Dry Fluorescence Immunoassay Analyzer

(FIA)

China Care Medical Equipment Co.,Ltd
Adress:Room B101, Zhongbang Business Building, PuXing Road No. 87, Tianhe, Guangzhou,
Chinaweb:www.chinacaremedical.com

User Manual

Introduction

Completely in accordance with the state bureau of technical supervision issued the manual of GB/T 9969-2008 "industrial product specification conditions", the state drug administration issued "medical equipment manual management regulation" carry on writing, conform to the enterprise standard. The contents described in this manual are completely consistent with the situation of this series of dry type fluorescence immunoassay analyzers. If there is any modification, the company will not notice.

According to the characteristics and needs of the product, this manual describes the main structure, performance, type, specification and installation, use, operation, maintenance, maintenance and storage methods, as well as the protection of operators and product safety measures, the detailed content is shown in each section.

The company has the right of final interpretation of the contents of this manual.

User Safety Tips

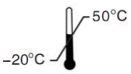
※ **Please read this instruction manual carefully before using the instrument.**

※ **Only trained technicians can use this instrument.**

At work do not stretch out his hand.

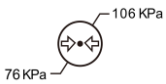
Warning label

No tumbling



Temperature range

Humidity range



Atmospheric pressure

- **Do not use wet hands to plug in the power supply, it may be electrocuted.**
- **Don't damage the wire and connection cable, etc., don't trample, twisted, pulling wire and cable, electric shock or would happen if broken wire and cable fire.**
- **Do not use damaged wires and connecting cables, etc., which may cause electric shock or fire.**
- **Do not use wires and cables that are not designed for them. If they have a small capacity, they may cause a fire.**
- **Have a abnormal action, should immediately stop operation.**
- **When you feel a burning smell or smell, abnormal error, immediately turn off the power, unplug the power cord.**
- **Must use a well-grounded power outlet, otherwise when the instrument leakage, will cause electric shock.**
- **Use and operation should be in accordance with the "User manual" provisions or instructions.**
- **Do not clean external stains with chemical agents such as turpentine oil and benzene, as it may cause color and shape changes, scrub with a soft or damp cloth, and for severe stains, clean with a cleaning agent or 75% alcohol.**
- **If screw or metal into instruments, to immediately stop affectation, qualified maintenance personnel, please remove metal start again after the operation, otherwise it may cause equipment failure.**
- **Do not put reagents and water on the instrument table to avoid liquid leakage into the instrument, causing damage to the instrument.**

Contents

I. Overview

1.1 Overview

This manual introduces the installation, operation, adjustment, maintenance and related matters needing attention of this model dry type fluorescence immunoassay analyzer in detail. Users should read this manual carefully before using the instrument.

1.2 Scope of application

The dry fluorescence immunoassay analyzer can be used in conjunction with the specific kit based on fluorescence immunochromatography, and is suitable for quantitative analysis of the tested substances in human samples.

1.3 Specifications and Models

This model.

1.4 Software Release Version

Software release version: V1

1.5 Operating environment

The instrument shall be installed in clean indoor ventilation, avoid corrosive gas and magnetic field interference, avoid direct sunshine and strong light source.

II. Technical performance

2.1 Working conditions

2.1.1 Ambient temperature: 10℃ ~ 30℃.

2.1.2 Relative humidity: ≤ 70% (no condensation).

2.1.3 Atmospheric pressure: 86 kPa ~ 106 kPa.

2.1.4 Surrounding environment: no strong electromagnetic field interference source, avoid direct exposure to strong light, with a good grounding environment.

2.1.5 Power condition: AC 220V; Frequency: 50Hz.

2.1.6 space requirements: the space required for at least can put down the instrument (length x width x height: 312 mm * 276 mm * 139 mm). No more than 2000 meters above sea level.

2.1.7 The equipment meets the emission and immunity requirements specified in part of GB/T 18268; The equipment is designed and tested according to Group I class B equipment. Users shall ensure that equipment electromagnetic compatibility environment, make the equipment can work normally. It is recommended that the electromagnetic environment be assessed before the device is used. Do not use the device near strong radiation sources (such as unshielded RF sources), otherwise it may interfere with the normal operation of the device.

2.1.8 Avoid direct exposure to strong light;

2.1.9 with good grounding environment, indoor use.

2.2 Transportation and storage conditions

2.2.1 Ambient temperature: -40℃ ~ 55℃

2.2.2 Relative humidity: ≤93%

2.2.3 Atmospheric pressure: 86kPa ~ 106kPa

2.2.4 The instrument should be restored (placed) under normal working conditions for more than 24 hours before it is taken out for use under such transportation and storage conditions. The instrument should be handled lightly. If it is to be moved, it is best to use the original packaging to prevent damage due to severe vibration. Avoid violent impact during transportation, causing

damage to packaging and products. If the used instrument is to be shipped, it should be disinfected according to the internal norms of the medical institution before shipment, and marked as "disinfected", otherwise it should be marked as "not disinfected" to remind the personnel who receive the instrument to pay attention to protection.

2.3 Technical parameters and functions

2.3.1 Input power 60VA.

2.3.2 measurement channels Single channel.

2.3.3 external touch screen displays.

2.3.4 Print the built-in micro printer, can also be connected to the external ordinary printer.

2.3.5 Interface USB, RS232, network and other interfaces.

2.3.6 Weight Host net weight: 2.5kg.

2.3.7 Volume length × width × height: 312mm×276mm×139mm

2.3.8 Service life of the product: 5 years.

2.3.9 Safety classification:

A) prevent to get an electric shock level: type I; b) Equipment class (overvoltage class) : Class II; C) the registration class is Class II.

2.3.10 Repeatability: coefficient of variation ≤3%.

2.3.11 Stability: The relative bias between the test results at 4h and 8h after the analyzer was turned on and the test results at the beginning of the stable working state should not exceed ±5%.

2.3.12 Cross contamination: Not applicable

2.4 Network security related instructions

2.4.1 Data interface: The analyzer has USB, network and other interfaces, and can export test results through the network interface;

2.4.2 The instrument has the function of user access control. When the software runs, the user name and password are required to log in. After logging in, different permissions can be set through the user level.

2.5 Components and main structures of the instrument system

System Components

After opening the package, please check each component according to the following standard table, at the same time to check whether there is loss of or damage to the equipment components.

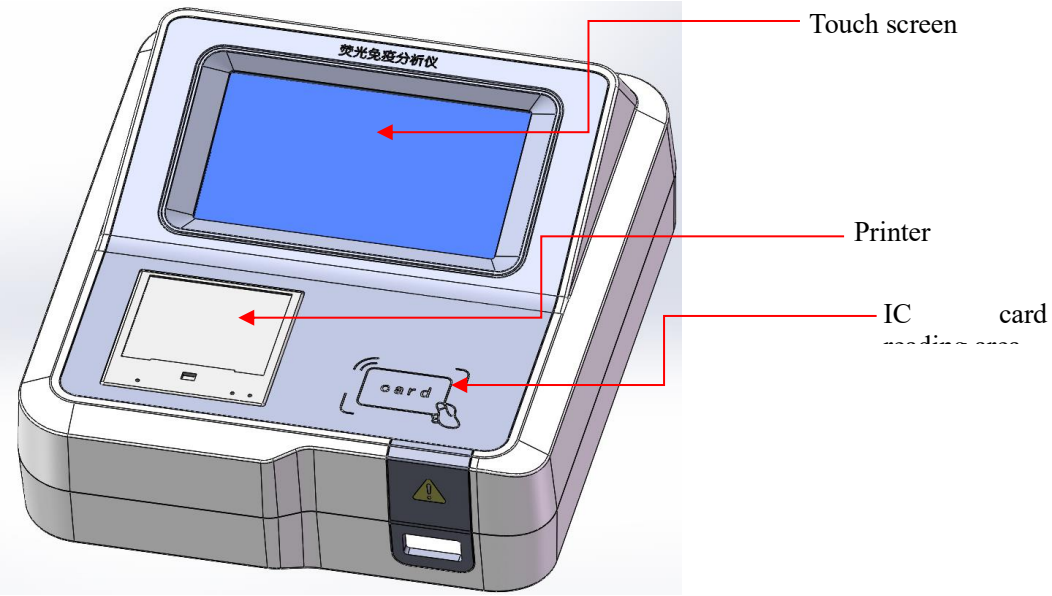
Instrument Standard Configuration Sheet

Serial number	Name	Quantity	Units
1	Main unit	1	Unit
2	Power adapter	1	Pcs
3	Printer paper	1	Roll
4	Power cable	1	Pcs
5	Certificate of QC pass	1	Pcs

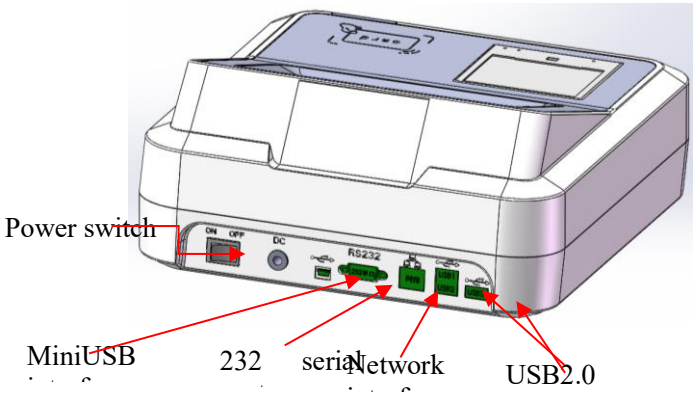
Main structure

1 Front of the instrument

Diagram of the main structure on the front



2. Side interface of the instrument



Note: the instrument appearance in kind shall prevail.

3. Structure: It is composed of optical unit (excitation module, receiving module), mechanical unit, control unit (signal processing module, measurement module, circuit control module), output/display unit (display module, printing device), system detection card and software part.

III. Installation

3.1 Installation of the main instrument

3.1.1 Open the special packaging carton of the instrument, and carefully check whether the packing list is consistent with the instrument and accessories in the packing box. If there is any missing or damage, please contact the supplier immediately;

3.1.2 After the inventory is correct, take out the instrument carefully and place it on a stable and smooth working surface to prevent strong vibration. It is very important for the optical system to keep the instrument environment clean and dust-free; Do not place the device in a position where it is difficult to operate the disconnection device.

3.1.3 Remove the power cord and power adapter of the instrument, connect the power cord to the power adapter, connect to the power jack on the right side of THIS MODEL rear panel, and connect the other end to the three-core socket installed with ground

wire;

3.1.4 Install the printing paper, open the cover of the printer, pull off the handle of the printer, pull out a little paper, cover the cover of the printer, and pull back the handle of the printer.

3.1.5 The instrument provides the interfaces required for the following connections:

3.1.5.1 USB mini interface

3.1.5.2 RS232 can be connected to a computer

3.1.5.3 LAN network interface can be connected to the network line

3.1.5.4 USB interface

3.2 Power supply and environmental requirements

3.2.1 Dry type fluorescence immunoassay analyzer normal working power supply: AC 220V, 50Hz.

3.2.2 protection grounding: dry protective earthing of the instrument USES is the power cord plug connected with the protection of network power supply ground wire method, so the required dry work when the power cord plug must be plugged into the instrument with reliable protective earthing network power (ac 220 v, 50 hz) socket.

3.2.3 The instrument should be dustproof and shockproof, and keep away from strong electromagnetic interference and corrosion places. At the same time, the instrument has no strong electromagnetic interference to the grid power supply and other equipment. The instrument is required to operate under the normal working conditions specified in Article 2.1 above. The instrument should not be placed close to the wall, and a space of no less than 20 cm should be left to ensure air circulation. The place where the power cord plug is inserted into the network power supply (AC220V,50Hz) should be left enough space to ensure that the power plug can be quickly and smoothly unplugged from the power outlet in case of emergency.

3.3 Prepare for power on

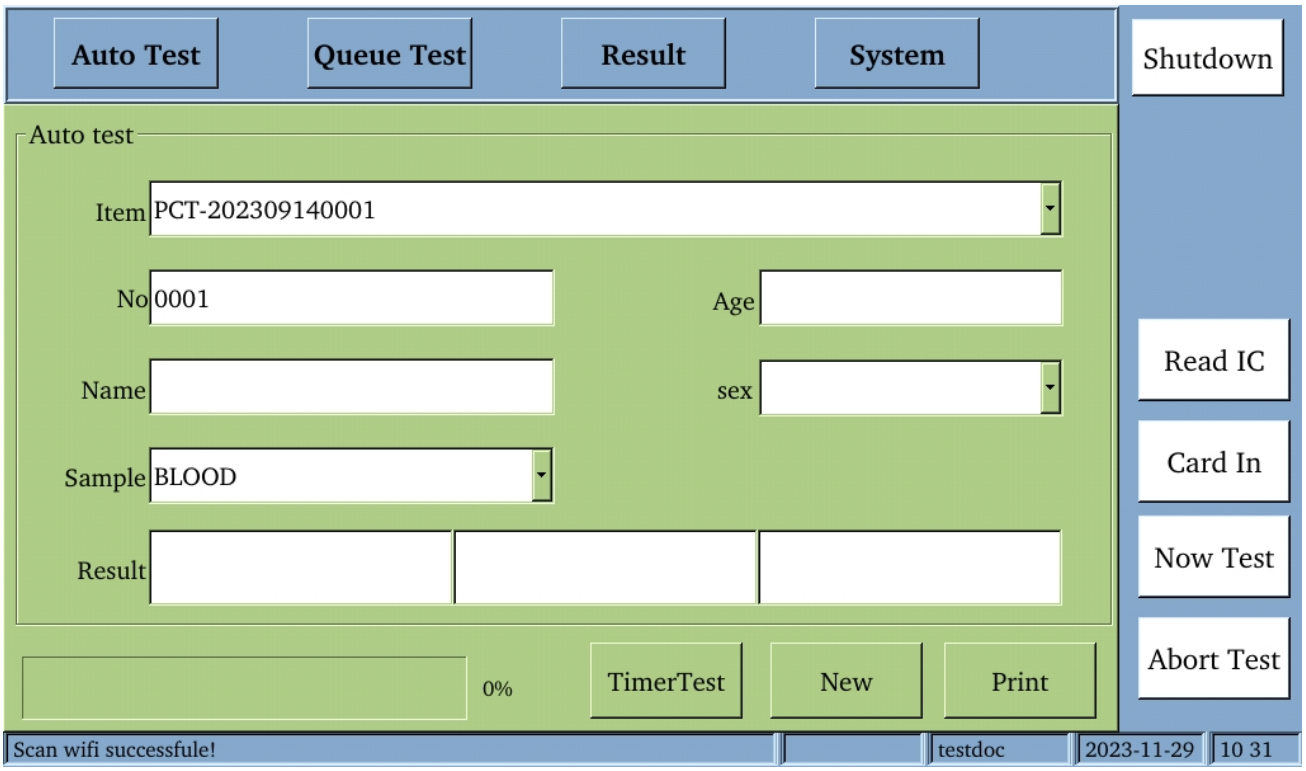
3.3.1 Turn on the power switch of the instrument, and the instrument starts and starts the self-test. (including basic software and hardware function is normal.)

3.3.2 Enter the main menu if the device is turned on normally (default automatic test mode)

2.3.3 If the system interface cannot be started normally, or some hardware is faulty, but the instrument can be entered into the system interface, please contact the manufacturer to solve the problem;

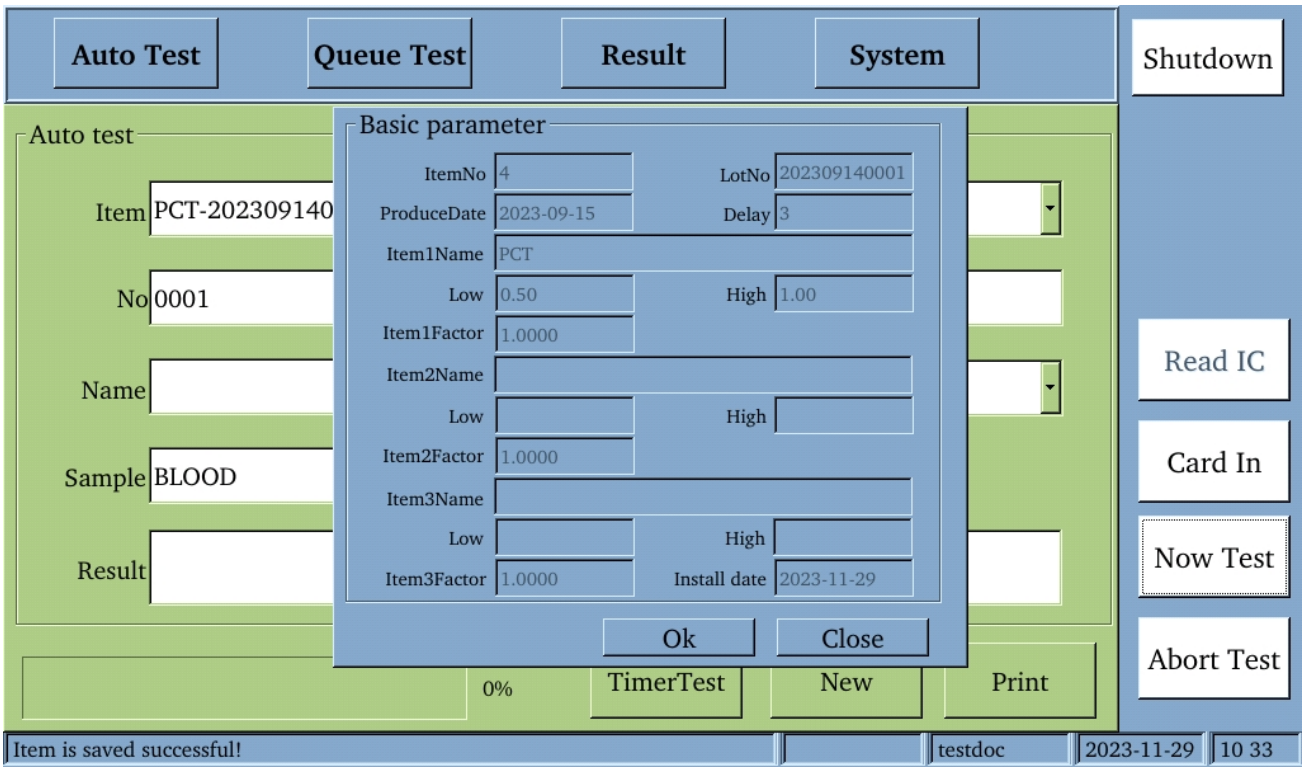
3.4 Automatic test mode

3.4.1 Automatic mode initial interface. (the system default to automatically after boot into the automatic test mode)



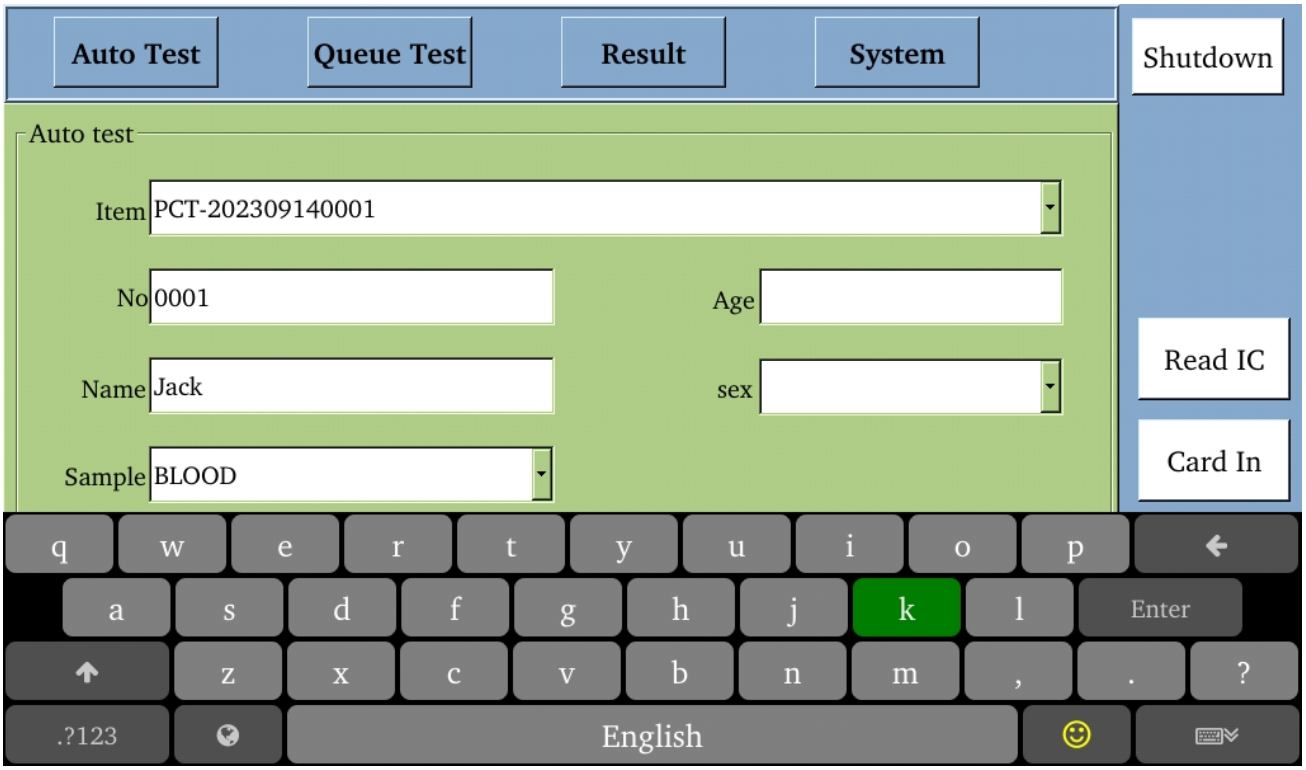
3.4.2 Automatic mode test process

3.4.2.1 Put the item IC card into the IC card reading area and click "Read IC" (save to the instrument when the card is read successfully); Check whether the project, batch number, expiry date and other information are correct in the pop-up window of "Basic Parameters", and click "Close".

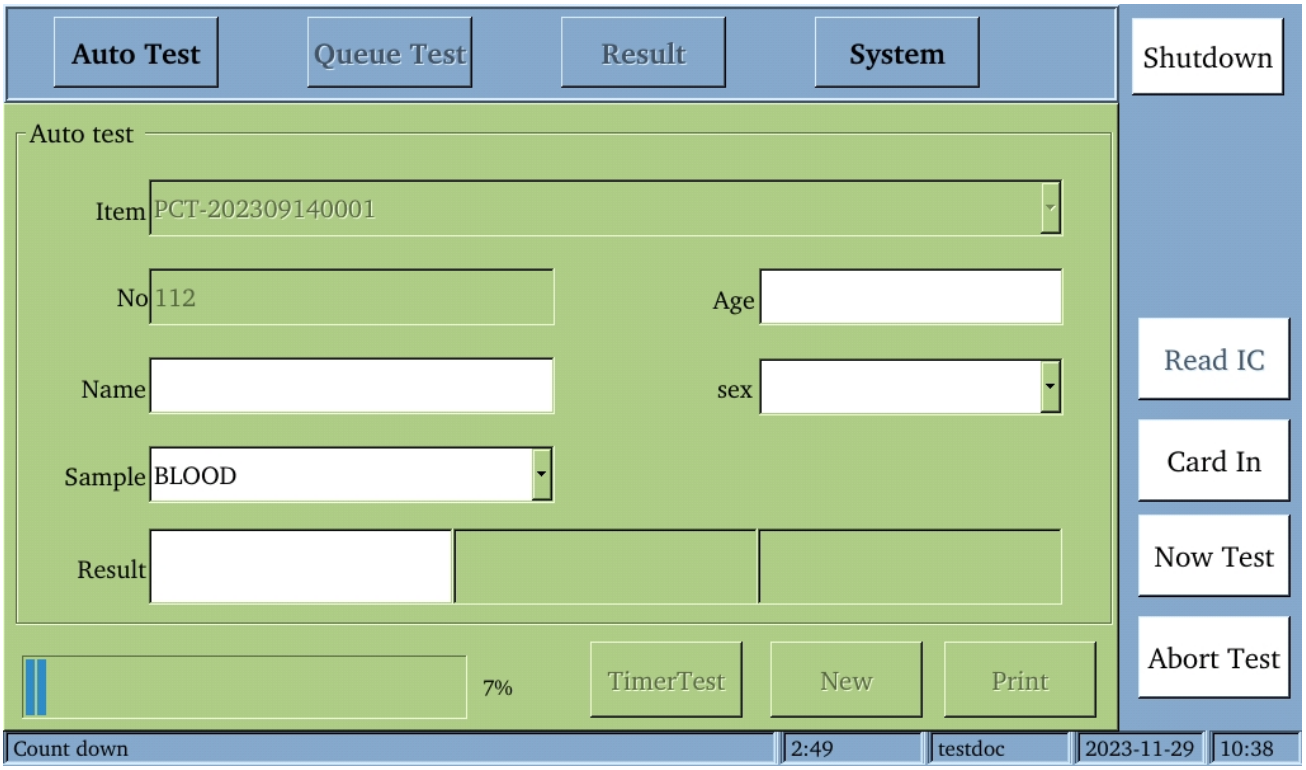


3.4.2.2 Input of sample information. Input the sample information in the test interface, including No, Age, Item, Sex, sample type

and other information.



3.4.2.3 Add the sample to the test cassette and click "Timer Test" after adding it.



3.4.2.4 click Timer test, the system to start the countdown.

After the countdown, the sample cassette is moved into the machine for internal detection, and the results are

automatically displayed after the calculation is completed.

If you want to print the result, click the "Print" button.

If you want to stop the countdown, click "Abort Test."

3.5 Now Test mode

This mode allows the user to test the sample immediately without waiting for the countdown to end.

3.5.1 Test process

3.5.1.1 First adding sample to the test cassette, and wait for reaction time to completed, and then insert the test cassette into the machine. Click on "Now Test".

When the test is finished, the results are displayed, and if you want to print the results, click the "Print" button.

3.6 Queue test mode

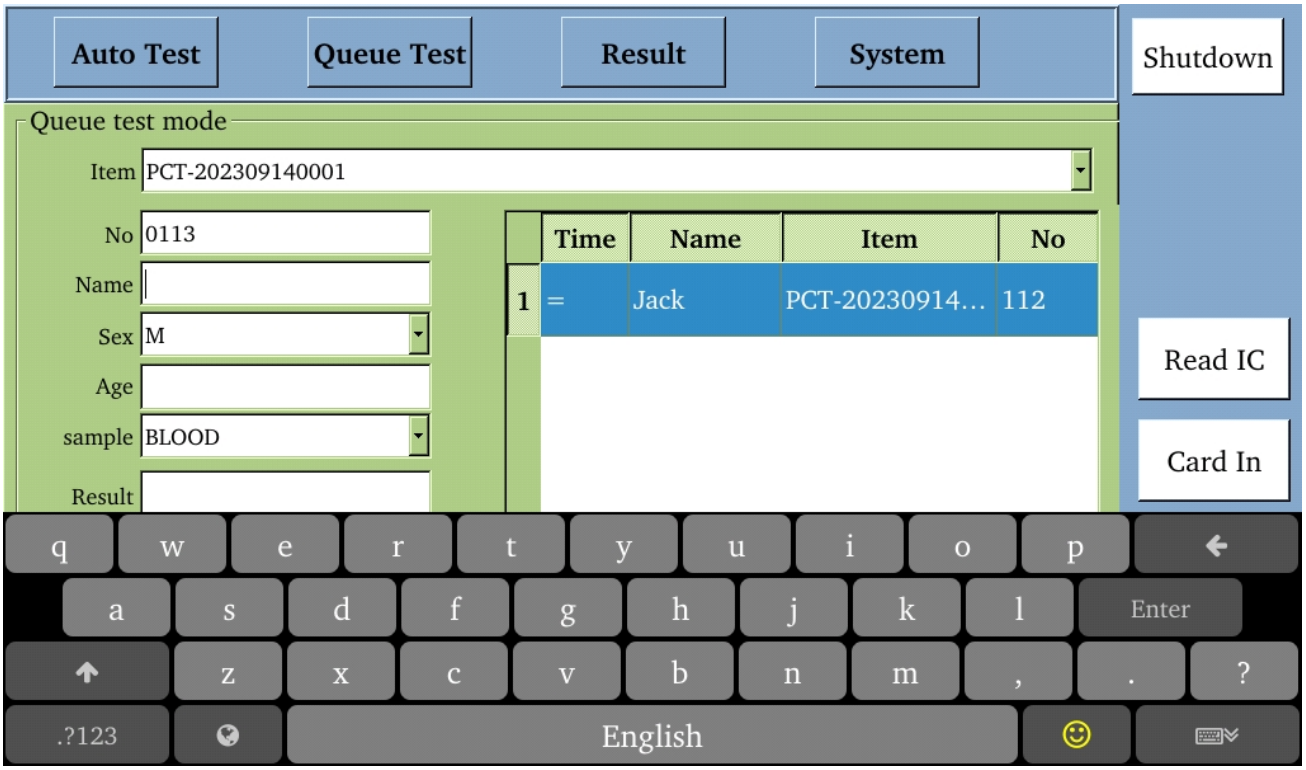
3.6.1 Enter the interface in queue test mode

Click "Test Mode" and select "Queue Mode" to enter the queuing test mode.

3.6.2 Queuing mode test process

3.6.2.1 Input of sample information

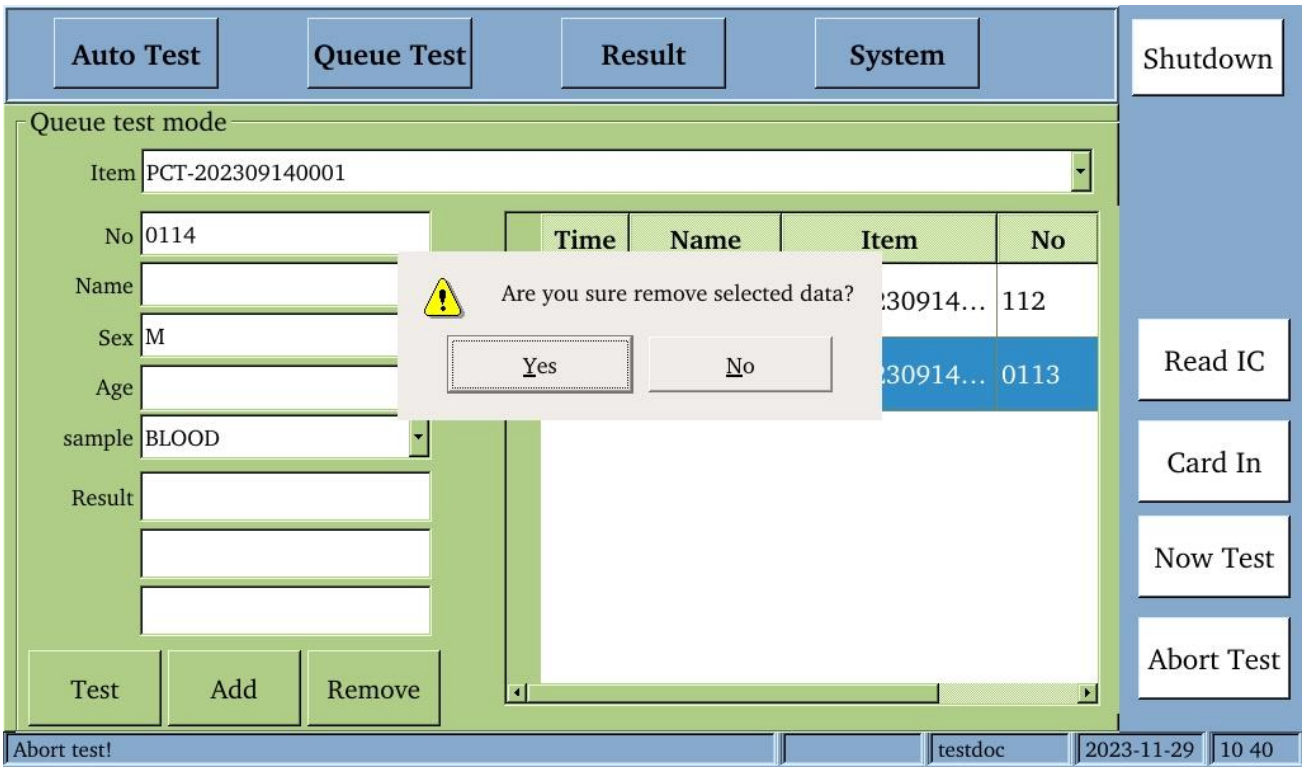
In line testing interface information input samples, such as serial number, name, sex, age, item, sample type.

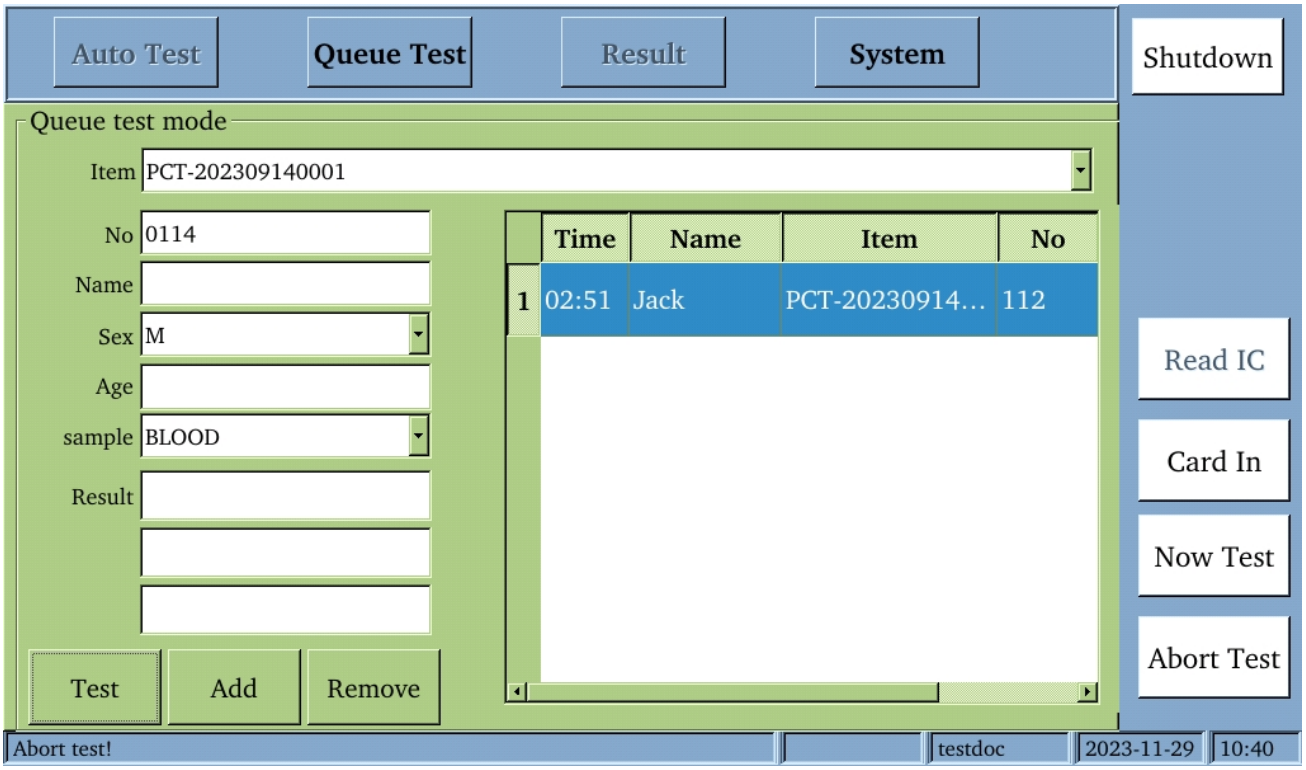


3.6.2.2 Click "Add" after filling in the information.

If a new blank queue appears, you can continue to fill in the information;

If you need to delete a group of samples, you can select the group of samples in the left "Test queue" and click "Remove".





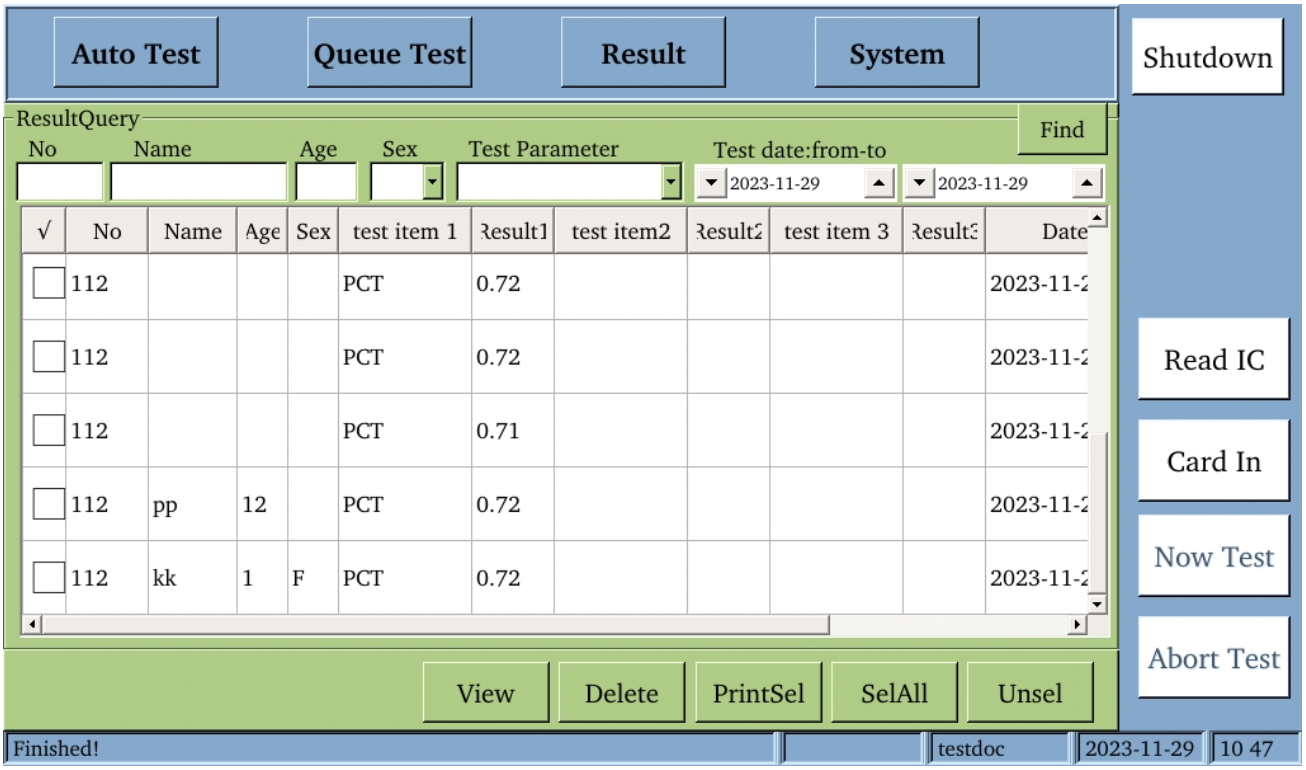
Add the sample to the test card, after adding, click test, and the sample will enter the test countdown queue;

After clicking test, there is a minimum interval (15 seconds) to start the next test. A sample test after completion and automatically according to the test result, please pull out test cassette, insert the next test cassette to continue testing.

3.7 the results of the query module

This module can query the test results, search and display the matching results according to the selected date, number,

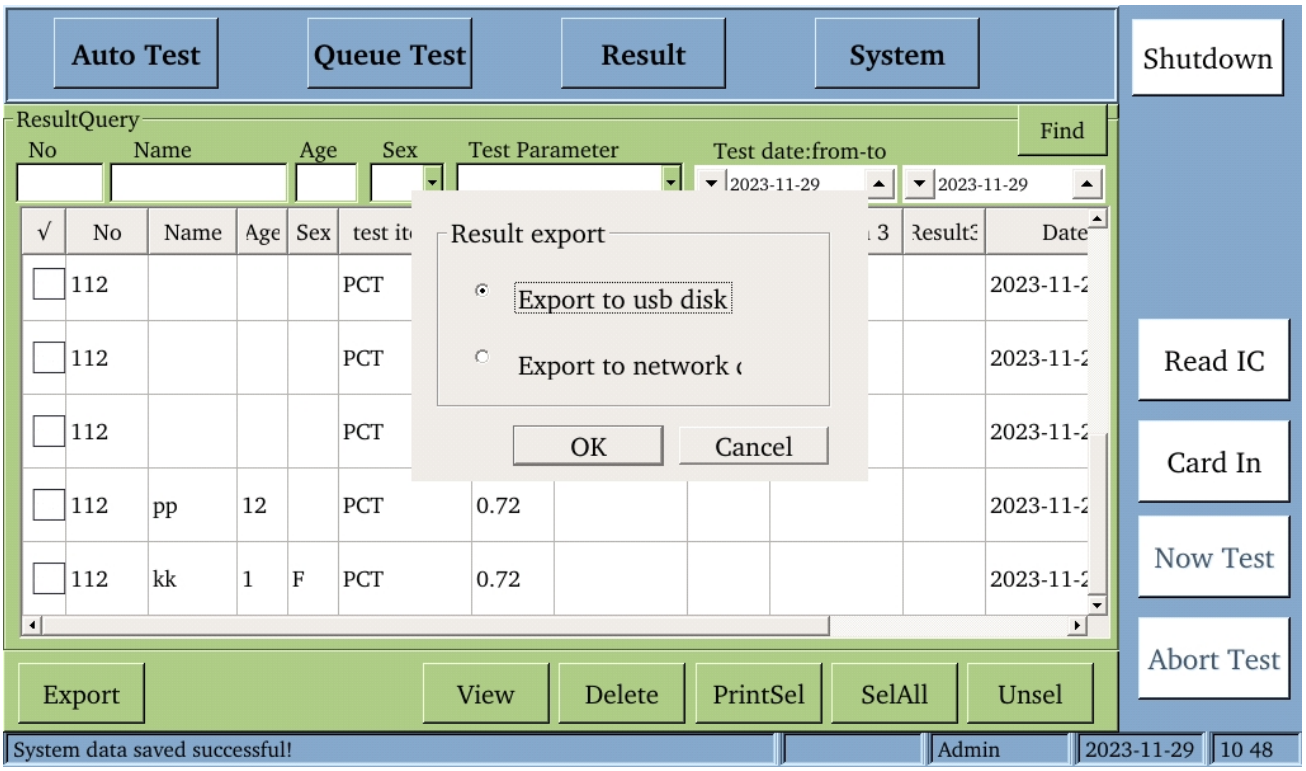
name, test item, etc.



3.7.1 Instructions for using the result query

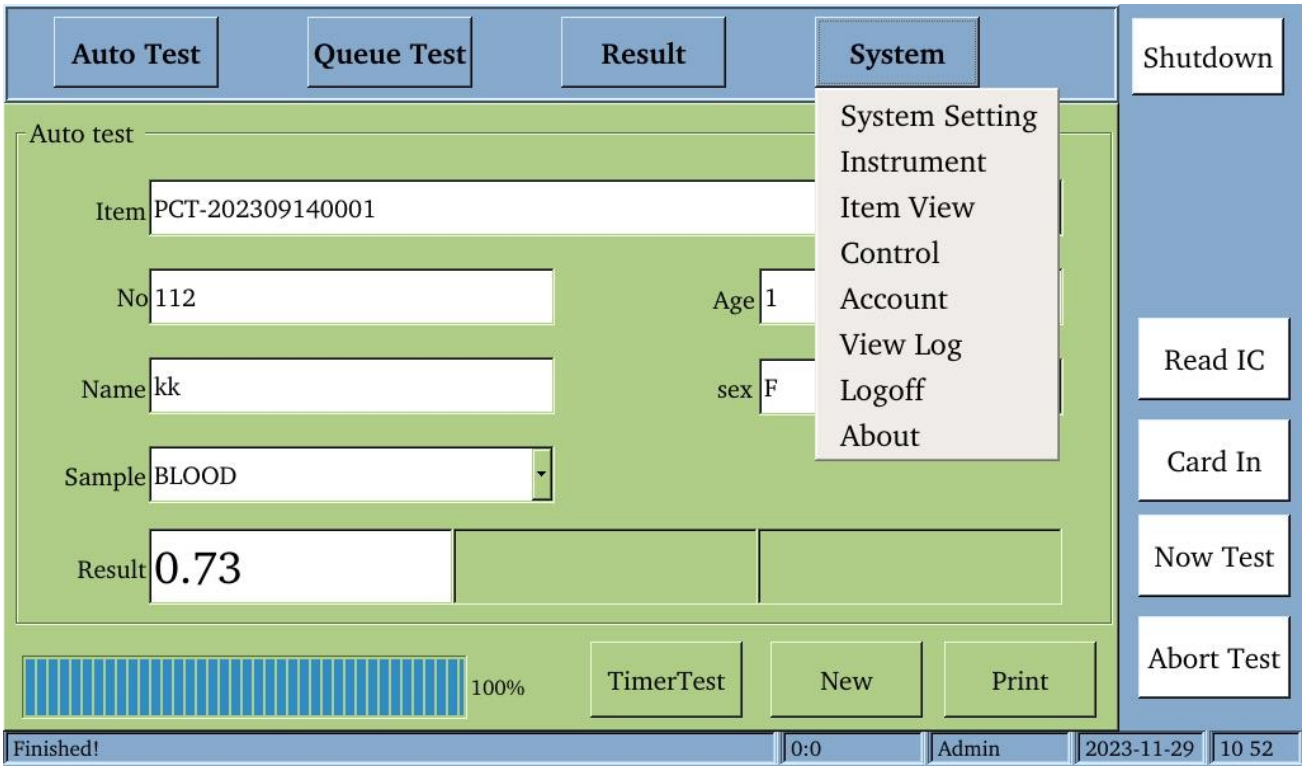
Click the "Result" button to restrict one or more search criteria in the number, name, age, gender, test item and test date.

After the search results are displayed on the screen, you can view, delete, print and export according to one or more results selected by the user. Test results export function, can be exported to the access USB drive or through the network transfer to the computer.



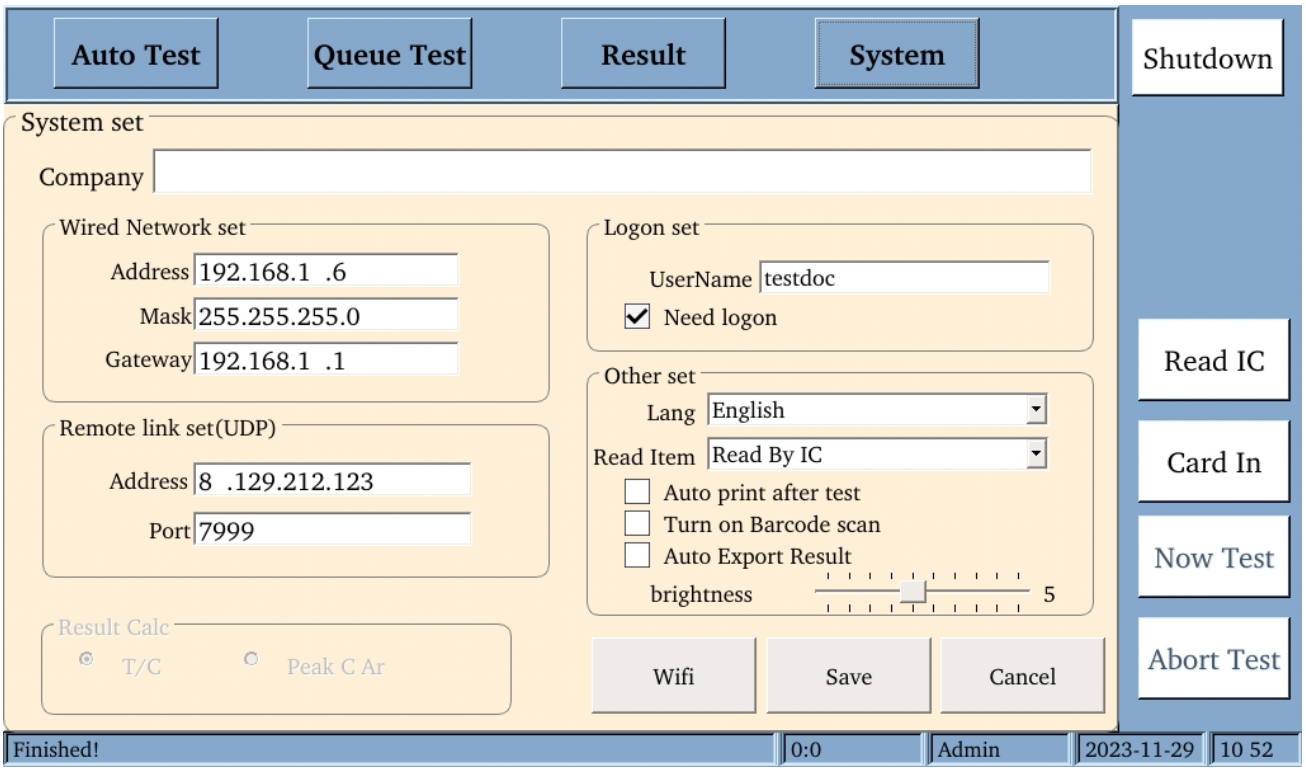
3.8 System Management module

System management includes the functions of using system Settings, Instrument, Item View, Control, Account, View Log, Logoff and About.



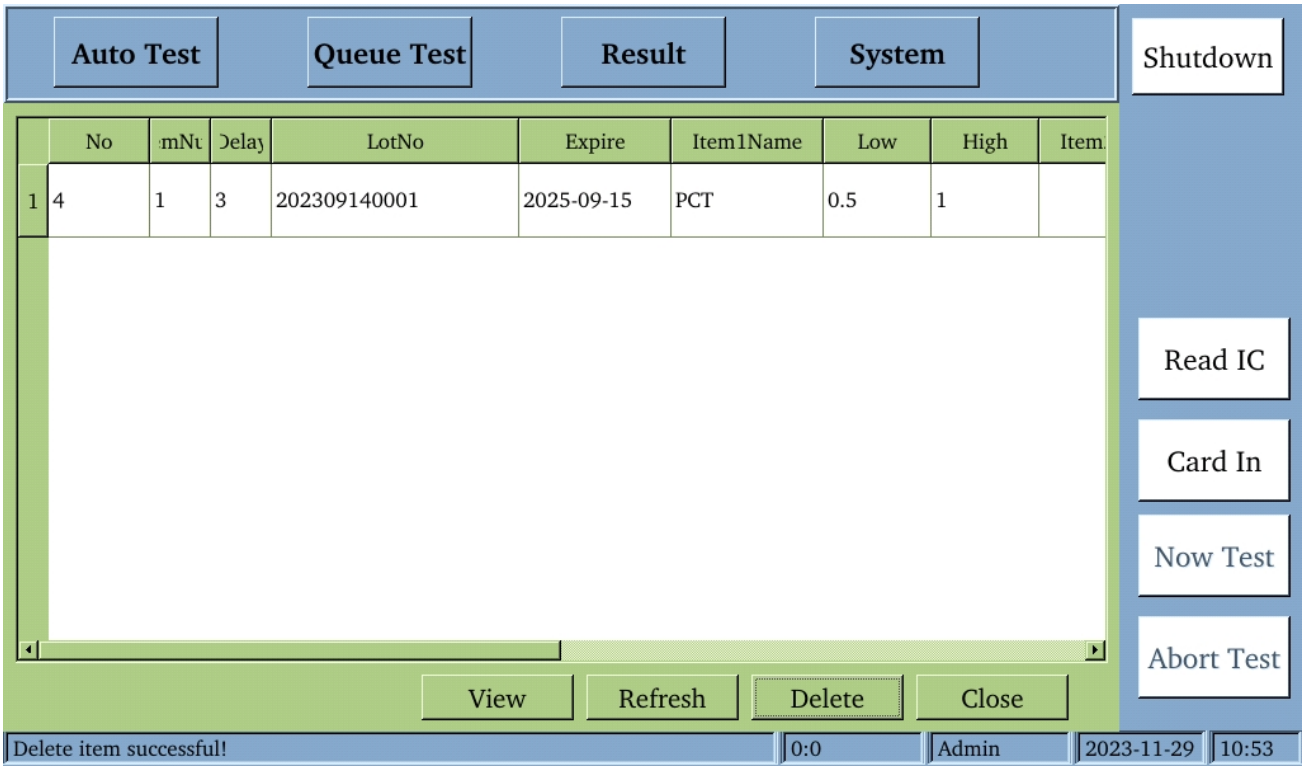
3.8.1 System Settings

You can set the name of the company, set the network address, and select the system language. You can choose the way to read the item.



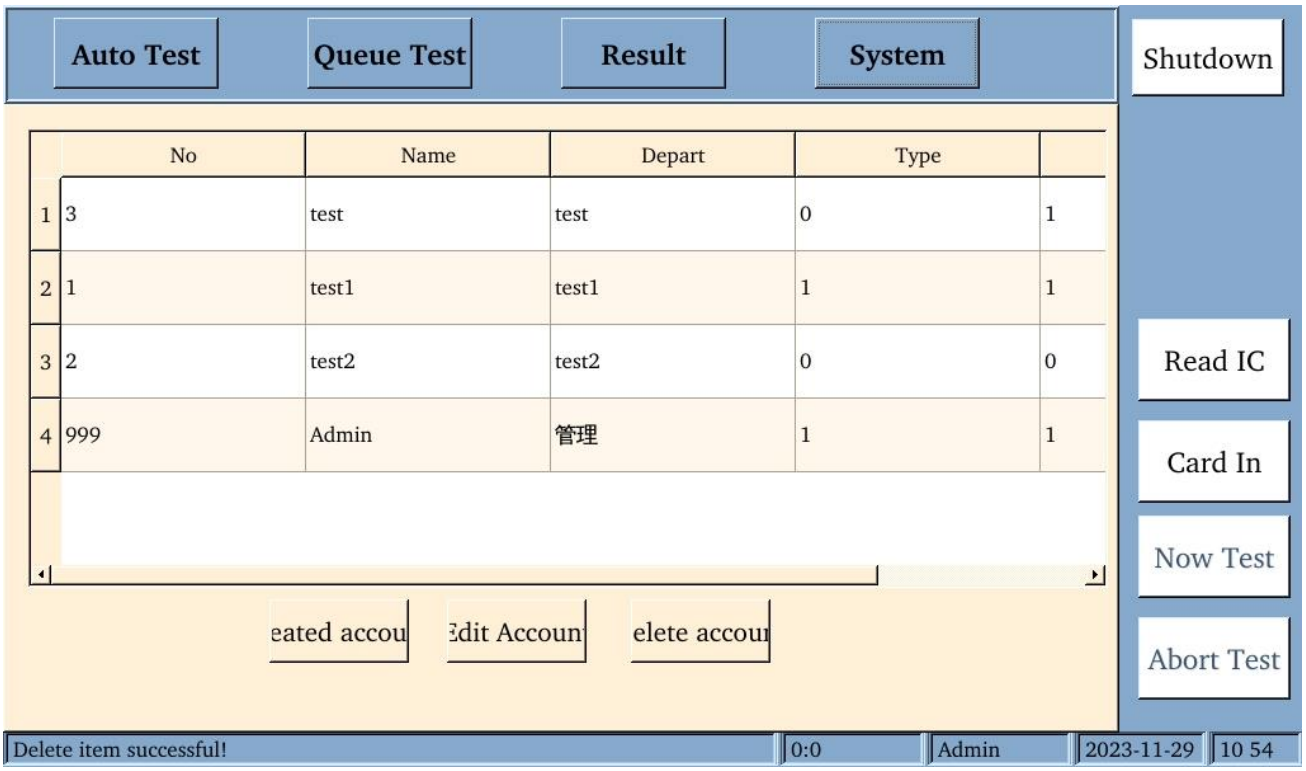
3.8.2 Item View

To view or delete the project.



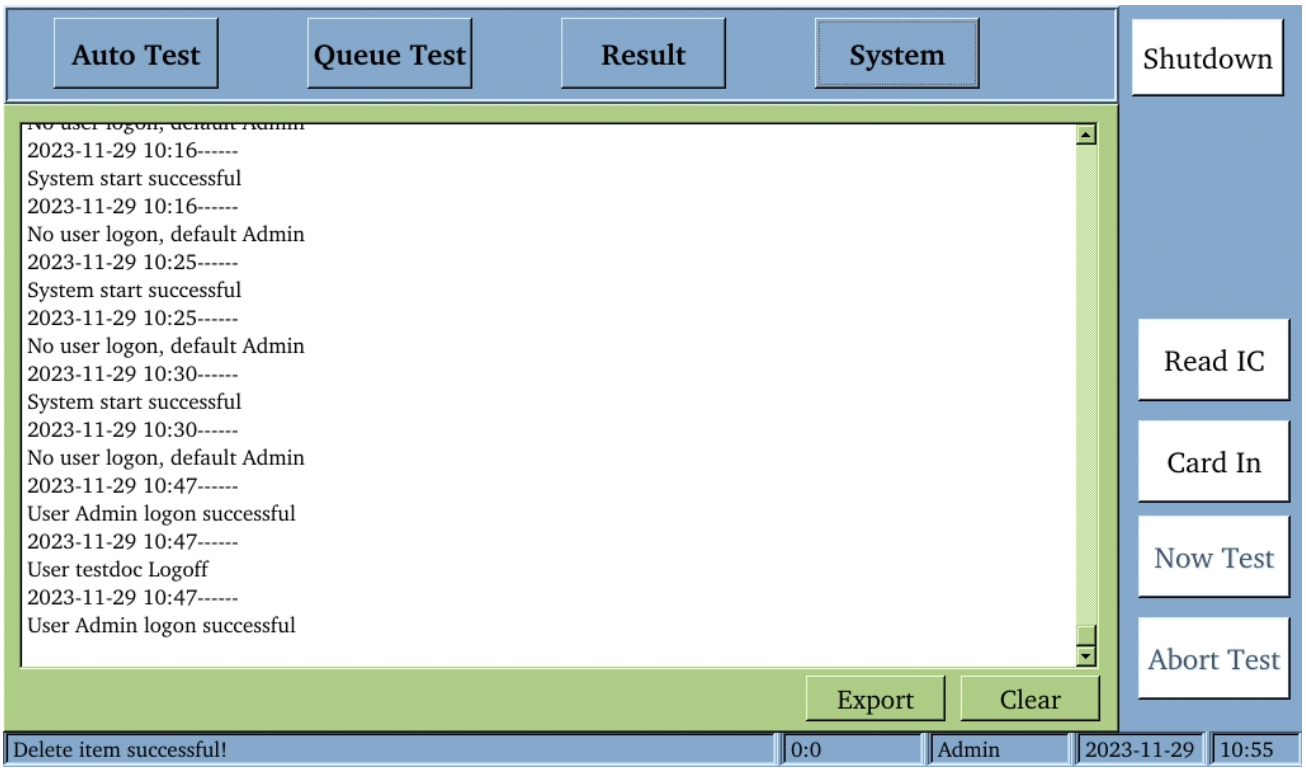
3.8.3 Account management

Can create, modify, or delete accounts.



3.8.4 View Log

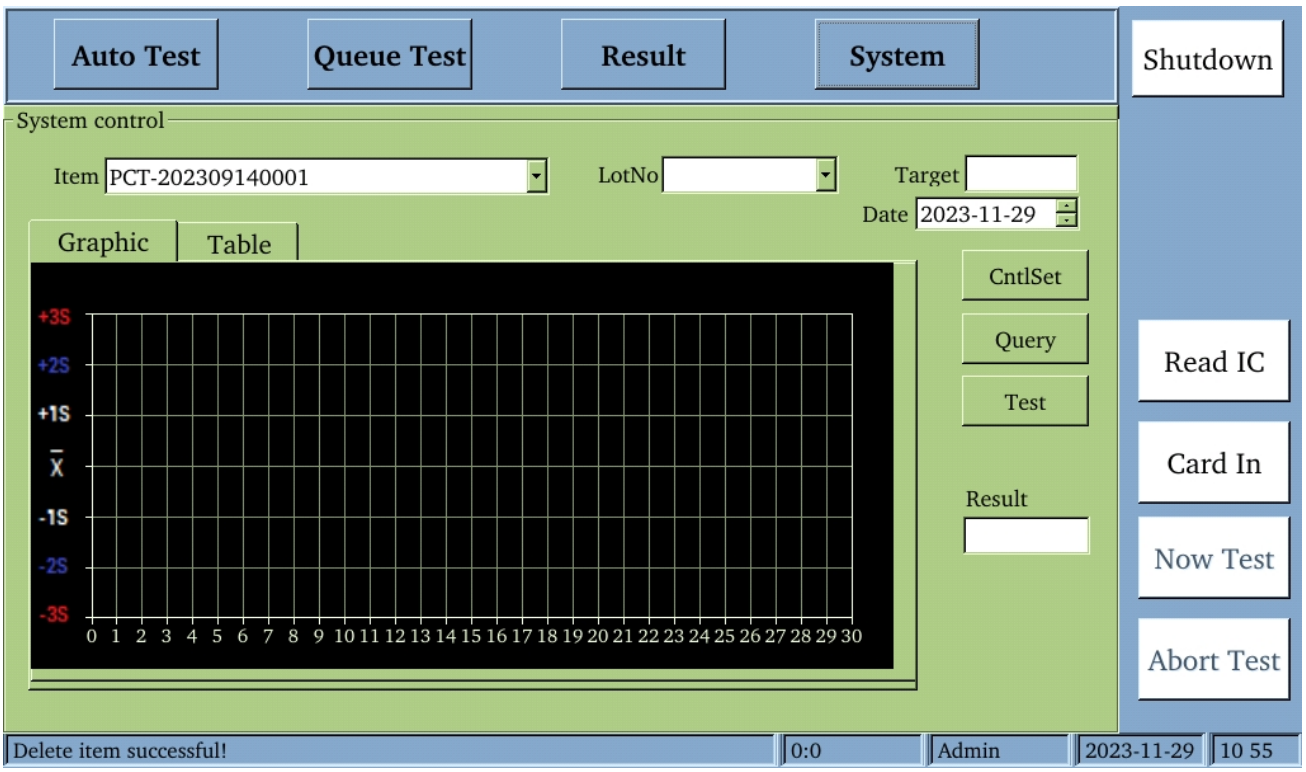
Query system login record, test failure, export login logs to instrument internal memory, again through the network function/USB, log can be exported to the computer/U disk.



3.9 System quality control

The system quality control can detect the standard quality control card, calculate the SD value through the target value, and save it in the machine. The difference value can be obtained by testing once a day for 30 consecutive days.

Test results can be presented graphically or in tabular form.

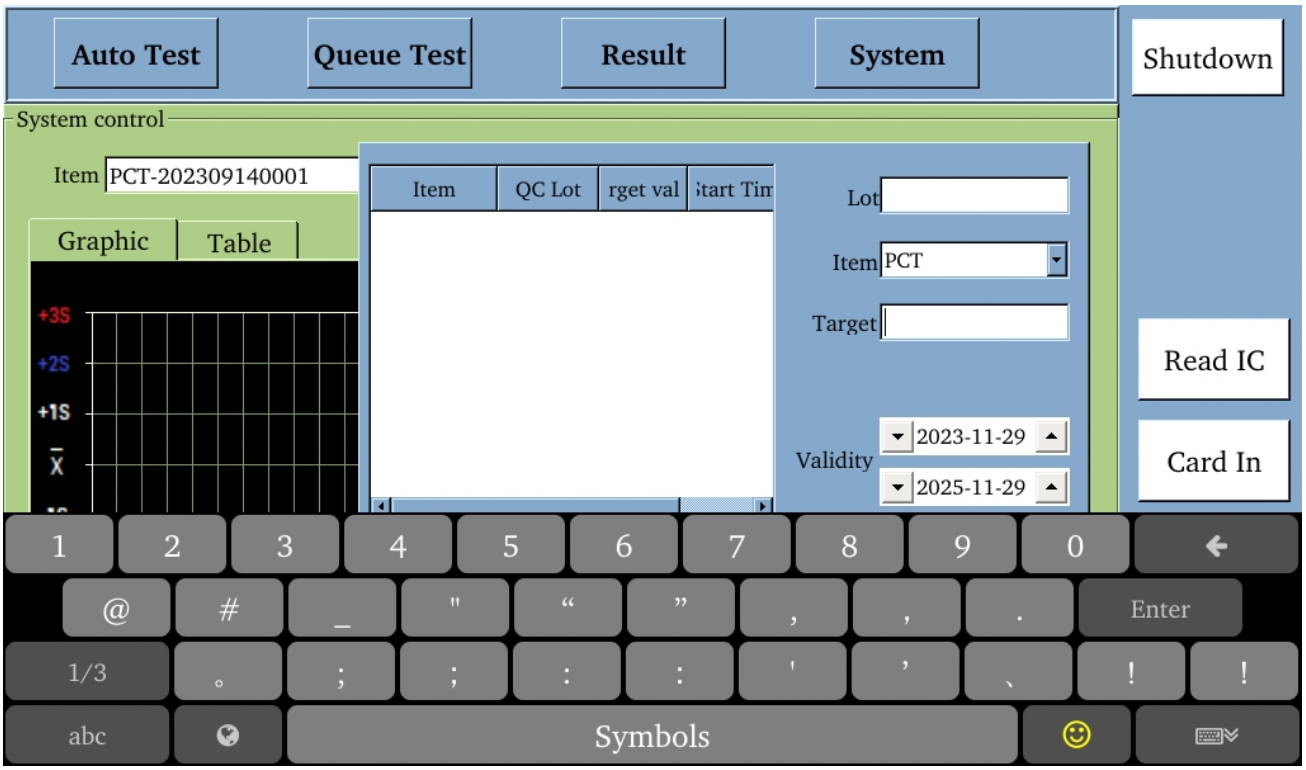


3.9.1 Instructions for Use

In the interface of "Item", "Lot No", fill in the "Target value" and "start date".

Click "Determine".

3.9.2 Quality control Settings



Quality control Settings allow users to add or delete quality control items.

Fill in the quality control, target value, and the period of validity, batch number, project click save.

3.10 Shut down the machine

Use the Shutdown button to safely turn off the instrument.

IV. Matters needing attention

4.1 Users should read this manual carefully before using the instrument.

4.2 Do not place items that are not related to the fluorometer reading on the work table so as not to affect the movement of the bracket.

4.3 use end or when not in use for a long time to turn it off and unplug the power plug.

4.4 During operation, if not used according to the prescribed method, the protection provided by the equipment may be damaged!

4.5 The remaining test samples and accessories after the use of the instrument should be treated before being discarded, so as to meet the requirements of national regulations and local environmental organizations.

4.6 please wear lab coats, especially close to the instrument location was laid.

4.7 The manufacturer declares that the instrument and its internal parts are designed and manufactured in accordance with guidelines to avoid hazards to the operator's safety.

4.8 The use of the instrument does not guarantee that there is no harm to the exposed parts of the body.

4.9 The manufacturer reminds that all parts of the instrument may come into direct contact with blood and serum and must be treated as potential infectious agents.

4.10 For handling potentially contaminated serum, the operator must wear: test coat, disposable gloves and safety glasses to avoid spatter, spillage of the dye solution and possible contact with any exposed parts of the body.

4.11 In case of failure, turn off the power immediately, cut off the power cord, contact with the dealer or manufacturer, do not open the equipment without authorization, do not connect the power supply, turn on the power supply of the equipment without the manufacturer to detect the faulty products, to avoid secondary damage to the equipment and cause danger to the human body.

V. Daily maintenance

5.1 Maintenance

5.1.1 In order to ensure the continuous stability and accuracy of this model dry type fluorescence immunoassay analyzer, do not place the instrument in the environment with strong magnetic field interference, and at the same time, the environment should be ensured to have good ventilation and air permeability.

Note: The maintenance inspection should be completed by the manufacturer and its agents or other qualified personnel; For parts that need to be replaced, use parts provided by the manufacturer and its agents. Failure to use the control or adjustment device, or perform the steps as described herein, may result in harmful radiation exposure.

5.2 Cleaning

5.2.1 to turn off the power switch and unplug dry power plug of the instrument, and network to ensure that the instrument power disconnect.

5.2.2 use disposable gloves, use dry, clean cloth to wipe the MPP bracket on the residual liquid.

5.2.3 Use disposable gloves and a disposable rag with less water or mild detergent to clean the external surface of the instrument. After using dangerous infectious substances, disinfect the instrument with the following methods:

Warning: Turn off the power switch and unplug the dry immunofluorescence analyzer first.

5.3 Disinfection

5.3.1 Use disposable gloves, and use a disposable wipe cloth with 75% ethanol (damp cloth, not dripping liquid) to clean the inside and outside surface of the microplate holder and door of the instrument.

5.4 Periodic check

Periodic	Checking part	Checking content	Purpose
Every day,	Power supply	Plugs, sockets, power supply cord	Prevent bad contact or even electric leakage from injuring people
Every day,	The moving parts	Sample delivery parts	Prevent accurate positioning when reading

VI. Troubleshooting

Trouble	Reasons	How to solve
Instrument no response	Power failure	Check the power plug
	Poor wire contact between the instrument and the adapter	Unplug the power cord and rewire it
	The power switch is not turned on	Power on
	Damaged power adapter	Call the manufacturer's customer service
Run over but no result	Excessive computational load	Wait until the calculation is complete
	Calculate exceptions	Turn off the power and turn on again
Detection card holder is not ejected	Initialization exception	Click on the "card out"
	Mechanical failure (noise)	Call the manufacturer's customer service
	Software abnormality	Turn the power off and then restart
Abnormal display	Electrostatic effect	Steps 1 Place the instrument on the ground to release static electricity 2 Turn on again
	Circuit fault	Call manufacturer customer service
Test card detection and in and out having noise	The normal mechanical voice	No need
Information: Test card does not conform	Test card lot number and IC card information do not match	Check whether the test card and IC card is consistent
Info: Error in reading the card number	The IC card was not placed in the specified area	Place the IC card in the IC card reading area to re-read
	Mechanical failure	Call the manufacturer's customer service

VII. Maintenance services

7.1 Maintenance

1. The non-artificial damage, one year free warranty manufacturer; After the warranty period, the manufacturer is responsible for maintenance, and charge a reasonable fee. For service or repair, call the manufacturer: the instrument generally does not require special maintenance other than paper replacement or regular cleaning, and wiping the external surface of the instrument with a soft dry cloth will ensure the proper operation of the instrument.

2. During the warranty period, the user shall not disassemble and assemble the parts that are not allowed in the manual, so as not to expand the fault due to unfamiliarity, otherwise the maintenance cost shall be borne by the user during the warranty period.

3. If the user wants to repair itself, should be made by qualified technical personnel in the familiar with the structure of the instrument and circuit principle of rear can repair, and maintenance personnel in the quality of instrument maintenance after the

personal safety of manufacturers disclaim all responsibility.

4. If users need to order instrument parts or repair the instrument, they can contact the after-sales service department of the manufacturer.

7.2 recall process

If the instrument fails, please call our customer service representative for consultation first. If the equipment is really need returned to the factory, you will get a back number. We will send a replacement dry type fluorescence immunoassay analyzer. The customer can check the recall number on the package and ship the faulty instrument back in this replacement package.

7.3 Transportation

The packaged instrument can be transported with general tools. During the journey, attention should be paid to preventing moisture, sun protection and shock. The transportation requirements should be the same as the contract rules according to the order.

7.4 Storage

The packaged instrument should be stored in a room with stable -40℃ ~ 55℃, relative humidity less than or equal to 93%, no corrosive gas, and good ventilation.

7.5 Destruction

If, for any reason, the user wants to destroy the instrument, the user is advised to do so according to the Category B Electronic instrument list.

VIII. Manufacturer

Product name: Dry fluorescence immunoassay analyzer

Input power: AC220V ~ 50Hz

Input power: 60VA

Production license number: Guangdong Food and Drug Supervision and Equipment Production license 20173022

Medical Device Registration Certificate No. : Yue Device Registration No. 20222220842

Date of production and the life: see the label

Appendix 1 Technical Specifications

Appendix 1.1 Environmental Requirements

The equipment meets the environmental requirements stipulated in GB/T 14710-2009 "Medical electrical equipment Environmental requirements and test Methods".

		Storage and shipping	Work
analyzer	**Ambient temperature**	-40℃ ~ 55℃	10 ℃ ~ 30 ℃
	Relative humidity	25% RH to 93% RH (No condensation)	25%RH ~ 70%RH (No condensation)
	Atmospheric pressure	86 kPa -106 kPa	86kPa -106 kPa

Appendix 1.2 Mechanical and Electrical Specifications

Instrument Category	POCT
Mainframe mechanical dimensions	**Length 312mm* width 276mm* height 139mm**
Host net mass	2.5Kg (adapter not included)
LCD screen	External touch screen display 7 inches, resolution
Power supply	Adapter input voltage 100 v ~ 240 vac, the input current is 1.4 A, input frequency 47 ~ 63 hz The rated output voltage of the adapter is 12V and the output power is 60W
Communication interface	3 USB ports, 1 miniUSB port, and 1 Ethernet port The data packet loss rate should be no more than 1%

Appendix 2 EMC

Appendix 2.1 Guidelines and Manufacturer's Statement

Guidelines and Manufacturer's Statement - Electromagnetic Emission - for all equipment and systems.

Note:

- The dry type fluorescence immunoassay analyzer meets the emission and immunity requirements specified in GB/T 18268.26, as shown in the table below.
- The user is responsible for ensuring the electromagnetic compatibility environment of the equipment so that the equipment can work properly.
- It is recommended that the electromagnetic environment be assessed before the device is used.

Warnings:

- Banned in strong radiation source (for example, the shielding of the rf source) by using this equipment, otherwise it may interfere with equipment to work normally.
- **Table I:**

Electromagnetic emission	
Launch test	**Compliance**
GB 4824 Conducted emission	Group 1 Class B
GB 4824 Radiation emission	
GB 17625.1 Harmonic emission	Class A
GB 17625.2 Voltage fluctuation/flicker emission	Conform

Appendix 2.2 Guidelines and Maker's Statement

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity - for all equipment and systems.

Table II:

Electromagnetic immunity			
Immunity test items	**Basic standards**	**Test values**	**In line with the performance criterion**
Electrostatic Discharge (ESD)	GB/T 17626.2	Contact discharge: ±2kV, ±4kV Air discharge: plus or minus 2 kv, plus or minus 4 kv, plus or minus 8 kv	B
Radio frequency electromagnetic fields	GB/T 17626.3	3V/m, 80mhz-2.0ghz, 80%AM	A
Pulse train	GB/T 17626.4	Power cord: ±1kV(5/50ns,5kHz)	B
Surge	GB/T 17626.5	Line to ground: ±2kV Line to line: ±1kV	B
Rf conduction	GB/T 17626.6	The power cord: 3 v/m, 150 KHZ to 80 MHZ, 80% for AM	A
Power frequency magnetic field	GB/T 17626.8	3A/m, 50Hz	A
Voltage drop, interruption	GB/T 17626.11	1 cycle 0%; 40% for 5 cycles; 25 cycles 70%; 5% for 250 cycles	B C C C
Performance discrimination: A. During the test, the performance was normal within the normative limit. B. During the test, the function or performance is temporarily reduced or lost, but it can recover spontaneously. C. Temporary reduction or loss of function or performance at the time of the test that requires operator intervention or system reset			

Our company states that:

- The dry type fluorescence immunoassay analyzer meets the electromagnetic compatibility requirements of GB/T 18268.1-2010 and GB/T 18268.26-2010.
- This equipment complies with GB 4793.1-2016 "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements" and GB 4793.9-2013 "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 9: "Special requirements for automatic and semi-automatic equipment for analytical and other purposes for laboratory use", "Safety requirements for electrical equipment for measurement, control and laboratory use", YY

0648-2015 "Safety requirements for electrical equipment for measurement, control and laboratory use part 2-101: Special requirements for medical equipment for in vitro diagnostics (IVD)"."

- The equipment meets the environmental requirements specified in GB/T 14710-2009 "Medical electrical Environmental requirements and test methods".

- **It is forbidden to use this equipment near strong radiation sources, otherwise it may interfere with the normal operation of the equipment.**
- **Keep the system dry and avoid moving it from a cold place to a warm place quickly, otherwise it may condense and cause electrical safety risks.**
- **When using this system, make sure that the date and time of the system are consistent with the current date and time, otherwise it may cause misdiagnosis.**
- **This instrument is only used for out-of-donor diagnosis.**
- **Dimensions of the machine: length 312mm* width 276mm* height 139mm, net weight (2.5Kg), etc.**
- **The instructions must be consulted in all cases marked with this symbol.**

China Care Medical Equipment Co.,Ltd
Adress:Room B101, Zhongbang Business Building, PuXing Road No. 87, Tianhe, Guangzhou,
Chinaweb:www.chinacaremedical.com