.3

1.The interface of [Batch Test] is shown in Fig. 4.3, the user can select the sample type, test items, and add and delete items to be tested

2.First select the detection item to determine the time.

3.Select [SAMPLE+1] to add test samples, if you want to delete redundant test samples, you need to select the corresponding samples, and then click the delete button;

4.After the sample is added, the sample code is automatically assigned. If you want to customize the code, select the sample and click [CHANGE NO] to modify the code.

5.Click [Timer], the instrument will start the countdown, and will also count down the interval time for the next sample.

4.4. Result view interface

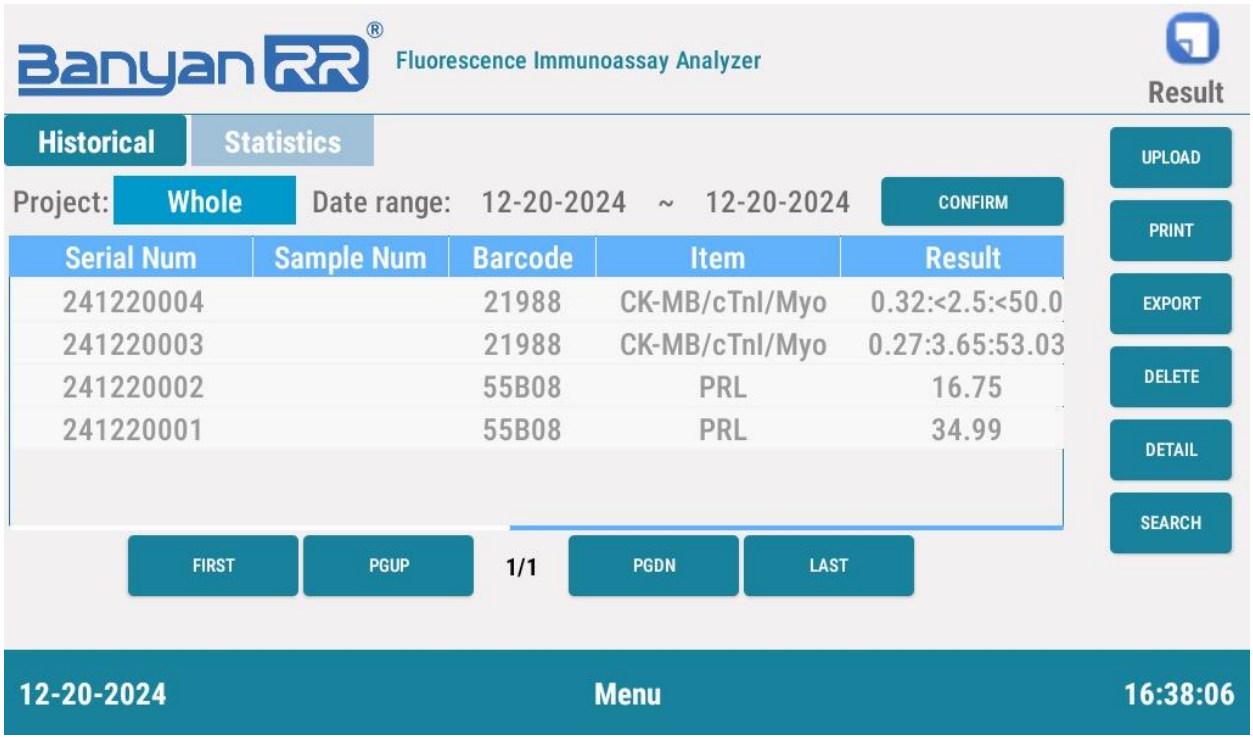


Fig. 4.4

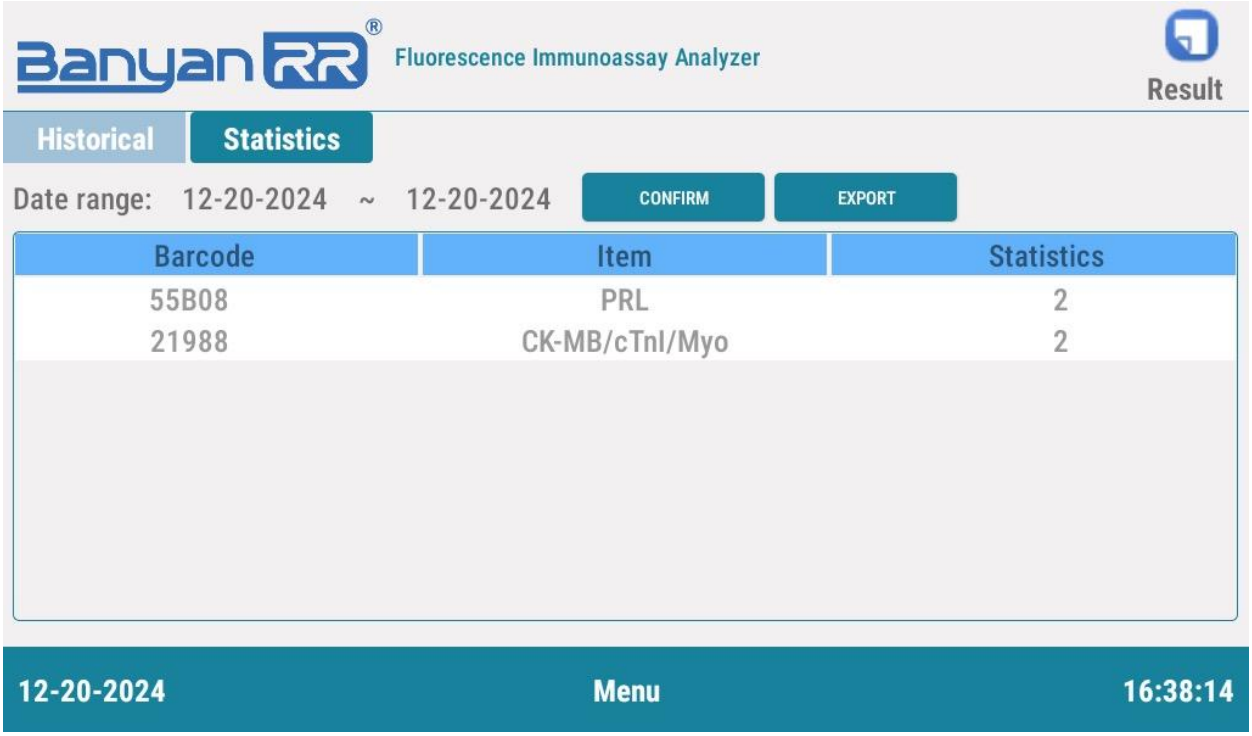


Fig. 4.5

1.In the [Result] interface, the user can perform historical viewing, classification and statistics operations;

2.After each test result comes out, the system will automatically save the data locally, and the user can select [Historial] to view it;

3.Click [Date] in Fig. 4.4, select the date range to be viewed, and click [CONFIRM] to view

the record;

4.After selecting the item code to be viewed, click [CONFIRM] to filter out the corresponding item record;

5.Click [UPLOAD] in Fig. 4.4, you can choose to upload the selected records or upload them all;

6.Click [PRINT] in Fig. 4.4, you can choose to upload the selected records or print them all;

7.Click [EXPORT] in Fig. 4.4, you can choose to upload the selected records or export them all;

8.Click [DELETE] in Fig. 4.4, and then select a single history record to view detailed information;

9.Click [Statistics] in Fig. 4.5, select the date range to be viewed, and click [CONFIRM] to view the statistical results.

4.5. Item interface

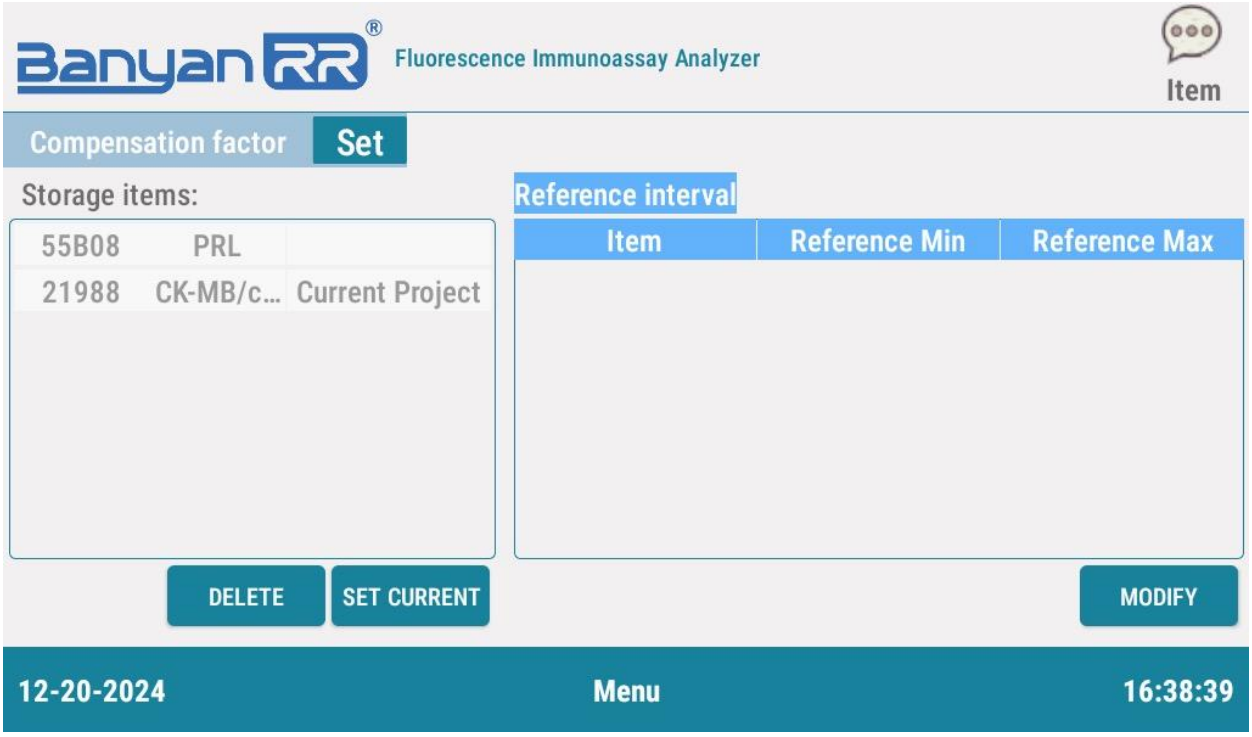


Fig. 4.6

1.As shown in Fig. 4.6, the item list can be viewed in the item settings, and the item reference value can be set;

2.The system supports viewing the list of items stored in the system, and can replace items;

3.The user can modify and delete the item reference value.

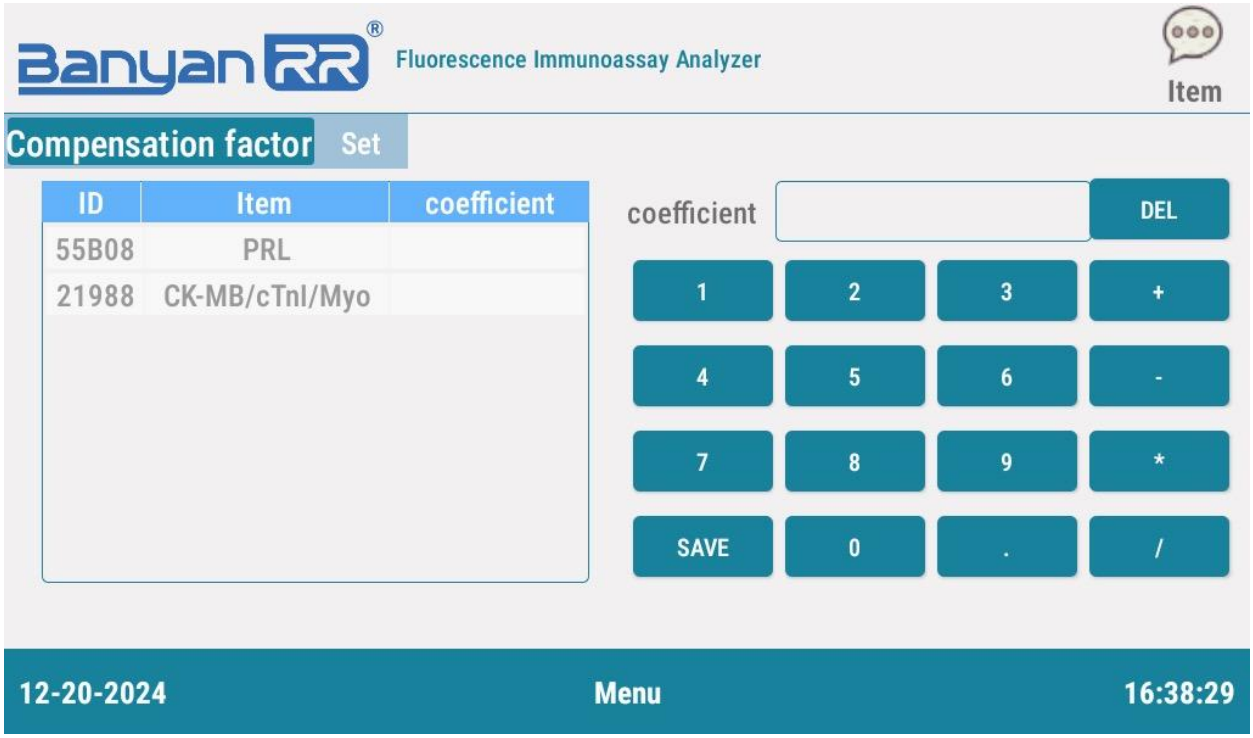


Fig. 4.7

1.As shown in Fig. 4.7, in the "coefficient" item of the compensation coefficient, "symbol + number" can be input;

2.The symbols supported by the system are "+", "-", "*", "/", etc., which can represent addition, subtraction, multiplication, and division respectively;

3.The function of the compensation coefficient is: when there is a deviation in the test value due to the influence of external factors, the user can manually eliminate the deviation through the correction coefficient.

4.6. Settings

In [Settings], users can view institutional information, LIS/HIS link parameter setting, test setting, system setting, about, and user management.

(1) [Institutional Info]: Users can view the institution name, institution address, and re-register the institution name.

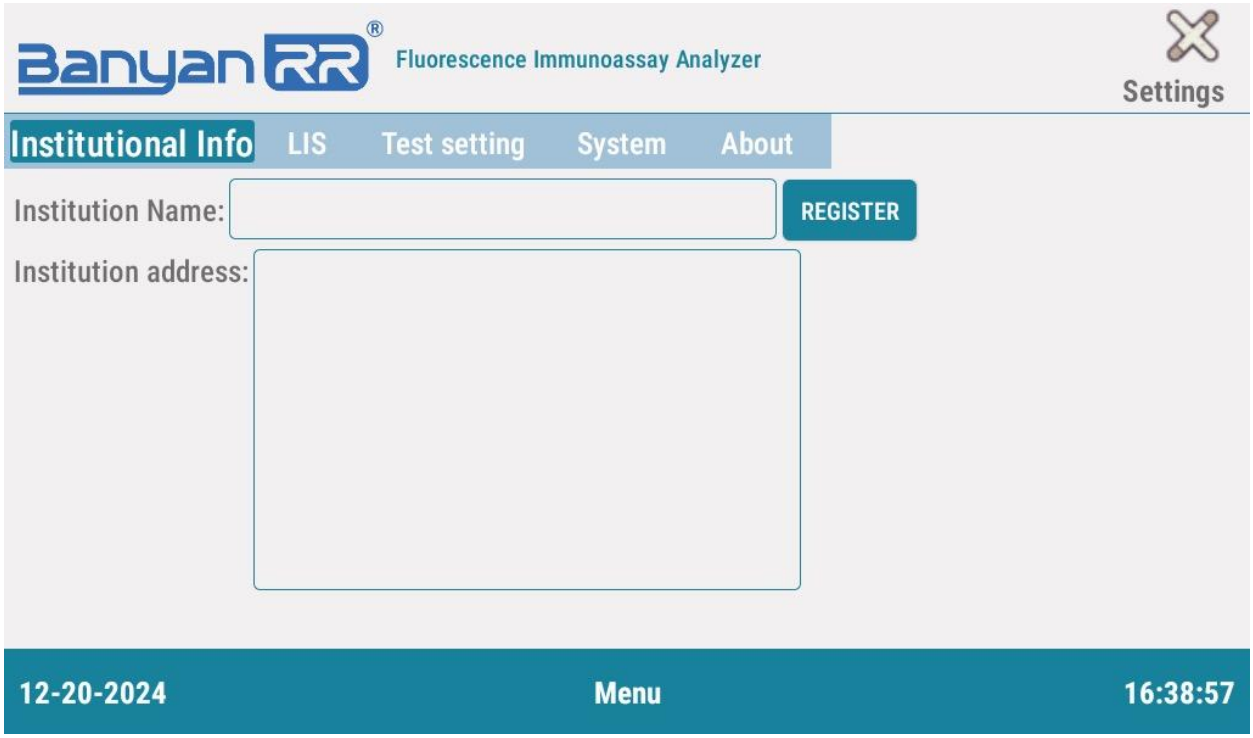


Fig. 4.8

(2) [LIS]: To set the LIS upload parameters, first select the upload method, and then set the corresponding parameters.

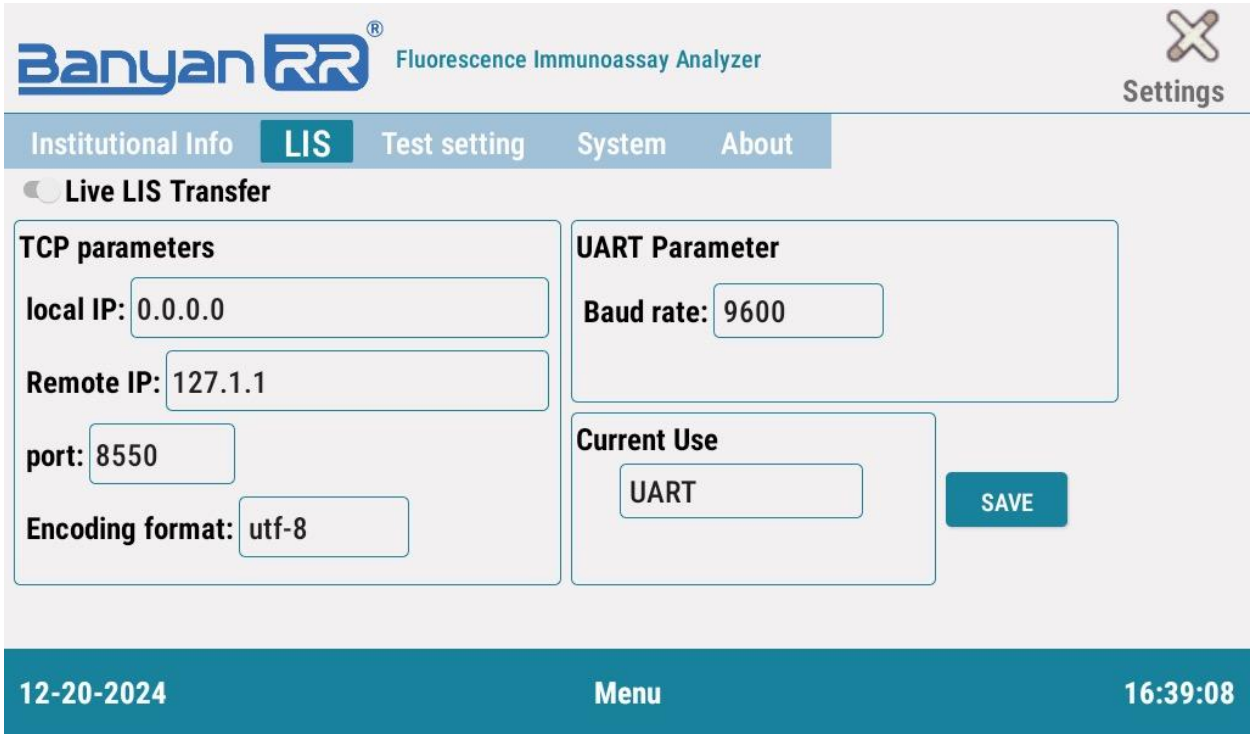


Fig. 4.9

(3) [Test Setting]: Set the initial value;

① Set real-time printing results, if selected, the report will be automatically printed after each test;

② Set the record keeping days, when the record keeping days exceeds the set days, it will be automatically deleted;

③ Set whether to test automatically. If this option is selected, once the system detects that

a reagent card is inserted, the system will automatically perform the test.

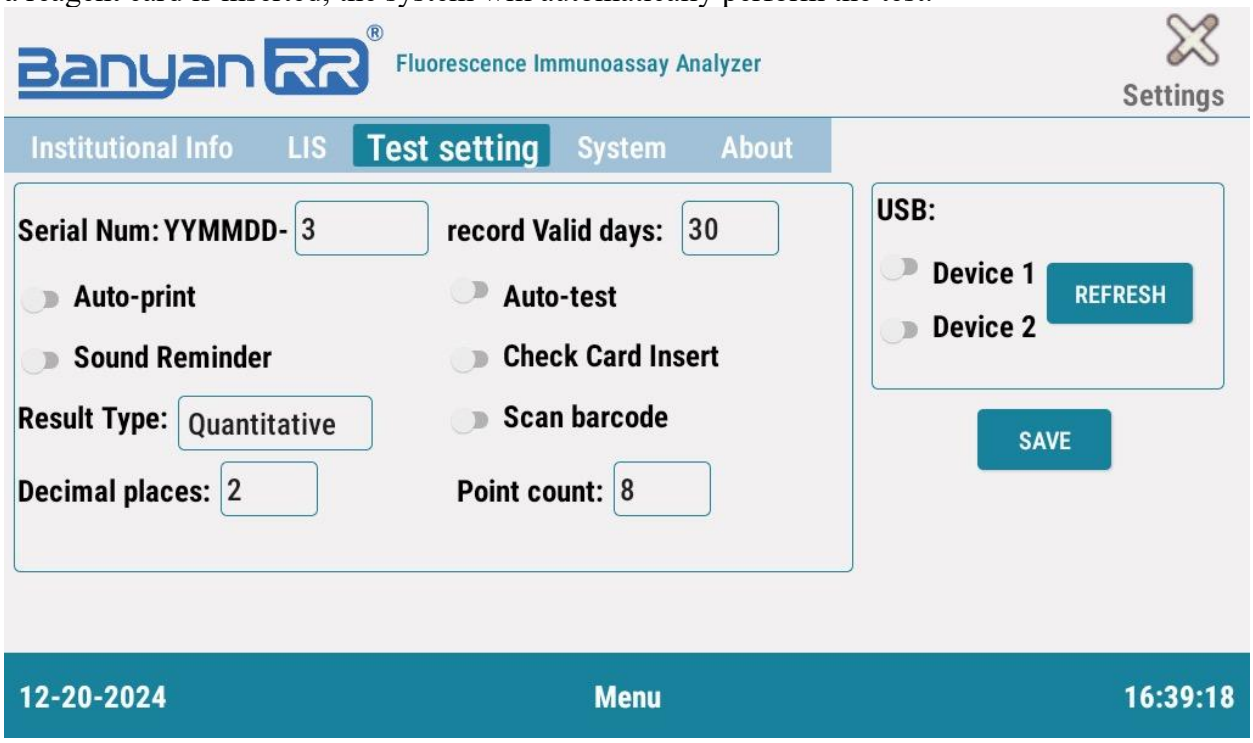


Fig. 4.10

(4) [System]: Set the system time. After setting the system time, you need to save it to take effect.

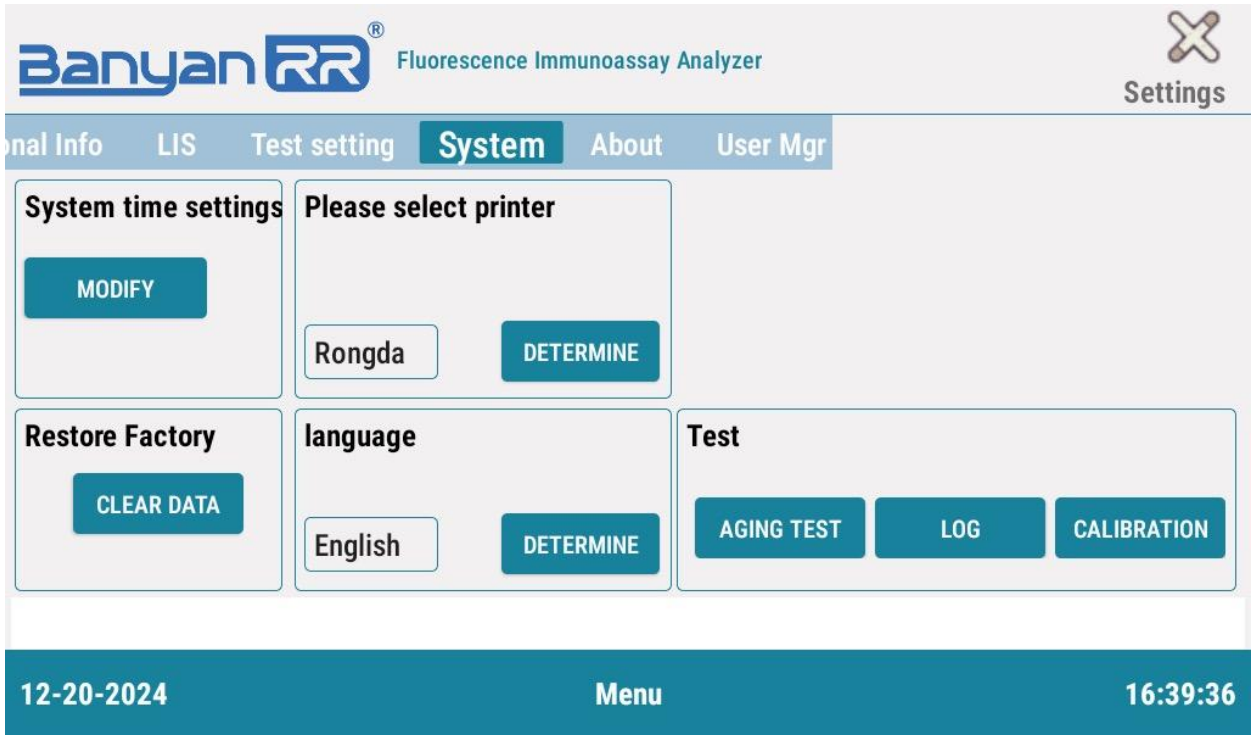


Fig. 4.11

(5) [About]: To check the software version, you can put the software upgrade package into the U disk and insert it into the USB port of the instrument. After the system detects the upgrade program, the software can be upgraded.

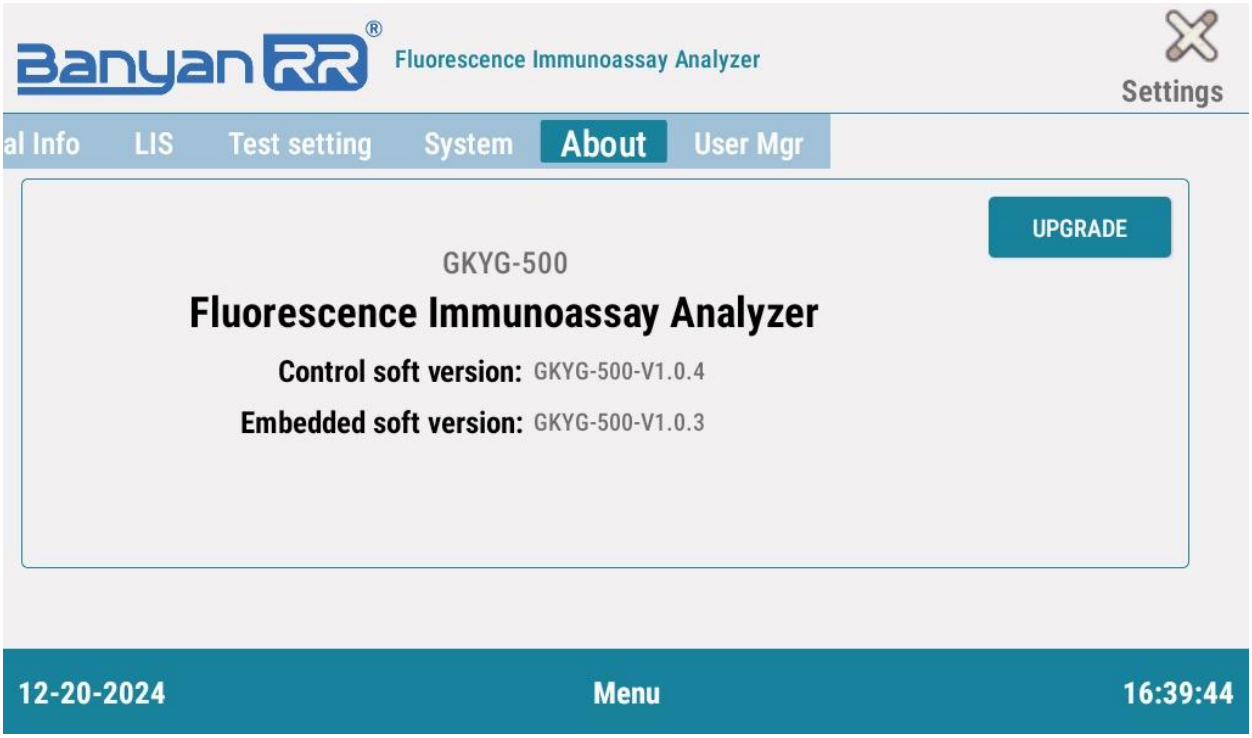


Fig. 4.12

(6) [User Mgr]: User management, logout, modify, add, delete users.

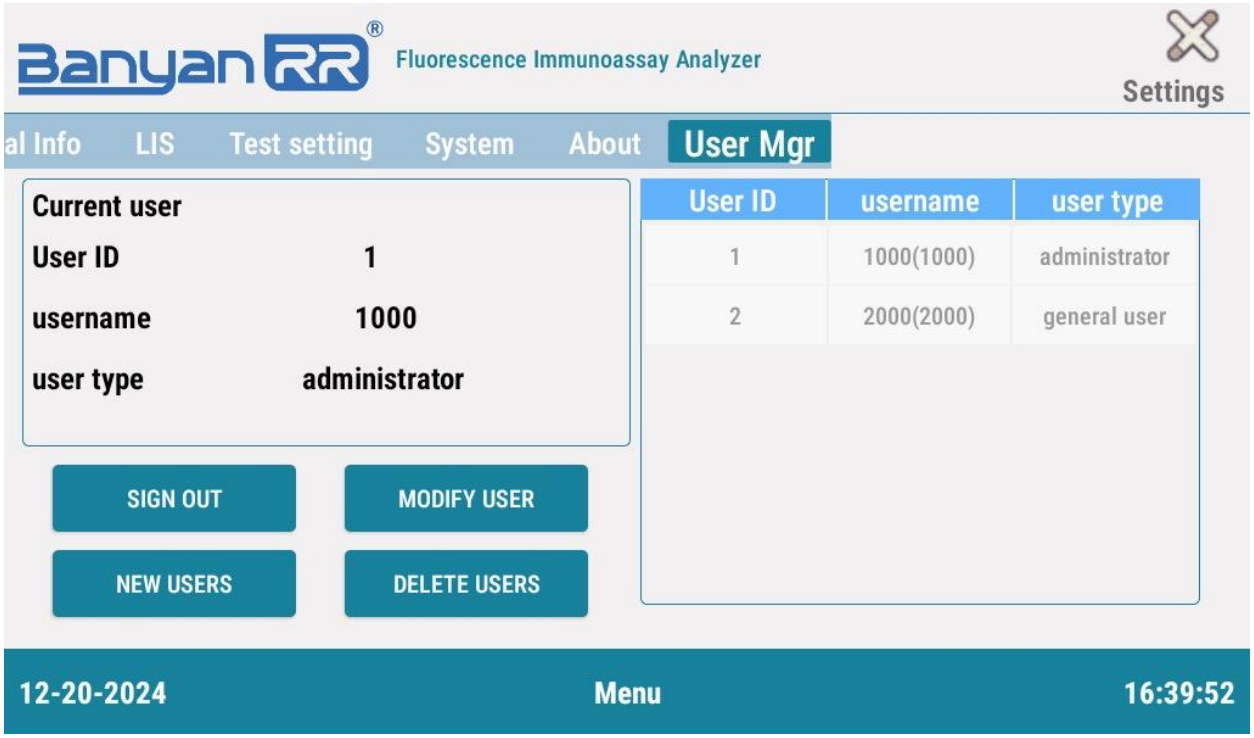


Fig. 4.13

5. Specific operation steps

5.1. Preparation before use

1) Turn on the power switch of the instrument, the instrument will perform a self-check, and the loading tab will reciprocate once;
2) The test software starts automatically, and the main interface appears automatically;
3) For the use and storage of reagents, please refer to the instructions that come with the reagents;
4) Put the reagent card containing the sample to be tested smoothly on the loading tab, and test according to the software operation instructions;
According to the different test items, select the appropriate parameter settings (the technician will guide and train the operator).

5.2. Start testing

The instrument action is controlled by the software to carry out the test.

 Notice:
At this time, the loading tab is moving, do not approach the outlet of the loading tab;
The software cannot be operated during the test.

5.3. End of test

1) After the project test is completed, the instrument will automatically save the test results, and the operator can output the results through the built-in printer, external printer or Lis system.
2) When the test is over, the reagent card is dropped from the discarding port to the outside of the instrument;
3) The loading tab is automatically reset to the loading position;
4) Turn off the power to end the test.
5) The waste generated during the use of the instrument should be handled uniformly by professionals in accordance with the "Medical Waste Management Regulations" and other relevant regulations.

6. Quality control and calibration

6.1. Quality control

The instrument has been quality controlled before leaving the factory. After the instrument is debugged and installed, it can be directly tested with reagents. If you need to perform quality control on the instrument again, you can perform quality control by testing the quality control strip.Quality control is implemented in the same way as when testing normal samples,that is, directly use the Dry Fluorescence Immunoassay Analyzer to test the concentration of the quality control strip.

If the reading value of the instrument is compared with the target value of the quality control product, if the reading value meets the target value range requirements of the quality control product, the instrument can be tested; if it does not meet the target value range requirements, it is prohibited to use! And contact the company's customer service center in time to return to the factory for calibration or maintenance.

6.2. Calibration

After 1 year of normal use, the user needs to use the standard for calibration. The calibration method is the same as when testing ordinary samples, that is, directly use the Dry Fluorescence Immunoassay Analyzer to test the concentration of the reagent card (with the standard added). If the reading value meets the target value range of the standard, it can continue to be used.

If the reading value is deviated, do not use it! And timely contact the company's customer service center for processing.

7. Cleaning and disinfection

"Dry Fluorescence Immunoassay Analyzer" is an inspection instrument, which is a non-sterile medical device and does not require sterilization. It only needs to be maintained and maintained according to ordinary medical equipment, and the outside can be kept clean.

Recommended cleaning and disinfection methods: The analyzer casing or frequently touched places are very easy to become dirty. In order to keep the working environment clean and reduce biological risks, the exposed parts of the analyzer should be cleaned in a timely manner.

External cleaning and maintenance method: Use lint-free gauze and 75% ethanol to clean the outer surface of the instrument. After cleaning, please dry the surface with a dry cloth. Be careful not to clean any internal parts or interior surfaces with cleaning agents.

The basis for the determination of the disinfection process: because the ordinary dust on the surface of the equipment shell can be wiped directly with a cloth dipped in water, the dust can be removed; the use of ethanol for product disinfection is because ethanol is a medium-effective disinfectant, which is medium-effective, fast-acting, non-toxic, and effective. The skin and mucous membranes are irritating and non-corrosive to metals. This method is formulated according to WS/T 367-2012 "Technical Specifications for Disinfection in Medical Institutions" and GB/T 27949-2011 "Hygienic requirements for medical items disinfection".

Prohibited: Do not clean or maintain the instrument while it is powered on or in operation.

Prohibited: Never pour water or other solutions into any of the instrument parts. When the instrument is energized, inflow of liquid may cause electric shock!

Note: Ethanol is a flammable and volatile liquid. Exposure can irritate eyes, skin and respiratory tract and may cause central nervous system hypofunction and liver

damage. Wear suitable protective eyewear, clothing, and gloves when cleaning with ethanol.

Biohazard: Please treat and handle all samples as potentially biohazardous.If a liquid sample is spilled or splashed, immediately sterilize with an appropriate disinfectant to avoid spreading contaminants that contaminate instruments or cause injury to laboratory personnel.

Biohazard: Do not handle or manipulate any potentially biohazardous samples without taking any safety precautions.

8. Product maintenance

The instrument does not require extensive maintenance under normal use. If the instrument is used for a long time, regular cleaning and a small amount of maintenance are required to ensure the normal operation of the instrument. Before cleaning the instrument, please read this chapter carefully. Correct maintenance and cleaning of the instrument will help prolong the service life of the instrument.

We should pay attention to the following issues in the maintenance process:

1) Arrange someone to be responsible for maintaining the machine;

2) The specific maintainer of the machine should emphasize the importance of maintenance to all users of the machine in their daily work;

3) During the maintenance work, be sure to wear gloves, work clothes to prevent infection, and protective glasses if necessary. Do not throw away the gauze used for wiping, please dispose of it properly in accordance with relevant regulations.

8.1. Daily maintenance

When the instrument is turned on every day, it can automatically complete an initialization and perform self-test reset.

8.1.1. Check the printing paper

Check whether there is printing paper in the printer, and replenish it in time, so as not to affect the printing of the experimental results.

8.1.2. Check the loading tab

Check whether there is any foreign object at the loading tab, whether the operation is smooth, and whether there is a stuck phenomenon.

8.2. Weekly maintenance

8.2.1. Clean up the printer

Check the printer to see if the print roller is glued.

When cleaning, turn off the printer, slide the upper cover limit block, and open the upper cover assembly position of the printer; turn the printing roller, and at the same time use a 75% ethanol cotton swab (should be wrung out) to wipe off the dust and stains on the surface of the printing roller;wait 5-10 minutes and close the lid when it evaporates completely.

8.2.2. Cleaning the discarded bayonet

The reagent card after the test is discharged from the discarding port. After a long time, there will be a risk of biological infection hazards. It should be cleaned and disinfected in time. When cleaning, please wear gloves and use a piece of lint-free gauze and 75% ethanol to clean only the surface. , after cleaning, please dry it with a dry cloth.

8.2.3. Clean the loading tab

The reagent card enters from the loading tab, and there is a risk of biological infection. It should be cleaned and disinfected in time. When cleaning, please wear gloves, and use a piece of lint-free gauze, cotton swab and 75% ethanol to clean only the surface. After cleaning, please dry with a dry cloth.

8.2.4. Clean the outside of the instrument

The analyzer casing or frequently touched places are very easy to become dirty. In order to keep the working environment clean and reduce biological risks, the exposed parts of the analyzer should be cleaned in a timely manner. When cleaning, turn off the switch of the immunoassay analyzer, wear gloves, and use a piece of lint-free gauze and 75% ethanol to clean only its outer surface. After cleaning, please

dry it with a dry cloth.

Precautions:

Warning:

Do not spill liquid on the analyzer to avoid liquid immersion and damage to the immunoanalyzer.

Biological Infection Hazard:

During Maintenance Work, Be Sure To Wear Gloves, Work Clothes To Prevent Infection, And Protective Glasses If Necessary.

Do Not Throw Away The Gauze Used For Wiping, Please Dispose Of It Properly In Accordance With Relevant Regulations.

8.3. Keep air circulation

This instrument requires air circulation, so periodically check the area where the instrument is placed to ensure that there is adequate ventilation and that no other objects are interfering with the air flow around the instrument.

8.4. Keep the power supply stable

The normal operation of this instrument requires a stable power supply, so please check the power supply of this instrument regularly to ensure that the power supply voltage is consistent with the voltage required by the instrument (±10% deviation is allowed). And ensure that the rated load of the power socket is not less than the requirements of the instrument.

8.5. Other maintenance

- Please use the parts provided by our company.
- For daily cleaning and maintenance of the immunoassay analyzer, please clean the surface of the immunoassay analyzer with lint-free gauze after the power is turned off, and use 75% ethanol to clean the parts of the

immunoassay analyzer.

- Users can contact the customer service center of the company if they have any questions.
- After use in a clinical setting, if the instrument does need to be repaired or replaced, it should be decontaminated before repackaging and shipping. Thoroughly scrub the outer surfaces of the instrument with an inorganic laboratory disinfectant (containing less than 0.1% bleach) and lint-free gauze. Do not spray the instrument with disinfectant or clean any internal parts and surfaces.

Warning:

Hazardous radiation exposure may result if control or adjustment devices are not used, or procedures are performed in accordance with this specification.

8.6. The key to the maintenance of system hardware

Warning:

Do not switch the immune analyzer on and off frequently, and the interval between switching on and off should be more than 1 minute.

Regularly clean and disinfect the discarding bayonet.

Do not place items on top of the immunoassay analyzer.

When moving the immunoassay analyzer, avoid vigorous shaking.

The equipment contains no operator serviceable components and regular maintenance must be performed by an authorized service technician to avoid electric shock.

9. Common faults and troubleshooting methods

Fault phenomenon	Analysis of causes	Exclusion method	Remark
The instrument can't be turned on	The power switch is not turned on	Turn on the power switch	/
	The power adapter is not connected	Please reconnect the power adapter	/
Display does not start	Screen cable failure	Contact the company customer service center	/
	Problem with the operating system	Contact the company customer service center	/
Software system failure	Operating system malfunction	Contact the company customer service center	/
	The test analysis software cannot be started	Contact the company customer service center	/
	Other prompts appear during the operation of the test analysis software	Please record the complete error message code and error message prompt, and then contact the company customer service center	/
Abnormal sound during testing	Possibly the carrier tab is stuck	Turn the analyzer power off and on, let it reset automatically, and start working again	/
	Mechanical movement failure	Please contact the company customer service center	/
The testing process stopped suddenly	Possible analyzer power outage	Turn the analyzer switch back on and test again	/

	There is a communication failure	Turn the analyzer switch back on and test again	/
	Problem still exists	Contact the company customer service center	/
Abnormal test results	Abnormal measurement results	Contact the company customer service center	/
	Pollution problem	Reduce pollution	/
Other faults	When other failures occur	Please contact the after-sales service department in time	/

Note:

The above daily failure analysis and handling methods are for reference only, if necessary, please contact the technical service personnel for handling. When the instrument fails, but the displayed error code is not in the above table, stop the operation immediately and contact the technical service personnel to deal with it.

10. Accessories list

To ensure personal safety and ensure the performance of the immunoassay analyzer, please use accessories manufactured or recommended by Dezhou Guoke Medical Technology Co.,Ltd. If necessary, please contact Dezhou Guoke Medical Technology Co.,Ltd. or your regional distributor. Please order all kinds of consumables and accessories from our company one month in advance. Do not use consumables from any other company. Some of the chemical components in them will speed up the damage of your instrument and cause greater losses. If the accessories are damaged, please contact our company or the local distributor in time for replacement.

Name	Replacement cycle and method
Power adapter	In case of aging or damage, please contact the manufacturer or agent
Network cable	In case of aging or damage, please contact the manufacturer or agent
Printer paper	If necessary, please contact the manufacturer or agent

11. After sales service, repair and destruction

For service or repair, please call: +86 534 7057266.

When the Dry Fluorescence Immunoassay Analyzer fails, please call Dezhou Guoke Medical Technology Co.,Ltd. for consultation first, and we will provide telephone technical support to help guide customers to troubleshoot.

If the instrument needs to be recalled for repair, please send the instrument back for repair as required. The general repair cycle does not exceed seven working days.

If the instrument really needs to be scrapped, the company will provide a new instrument during the warranty period.

If for some reason the user needs to destroy the Dry Fluorescence Immunoassay Analyzer, it is recommended that the user do so in accordance with the Class B Electronic Instrument Regulations.

The company declares that the above service guarantee can only be obtained if the manufacturer's instruction manual is fully complied with, and the company will not be responsible for any damage caused by this.

Dezhou Guoke Medical Technology Co.,Ltd.

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