

Intellectual Property

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Statement

Genrui shall be liable for product safety, reliability and performance provided that the following requirements are met:

- 1) All installation operations, expansions, changes, modifications and repairs of this product are conducted by Genrui authorized personnel.
- 2) All replaceable parts involved in maintenance as well as the related accessories and consumables are original or

approved by Genrui.

- 3) Any associated electrical equipment complies with national standards and the requirements of this manual.
- 4) Use and operation of this product are performed in strict accordance with this manual.

Warranty

Genrui warrants that Genrui' products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- Damage caused by accidents.
- Damage caused by mishandling during shipping.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by improper operation or repair by unauthorized service people.
- Malfunction of the analyzer whose serial number is not legible enough.
- Others not caused by instrument itself.

If a product covered by this warranty is determined to be defective because of defective materials, components or workmanship, and the warranty claim is made within the warranty period, Genrui will, at its discretion, repair or replace the defective part(s) free of charge.

Customer Service Department

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⚠WARNING

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

- This analyzer can only be operated by test professionals, doctors or laboratory technicians who have been trained by Genrui or its distributors.
- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.
- Be sure to operate the analyzer under the situation specified in this manual; otherwise, the analyzer will not work normally and the test results will be unreliable, which would damage the analyzer components and cause personal injury.

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NOTE

This operation manual is written for the following laboratory professionals:

1. Daily system operator.
 2. Personnel for system maintenance and troubleshooting.
 3. Learners for system operation.
-

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Introduction

We would like to sincerely thank you for choosing to purchase Genrui product.

Please read this manual carefully in order to ensure correct use of the product. After carefully reading this manual, please keep it safely stored so that you can refer to it when necessary.

Product Name: Quantitative Immunoassay Analyzer

Model: FA50

Product Composition: The analyzer is mainly composed of the host, which includes microprocessor, detection system, LCD screen and printer.

Scope of Product Application: The analyzer is used to quantitatively test human samples with particular dry reagents, which are based on the immunofluorescence technique.

Manufacturer: Genrui Biotech Inc.

Registered Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China

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Date of Manufacture: See the nameplate of the instrument

Manual Preparation Date: August 22, 2019

Manual Revision Date: January 7, 2021

Item No.: P01.91.300417-02

REF 51000001

FCC ID: 2AZC7FA5001

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Manual Overview

This chapter introduces how to use the operation manual of your FA50 Quantitative Immunoassay Analyzer (hereinafter called the analyzer). This manual is supplied with the analyzer and contains detailed descriptions of the usage, function and operation of the analyzer. Before operating the analyzer, read this manual carefully and understand its contents, in order to use the analyzer properly to play its best performance and guarantee the operator's safety.

NOTE

●Strictly follow instructions in this manual to operate the analyzer.

Who Should Read This Manual

This manual contains information written for clinical laboratory professionals or trained doctors, nurses or laboratory technicians to:

- 1.Learn about hardware and software of the analyzer.
- 2.Set system parameters.

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3.Perform daily operations.

4.Perform system maintenance and troubleshooting.

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How to Find Information

If you want to...	Please refer to...
learn about the use of the analyzer	1.Precaution, warning and note
learn about the installation requirements	2.Installation
learn about the intended use and measurement parameters of the analyzer	3.System Description
learn about the measuring principle and process	4.Working Principle
learn about the settings of date, time, parameters, units, etc. and result query	5.Interface and Operation
learn about the sample collection and preparation methods and sample analysis process	6.Sample Test Process





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If you want to...	Please refer to...
learn about the maintenance, service and detection methods	7.Maintenance
learn about fault causes and handling methods	8.Troubleshooting
learn about the transportation and storage conditions of the analyzer	9.Transportation and Storage
learn about common reagents and consumables for the analyzer	10.Reagents and Consumables
learn about the technical specifications of the analyzer	Appendix A. Specifications
learn about the hazardous substances that may contain in the analyzer parts	Appendix B. Hazardous Substances

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Symbols

You will find the following symbols in this manual:


Symbols	Meaning
	Alerts the operator to follow the statement below the symbol, otherwise it may take the risk of potential biohazard.
 WARNING	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may cause personal injury.
 CAUTION	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may lead to analyzer damage or unreliable analysis results.
 NOTE	Alerts the operator to follow the statement below the symbol, which emphasizes the important information or special attention to be paid while in operation.

You may find the following symbols on the analyzer, reagent, QC or calibrator:







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Symbols	Meaning
	Consult accompanying documents.
	Inflammation Do not use inflammable hazardous articles near the instrument, such as alcohol, diethyl ether, etc.
	Electric Shock 1) When the power supply is turned on, unauthorized service technicians are prohibited to open the analyzer's panel. 2) Avoid spilling any liquid onto the workbench. If liquids penetrate into the analyzer, please turn off the power supply immediately and contact Genrui promptly.
	Strong Light Do not stare at the laser beam directly, otherwise, the eyes will be injured.







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Symbols	Meaning
	<p>Biohazard</p> <p>Description for this label:</p> <p>background color – yellow</p> <p>symbol and outline – black</p> <ol style="list-style-type: none">1) All the test samples, calibrators, quality controls, etc. should be regarded as infectious. Gloves should be worn when handling them.2) All the waste liquids should be regarded as infectious, gloves should be worn while in touch; All the items contacted with the test samples, such as test cards, pipette tips, etc. should be regarded as infectious, gloves should be worn while in contact.3) All the wastes are potentially infectious and should be regarded as medical wastes and disposed according to the current regulatory requirements.4) When the service life of the instrument ends, it should be disposed according to the local requirements of environment department; it cannot be disposed and discarded as common wastes.



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Symbols	Meaning
	Warning symbol for high temperature
	Corrosion Cleaning solution has potential chemical corrodibility. Wear protective gloves while in operation.
	Symbol for protective earthing
	Symbol for functional earthing
	Alternating current symbol
	For in vitro diagnostic use only

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Symbols	Meaning
 The symbol consists of the word "LOT" in a bold, sans-serif font, enclosed within a rectangular border.	Batch code
 A simple line drawing of an hourglass, with the bottom bulb shaded black to indicate the passage of time.	Expiry date
 The symbol consists of the letters "SN" in a bold, sans-serif font, enclosed within a rectangular border.	Serial number
 A stylized icon of a factory with a sawtooth roof and a chimney on the right side.	Production date
 A solid black silhouette of a factory building with a sawtooth roof and a chimney.	Manufacturer
 A simple line drawing of a thermometer, showing the bulb and the scale.	Storage temperature

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Symbols	Meaning
	Refer to the <i>Operation Manual</i>
	This electronic product contains some poisonous and harmful substances. The environmental protection use period is 20 years, after this period, it should be put into the recycling system.

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1 Precaution, warning and note

(1) Potential safety hazards and use restrictions

There is a potential biohazard when testing samples with this instrument, follow the related testing safety requirements of hospitals during sample processing and operations. Do not put your hands or any objects into the moving assembly of the instrument during the test.

(2) Protection measures for operators and users, as well as emergency and corrective measures that should be taken when accidents occur in the course of proper use of the instrument are required.

The probability of accidents occur in the course of proper use of the instrument is very small. If there is an accident, power off the instrument immediately.

(3) Necessary monitoring, evaluation and control means are required.

(4) Disposable products should be marked "for single use".

(5) This product is used together with supporting test cards. Refer to section 7.4.2 for the usage.

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(6) Diagnosis and treatment can not only rely on this instrument's test results, taking into account the clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on the detected patient population.

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2 Installation

2.1 Introduction

The analyzer is tested and packed with care before it is shipped from the factory. Inspect the carton carefully when you receive your analyzer. If any sign of damage is found, contact Genrui customer service department or your local distributor immediately.

2.2 Installation Requirements

Before the installation, the operator must ensure to satisfy the following requirements for space, environment and power.

2.2.1 Installation environment

Content	Requirements
Location	1) Flat workbench with tilt < 1/200 and sufficient intensity, which can bear the weight of 50kg; 2) Dust-free, without corrosive and

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Content	Requirements
	inflammable gases, without heat source and wind source, without mechanical vibration; 3) Good ventilation, avoid direct sunlight.
Space	Has enough space to place the analyzer, with a minimum area of 0.8m ² .
Environment temperature	10°C-30°C
Relative humidity	≤ 70%
Atmospheric pressure	70.0kPa-106.0kPa
Ventilation	Able to exchange air with outside, smooth air flow, no direct wind blowing to the analyzer.
Power supply	100-240V~, 50/60Hz, correctly grounded and the grounding impedance is less than 0.1Ω.
Electromagnetic wave	Do not close to the electric-brush engine or electric devices which are frequently switched on/off.
Ambient light	Avoid direct exposure to intensive light.

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Content	Requirements
Electromagnetic interference	The analyzer is susceptible to electromagnetic interference during running, which may affect the test results and lead to incorrect operation. During its running, do not use devices generating electromagnetic waves, such as electric drill, mobile phone, intercoms, etc., and keep it far away from strong electromagnetic interference.
Electromagnetic radiation	The analyzer will emit electromagnetic waves during running. Do not install and use electromagnetic-sensitive equipment near the analyzer.

⚠ WARNING

- The analyzer should not be used in an inflammable and explosive environment.

2.2.2 Power requirements

1. Must use a well-grounded and independent power socket, the grounding impedance should be less than 0.1Ω. The power

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socket should not be blocked by any objects. In case of emergency, the operator can easily pull out the power cord from the socket to disconnect the power immediately.

- 2.The equipotential ground terminal at the rear panel of the instrument must be connected with the ground cable, if possible, connected to a dedicated ground cable. Users have the obligation to ensure the reliability of the grounding power supply at the instrument's working site.
- 3.Frequent power failure will greatly degenerate the performance and reliability of the instrument. Users should solve this problem before the use, for example, choose the instrument's optional backup direct current power supply or equip the Uninterruptible Power Supply (UPS) by themselves.
- 4.The operator should use the specified fuse.
- 5.Make sure the input voltage meets the instrument's requirement.

2.3 Connection of the Analyzer

2.3.1 Unpacking and placing the analyzer

Open the dedicated packaging box of the analyzer and carefully check if the analyzer and accessories in the box are consistent with the packing list. If there is any loss or damage, please contact the supplier immediately.

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If all the items are there, carefully take out the analyzer and put it on a stable countertop. Do not place the analyzer near the wall or other places where are difficult for disconnection, for it is a non-permanently connected device.

2.3.2 Connecting the power cable

Make sure the power switch at the rear panel is turned off. Plug one end of the power cable into the instrument's power port, another end into the power supply interface.

The specification of the fuse used for this instrument is "F3AL250V", with rated current of 3A and rated voltage of 250V, which is a double cap fast-blow glass tube lead fuse.

2.3.3 Connecting the equipotential terminal

When need to work together between different devices, in order to achieve certain functions, a same reference potential is required, at this time you need to connect the equipotential terminal. Inhibit the potential difference by equipotential connection to eliminate the electromagnetic interference.

To connect the equipotential terminal, take out the supplied ground cable and directly connect the equipotential terminal at the rear of the instrument to the earth wire through the ground cable.

2.3.4 Installing (replacing) the printing paper

1) Slightly press to open the cover of the built-in printer.

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- 2) Put in the new paper roll (take out the empty scroll and put in the new paper roll) and make sure the free end is at the bottom.
- 3) Put one end of the paper roll into the printer head (i.e., between the metal plate and black plastic printer head), the printing paper is drawn in and one end is revealed through the printer head's narrow slot.
- 4) Close the printer cover and pull the paper out from the exit.



Inner structure of the printer



This label appears near the printer head.

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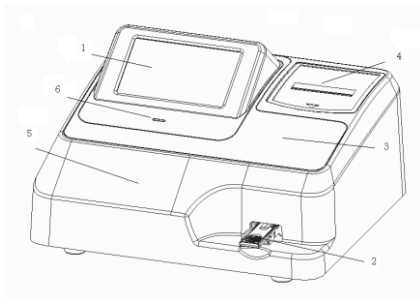
Contact with the printer head and its surrounding metal parts can cause scald. Turn off the analyzer and wait for 20 minutes to replace the printing paper.

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3 System Description

The analyzer is mainly composed of the host, which includes microprocessor, detection system, LCD screen and printer.

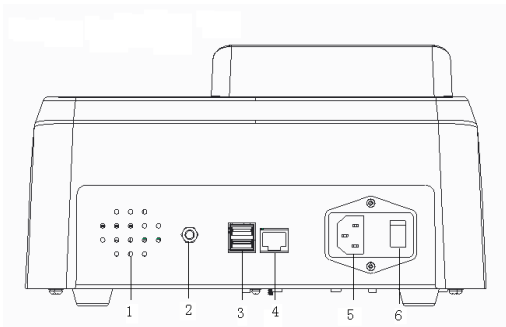
3.1 Front View



- | | |
|---------------------------|--------------------|
| 1. LCD screen | 2. Test slot |
| 3. Magcard induction zone | 4. Printer |
| 5. Upper housing cover | 6. Power indicator |

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3.2 Back View



- | | |
|------------------|---------------------------|
| 1. Vents | 2. Equipotential terminal |
| 3. USB connector | 4. Network port |
| 5. Power port | 6. Power switch |

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3.3 Function of the Parts

3.3.1 LCD screen

The touch screen is used to perform interface operations and display information.

3.3.2 Test slot

This analyzer provides one test slot, which is used to carry the test card.

3.3.3 Magcard induction zone

Magcard induction zone is used to read the relevant information for different items of different batches to the instrument.

3.3.4 Printer

The printer is inside the instrument and is temporarily unable to feed paper automatically, so you need to manually replace the paper, see section 2.3.5 for the detailed replacing method.

3.3.5 Network port

The network port is on the back of the analyzer. It can be used to

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connect the analyzer and the LIS system.

3.3.6 Power switch

The power switch is located at the rear of the analyzer and used to turn on and off the required power to control the analyzer's switch.



- Use the instrument when it is properly grounded.
- To avoid electric shock, disconnect the power supply before servicing.
- To prevent fire, use the fuse with specified model and current.

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4 Working Principle

4.1 Overview

This analyzer uses immunofluorescence technique to quantitatively measure the concentration of the analyzer. Under certain conditions, the fluorescence emission intensity is proportional to the concentration of the analyzer.

4.2 Measuring Principle

Some substances absorb incident light of certain wavelengths when they are exposed to light, they can emit light which is slightly longer than the incident light, the emitted light will disappear once there is no light, this emitted light called fluorescence and such substances are called fluorescein. Take fluorescein as a marker and combine it with a known antibody, without affecting its immunological properties, then use fluorescein-labeled antibody as a standard reagent to detect and identify unknown antigens.

The analyzer uses violet light for excitation source, when detecting, add the test sample to the sample port on the test card, the analyzer in the sample forms immune complexes in the

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chromatographic process. When the test card is inserted into the analyzer, light source illuminates to the testing zone and control zone of the test card, and excites the attached fluorescent substance, the emitted light is collected and converted into electrical signals, the intensity of the electrical signals is strictly related to the number of fluorescent molecules. Under certain conditions, the higher the concentration of the test substance (antigen), the stronger the emitted fluorescence after light irradiation, conversely, the lower the concentration, the weaker the emitted light, accordingly, the substance to be tested can be quantitatively analyzed.

Draw the standard curve according to the fluorescence intensity of calibrators with different concentrations and record it into the magcard of the corresponding batch of test card, when the magcard information is read into the instrument, the analyzer can automatically calculate the concentration of the analyzer.

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5 Interface and Operation

5.1 Overview

The analyzer has been initialized before it is shipped from the factory, after the first-time startup, the system default interface displays. In order to meet different needs in practical applications, you can reset some of the parameters of the analyzer.

5.2 Common Interface Operations

Name	Executed Operation
Click	Slightly click "xx" by finger on the touch screen.
Input	Click "xx" edit box to move the cursor there and use the interface keypad to complete data input.
Delete	Click the left key of the mouse or directly click the area to be deleted, then click "Delete" to delete it.

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5.3 Startup

Turn on the power switch at the rear of the analyzer, the analyzer starts initializing, as shown in Fig. 5-3-1.

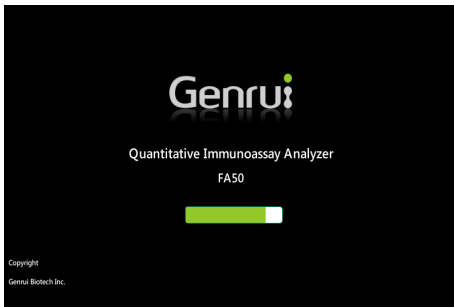


Fig. 5-3-1 Startup interface

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5.4 Main Menu

The instrument enters the main menu after the power-on self-test is completed, as shown in Fig. 5-4-1:



Fig. 5-4-1 Main menu interface

Directly click the menu item to enter the corresponding interface to perform the operation.

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5.5 Test

Click "Test" in the main menu to enter the measurement interface as shown in Fig. 6-5-1:

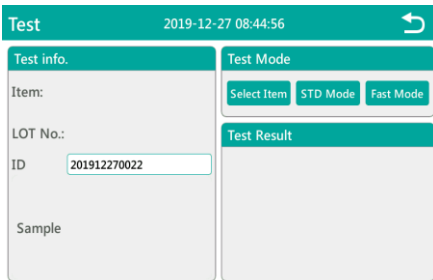


Fig. 5-5-1

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5.5.1 Item Set

When the scan code setting status of the reagent card is automatic, no item setting is required before measuring the reagent card; when the scan code setting status of the reagent card is manual, you need to manually select the item before measuring the reagent card, and click the item setting, as shown in Fig. 6-5-2, click on the item to be tested, and then click “Confirm” to select the item to be tested.

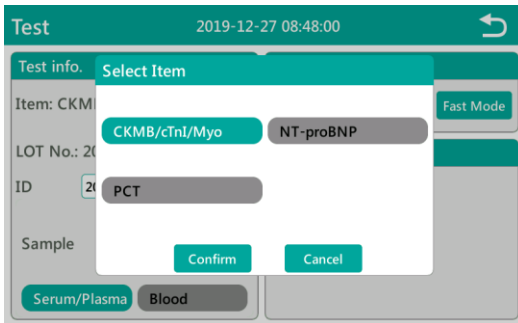


Fig. 5-5-2

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5.5.2 ID Set

You can set the ID number before measuring the sample. The ID number can be set to 1-999999999999999999. You can also use the default ID serial number, as shown in Fig. 5-5-3.

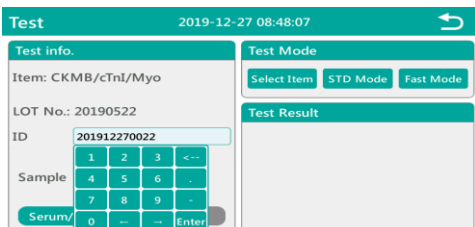


Fig. 5-5-3

5.5.3 STD Mode

If the current reagent batch has already been swiped, you do not need to swipe it; if you replace the new batch of reagent cards, you need to swipe the card again for the first measurement. For details on the swipe process, see 5.8.3.6 Swipe card.

When the scan code setting status of the reagent card is automatic, click "STD Mode", the analyzer will recognize the barcode on the reagent card, and automatically switch to the item to be tested. And prompts "Please insert reagent card with sample and confirm the sample information", and confirm the sample information If you

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need to change the sample type, click "Cancel". After reselecting the sample type, click "STD Mode" to start the test again. If the current test item is the same as the last test item, the analyzer will enter the standard measurement process, as shown in Fig. 5-5-5. If the current test item is different from the last test item, the instrument will prompt "Item information changed, please confirm the information before starting the test", as shown in Fig. 5-5-4. After confirming that the item information and sample information are correct. Click "STD Mode" again, the analyzer starts measuring, as shown in Fig. 5-5-5. When the countdown ends, the measurement starts automatically, as shown in Fig. 5-5-6. After the test is completed, the result is displayed in the lower right corner of the measurement interface. The results displayed in the display box are shown in Fig. 5-5-7:

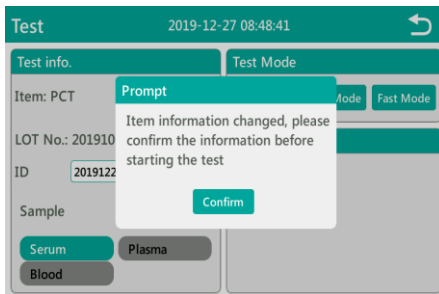


Fig. 5-5-4

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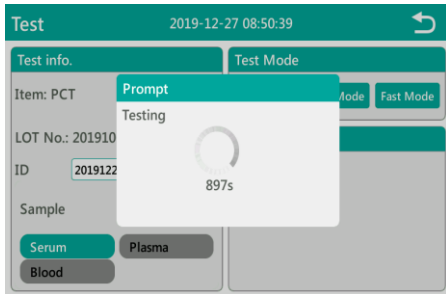


Fig. 5-5-5

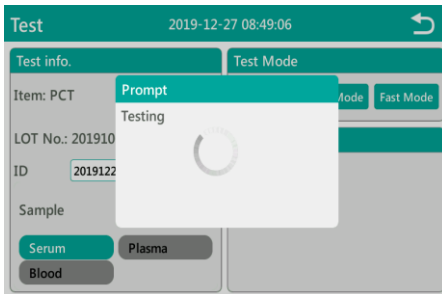


Fig. 5-5-6

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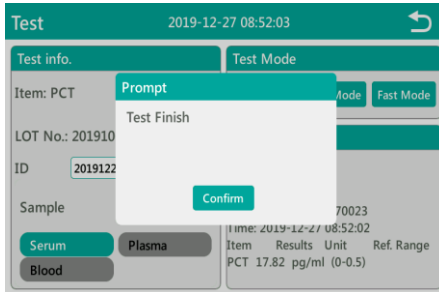


Fig. 5-5-7

5.5.4 Fast Mode

If the current reagent batch has already been swiped, there is no need to swipe the card; if you replace the new batch of reagent cards, when you replace the new batch of reagent cards, you need to swipe the card again. For details on the card swiping process, see 5.8.3.6 Swipe card.

When the scan code setting status of the reagent card is automatic, click "Fast Mode", and the analyzer will recognize the barcode on the reagent card and automatically switch to the item to be tested. And prompt "Please insert the incubated reagent card and confirm the sample information", as shown in Fig. 5-5-8; if you need to change the sample type, click "Cancel". After selecting the sample type again, click "Fast Mode" to start the measurement again. If the

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current test item is the same as the last test item, the analyzer will start directly, as shown in Fig. 5-5-9; if the current test item is different from the last test item, the instrument will prompt “Item information changed, please confirm the information before starting the test”. After confirming the item information is correct, click “Fast Mode” again. The analyzer will skip the waiting time and start the measurement directly, as shown in Fig. 5-5-9. After the measurement is completed, the result will be displayed in the result display box at the lower right corner of the interface, as shown in

Fig. 5-5-10. Click the  button to return to the main menu.

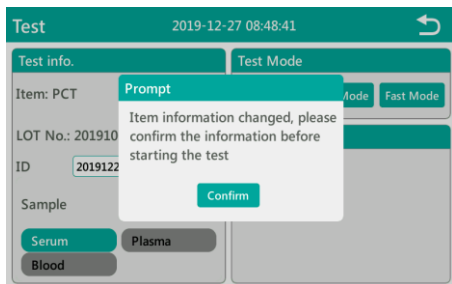


Fig. 5-5-8

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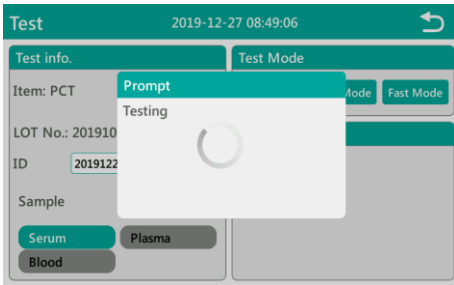


Fig. 5-5-9

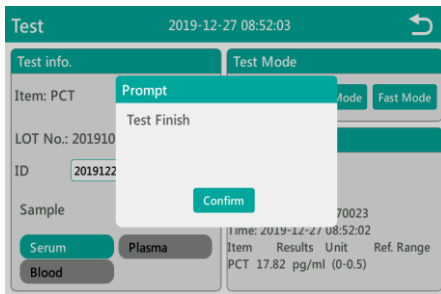


Fig. 5-5-10

5.6 Result

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The instrument automatically stores the test data after each sample is tested. Users can review, query, and print sample data through the results introduced in this section. The instrument can store 50,000 test records, which can be connected to the inspection department system to achieve unlimited storage. On the main menu, click "Result" to enter the results review menu, as shown in Fig. 5-6-1.

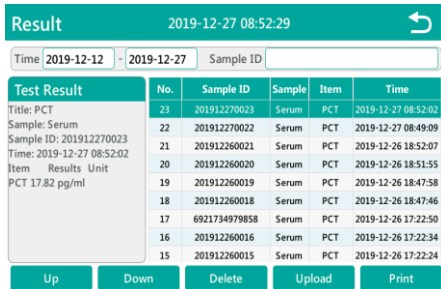


Fig. 5-6-1

Searching sample results: 1. Accurately search by entering the sample ID. After clicking the sample ID input box, a numeric input keyboard will pop up. Enter the sample ID you want to find, as shown in Fig. 5-6-2.

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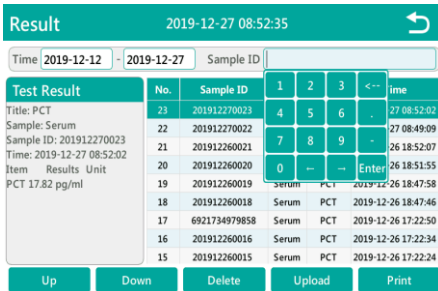


Fig. 5-6-2

2. Find the sample results by entering the time range. After clicking the first time input box, a numeric keyboard will pop up.

Enter the starting point of the search time, click **Enter** button to save, as shown in Fig. 5-6-3, click the second time input box, a numeric keyboard will pop up to enter the end point of the search time, as shown in Fig. 5-6-4. After clicking **Enter** button to save, you can search for the sample result according to the currently set time range. When the sample result exceeds one page, you can click the Up/Down button to search through the pages.

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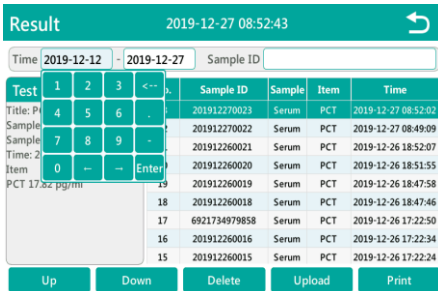


Fig. 5-6-3

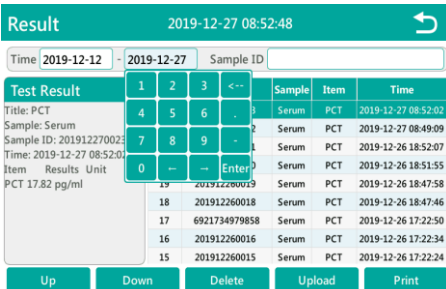



Fig. 5-6-4

3. Delete results

Select the sample results that need to be deleted and click "Delete". A

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dialog box “Confirm delete” will pop up, as shown in Fig. 5-6-5. Click “Confirm” to delete the currently selected results. Click  button to return to the main menu.

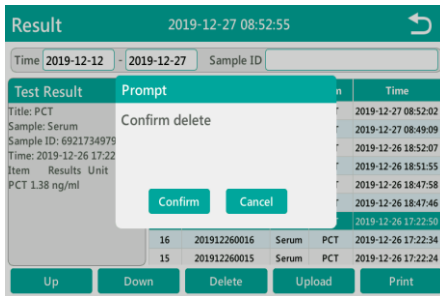


Fig. 5-6-5

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5.7 QC

In the main interface, click the QC button to enter the QC test interface, as shown in Fig. 5-7-1.

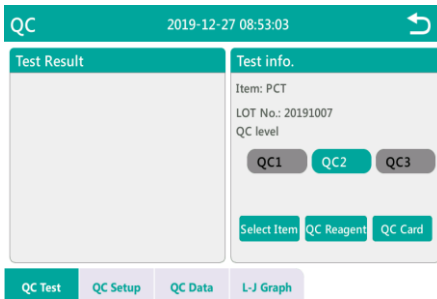


Fig. 5-7-1

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5.7.1 QC Setup

Before the QC test, you need to perform QC setup. Click “QC setup” button to enter the QC setup interface. As shown in Fig. 5-7-2, select the QC items to be set, click the target value input box, and enter the target value, click the limit input box and enter the relative deviation range.

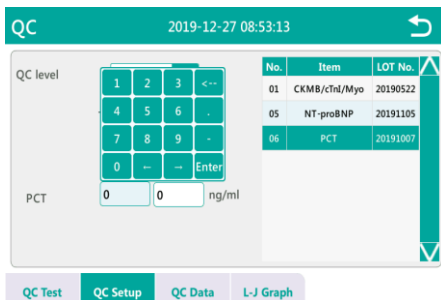


Fig. 5-7-2

5.7.2 QC Reagent

Click “QC Test” button to enter the QC Test interface, as shown in Fig. 5-7-3.

When the scan code setting status of the reagent card is automatic, no item setting is required before the QC test; when the scan code setting status of the reagent card is manual, you need to manually

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select the item before measuring the reagent card, and click "Item Set", as shown in Fig. 5-7-4, click the item that needs to be tested at present, and click "Confirm" to select the item to be tested.

Select QC2 and click "QC Reagent" button to start QC reagent test. (Note: QC Reagent is fast measurement. Please insert the reagent card that has been incubated to start the test)

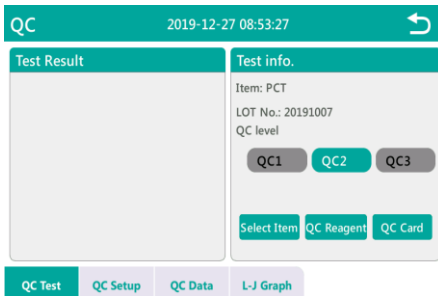


Fig. 5-7-3

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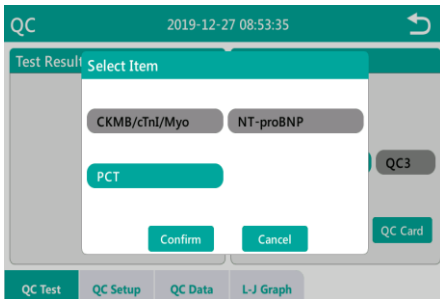


Fig. 5-7-4

5.7.3 QC Card

Before the QC card test, please enter the maintenance menu to use the QC magnetic card to swipe the card. For details, refer to 5.8.3.6 Swipe card.

Click “QC Card” button, the interface prompts “Insert the QC cassette”, as shown in Fig. 5-7-5. After inserting the special QC card in the test position, click the “Confirm” button to start the test;

If the QC card test passes, the current interface will prompt “Quality control success”, as shown in Fig. 5-7-6, if the QC test fails, it will prompt “Quality control failed” on the current interface, as shown in Fig. 5-7-7 After the interface prompts that the QC fails, please check whether the QC card is inserted in place. After checking that it is correct, perform the QC card test again. If the QC fails, please

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contact the after-sales service department of the company.

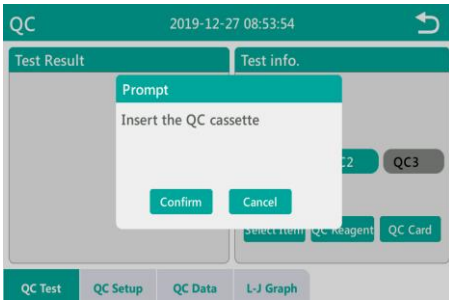


Fig. 5-7-5

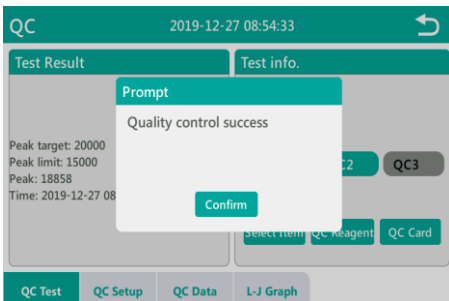


Fig. 5-7-6

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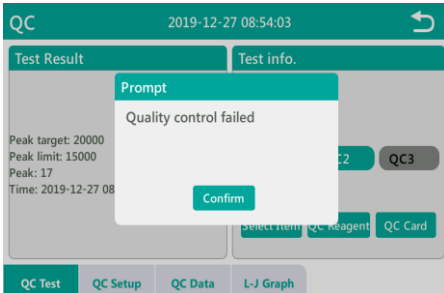
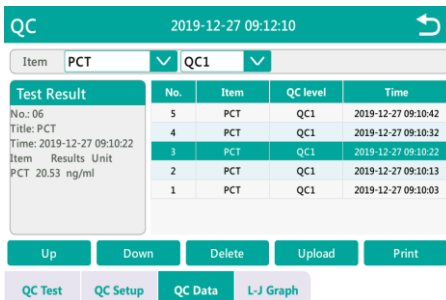


Fig. 5-7-7

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5.7.4 QC Data

Click “QC data” on the QC interface to enter the QC data query interface, as shown in Fig. 5-7-8. You can view the QC data of different items by selecting the item and QC type.



The screenshot shows the QC Data interface. At the top, there is a header bar with "QC" on the left, the date and time "2019-12-27 09:12:10" in the center, and a refresh icon on the right. Below the header, there are two dropdown menus: "Item" set to "PCT" and "QC level" set to "QC1".

On the left side, there is a "Test Result" panel with the following text:

- No.: 05
- Title: PCT
- Time: 2019-12-27 09:10:22
- Item Results Unit
- PCT 20.53 ng/ml

The main area contains a table with the following data:

No.	Item	QC level	Time
5	PCT	QC1	2019-12-27 09:10:42
4	PCT	QC1	2019-12-27 09:10:32
3	PCT	QC1	2019-12-27 09:10:22
2	PCT	QC1	2019-12-27 09:10:13
1	PCT	QC1	2019-12-27 09:10:03

Below the table, there are five buttons: "Up", "Down", "Delete", "Upload", and "Print". At the bottom, there is a navigation bar with four tabs: "QC Test", "QC Setup", "QC Data" (which is selected), and "L-J Graph".

Fig. 5-7-8

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5.7.5 L-J Graph

Click “L-J Graph” on the QC interface to enter the LJ QC graph interface, as shown in Fig. 5-7-9. You can view the L-J QC graphs of different items by selecting the item and QC type.

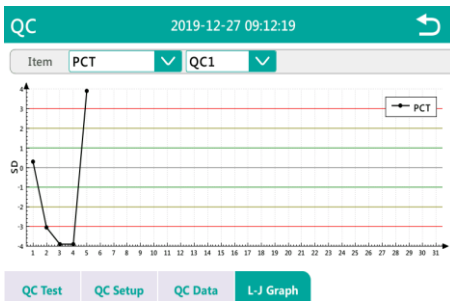
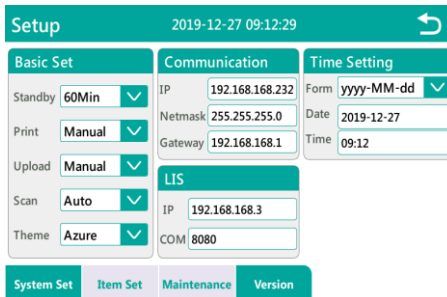


Fig. 5-7-9

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5.8 Setup

Click the "Setup" button under the main interface to enter the setup menu, as shown in Fig. 5-8-1. The setup menu is divided into four submenus: System Set, Item Set, Maintenance and Version.



The screenshot shows the 'Setup' menu with a teal header bar containing the title 'Setup', the date and time '2019-12-27 09:12:29', and a refresh icon. Below the header are three main sections: 'Basic Set', 'Communication', and 'Time Setting'. 'Basic Set' includes dropdown menus for Standby (60Min), Print (Manual), Upload (Manual), Scan (Auto), and Theme (Azure). 'Communication' includes input fields for IP (192.168.168.232), Netmask (255.255.255.0), and Gateway (192.168.168.1). 'Time Setting' includes a dropdown for Form (yyyy-MM-dd) and input fields for Date (2019-12-27) and Time (09:12). Below these is an 'LIS' section with input fields for IP (192.168.168.3) and COM (8080). At the bottom, there are four tabs: 'System Set', 'Item Set', 'Maintenance', and 'Version'.

Fig. 5-8-1

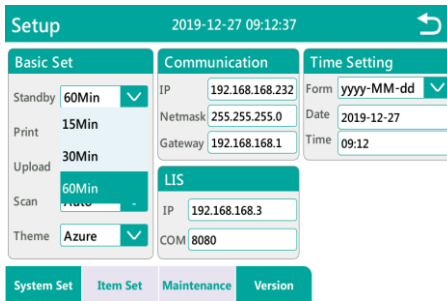
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5.8.1 System Set

Click “Setup” button under the main interface. After entering the setup menu, the default interface is the system set interface, as shown in Fig.5-8-1. The interface is divided into Basic Set, Communication, and Time Setting.

5.8.1.1 Standby

Click “Standby” drop-down box, as shown in Fig. 5-8-2. The standby setting time is 15 Min, 30 Min, and 60 Min. When the standby time is set to 15 Min, the instrument is not operated, the instrument will enter standby mode after 15 minutes.



The screenshot shows the 'Setup' interface with a teal header bar containing the title 'Setup', the date and time '2019-12-27 09:12:37', and a refresh icon. Below the header are three main tabs: 'Basic Set', 'Communication', and 'Time Setting'. The 'Basic Set' tab is active and contains several settings: 'Standby' (60Min), 'Print' (15Min), 'Upload' (30Min), 'Scan' (60Min), and 'Theme' (Azure). The 'Communication' tab contains 'IP' (192.168.168.232), 'Netmask' (255.255.255.0), and 'Gateway' (192.168.168.1). The 'Time Setting' tab contains 'Form' (yyyy-MM-dd), 'Date' (2019-12-27), and 'Time' (09:12). Below these tabs is an 'LIS' section with 'IP' (192.168.168.3) and 'COM' (8080). At the bottom, there are four navigation buttons: 'System Set', 'Item Set', 'Maintenance', and 'Version'.

Fig. 5-8-2

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5.8.1.2 Print

Click the “Print” drop-down box, as shown in Fig. 5-8-3. The print settings are divided into Auto printing and Manual printing. When the setting status is Auto, when the sample measurement and QC reagent measurement, after each test is finished, real-time printing will be performed. If the print setting status is Manual, real-time printing will not be performed during sample measurement and QC reagent measurement.

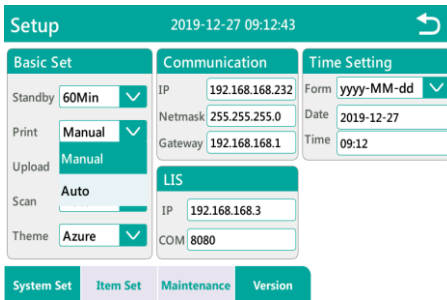


Fig. 5-8-3

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5.8.1.3Upload

Click the “Upload” drop-down box, as shown in Fig. 5-8-4. There are Manual upload and Auto upload. When the setting status is Auto, the instrument will upload the results to the LIS system in real time when the sample is measured. If the upload is set to Manual, the results will not be automatically uploaded to the LIS system during sample measurement.

Setup		2019-12-27 09:12:46		↻	
Basic Set		Communication		Time Setting	
Standby	60Min	IP	192.168.168.232	Form	yyyy-MM-dd
Print	Manual	Netmask	255.255.255.0	Date	2019-12-27
Upload	Manual	Gateway	192.168.168.1	Time	09:12
Scan	Manual	LIS			
Theme	Auto	IP	192.168.168.3		
		COM	8080		
System Set		Item Set		Maintenance	
				Version	

Fig. 5-8-4

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5.8.1.4Scan

Click "Scan" drop-down box, as shown in Fig. 5-8-5. The scan code setting is divided into Auto and Manual. When the setting state is Auto, the instrument will automatically switch to the item currently being tested by scanning the barcode on the reagent card when the sample is measured; when the setting status is Manual, the item needs to be manually switched before the sample can be measured for sample measurement.

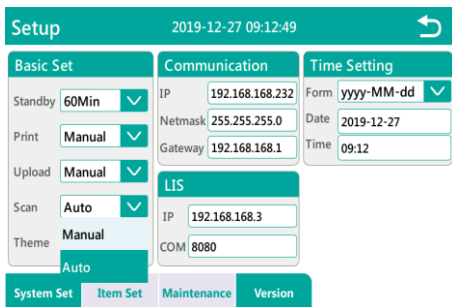


Fig. 5-8-5

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5.8.1.5 Theme

Click “Theme” drop-down box, as shown in Fig. 5-8-6, to set the skin color of the instrument operation interface. Set the colors to five colors such as Azure, Blue, Orange, Red, and Rose.

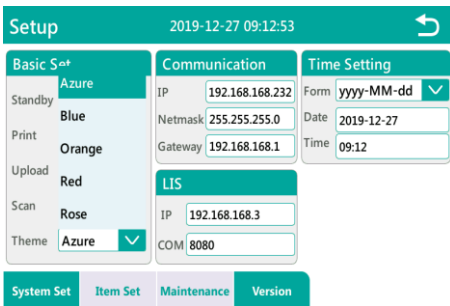




Fig.5-8-6

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5.8.1.6 Communication

Communication settings are divided into network communication settings and LIS settings, as shown in Fig. 5-8-7. Click the address to be modified, press the  key, delete the currently displayed content, enter the IP address to be set, and then click the  key to save.

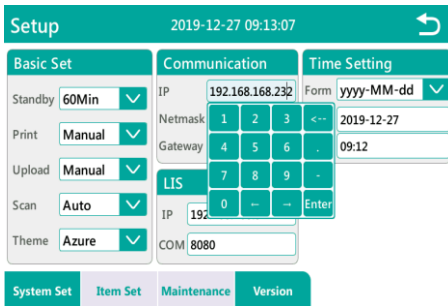


Fig. 5-8-7

5.8.1.7 Time Setting

The “Time Setting” is divided into year, month, and day format settings and date and time settings. The year, month, and day display format settings are divided into three formats: yyyy-MM-dd,

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dd-MM-yyyy and mm-dd-yyyy.

The time and date can be set in the time and date settings.

5.8.2 Item Set

In the settings menu, click “Item Set” to enter the item set interface, as shown in Fig. 5-8-8. Item Set is divided into Ref. Range and Correct.

No.	Item	LOT No.
01	CK-MB/cTnI/Myo	20190522
05	NT-proBNP	20191105
06	PCT	20191007

Item	Ref. Range	Unit
CK-MB	0 - 5	ng/ml
cTnI	0 - 0.3	ng/ml
MYO	0 - 58	ng/ml

Fig. 5-8-8

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5.8.2.1 Ref. Range

In the "Item Set" menu, click the "Ref. Range" and select the item to be set. Taking PCT as an example, click PCT item, as shown in Fig. 5-8-9. In the reference range input box, you can enter the reference range according to the actual situation, and click the "Reset" button to restore the reference range to the initial value.

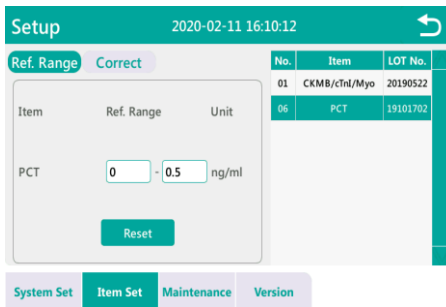


Fig. 5-8-9

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5.8.2.2Correct

In the “Item Set” menu, click the “Correct” button and select the item to be calibrated. Taking PCT as an example, click the PCT item, as shown in Fig. 5-8-10. In the reference range input box, you can enter the correction parameters according to the actual situation, and click the “Reset” button to restore the correction parameters to the initial values.

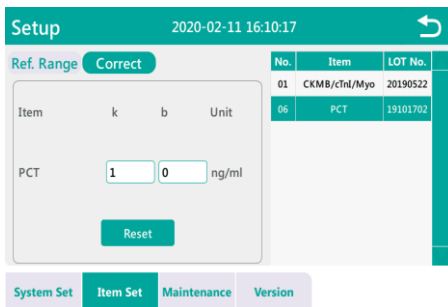


Fig. 5-8-10

Calibration method

The analyzer has been calibrated before it is shipped from the factory. Calibration coefficient is defaulted to be 1 and needs no changes. If necessary, you can calibrate the coefficient according to the following method:

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Take two calibrators, respectively test each one for 5 times on the analyzer to get the average value, and then calculate according to the following calibration formula:

$$Y=KX+B$$

Y stands for the calibrator's target value


X stands for the calibrators' average values tested on the reference machine

Substitute these two groups of data into the formula to calculate the calibration coefficient K and B. Enter the K value and B value into

the dialog box in Fig. 5-8-10, and click the  button to return to the main menu to save the calibration parameters.

Modify K or B according to formula $Y=KX+B$, among which, K refers to the slope, B refers to the intercept. $0.000 \leq K \leq 9.999$, $0 \leq B \leq 999.99$ (for NT-proBNP: $0.000 \leq K \leq 9.999$, $0 \leq B \leq 99999$)

After modifying K or B, the test results changed accordingly. Each item's K or B value only works on this item.

Click the  button to return to the main menu interface.

NOTE

- Unnecessary or incorrect calibration may lead to unreliable test

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results. Please confirm the necessity of the operation.

5.8.3 Maintenance

Click the "Maintenance" button in the setup menu to enter the "Maintenance" interface, as shown in Fig. 5-8-11. This interface can complete Screen Calibration, Delete result, Delete QC, Export results, In, Out, card Swipe card and Upgrade maintenance operations.

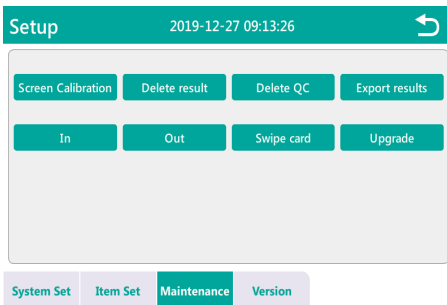


Fig. 5-8-11

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5.8.3.1 Screen Calibration

Screen calibration is used to calibrate the sensitivity of the touch screen. Click the "Screen Calibration" button, the interface prompts whether to enter screen calibration, as shown in Fig. 5-8-12, click "Confirm" to enter the calibration interface, and then click the cross icon to complete the screen calibration.

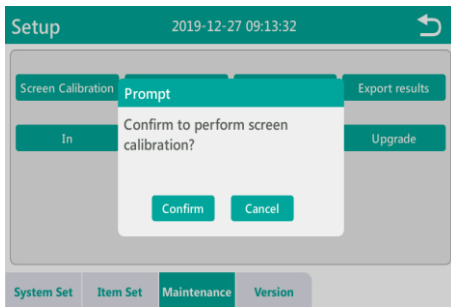


Fig. 5-8-12

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5.8.3.2 Delete result

In the maintenance interface, click the “Delete result” button, the instrument maintenance interface will prompt “Confirm to delete all test results?”, as shown in Fig. 5-8-13, after clicking "Confirm", the instrument will delete all sample measurement results.

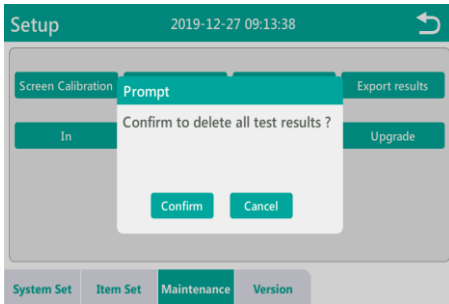


Fig. 5-8-13

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5.8.3.3 Delete QC

In the maintenance interface, click the “Delete QC” button, the instrument maintenance interface will prompt “Confirm to delete all QC results?”, as shown in Fig. 5-8-14, after clicking “Confirm”, the instrument will delete all QC measurement results.

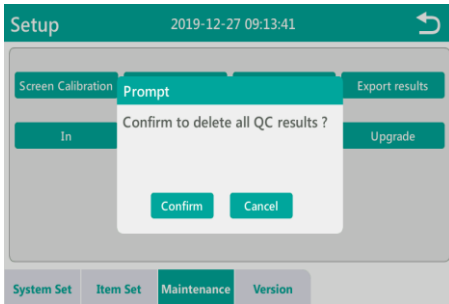


Fig. 5-8-14

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5.8.3.4 Export results

Click the "Export results" button in the maintenance interface, the instrument maintenance interface will prompt "Confirm to export the results?", as shown in Fig. 5-8-15. To export the measurement results, first insert the USB flash drive into the USB interface of the instrument, and then click the "Confirm" of dialog box to export the test results.

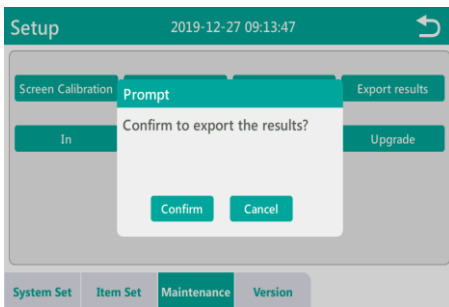


Fig. 5-8-15

5.8.3.5 In/Out

In the maintenance interface, click the "In" or "Out" button to complete the card entry and exit operations in the test slot.

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5.8.3.6 Swipe card

When replacing a new batch of reagents, you need to perform a swipe operation. On the maintenance interface, click the “Swipe card” button. The interface prompts “Please put the magnetic card on the card swiping area, card is reading.”, as shown in Fig. 5-8-16. When the reagent magnetic card is placed in the card swiping area, it will prompt “Reading Succeed”. As shown in Fig. 5-8-17.

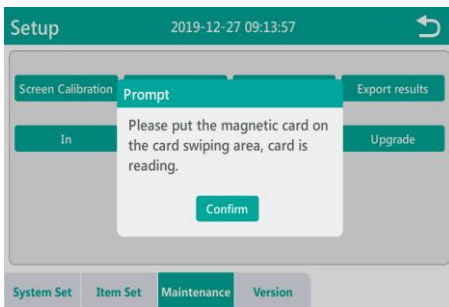


Fig. 5-8-16

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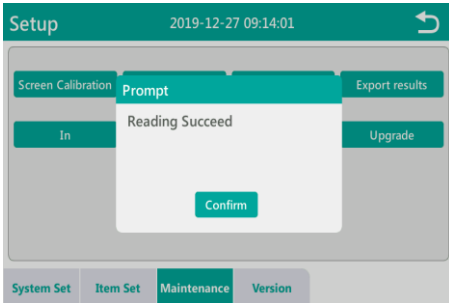


Fig. 5-8-17

5.8.3.7 Upgrade

Before preparing to upgrade the software, first place the software upgrade package in the root directory of the USB flash drive, insert the USB flash drive into the USB interface on the back panel of the instrument, and click the “Upgrade” button in the maintenance interface. The current interface will prompt “Program upgrade may cause data loss. Please back up your data. Confirm now?”, as shown in Fig. 5-8-18, click the “Confirm” button to start the software upgrade. After the upgrade is completed, it will prompt “Program upgrade successful, please restart the instrument”.

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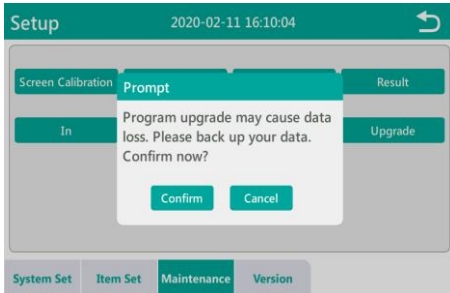


Fig. 5-8-18

5.8.4 Version

In the "Setup" menu, click "Version" to view the current model, SN number, driver version, software version and other related information.

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6 Sample Test Process

The operator should check whether the instrument's power cable is safely and reliably plugged into the power port.

6.1 Startup

If there is externally connected device, like scanner, turn on its power and make sure the device is ready, then turn on the power switch at the rear of the analyzer, the analyzer starts initializing, as shown in Fig. 6-1.



Fig. 6-1 Startup initializing

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The analyzer will automatically perform a self-test during the startup process. After initialization, the instrument enters the main interface as shown in Fig. 6-2:



Fig. 6-2 Main menu

Directly click the menu item to enter the corresponding interface to perform the operation.

6.2 Sample analysis

6.2.1 Sample

Blood, Serum, Plasma, Others. The specific sample types are different according to the different reagents. For details, see the

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description of the sample types in the instructions of each reagent. The type of anticoagulant is generally EDTA or sodium citrate, which varies depending on the supporting reagents. For details, see the description in the supporting reagent instructions.

6.2.2 Sample analysis

Take procalcitonin (PCT) as an example:

1. Place the test card and sample at room temperature. Use the unpacked test card within 1 hour.
2. Turn on the analyzer, enter the main menu, click the "Setup" button, and then click the "Maintenance" button to enter the maintenance interface, prepare the PCT magnetic card, click "Swipe card", and place the magnetic card in the card swipe area according to the prompt. After successfully completing the card swipe, return to the main menu after successful swipe. Note: Unscratched items need to be swiped before the first use. Swipe the card again when replacing a new batch of reagent cards.
3. Pipette 100 μ l of serum, plasma or whole blood sample and add it vertically to the sample well (when the sample is whole blood, immediately add 1 drop of the matching whole blood dilution solution). The reagent card is immediately inserted into the analyzer's test slot. Click "STD Mode". When the scan code setting status of the reagent card is Auto, the analyzer will recognize the barcode on the reagent card and automatically switch to the item to be tested, and prompt "Please insert

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reagent card with sample and confirm the sample information”, if you need to change the sample type, click “Cancel”, reselect the sample type, click “STD Mode” to start the test again; if the current test item is the same as the previous test item, the analyzer will enter the “STD Mode” process; if the current test item is different from the last test item, the instrument will prompt “Item information changed, please confirm the information before starting the test”. After confirming that the item information and sample information are correct, click “STD Mode” again, and the analyzer will start the countdown. When the countdown is over, the measurement will start automatically. After the test is completed, the result will be displayed in the result display box in the lower right corner of the measurement interface.

- 4.If fast measurement is required, please place the sampled reagent card at room temperature for 15min (to ensure the accuracy of the result, please use a timer to time), and quickly insert the reagent card into the analyzer's test slot (sample hole facing in), press the “Fast Mode” button. When the scan code setting status of the reagent card is Auto, click “Fast Mode” and the analyzer will recognize the barcode on the reagent card and automatically switch to the item to be tested. At the same time, prompt “Please insert the incubated reagent card and confirm the sample information”; if you need to change the sample type, click “Cancel”, and then select the sample type again, click “Fast Mode” to start the measurement again. If the current test item is the same as the last test item, the analyzer will start measurement; if the current test item is

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different from the last test item, the instrument will prompt "Item information changed, please confirm the information before starting the test". After confirming that the item information is correct, click "Fast Mode" again. The analyzer will skip the waiting time. Start the measurement directly. After the measurement is completed, the result is displayed in the result display box in the lower right corner of the interface.

5. After the measurement is completed, if the print is set to print in real time, the measurement results will be printed automatically;
 6. If the printing paper runs out, the screen will prompt "Printer is out of paper or abnormal", please replace the printing paper according to the method provided in section 2.3.5 of this manual.
-

▲WARNING

- Under any circumstances, do not contact the blood sample directly. When handling these objects, strictly comply with the laboratory or clinical operation regulations.
 - Bring all the reagents to room temperature before the test. Otherwise, it may lead to inaccurate results.
 - When the interface displays "Testing", do not take the test card out from the test slot, otherwise, it may lead to inaccurate test results or test interruption.
-

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6.3 Shutdown

When the tests finished, make sure the test slot is inside the analyzer, preventing dust and other substances falling into it, then directly turn off the power switch at the rear of the analyzer.

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7 Maintenance

7.1 Overview

In order to get a good performance of the analyzer, ensure its reliability and extend its lifetime, please strictly follow this chapter to perform maintenance for this analyzer.

7.2 Clean the Instrument's Surface

The analyzer's workbench is easily spattered with reagents, reaction fluid and serum, which should be removed in time. After the daily use, perform the following steps to do the cleaning:

- (1)Clean: Use a wet towel dipped with cleaning solution to wipe the analyzer's workbench until all the stains are wiped clean. It is suggested to do the cleaning once a day.
- (2)Disinfect: Use a wet towel dipped with 75% alcohol or disinfectant to wipe and disinfect the instrument's shell. 15 minutes later, use a clean wet towel to wipe the workbench and remove the remaining disinfectant. It is suggested to do the disinfection once a week.

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Cleaning solution is corrosive, protective gloves should be worn while in operation.



Workbench should be deemed to be infectious, protective gloves should be worn while in operation.

7.3 Fuse Replacement

The instrument's fuse must be replaced by maintenance personnel. The specified specification is F3AL250V.

7.4 Instructions for Eliminating or Reducing Disuse

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Provide the responsible person with an instruction to eliminate or reduce disuse and risks involved in transportation or disposal. The instruction should contain the requirement to minimize the biohazard:

Serum, reagents or other liquids are deemed to be infectious. If a small amount of liquids spattered onto the instrument's surface, use a cotton ball dipped with "75% alcohol" to wipe it away, otherwise, contact with the surface may lead to infection and other biohazard; if a large amount of liquids splashed and penetrated into the instrument, stop using it and pull out the plug, then contact Genrui or your local agent.

For any transporting, changing the place of operation, donating, lending, maintenance, etc. of the instrument, thoroughly disinfect the surface of the instrument to minimize the biohazard. Once the instrument gets any collision or falls off, no matter if there's any obvious surface or internal damage, stop using it immediately and contact Genrui or your local agent.

If the instrument breaks down after the warranty period, you should ask Genrui service engineer, hospital equipment department engineer or other authorized maintenance engineer to repair it. Otherwise it may lead to electric shock. It is suggested to get in contact with Genrui before the maintenance.

It is suggested to disuse the instrument when it reaches the retirement period or reuse it based on an overall inspection and maintenance of Genrui.

Only trained and authorized personnel by Genrui or its agents can

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use this instrument, otherwise it may damage the protection provided by the instrument or greatly affect the testing results.

7.5 Preventive Maintenance and Inspection for Safety Purposes

Check whether the power cable is well connected and grounded or not before starting up the instrument.

Check whether the equipotential rod is well connected or not before starting up the instrument.

Strictly comply with the maintenance method described in this chapter to perform maintenance for this instrument.

7.6 Components' Replacing List

7.6.1 Consumables that can be replaced by users

Printing paper

Supporting test card

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7.6.2 Parts need to be replaced by service engineers

Laser source (365nm)

Fuse (F3AL250V)

Switching power supply

Power switch

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8 Troubleshooting

8.1 Overview

This chapter introduces the solutions and steps for the common faults. After referring to these instructions in this chapter, if the problems cannot be solved or need more and detailed information, please contact with Genrui customer service department.

NOTE

- This operation manual is not a service manual, only provides measures that should be taken for operators facing instrument fault alarm.
-

8.2 Common Fault and Handling

Faults	Possible reasons	Suggested solutions
Frame	Communi	It is recommended to check whether

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detection related errors	cation failure	there are internal or external interference network port signals
Data collection exception	Light source failure	<ol style="list-style-type: none"> 1. Check whether the light source power cord is loose, the light source is burned out, or the sample concentration is too high and the magnification is reduced. 2. Check whether the power cable of the optical module is loose. 3. When the power cord of the optical module is loosened, the power of the motor is also loosened, which will cause abnormal data collection.
Motor out of warehouse abnormal	Motor failure	In the customer mode, check whether the motor is moving normally or the driving current is too small, which will cause the motor speed to be too slow and an error will be reported over time.
Motor entering warehouse is abnormal	Motor or optocoupler failure	<ol style="list-style-type: none"> 1. In the customer mode, check if the motor is moving normally or the driving current is too small, which will cause the motor speed to be too slow and an error will be reported over time. 2. Check whether the optocoupler is invalid. In the customer mode, cover the

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		optocoupler with an object, then move the object away, and observe whether the status display of the photocoupler on the host computer changes.
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8.3 Abnormal Result Modes Analysis

Type	Possible reasons	Solutions
Operation abnormal	Test card is moved during the measurement	Re-measure it
	Reagent card placed incorrectly	The reagent card is not fully inserted into the test slot or placed in the opposite direction
QC card test failed	Light source light is off	Please contact customer service

Table 8-1

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9 Transportation and Storage

9.1 Storage Condition

The packaged analyzer should be stored in a well-ventilated room that has the environmental temperature of -10°C to $+55^{\circ}\text{C}$, relative humidity not greater than 93% and is free from corrosive gases.

9.2 Transportation Condition

The analyzer can be delivered by general transportation, however, fierce impact, vibration, or exposure in rain or snow should be avoided during shipment. The shipment requirements are determined by the order contract.

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10 Reagents and Consumables

10.1 Common reagents

No.	Name	Specification
1	Procalcitonin (PCT) Test Kit (Immunofluorescence)	10T/kit
		25T/kit
		50T/kit
		100T/kit
2	High Sensitive C-Reactive Protein (hs-CRP) Test Kit (Immunofluorescence)	10T/kit
		25T/kit
		50T/kit
		100T/kit

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No.	Name	Specification
3	Myoglobin (Myo) Test Kit (Immunofluorescence)	10T/kit
		25T/kit
		50T/kit
		100T/kit
4	Cardiac Troponin I (cTnI) Test Kit (Immunofluorescence)	10T/kit
		25T/kit
		50T/kit
		100T/kit
5	Creatine Kinase Isoenzyme (CK-MB) Test Kit (Immunofluorescence)	10T/kit
		25T/kit
		50T/kit
		100T/kit
6	N-terminal Pro-brain Natriuretic	10T/kit

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No.	Name	Specification
	Peptide (NT-proBNP) Test Kit (Immunofluorescence)	25T/kit
		50T/kit
		100T/kit
7	Heart-type Fatty Acid-binding Protein (H-FABP) Test Kit (Immunofluorescence)	10T/kit
		25T/kit
		50T/kit
		100T/kit
8	Cardiac Troponin I/Creatine Kinase Isoenzyme/Myoglobin (cTnI/CK-MB/Myo) Test Kit (Immunofluorescence)	10T/kit
		25T/kit
		50T/kit
		100T/kit

10.1.1 Reagent card

The reagent card is the place where the reaction takes place. Do not inhale air bubbles during sampling.

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10.1.2 Calibration

The calibration parameters are written directly into the magnetic card, and no separate calibration is required by the customer.

10.2 Sample Type

Sample type: Whole blood, serum, urine and other body fluids.

The specific sample types vary depending on the ancillary reagents, refer to the corresponding reagent instruction for more details. EDTA or sodium citrate is commonly used as the anticoagulant, and there are differences depending on the various ancillary reagents, refer to the corresponding reagent instruction for detailed descriptions.

10.3 Sample Volume

Sample volume is different according to the reagent type, refer to the corresponding reagent instruction for detailed descriptions.

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Appendix A. Specifications

A.1 Performance Indicators

A.1.1 Repeatability

The repeatability of the analyzer shall comply with one of the following requirements:

- (1) QC card: repeatedly test the reflection ratio of the quality control (QC) card, the coefficient of variation (CV) of the test results should not be more than 1%.
- (2) Test card: repeatedly test the card of one item, the coefficient of variation (CV) of the test results should not be greater than 10%.

A.1.2 Accuracy

Test the reference material (calibrator) with a fixed value, the bias (B) of its average value and marked value should not be greater than 10%.

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A.1.3 Stability

After turning on the analyzer for 4 hours and 8 hours, test the reference material (calibrator) with a fixed value, the bias (B) of its average value and marked value should not be greater than 10%.

A.1.4 Linearity

The correlation coefficient r^2 should be equal or greater than 0.990.

A.2 Supporting Reagents

There are corresponding test cards for different items.

A.3 Test Parameter Information

Category	Item No.	Item Name	Full Name	Unit
Infection	1	hs-CRP	High sensitive C-reactive protein	mg/L
	2	PCT	Procalcitonin	ng/ml

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Category	Item No.	Item Name	Full Name	Unit
Cardiac	3	NT-proBNP	N-terminal pro-B-type natriuretic peptide	pg/ml
	4	cTnI	Troponin I	ng/ml
	5	Myo	Myoglobin	ng/ml
	6	CK-MB	Creatine kinase isoenzymes MB	U/L
	7	H-FABP	Heart-type fatty acid-binding protein	ng/ml
	8	Cardiac panel	Troponin I / Creatine kinase isoenzymes MB / Myoglobin	ng/ml

Note: This parameter information may be changed, please refer to the latest parameter information.

A.4 Instrument's Basic Parameters

Parameter	

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Parameter	
Light source	LED
Wavelength	365±10nm
Light power	60-150mW
Test method	Immunofluorescence
Reagent card	Disposable
Power	≤50VA
Work type	Continuous operation equipment
Barcode device	Support barcode scanning input

A.5 Working Environment

Ambient temperature: 10℃-30℃

Relative humidity: ≤70%

Atmospheric pressure: 70.0kPa-106.0kPa

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NOTE

- Strictly follow the specified environment requirement to store and use the analyzer.
-

A.6 Product's Outer Packaging

Illustration



—“Fragile”: Carefully carry and place.



—“Up”: Upward to place and transport the product.



—“Rain proof”: Protect the package from the rain.



—“Layer limit”: Maximum pile up layers of the same package.

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—“Humidity limit”: Humidity limit for transportation and storage environment.



—“Temperature limit”: Temperature limit for transportation and storage environment.

Note: The illustrations are for reference only, subject to pictures on the outer package.

A.7 Dimension and Weight

Box size 350mm(length)x350mm(width)x282 mm(height)

Instrument size: 300mm(length)x270mm(width x160 mm(width

Net weight: 4Kg

Gross weight: 6Kg

A.8 Contraindications

None

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Appendix B. Hazardous Substances

Parts name		Hazardous substances					
		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Host	Host shell	○	○	○	○	○	○
	Host PCBA	x(1)	○	○	○	○	○
	Host sheet metal parts	○	○	○	○	○	○
	Host machining part	○	○	○	○	○	○
	Host plastic pieces	○	○	○	○	○	○
	Host metal pieces	○	○	○	○	○	○
	Host connection cable	○	○	○	○	○	○

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Parts name		Hazardous substances					
		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Accessories	Labels	○	○	○	○	○	○
	Closure assembly	○	○	○	○	○	○
	Maintenance tools	○	○	○	○	○	○
Package	Packaging materials	○	○	○	○	○	○
<p>○: means the content of the hazardous substance in all homogeneous materials of the part is in the limited requirement according to the standard of SJ/T 11363-2006.</p> <p>×: means the content of the hazardous substance in at least one of the homogeneous materials of the part is beyond the limited requirement according to the standard of SJ/T 11363-2006.</p> <p>(1): some parts of the circuit board used lead solder during processing.</p> <p>Notice: the product marked with "×" is because there has no other technologies or parts to be replaced at present stage, under normal use conditions, leak and mutation will not occur in 5 years, and it will not cause environment pollution or harm to people and property.</p>							