VACURE

Fluorescent Immunoassay Analyzer

User Manual

(LYOFIA8)

Hunan Kangxin Biotechnology Co., Ltd.

Revision history

Version	Revision date	Change Description
Initial release	2022-09-21	Initial release

Declaration

Thank you for choosing our Fluorescent Immunoassay Analyzer. Please carefully read the contents of this manual before use.

This analyzer has a data storage function inside, and the company is free of responsibility for user losses caused by analyzer damage or data loss, which was caused by user operations.

Please do not disassemble or repair the analyzer without authorization, otherwise the post-sales service provided to you will be automatically terminated. Please use the reagents provided by our company, otherwise our company is free of responsibility for the wrong test results. The company has the right to change product design and specifications without prior notice. A slight difference between the picture and the actual product may occur due to the printing process of this manual, please refer to the actual product.

You need to ensure that the accessories expansion, re-commissioning or maintenance of the analyzer are carried out by the personnel approved by the company; the relevant electrical equipment conforms to the local standards; the operation is strictly followed to instruction described in this manual. Otherwise, the company is not responsible for the safety, reliability and performance of the device.

This manual is formed in accordance to the requirements of EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements, EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)

- Part 1: Terms, definitions and general requirements, EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use, and point 20.1 of Annex I describe in Regulation EU 2017/746. This device meets the safety requirements specified in EN 61010-1:2010/A1:2019/AC:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements, and EN 61010-2-101:2017 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment. This device also meets the electromagnetic compatibility requirements specified in EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements and EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment.

Content

Chapter I Warnings and Precautions

1. For *in vitro* diagnostic use only.

2. Before using, you should be acknowledged with relevant professional medical knowledge.

3. Please put the analyzer into use according to the intended use and operation method described in the manual, otherwise the protection that comes with the analyzer may be damaged, and any incorrect operation may lead to inaccurate test results.

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

5. Before starting the analyzer, make sure that the power supply is the working voltage that the analyzer conforms to. Please use the special power adapter provided with the analyzer. After starting, please do not leave the analyzer unattended.

6. This device is intended to be used by specially trained operators only, and it is recommended to follow the given procedures. The protection comes with the analyzer may be compromised if the operation is deviated from the methods specified in the manual.

7. Please wear protective gloves when operating the analyzer to avoid infection.

8. A well-ventilated room is required and the analyzer's surface should not be covered by any objects, including but not limited to large amounts of liquid or droplets. Also do not place the analyzer

in liquids.

9. Since the standard curve parameters vary among different batches of reagents, the batch number of reagent must be consistent with that of the standard curve during the assay.

10. All equipment maintenance must be operated by the technicians designated by our company. If parts need to be replaced during maintenance, new parts must be provided by our company.

11. If the analyzer is damaged during use or transportation, it cannot be turned on until repaired by the technicians designated by our company.

12. Disassembling the analyzer by yourself may cause leakage of harmful radiation and damage to the analyzer. For radiation warning prompts and symbols, please kindly see Chapter IX and X.

13. Cut the power off if the device is not used for a long time.

14. If the analyzer works abnormally, please refer to Section VIII, if the failures cannot be eliminated, please contact the supplier.

15. Electrostatic protection should be well performed in a dry environment or other places that may easily cause static electricity (such as artificial fabric carpets, etc.), otherwise it may cause destructive electrostatic discharge, resulting in wrong test results or damage to the analyzer.

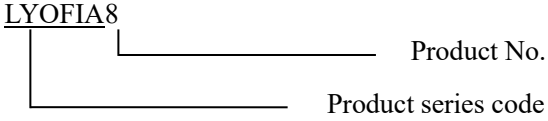
Chapter II Analyzer Summary

This device is a quantitative determination analyzer developed basing on modern optoelectronic technology and intended to be used in combination with fluorescent immunoassay strips to detect relevant parameters of human samples. The detection results could be used for clinical auxiliary diagnosis.

The analyzer applies a time-resolved method for detection. The principle is to use the characteristics of the wide Stocks shift and long duration of the lanthanide elements labeled in the test strip, that is, after removing the excitation light, the lanthanide elements can still maintain the continuous emission of the emitted light for a long time. However, other substances that can be excited to emit fluorescence cannot generate emission light in a very short time after the excitation light is removed. It is the application of the time-resolved method for detection that after turning off the excitation light for a certain period of time, and after other interfering substances cannot generate the emitted light, the light intensity is read. Through the optimized design of the optical path and the amplifier circuit, the weak fluorescence emission light signal can be detected, so as to achieve the purpose of reducing the background and interference.

Product name and model: Fluorescent Immunoassay Analyzer LYOFIA8

Naming rules: Model description:



Software name: Fluorescent Immunoassay Analyzer Software System

Software release version: LYOFIA8.V1

Chapter III Intended Use

This device is based on fluorescence immunoassay technology and intended to be used in combination with the detection kits manufactured by our company to quantitatively detect analytes in human serum, plasma or other body fluid samples in clinical practice.

And it is for professional use only, not for self-testing of untrained individuals, nor for near-patient testing.

Contraindications: None.

Chapter IV Technical Characteristics

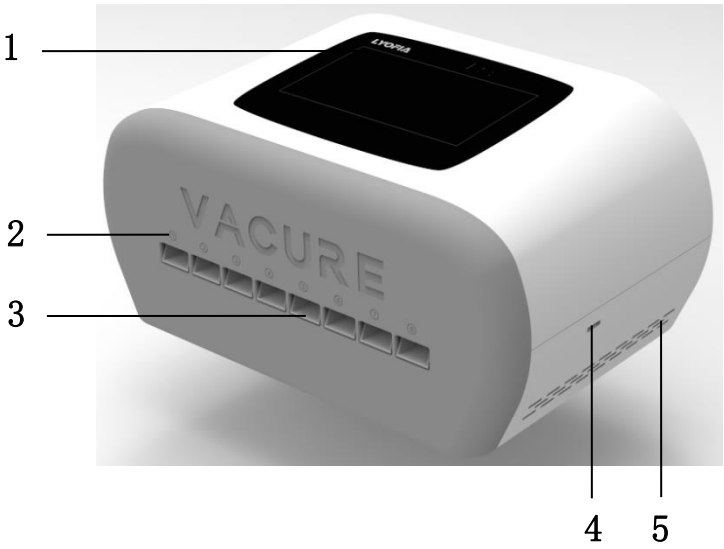
Detection principle	Fluorescence quantitative analysis
Number of channels	8
Storage	No less than 10,000 sample results
Interface	USB, RS232, LAN, power supply
Display	7 inch LCD
Power	96VA
Adapter input	200-240V~ 50/60Hz 2.5A
Adapter output	+24V⎓4A
Button	Capacitive touch screen

Weight	6 Kg
Size	365mm×255mm×180mm (Length × width × height)
Repeatability	Coefficient of Variation (CV) ≤ 5%
Linearity	Linear correlation coefficient (r) ≥ 0.99
Stability	Relative deviation ≤±10%
Accuracy	Relative deviation ≤±15%
Temperature Accuracy and Temperature Fluctuation	The temperature deviation does not exceed ±2℃, and the temperature fluctuation does not exceed ±1℃

Chapter V Analyzer Structure

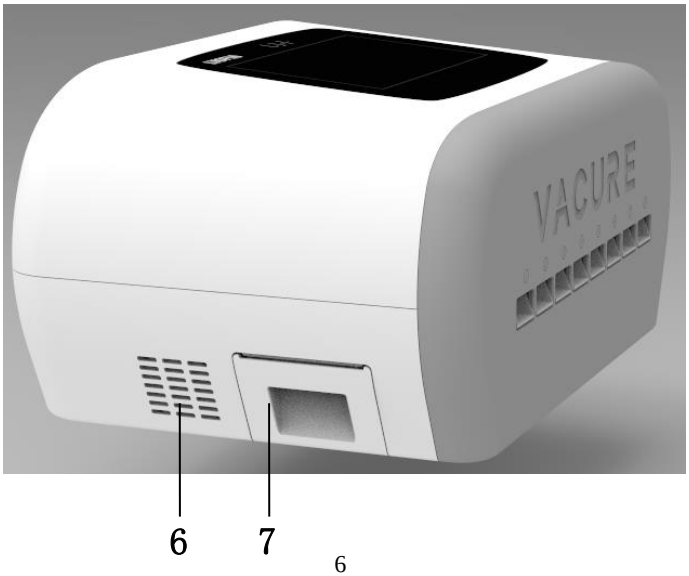
This device consists of mainframe and software (software release version: LYOFIA8.V1). The mainframe includes Reaction module, Optical detection module (fluorescence), Data processing module, Motion control module, Display screen and Printer.

The analyzer appearance and components are described as the following picture:

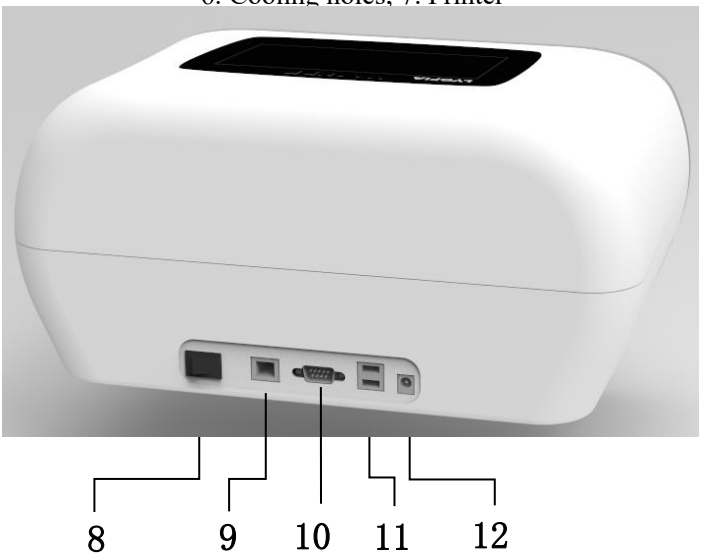


1. LCD screen; 2. Indicator light; 3. Reagent cassette interface;

4. Reagent information carrier interface; 5. Cooling holes



6. Cooling holes; 7. Printer



8. Switch; 9. Network interface; 10. RS232 interface; 11. USB interface; 12. Power adapter interface

Chapter VI Analyzer Installation

1. Analyzer standard configuration

1× Fluorescence immunoassay analyzer

1× Power adapter

1× Manual

1× Quality control card

2× Thermal printing paper

2. Analyzer installation

2.1 Before installation

Open the package according to the instructions of the packing box, check the accessories and documents provided with the analyzer against the packing list. After that, prepare for installation. If you have any questions, please contact our post-sales service department.

Notice:

The working environment of the analyzer:

Voltage: 200-240V～ 50/60Hz;

Ambient temperature: 10-30℃;

Relative humidity: ≤80%;

Keep away from strong electromagnetic interference sources;

Avoid direct exposure to strong light;

A good grounding environment;

Atmospheric pressure: 86 kPa～106 kPa.

2.2 Installation

Take the analyzer out of the carton. Check that the appearance of the analyzer is intact.

Take out the power adapter that comes with the mainframe and connect the AC power and the analyzer.

Before use, please follow the relevant chapters of the manual to check

whether the analyzer is functioning properly.

Please place the analyzer on a sturdy flat surface and allow some space around the analyzer. Do not place the it in a location where it is difficult to disconnect.

3.Transportation and storage

The analyzer is packaged in a carton outside and high-quality pearl cotton foam inside, which is firm and shockproof. The packing box is equipped with simple anti-vibration facilities, which are suitable for air, railway, road and ship transportation, while rain splashing, snow splashing, inversion and collision should be kept away.

Stacked in multiple layers should be avoid, as well as placed close to the ground, walls and roofs.

Transportation conditions: packaged analyzer, temperature: -20℃ to +55℃; relative humidity ≤85%, keep away from rain and sunlight.

Storage conditions: packaged analyzer, temperature: -20℃ to +55℃; relative humidity ≤85%, do not close to the ground, walls and roof.

Chapter VII Analyzer Operation

1. Operation

Please following the three steps:

a) Insert correctly the reagent information carrier(ID card), read and save the test information;

b) Put the test cassette with sample into the analyzer and edit

corresponding information for detection;

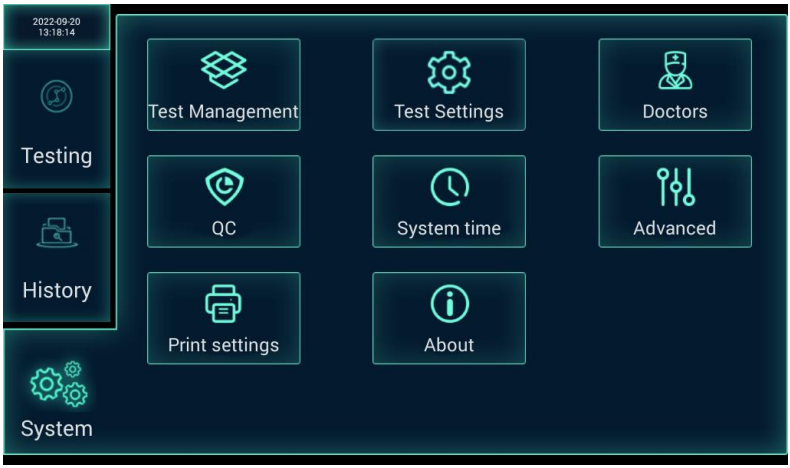
c) Result view and query.

Step 1. Read the reagent information carrier

a) Start: Turn on the power switch, the analyzer shows the Home Page.

b) Calibration: Calibration of analyzer testing requires reagent information carrier which is provided with supporting kits. The information recorded in the carrier mainly includes: Serial Number(SN), Sample No., Status, Channel(CH), Test Item, Results, Details, Reference Range, Sample Type, Patient Name, Inpatient No..

The method of importing the information is as follows: Click the "System" to enter the "system" Page.

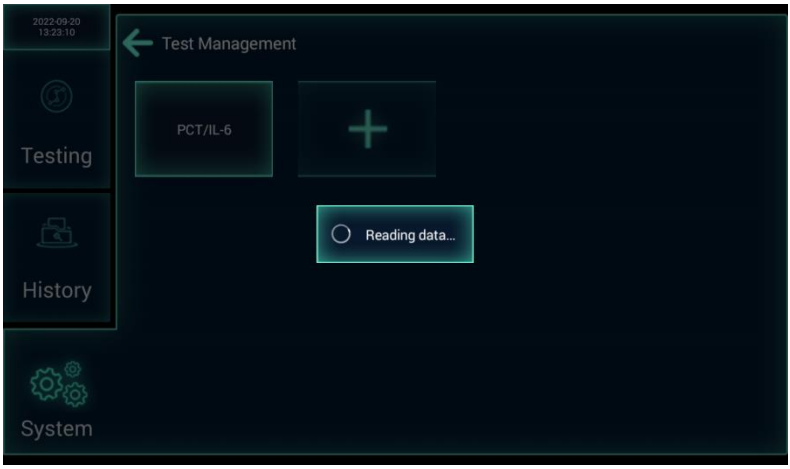


Then click the "Test management" to enter the test management interface.

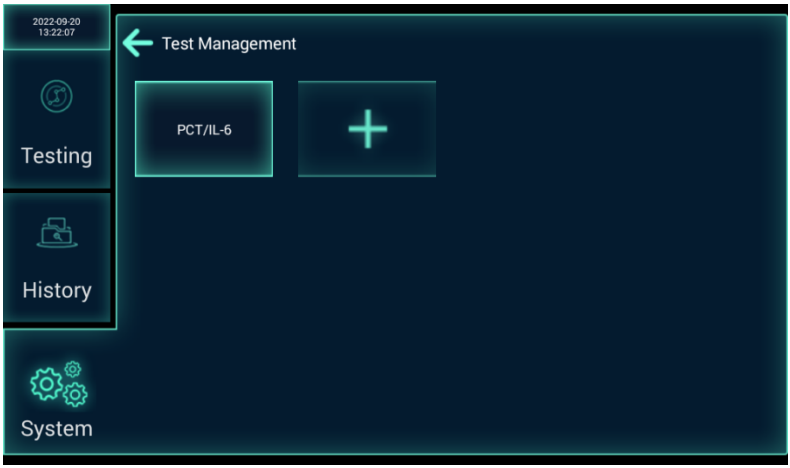
Insert the reagent information carrier that comes with a supporting kit, click the “ + ”, the analyzer will read the information in the carrier

which will be imported into the analyzer. The analyzer completes the calibration of the batch of kits according to the calibration curve by correlating the reagent information carrier with the corresponding batch of kits.

In the process of data reading.

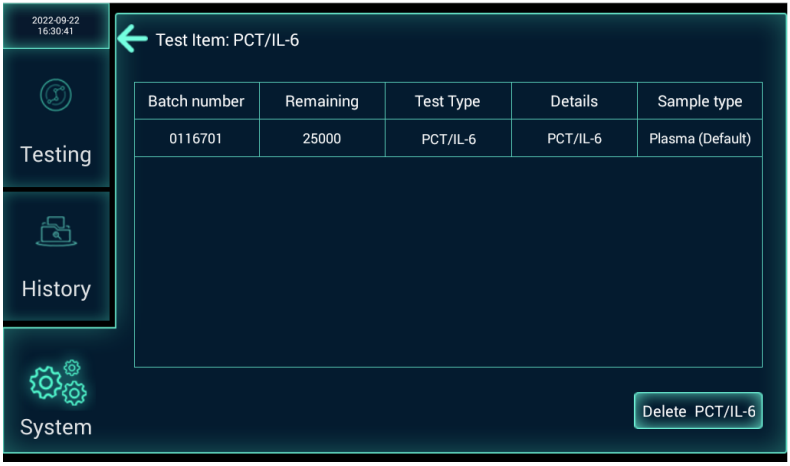


Data reading succeed.



c) Item details

Click a item name PCT/IL-6 and then enter a interface for the item details which shows the batch number, test type, remaining test times available, Details, and sample type.



d) Item deletion: Select the item parameter which is expected to be deleted according to the actual need.

Item deletion

If you need change the reagent batch or add new test items, you need to operate this step, otherwise you can skip this step.

Step 2. Sample detection

Turn on the analyzer, the analyzer enters the Home Page.

Edit sample information:

Once the instrument detects that the cassette is inserted, it will automatically associate the test items and start testing, the test-related information (sample type, doctor, department, etc.) will be set to default values. If you need to edit the relevant information, you can click the test during the test waiting process or edit it in the history interface after the test is finished.

Or,Click “ + ” , you can enter the information of the sample to

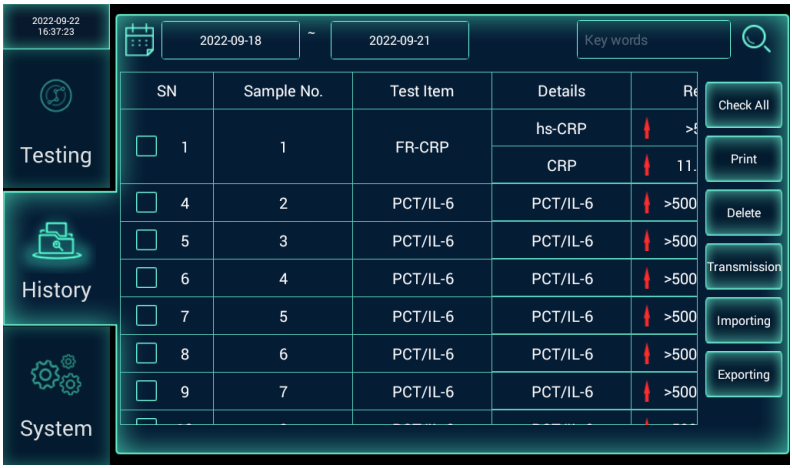
be tested to edit the sample information. After the information is input, click the "Confirm".

Dilute the sample and add it to the test cassette according to the instructions of the reagent, insert the cassette into the free channel of the 8 channels.

The analyzer automatically starts timing and testing, and automatically exits the discarded reagent cassette after the test.

Step 3. Result query.

a) On the Home Page, click the "History" to enter the history interface. This interface provides functions such as query, delete, print, importing, exporting, and transmission.



b) Query: The user can enter a time period to query data. You can also enter keywords to query data. When a keyword is entered, the data containing the keyword in a specific time period is queried.

c) Click a sample which needed to be edited, and modify the content of the selected sample.

Note: Precautions during use

a) Users must wear disposable rubber gloves when operating the analyzer.

b) The setting function for engineering adjustment and testing can only be accessed by entering a password. It is only used by the manufacturer in the process of production and engineering adjustments/testing, and the professional maintenance personnel, while ordinary users are not allowed. The analyzer has been set before leaving the factory, and reset is not need by yourself.

c) If a mechanical failure is found during the use or the analyzer cannot be used, you should immediately stop using it and turn off the power, and then report to the supplier for repair.

d) When the instrument is used, it is found that the temperature is abnormal (the temperature bursts red), which may affect the test

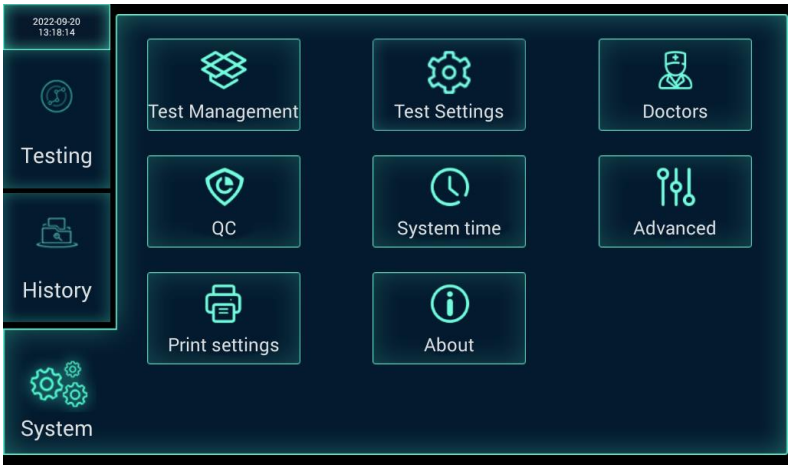
results

Solution: 1. If the ambient temperature exceeds the standard, reduce the ambient temperature 2. Contact the manufacturer

2. System setting

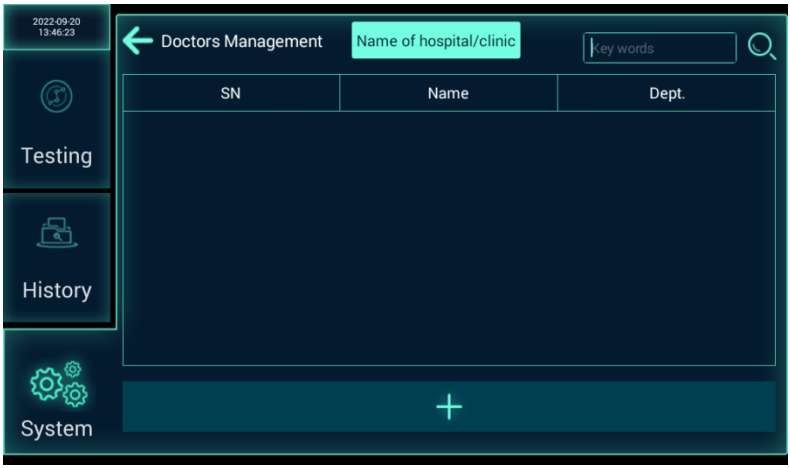
a) Turn on the power switch, the analyzer will automatically run the self-test program. After that, the analyzer automatically enters main menu interface.

b) Click the "System" to enter the following system Test settings interface, where the system could be set.

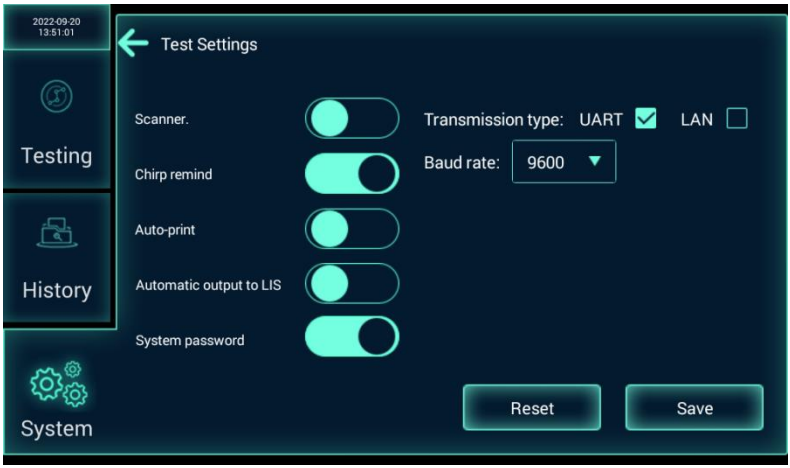


c) Test management.
It has been introduced forward.

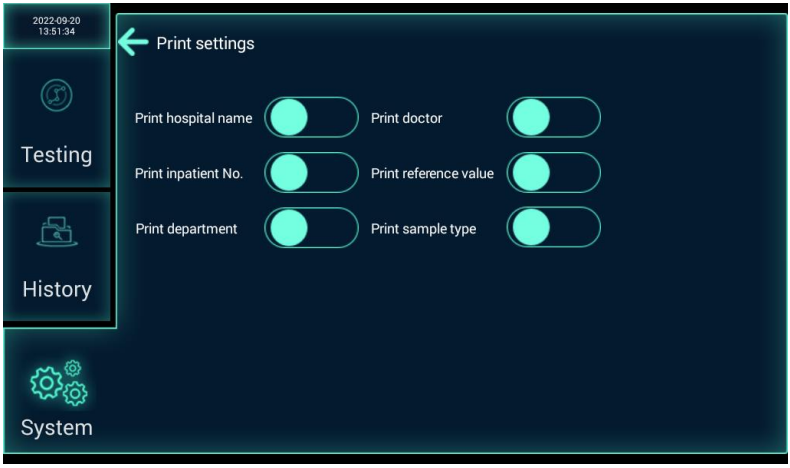
d) Click "Doctors" to enter the doctor management interface. This interface is for managing physician personal data. Click "+", and the dialog box for information input will pop up. In the dialog box, enter the doctor's name, department and choose whether to set it as the current testing doctor.



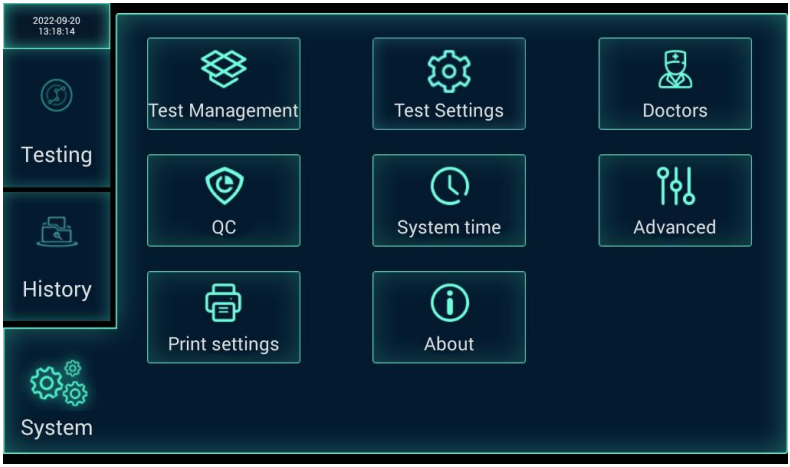
e) Click "Test Settings" to enter the test setting interface. It is available for test setting, transmission setting, reset and etc..



f) Print Settings: Click "Print settings" to enter the print settings interface. Users can select "print hospital name", "print inpatient No.", "Print department", "Print doctor", "Print reference value", "Print sample type" and other printing information.



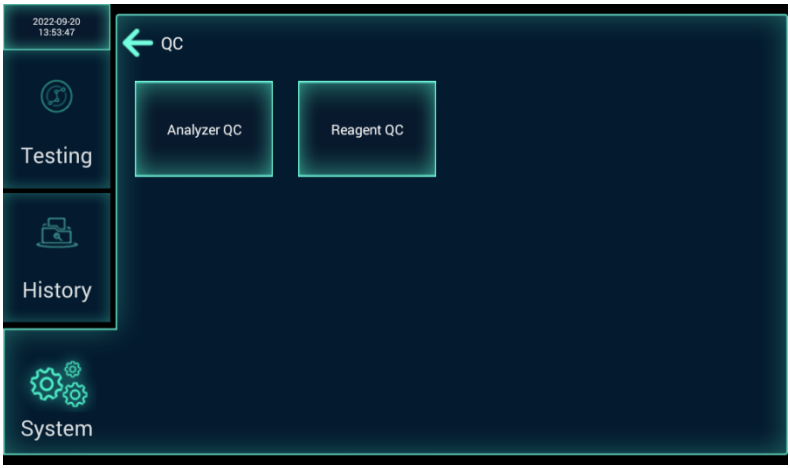
g) Time settings: Click "time settings" to enter the time settings interface. The user can manually set the time, and click "Confirm" to complete the setting.



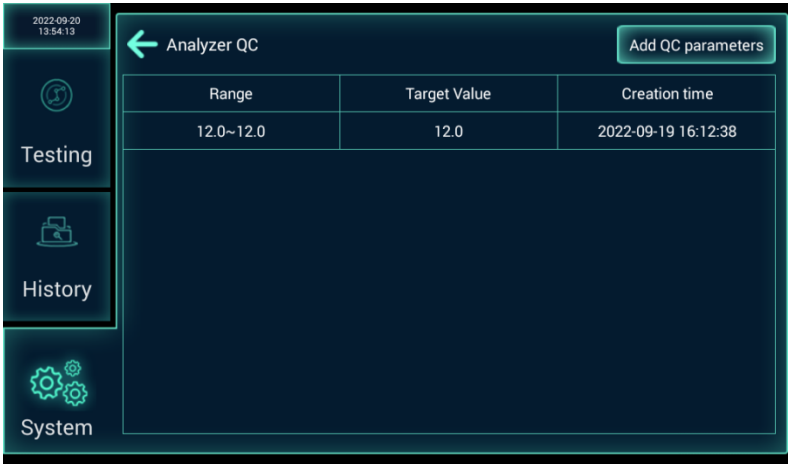
3. Quality control

Quality control (QC) includes Analyzer QC and Reagent QC. The Analyzer QC requires the quality control card provided with the analyzer, and the Reagent QC requires the reagent and quality control provided with the supporting kits.

a) Turn on the power switch, and click "QC" on the system interface.



Click " Analyzer QC " to enter the analyzer quality control interface.

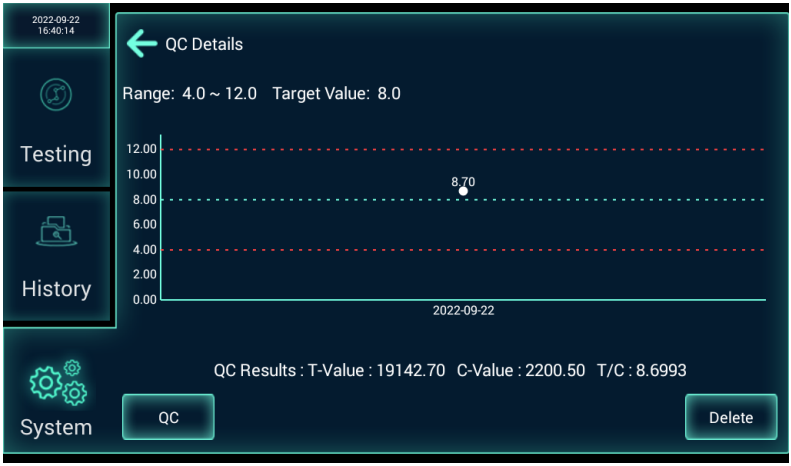


Click “Add QC parameters” to input the analyzer quality control parameters.

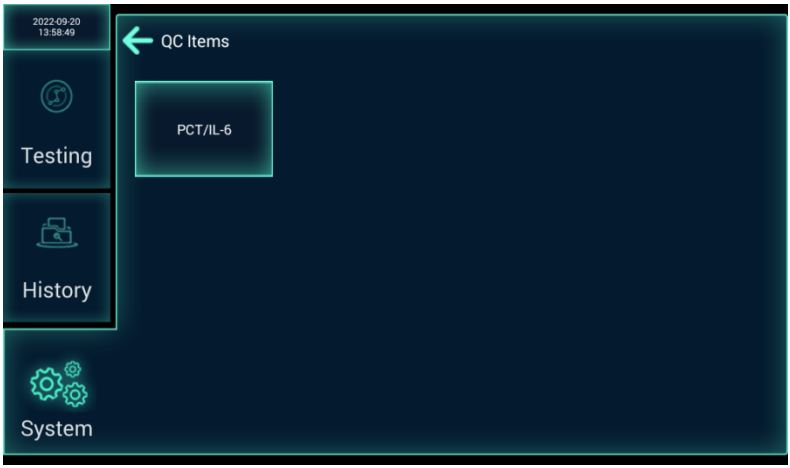
After entering the QC parameters of the quality control card, click “Confirm” to add the quality control parameters.

Click the quality control parameters in list to enter the corresponding quality control interface.

Click "QC" to start the analyzer quality control. QC results should be within the given target range. Quality control frequency: It is recommended that users perform analyzer quality control at least once a month.



Click "Reagent QC" to enter the interface for quality control items selection.



Select the item that needs quality control and enter the batch number selection interface.

Select the item batch that needs quality control, enter the interface for reagent QC details. Click "QC", then the reagent quality control starts.

QC results should be within the given target range. Quality control frequency: It is recommended that users perform reagent quality control at least once per batch.

If the reagent quality control fails, please replace the quality control product and perform the quality control again. If it still fails, please perform the analyzer quality control. If the analyzer quality control fails, please contact the local agent.

Chapter VIII Maintenance

1. Analyzer cleaning

a) Please use a neutral cleaning solution and a damp cloth to wipe the

surface of the analyzer and the touch screen.

b) If hazardous substances leak on the surface of the equipment or enter the inside of the equipment, appropriate disinfection should be taken, such as wiping with 75% medical alcohol.

c) Do not use cleaning agents or disinfectants that chemically react with equipment parts or materials, which may cause danger.

d) If in doubt about the compatibility of disinfectants or cleaning agents with equipment parts or materials, please consult the manufacturer or its agents.

2. Analyzer maintenance

a) Keep the working environment and the surface of the analyzer clean, prevent the touch screen from being bumped and malicious pressing.

b) Replace the printing paper: When the printing paper of the printer has a red edge, it means that the paper is almost used up, and it should be replaced as soon as possible. Open the printer cover to replace the printing paper.

c) Do not repair or disassemble the instrument by yourself. If there is a quality problem, or you need to replace the vulnerable parts and key parts, please contact our local agent for consultation, and any repairs can only be carried out by local authorized agent.

d) When equipment is taken out of service due to repair or disposal, please clean, sanitize, and package well to minimize hazards.

3. Waste disposal

a) The disposal of used samples, test cassettes, and protective gloves should be handled in accordance with the relevant local standards for medical waste disposal.

b) The disposal of the analyzer should be handled in accordance with the relevant local standards for electronic waste disposal.

4. Common failures handling

Failures	Reasons	Handling measures
Black screen on boot	Power is not reliably connected	Verify that the power supply is properly connected and turn on the switch.
	Electricity failure	Contact supplier.
Test cassette detection error	The cassette is not inserted correctly	Check if it is inserted in place.
	Project data is not input	Insert reagent information carrier and reading the information.
	The QR code on the cassette failed to be scanned	Check if the QR code is dirty, if it is dirty, please clean it. If the QR code is fuzzy, please replace it. If the failure occurs frequently, please contact the local agent.
The printer does not respond or prompts	Lack of printing paper	Install new printing paper.

Note: After the instrument has a failure that cannot be easily repaired, do not repair it by yourself, please immediately contact the post-sales department for repair.

5. Warranty Description

Within one year from the date of purchase, if the analyzer fails under normal use, our company will provide free maintenance. However, it does not include failures caused by improper use, self-disassembly or self-maintenance of the analyzer.

The warranty obligations are limited to situation where our company are responsible for repairing failures or replacing products.

6. Accessories, consumables, manufacture date, and service life

a) Accessories and consumables: none.

b) Manufacture date: labeled on the analyzer nameplate.

c) Service life: Valid for 5 years from the date of manufacture.

The service life of this product is determined according to the aging method. During the use process, maintenance and repair on the product should be performed according to the requirements of the product manual. Products that have been confirmed to maintain their basic safety and effectiveness after maintenance or repair can be used normally.

The validity period of the supplied quality control card is as follows:

- Unopened, the validity period is 1 year.
- After opening, store it in a dry and sealed environment, and keep it away from sunlight, the validity period is 1 month. Do not use it more than 2 times per day.
- After opening, store it in a dry and sealed environment, and

keep it away from sunlight. Do not use it more than 100 times in total.

Chapter IX Electromagnetic Compatibility Instructions

a) Our company can provide the electromagnetic compatibility information of the analyzer according to your needs.

b) It is your responsibility to ensure the electromagnetic compatibility environment of the analyzer so that it can work normally.

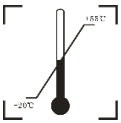
c) This analyzer complies with the emission and immunity requirements specified in IEC 61326-1/ EN 61326-1.

d) This analyzer is designed and tested in accordance with CISPR 11 Class A equipment. This equipment may cause radio interference in a domestic environment, which requiring taking precautions.

e) It is recommended to evaluate the electromagnetic environment before use, and do not use this analyzer near strong radiation (such as unshielded radio frequency sources), otherwise the normal operation of the analyzer maybe be interfered with.

Chapter X Symbols and description

IVD : IN VITRO DIAGNOSTIC MEDICAL DEVICE	 : KEEP DRY

 : FRAGILE	 : HUMILITY LIMIT
 : UPWARD	 : CAUTION
 : TEMPERATURE LIMIT	 : BIOHAZARD WARNING
 : REAGNTE INFORMATION CARRIER INTERFACE	RS232 : SERIAL RS232 INTERFACE
 : AUTHORIZED REPRESENTATITVE IN THE EUROPEAN COMMUNITY	 : DO NOT DISCARD IT CARELESSLY, HAND IT OVER TO APPROPRIATE FACILITIES
 : DATE OF MANUFACTURE	 : MANUFACTURER
 : DC POWER INTERFACE	

Chapter XI Contact

Manufacturer name: Hunan Kangxin Biotechnology Co., Ltd.

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Tel: +86 28 61800230

Website: www.vacurebiotech.com

E-mail: info@vacurebiotech.com

Our authorized representative in the European Community / Union

CMC Medical Devices & Drugs S.L.

Address: C/Horacio Lengo Nº 18, CP 29006, Málaga-Spain

Tel: +34 951 214054 Fax: +34 952 330100

E-mail: info@cmcmedicaldevices.com

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Chapter XII Vigilance

If any serious incident has occurred in relation to this product, please contact the local agent and report to the local competent authority.