



Fluorescence Immunoassay Analyzer

User Manual

AFR-301

HANGZHOU ALLTEST BIOTECH CO., LTD

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Chapter 1 Introduction

1.1 Intended Use

Fluorescence Immunoassay Analyzer is an analyzer that based on detection of fluorescence emitted during an immunoassay with antigen-antibody interaction. The analyzer is designed to be used for quantitative or qualitative detection of human samples with specific *in vitro* diagnostic test units including Inflammation Markers, Tumor Markers, Nephrology, Diabetes, Cardiac Markers, Coagulation, Endocrinology, Autoimmunity, Infectious Diseases and etc. Fluorescence Immunoassay Analyzer offers the advantages of high accuracy, strong stability and fast results. Fluorescence Immunoassay Analyzer should only be used with *in vitro* diagnostic tests manufactured by Hangzhou AllTest Biotech Co., Ltd. as per package insert provided with specific test kits.

For professional *in vitro* diagnostic use and Point of Care use.

Please read this User Manual carefully before operation.

1.2 Scope of Application

Fluorescence Immunoassay Analyzer works with certain fluorescent reagents. It's for professional *in vitro* diagnostic and Point of Care Use. It may be used in central laboratories of medical institutions, outpatient or emergency departments, clinical departments or medical services (such as community health centers), or medical center, etc. It can also be used in research laboratories.

1.3 Product Name

- **Product Name:** Fluorescence Immunoassay Analyzer

1.4 Software Description

1.4.1 Name and Version

Name: **FIA**

Version: **V1.5.891**

Chapter 2 Components and Structure

2.1 Standard Equipment List

Packing List

No.	Description	Model	Quantity
1	Analyzer	AFR-301	1
2	Power Adapter	/	1
3	QC ID Card	/	1
4	QC Standard Cassette	/	1
5	Print Paper Roll	57 mm*20 mm	1
6	User Manual	/	1
7	Rechargeable battery	3300mAh	1

On receiving the box, please check the contents with this list and ensure that all items mentioned in the list (2.1) are included.

Note: If some parts are missing or damaged, please contact with local distributor.

2.2 Fluorescence Immunoassay Analyzer

2.2.1 External View

Fluorescence Immunoassay Analyzer front view

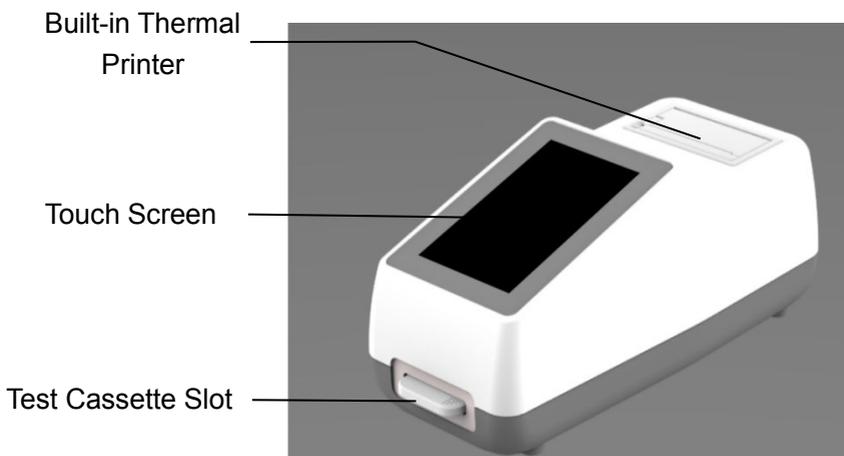


Fig 1

Fluorescence Immunoassay Analyzer left side view (Ref Fig 2)

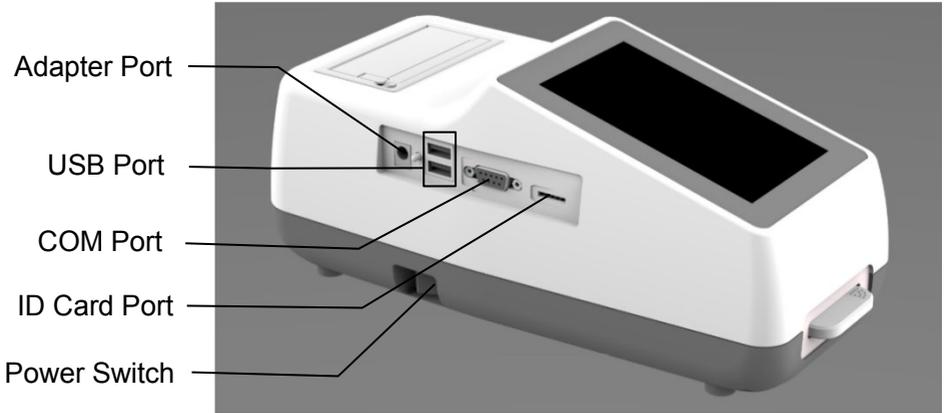


Fig 2

Adapter Port: Connect the power adapter.

USB Port: Update software system or connect the scanner.

COM Port: Connect the PC software, LIS system or scanner.

ID Card Port: Insert the ID Card.

Power Switch: Power on or off the analyzer.

2.2.2 Power Adapter (Ref Fig 3)



Fig 3

2.2.2 QC

QC ID card and QC Standard Cassette provided with the analyzer are used for the quality control of the analyzer. (Ref Fig 4).



Fig 4

2.3 Technical Specification

• Principle	Fluorescence Immunoassay
• Test Formats	Cassette
• Measurement	Quantitative, Qualitative
• Read Time	< 20 seconds
• Test Time	Ref: Analytes
• Specimen	Ref: Package Insert
• Power Source	AC 100-240 V / 50/60 Hz; DC 15 V
• Dimensions	270 mm (Width) × 127 mm (Depth) × 115 mm (Height)
• Weight	< 1.2 kg
• Excitation Light source	LED
• Spectrum	Excitation spectrum: Mean wavelength $\lambda_0=365$ nm Reception spectrum: Mean wavelength $\lambda_1=610$ nm
• Connecting Ports	RS232, USB
• Memory	8000 records
• Storage Conditions	Temperature: -10-40 °C, relative humidity: 20% to 90%, atmospheric pressure: 86 to 106 kPa; and in a ventilated environment free of corrosive gases. Measures should be taken to avoid moisture, and prevent impact and severe vibration during transportation.
• Operating Conditions	4-30 °C
• Printer	Built-in thermal printer

Chapter 3 Installation

3.1 Checklist upon Opening the Box

3.1.1 Check before opening the box:

Before opening the box, check if the packaging is in good condition and box was not damaged during transportation.

3.1.2 Check after opening the box:

- 1) Open the box carefully, check the contents according to **2.1 Standard Equipment List** to ensure it is complete.
- 2) Examine the power adapter of analyzer to see whether it is in good condition. If any defects are found, please contact the manufacturer or local distributor.

Note-1: Please keep the original box and packing materials of analyzer for any future shipping/reference purpose.

Note-2: Hangzhou AllTest Biotech Co., Ltd. strives to provide the right kind of power plug suitable for each country. However, in some cases, it may not be possible. Using right kind of adapter to connect to power is recommended in such cases.

3.2 Environmental Requirement

- Surrounding temperature: 4-30 °C;
- Relative Humidity: 20% to 90% RH;

Avoid strong magnetic field, vibration, shock, corrosive gases, direct sunlight, high humidity, and high temperature in working area, where the analyzer is placed for operation.

3.3 Placement

- 1) The analyzer should be placed on a stable and level countertop, and in an indoor environment free of dust, direct sunlight and corrosive gases. The countertop must be able to sustain a weight of 1.2 kg.
- 2) No strong vibration source and strong electromagnetic fields around.
- 3) The analyzer should be placed in a well-ventilated place. There should be at least 10 cm space around the analyzer to ensure the necessary space for operation and maintenance.

3.4 Power Supply Voltage Requirements



The power supply of the analyzer varies between 100-240 V / 50/60 Hz AC depending on countries where the analyzer is used. The input voltage is 15 V DC. The power is 30 W. Avoid short circuit and electric shock during the use. The analyzer is grounded through power adapter.

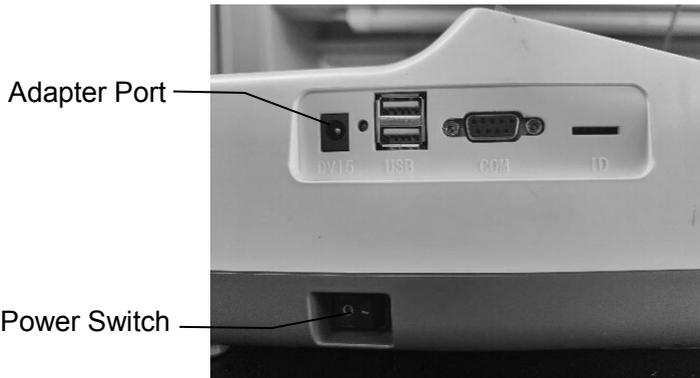
3.5 Analyzer Installation

Please use the analyzer under the proper conditions mentioned in **3.2 Environmental Requirement**.

- 1) Place the analyzer on a stable platform.
- 2) Load paper

Open the printer cover, place the printing paper into the printer, pull out approximately 5 cm of paper from the roll, then close the cover of the printer.

- 3) Connect the power adapter and the power connector of analyzer(Ref Fig 5).



Ref Fig 5

- 4) Turn on the power switch and start the analyzer.

Chapter 4 Directions for Use

The Fluorescence Immunoassay Analyzer can be operated by commands on touchscreen.

4.1 System Installation

- 1) Connect power with analyzer through the DC adapter, press the power switch to turn on the analyzer.
- 2) After starting the analyzer, the initializing screen will display. (Ref Fig 6)
Note: If the initializing failed, it is recommended to contact the manufacturer or the local distributor.
- 3) After initializing, the main interface will display. (Ref Fig 7)

This is the main operation interface of the analyzer. Here you can choose the **Test, Test Items, History and Settings**.



Fig 6

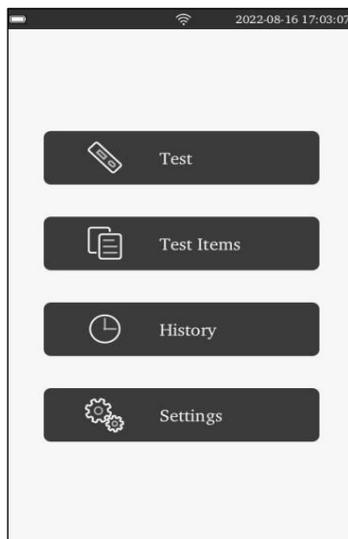


Fig 7

4.2 Settings

Tap "**Settings**" to display the secondary menu in the interface. (Ref Fig 8)

4.2.1 System Settings

- 1) Tap "**Time**" to enter the year, month, day, hour, minute, second and tap "**Set**" to modify the system time. Tap "**Time zone**" to adjust the UTC time. (Ref Fig 9)

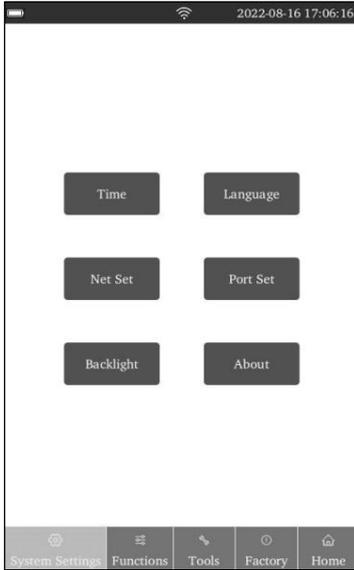


Fig 8

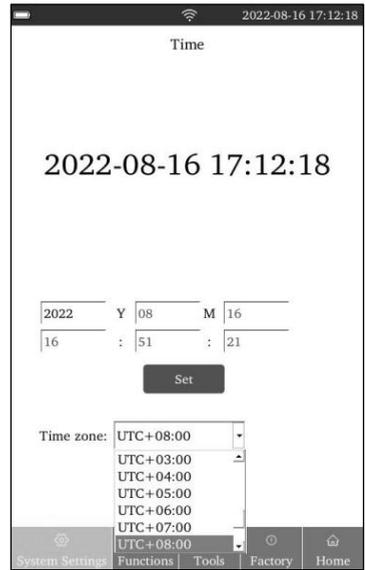


Fig 9

- 2) Tap "**Language**" to select the corresponding language, and tap "**OK**" to switch the system language. (Ref Fig 10)

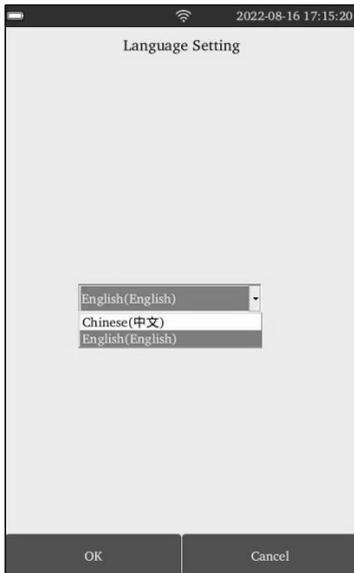


Fig 10

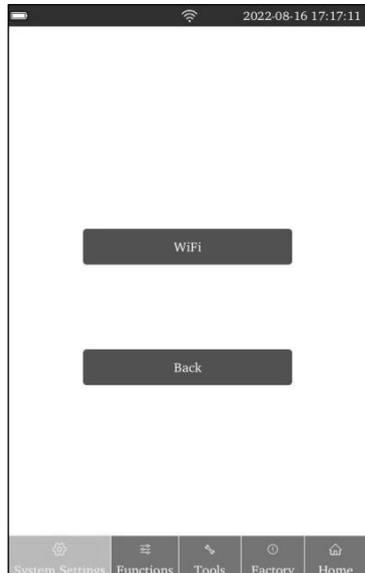


Fig 11

- 3) Tap "**Net Set**" to enter the interface. (Ref Fig 11) and tap "**WiFi**" to enter the interface below for wifi settings. (Ref Fig 12)

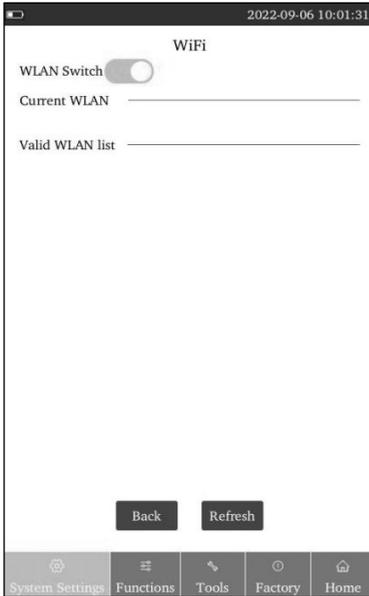


Fig 12



Fig 13

Tap the "**WLAN Switch**" and choose the WLAN you need in the "**Valid WLAN list**". Then enter the password. (Ref Fig 13)

4) Tap "**Port Set**" to enter the interface.

Generally the default serial port is connected to the LIS (Ref Fig 14). If it is used to connect to a scanner or PC, leave LIS port unchecked and then check the appropriate option.

5) Tap "**Backlight**" to adjust the brightness of the display. Tap "**LIGHTEN**" or "**DIM**" to adjust the screen brightness. (Ref Fig 15)

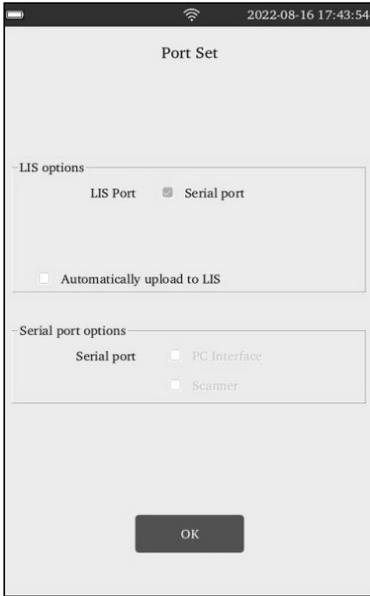


Fig 14

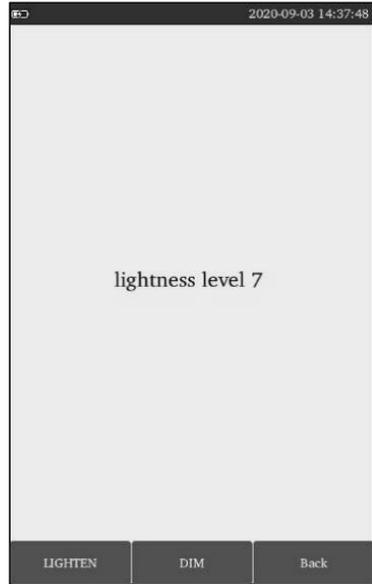


Fig 15

- 6) Tap "**About**" to enter the interface for more information related to the analyzer. The Software Version and Serial Number are displayed on the screen. (Ref Fig 16)

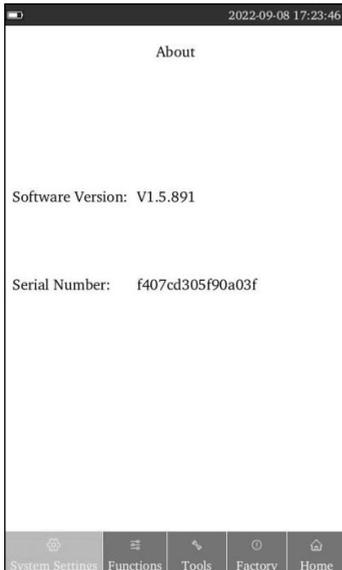


Fig 16

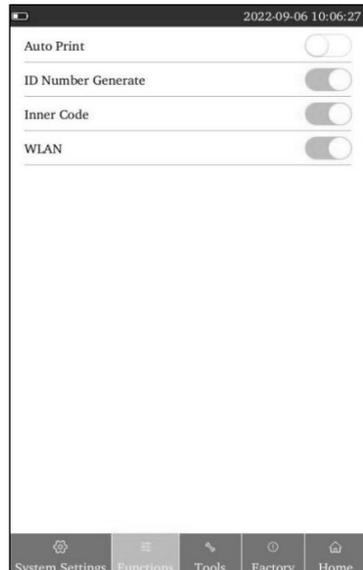


Fig 17

4.2.2 Function

Tap "**Functions**" to enter the interface as Fig 17. Tap  following the corresponding item to select options.

Note:  means on,  means off.

- Auto Print:
On-Print results automatically after the test is completed.
Off-Results are not automatically printed after the test is completed.
- ID Number Generate:
On-Generate ID number automatically according to date code. Off-Enter the ID number manually.
- Inner Code:
On-Scan the barcode to identify the test projects and batch numbers before test.
Off-Detect directly without scanning the barcode.

Note: If the barcode does not need to be scanned, please tap the "OFF" and select the ID card manually.

- WLAN: On-Open the WiFi. Off-Close the WiFi.

4.2.3 Tools

Tap "**Tools**" to enter the interface. (Ref Fig 18)

- 1) Tap "**Update**" to enter the interface, the interface will be appeared as Fig 19.



Fig 18

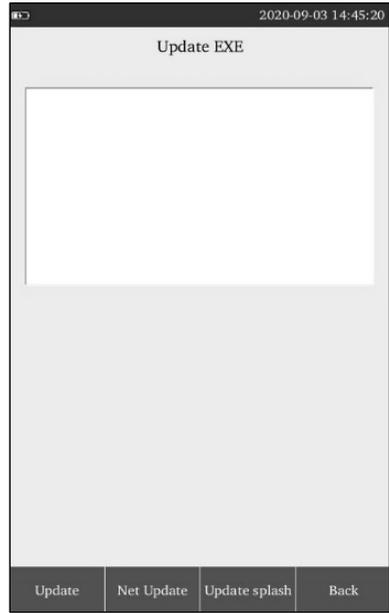


Fig 19

In this interface, **Update**, **Net Update** and **Update splash** can be selected.

Update: copy the update package to the USB flash drive, insert it into the USB port and tap “Update” to update the system step by step.

Net Update: get the latest version of the program from the server and update the system step by step.

Update Splash: copy the startup interface to the specified folder of the USB flash drive, insert it to the USB port to complete updating step by step.

Note: After the update is completed, please tap the “**restart**” to finish (Ref Fig 20).



Fig 20

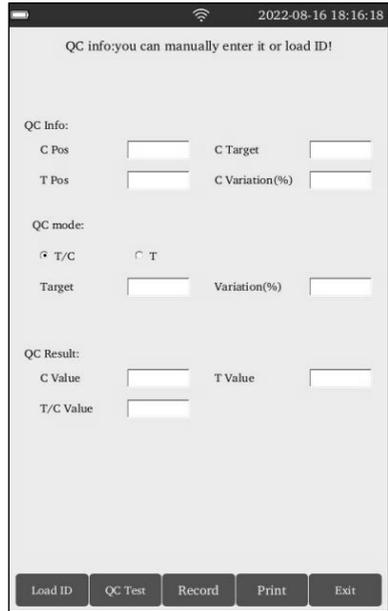


Fig 21

2) Tap **"QC"** to enter the interface. (Ref Fig 21)

Insert the QC ID Card to input information of the quality control or input manually.

Insert the QC Test cassette, and Tap **"QC Test"** to start the quality control test of analyzer.

If the analyzer passes the quality control, the interface of **"QC Passed"** will display. If the analyzer does not pass the quality control, the interface of **"QC Failed! Please contact manufacturers!"** will display. (Ref Fig 22, 23)

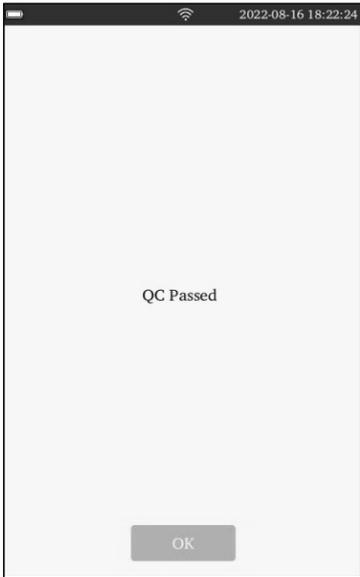


Fig 22



Fig 23

Note: If the quality control failed, it is necessary to contact the manufacturer for troubleshooting, and the test result is invalid.

Tap **"Record"** to view the quality control records. (Ref Fig 24)



Fig 24

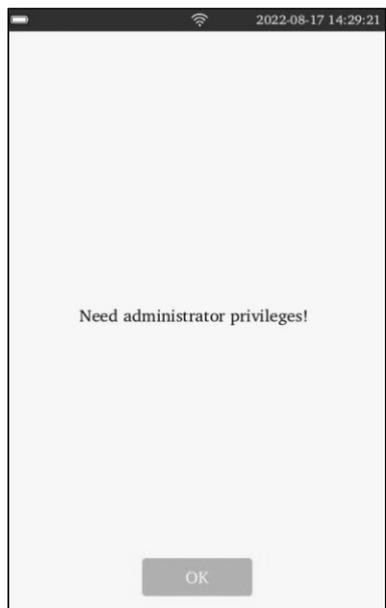


Fig 25

Tap **"Print"** to print the quality control results.

3) Tap **"Account"** to enter the interface. (Ref Fig 25)

Note: Account setup requires administrator privileges! If in doubt, please contact the manufacturer.

4) Tap **"Logout"** to enter the interface. (Ref Fig 26)

The initial username: admin, and the initial password: 666666.

Note:

- The analyzer has been set to log in automatically, so the login screen will not be displayed after initializing.
- The user in the drop down box can only be used by the manufacturer, in case of doubt, please contact the manufacturer.

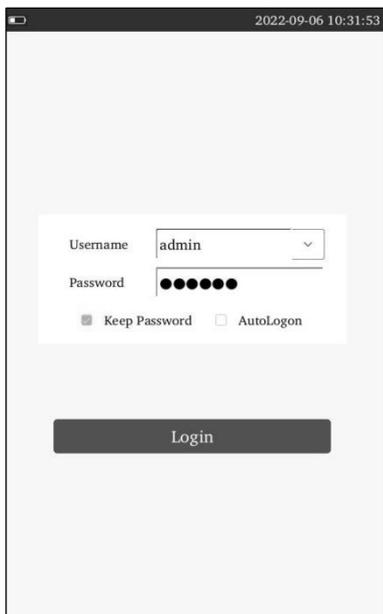


Fig 26



Fig 27

5) Tap **"Factory Reset"** to restore the factory settings of the analyzer and clear the data stored in the analyzer.

Note: Please backup the data before performing "Factory Reset".

6) Insert the USB disk to the USB port and Tap **"Export"** to backup the history data to the USB disk.

4.2.4 Factory

Tap **"Factory"** and input the password to enter the factory mode.

Note: The factory mode is only used by professional technicians for debugging.

4.2.5 Home

Tap "**Home**" to return to the main interface.

4.3 Test Items

Tap "**Test Items**" to enter the interface. (Ref Fig 27)

Insert the ID card and then the information of the test item was imported and stored in the analyzer.

The information can be reviewed and deleted in the interface.

4.4 Test

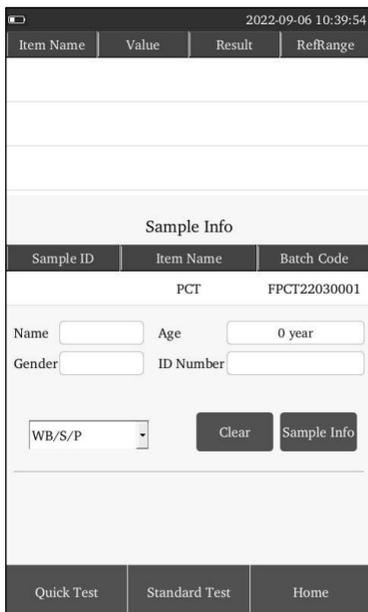
Tap "**Test**" to switch to the interface. (Ref Fig 28)

Step 1: Insert the ID card and select the sample type as needed.

Step 2: Tap the Sample Info to edit related sample information such as **Sample ID, Name, ID Number, Gender, Age and Tester.**

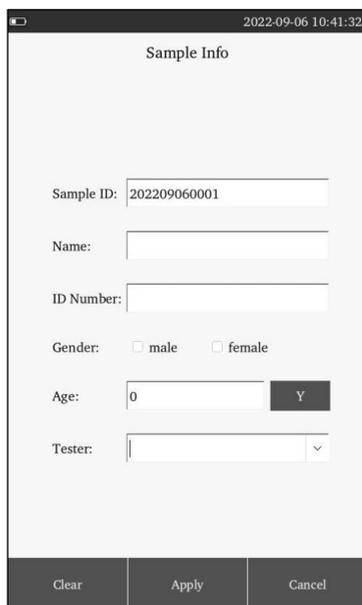
(Ref Fig 29)

Note: If the ID Number Generate is on, the ID number will be generated when testing.



The screenshot shows the 'Test' interface. At the top, there is a table with columns: Item Name, Value, Result, and RefRange. Below the table is a 'Sample Info' section. It contains a table with columns: Sample ID, Item Name, and Batch Code. The values are PCT and FPCT22030001. Below this table are input fields for Name, Age (0 year), Gender, and ID Number. There is also a dropdown menu for 'WB/S/P' and two buttons: 'Clear' and 'Sample Info'. At the bottom, there are three buttons: 'Quick Test', 'Standard Test', and 'Home'.

Fig 28



The screenshot shows the 'Sample Info' form. It contains input fields for Sample ID (202209060001), Name, ID Number, Gender (male and female), Age (0), and Tester. There is a 'Y' button next to the Age field. At the bottom, there are three buttons: 'Clear', 'Apply', and 'Cancel'.

Fig 29

Step 3: Select "**Quick Test**" or "**Standard Test**" to start the test.

1) **Quick Test:** In this mode, the incubation of the test cassette is done outside the analyzer. This Mode is suitable, when more than one test is to be performed as incubation time can also be utilized for another test.

2) **Standard Test:** In this mode, incubation of the test cassette is done inside the analyzer. Add the sample to the test cassette and do nothing after inserting the cassette into the slot. User can walk away from the analyzer and perform other task. After the incubation is complete, the analyzer will automatically test and display the results.

● **Quick Test**

Tap "**Quick Test**" to start the motor to scan the cassette and start the test.

(Ref Fig 30)

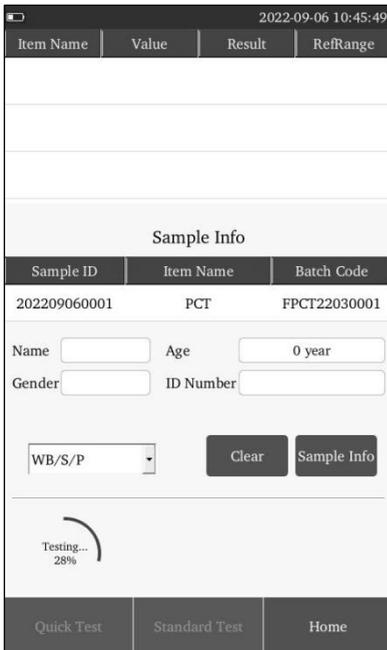


Fig 30

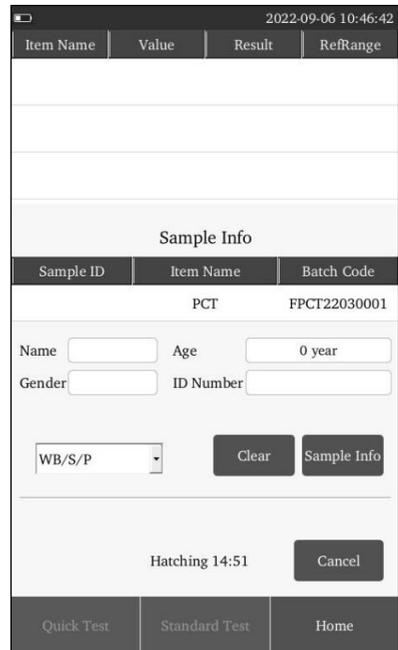


Fig 31

● **Standard Test**

Tap "**Standard Test**", the incubation countdown will appear, after the countdown is over, the analyzer will automatically test (Ref Fig 31) and display the results as shown in Fig 32.

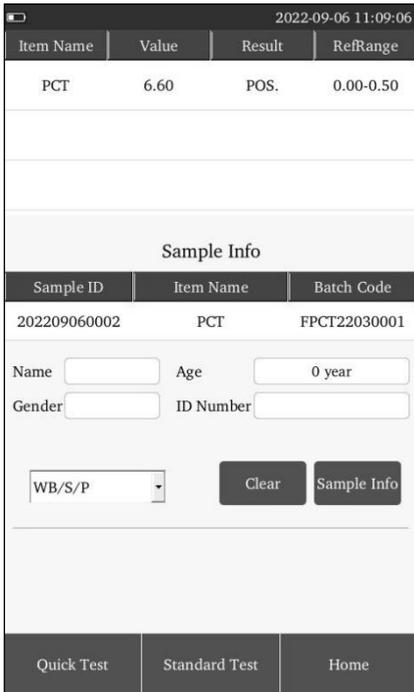


Fig 32

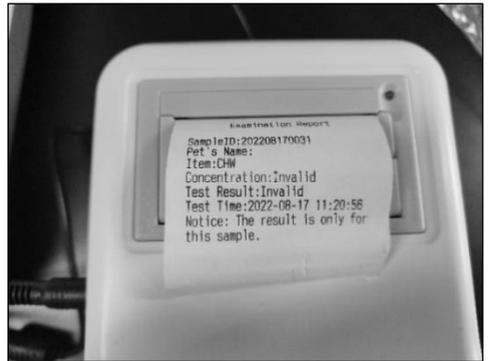


Fig 33

Step 4: After the test is completed, the analyzer will automatically print the results. If "**Auto Print**" is not turned on, manually tap "**Print**" to print the test results. (Ref Fig 33)

Step 5: Press "**Home**" to return to the main interface.

4.5 History

Tap "**History**" button on the main menu page to switch to the interface. This interface will provide record viewing and records related operations. (Ref Fig 34)

2022-09-06 11:13:06					
SN	Sample ID	Item Name	Result	Test Time	
<input type="checkbox"/>	67	202209060002	PCT	6.60 POS.	2022-09...
<input type="checkbox"/>	66	202209060001	PCT	6.61 POS.	2022-09...
<input type="checkbox"/>	65	202209050002	PCT	Invalid Invalid	2022-09...
<input type="checkbox"/>	64	202209050001	PCT	Invalid Invalid	2022-09...
<input type="checkbox"/>	63	202208300063	PCT	>50.00 POS.	2022-08...
<input type="checkbox"/>	62	202208300062	PCT	>50.00 POS.	2022-08...
<input type="checkbox"/>	61	202208300061	PCT	>50.00 POS.	2022-08...
<input type="checkbox"/>	60	202208300060	PCT	>50.00 POS.	2022-08...
<input type="checkbox"/>	59	202208300059	PCT	>50.00 POS.	2022-08...
<input type="checkbox"/>	58	202208300058	PCT	>50.00 POS.	2022-08...
<input type="checkbox"/>	57	202208300057	PCT	>50.00 POS.	2022-08...
<input type="checkbox"/>	56	202208300056	PCT	>50.00 POS.	2022-08...
<div style="display: flex; justify-content: space-between; padding: 5px;"> PrePage NextPage All Search Delete Print Home </div>					

Fig 34

2022-09-06 11:16:15

Search Condition

Time

2022 ▾ - 09 ▾ - 06 ▾ 00 ▾ : 00 ▾

2022 ▾ - 09 ▾ - 07 ▾ 00 ▾ : 00 ▾

Sample ID

Item Name

Search
Cancel

Fig 35

Tap **"PrePage"** or **"NextPage"** to view the test records.

Tap **"Print"** to print the selected detection results by the built-in printer.

Tap **"Delete"** to delete the selected test records.

Tap **"All"** to select all records on the current page.

Tap **"Search"** to enter various screening conditions to search for records as Fig 35.

Select Time, Sample ID, Item Name, Pet's Name and tap **"Search"** to find the corresponding record.

Chapter 5 Daily Maintenance and Cleaning

5.1 Maintenance

Basic maintenance is to keep the outside of the Fluorescence Immunoassay Analyzer clean.

External cleaning and maintenance method: Clean the outer surface of the analyzer with a damp cloth with no more than 70% alcohol. Do not use strong bleach ($\geq 0.5\%$ bleach solution), because oxidizing substances and solvents may damage the parts of analyzer and touch screen. **Do not clean any internal parts and inner surface.**



Turn off the power switch before cleaning! Ensure the power cord is disconnected to avoid the risk of short circuit and electric shock!

5.2 Maintenance Plan

Maintenance item	Every week	Every month	three When needed
Dust cleaning	X		
QC calibration		X	
Replace print paper			When the paper runs out

5.3 Precautions

- i. Do not place the analyzer in a position that is difficult to operate or inconvenient to disconnect.
- ii. Do not insert anything into the test cassette slot except for the test cassette provided by the manufacturer.
- iii. Treat tested samples as potentially contagious and use protective gloves and other protective measures, and avoid skin contact with sample loading port of the test cassette.
- iv. Please dispose the used cassettes according to “Medical Waste Management Regulations” complying with local regulations in force to avoid biohazards.
- v. Use test kits manufactured by Hangzhou AllTest Biotech Co., Ltd. and supplied by authorized distributors of Hangzhou AllTest Biotech Co., Ltd. only. Do not use the assay test from other manufacturer, it may lead to

inaccurate test result.

- vi. **Description of the procedures of data storage and recovery:** The analyzer can save the calibration curves related to projects and batches provided by the manufacturer, and records of tests by users. The analyzer will automatically save the calibration curves imported from ID cards. The analyzer can save up to 80 projects, and each project has 5 batches of calibration data. The test results will be saved to the analyzer automatically in the form of records during the normal use. The analyzer can save up to 8000 records. The stored data can be automatically restored after power failure. The data will be cleared when users select “Factory Reset” to return to factory settings.
- vii. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.

Chapter 6 Service, Repair and Disposal

Fluorescence Immunoassay Analyzer does not require special maintenance except for keeping it clean and replacing printing paper when needed. If service is required, please contact with the local distributor.

Fluorescence Immunoassay Analyzer internal parts, including the circuit boards, optical detection modules, display, printer, and two-dimensional bar code scanning module, can only be provided by manufacturer. Such items should not be sourced from any third-party, even if they claim to provide the same function. When issues related to the occur, contact with the local distributor. We provide technical support for users to perform troubleshooting. If the analyzer needs to be sent back to manufacturer, please contact with the local distributor and/ or Hangzhou AllTest Biotech Co., Ltd. It normally takes about a week to fix problems. If it turns out not repairable within warranty period, we will replace it with a new one. If for any reason the analyzer needs to be disposed off, please follow the procedures and rules of disposing off for Class B electric analyzers.

We provide technical support and software maintenance, including functional maintenance, corrective maintenance, software fixes or upgrade. We are only responsible and provide services when the analyzer is properly used in compliance with the manufacturer's instructions, otherwise any damages incurred will not be covered.

Electrical & Electronic Equipment (WEEE) Directive. If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.



Chapter 7 Troubleshooting

Operating and maintaining the Analyzer following the instructions in this User Manual usually enables the analyzer to function correctly. Some common faults may be encountered during the use of the analyzer. The following table will introduce the common faults and solutions:

Fault Phenomenon	Possible Cause	Elimination Method
The instrument cannot be powered on	Loose connection between power cable and adapter	Reconnect and try again, if doesn't work, contact after-sales engineer or the manufacturer
The screen fails to display	The screen connecting line is loose	Contact after-sales engineer or the manufacturer
Test result is invalid(N/A)	The sample is not loaded.	Loading the sample and retest.
	Test part of the instrument is abnormal	Perform QC procedure. If result is PASS, retest with new test cassette, otherwise contact after-sales engineer or the manufacturer.
	Test Cassette is abnormal	Retest with new test cassette. If also happened, contact after-sales engineer or the manufacturer.
The motor makes abnormal sound and gets stuck during test	Mechanical movement failure	Contact after-sales engineer or the manufacturer.
Testing don't perform	The sensor does not detect the test cassette	Check whether the test cassette is inserted into the end.
	The sensor is damaged	Insert the test cassette to the end and keep for a while. If it

		still doesn't work, most likely the sensor is damaged. Please contact after-sales engineer or the manufacturer timely.
Other faults	Other faults	Please contact after-sales engineer or the manufacturer timely.

Chapter 8 Manufacturer Information

Name: Hangzhou AllTest Biotech Co., Ltd.

Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China

Tel: +86-571-56267891

Web: www.alltests.com.cn

Email: info@alltests.com.cn

Index of Symbols

	Consult Instructions For Use		Tests per kit		In vitro diagnostic medical device
	Temperature limit -10-40 °C		Catalog #		Keep dry
	Manufacturer		Keep away from sunlight		Caution
	Fragile, handle with care		Protect from heat and radioactive sources		Biological risks
	CE Mark		Authorized Representative in the EU		Unique device identifier



Hangzhou AllTest Biotech Co.,Ltd.

#550, Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn



MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Number: F145108000

Revision date: 2022-09-21

Appendix

A. Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within one year of purchase.

For your records, write the purchase date of your starter kit here:

Note: This warranty applies only to the analyzer in the original purchase. It does not apply to the other materials included with the analyzer.

AllTest Biotech Co., Ltd. warrants to the original purchaser that this analyzer will be free from defects in materials and workmanship for a period of one year (12 months).

The one year starts from the later of the date of original purchase or installation (except as noted below). During the stated one year period, **AllTest** shall replace the unit under warranty with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective. **AllTest** shall not be responsible for shipping charges incurred in the repair of such an analyzer. This Warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. **AllTest** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the analyzer in accordance with the operations manual, or maintenance by anyone other than **AllTest**.

Furthermore, **AllTest** assumes no liability from malfunction or damage to analyzers caused by the use of products other than products manufactured by **AllTest**. **AllTest** reserves the right to make changes in the design of this analyzer without obligation to incorporate such changes into previously manufactured analyzers.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties express or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by **AllTest**.

Limitations of Liability

In no event shall **AllTest** be liable for indirect, special or consequential damages, even if **AllTest** has been advised of the possibility of such damages. For warranty service, please contact your local distributor.

B. Warranty Card

Please complete this warranty card and mail it to your local distributor to register your purchase within one year of purchase.

Purchaser	
Model	
Serial Number	
Date of Purchase	
Address	
Telephone Number	
E-Mail Address	



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