



Novatrend™

Fluorescence Immunoassay Analyzer

User Manual

AFR-200/200S

HANGZHOU ALLTEST BIOTECH CO., LTD

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Chapter 1 Introduction

1.1 Intended Use

Novatrend™ Fluorescence Immunoassay Analyzer is an analyzer based on detection of fluorescence emitted during an immunoassay with antigen-antibody interaction. Fluorescence Immunoassay Analyzer offers the advantages of high accuracy, good stability and fast results. Novatrend™ 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 use and use at Point of Care only.

Please read this user manual carefully before operation.

1.2 Scope of Application

Fluorescence Immunoassay Analyzer works with certain fluorescent reagents. It's for *in vitro* diagnosis professional 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: Novatrend™ Fluorescence Immunoassay Analyzer**

1.4 Software Description

Hardware Version: V1.0

Software Version: V1.0

1.5 Principle

The analyzer uses UV led array as excitation light source. As the test cassette inserted into the fluorescence analyzer, UV light irradiates to the testing and control area of the test cassette, stimulates the adhesion of fluorescent material to emitting red light. The emitting lights are collected and translated into electrical signals, the strength of the electrical signals and fluorescence molecular quantity strictly related, analyzer automatic scanning and calculate the analytes in the sample under test.

Chapter 2 Components and Structure

2.1 Standard Equipment List

Packing List

No.	Description	Model	Quantity
1	Fluorescence Immunoassay Analyzer	AFR-200/200S	1
2	Power Adapter	DJ-U48s-12	1
3	USB 2.0 to RS232 Cable	/	1
4	QC ID Card	/	1
5	QC Standard Cassette	/	1
6	Print Paper Roll	57mm*40mm	1
7	User Manual	/	1
8	Barcode Scanner	/	Optional

On receiving the box, please check the contents with this list and ensure that all the items mentioned in the list (2.1) are included. Barcode Scanner is an optional accessory, which is available only for specific requirement and not as standard accessory.

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 (Ref Fig 1)



Fig 1

Back Side Structure (Ref Fig 2)

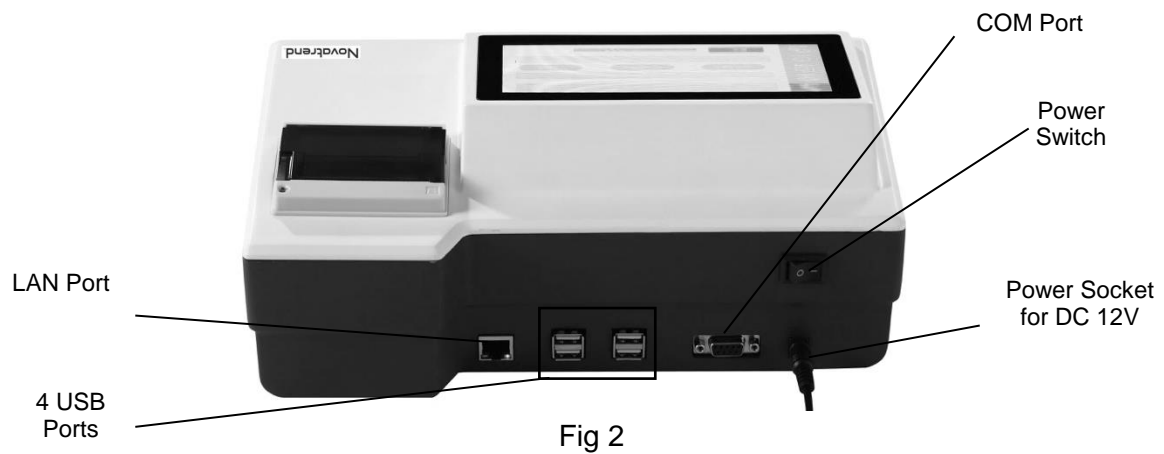


Fig 2

2.2.2 Power Adapter (Ref Fig 3)

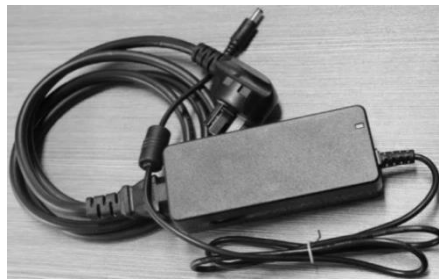


Fig 3

2.2.3 USB 2.0 to RS232 Cable (Ref Fig 4)



Fig 4

2.2.4 QC Card (Ref Fig 5)

QC ID card and QC Standard Cassette provided with the analyzer are used for the quality control of the analyzer. (Ref Fig 5)

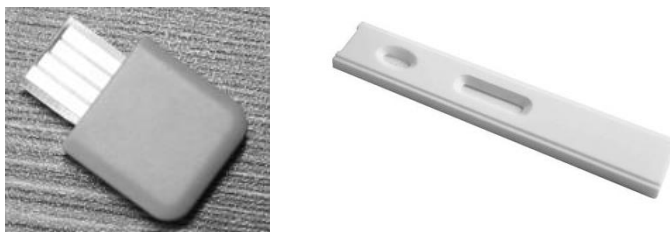


Fig 5

2.2.5 Barcode Scanner

The Barcode Scanner and the connect cable provided with the analyzer are as below. (Ref Fig 6).



Fig 6

The connection between the Analyzer and the Barcode Scanner is as Fig 7.



Fig 7

Note: The USB plug must be inserted into one of the two USB-COM ports (as Fig 7) on the back of the instrument, not the USB port, otherwise the scanner will not work.

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	DC 12V
• Dimensions	280 mm (Length) × 240 mm (Width) × 130 mm (Height)
• Display Dimensions	7 inch
• Weight	< 2.5kg
• OS	Linux-based, Windows-Compatible program
• Excitation light source	LED
• Spectrum	Excitation spectrum: Mean wavelength $\lambda_0=365\text{nm}$ Reception spectrum: Mean wavelength $\lambda_1=610\text{nm}$
• Connecting Ports	RS232 Port-1, USB Port – 4, LAN Port -1
• Memory	8000 records
• Storage Conditions	-10°C to 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 transport.
• Operating Conditions	4-30°C
• Printer	Built-in thermal printer
• Repeatability	CV≤10%
• Stability	CV≤10%
• Scanner(Optional)	Laser barcode scanner with USB-COM port

2.4 Description of Ports



Port Name	Description	Connection Object	Input/outputMax Voltage
LAN	Connect to LIS via network	network cable	3.3V
USB	Connect USB disk for data export and software upgrade	USB Disk	5V
USB-COM	Connect the optional scanner	Scanner	15V
COM	Connect to LIS through the supporting COM to USB cable	COM to USB Cable or other cables	15V
Note:The connected external equipment is required to meet reinforced insulation and safe isolation from live parts			

Chapter 3 Parameters and Conditions

3.1 Checklist upon Opening the Box

3.1.1 Check Before Opening the Box:

Before opening the box, check 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 analyzer power adapter to see whether it is in good condition. If any defects are found, please contact with the manufacturer or local distributor.

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

Note-2: AllTest 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;
- Overvoltage category: Class II
- Pollution degree: Level 2
- Altitude: ≤3000 meters

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 2.5kg.
- 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 10cm 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 100-240V / 50/60Hz AC depending on countries where the analyzer is used. The input voltage is 12V DC. The power is 48VA. Avoid short circuit and electric shock during the use. The analyzer is grounded through power adapter.

Chapter 4 Analyzer Installation

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

1 Place the Fluorescent Immunoassay Analyzer on a stable platform.

2 Load paper:

Open the cover of the printer, place the printing paper into the printer, pull out approximate 5cm of paper from the roll, then close the cover of the printer. (Ref Fig 8)

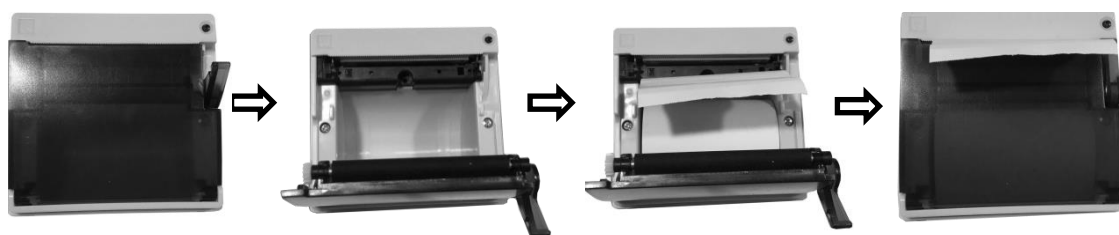


Fig 8

Note: Heat sensitive paper must be placed flat and straight to avoid slanted printing or paper roll jamming the printer.

1 Connect the power supply adapter with the power supply interface of the Fluorescent Immunoassay Analyzer. (Ref Fig 9).



Fig 9

2 Turn on the power switch to start the analyzer.

Chapter 5 Operation for Touch Screen

Connect power with Analyzer through the DC adapter, press the power switch to start the analyzer. The analyzer will initialize (Ref Fig 10) and the Self-testing will run automatically, if the self-testing passes, display will show up as Ref Fig 11.



Fig 10

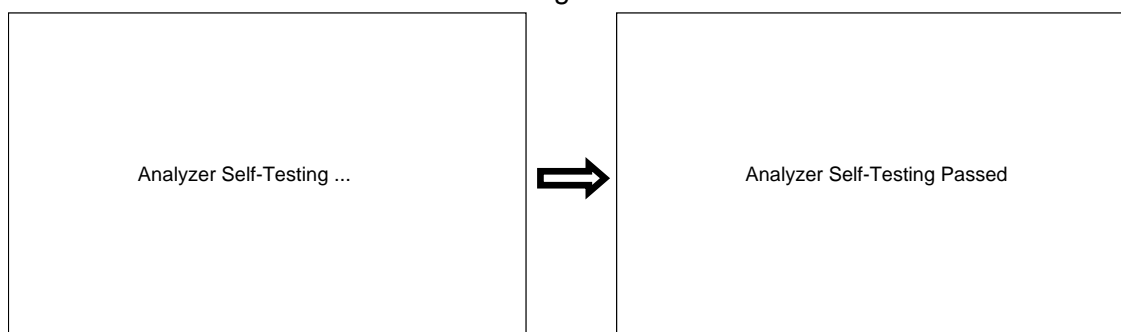


Fig 11

If the self-testing fails, a Failed Screen will be displayed. The analyzer cannot be operated. Turn off the power and then re-test. If the Failed result repeatedly shows up few times, do not use the analyzer, contact with your local distributor or manufacturer.

After initializing, touch the screen and the Auto Login interface will be shown as in Fig 12. Select the username, fill in the password (original password is 666666), click “ **Login** ” to enter the main operation interface as Fig 13.

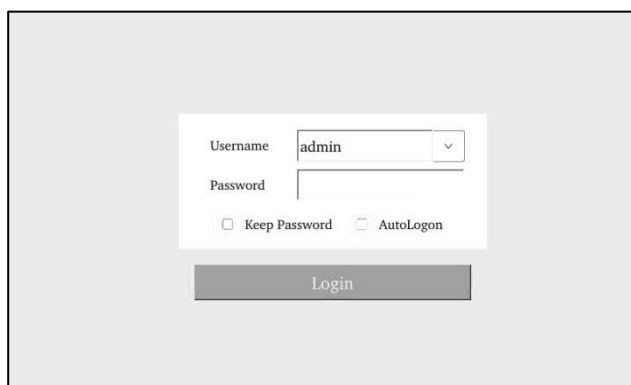


Fig 12

Note: the setting of login can be referred to “ **Account** ” in **5.1.2**.

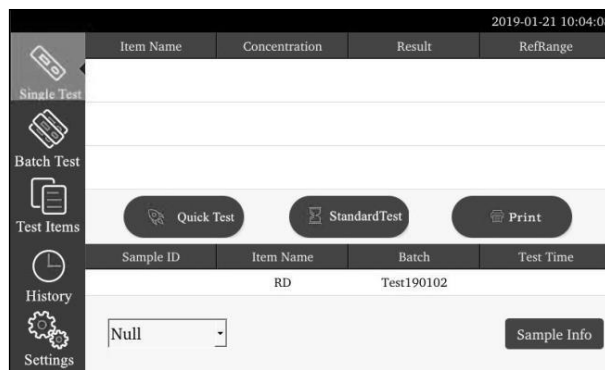


Fig 13

In the main operation interface, where you can choose different modes, such as **Single Test**, **Batch Test**, or **Test Items**, or **History** and **Settings**.

5.1 Settings

Click “ **Settings** ” to access setting interface. (Ref Fig 14)

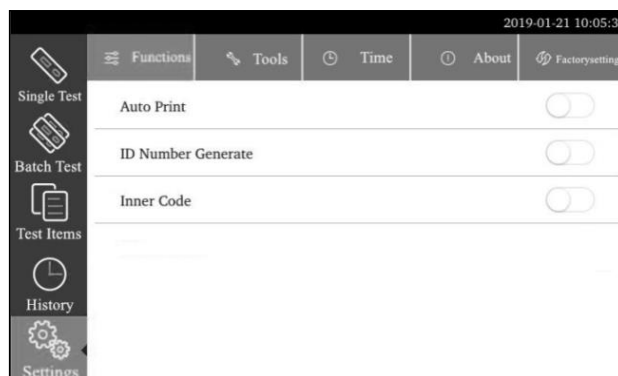





Fig 14

5.1.1 Functions setup

Click “ **Functions** ” to access the following interface. (Ref Fig 15) Click the icon  by the side of any command to switch on position  to enable the command or to switch off position  to disable the command.

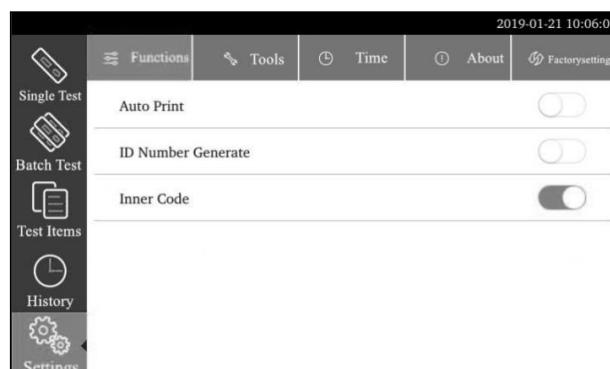


Fig 15

- **Auto Print:**

 The result will be printed automatically after testing.



The result will not be printed automatically after testing.

- **Automatic generation of ID number:**



ID number will be generated automatically according to the data encoding.



ID number should be keyed in manually.

- **Start the inner barcode:**



Barcode information on the test cassette will be scanned to identify the analyte information and batch number.



Scanning the barcode is disabled.

5.1.2 Tools

Click “ **Tools** ” to access the interface. (Ref Fig 16) The main tools include: **Update, Backlight, QC Test, Port Set, Manager, Language, Net Set, Account and Export.**

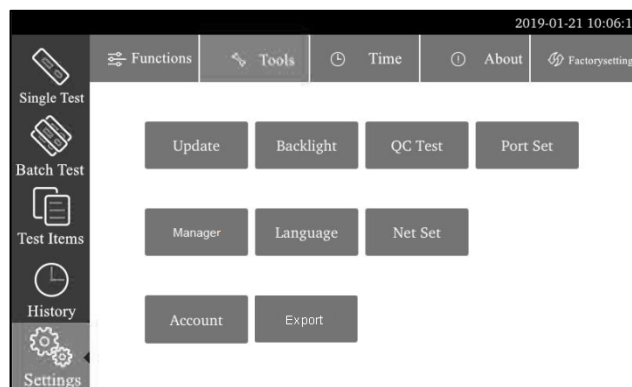


Fig 16

- **Update**

Click “ **Update** ” to enter the interface. (Ref Fig 17)

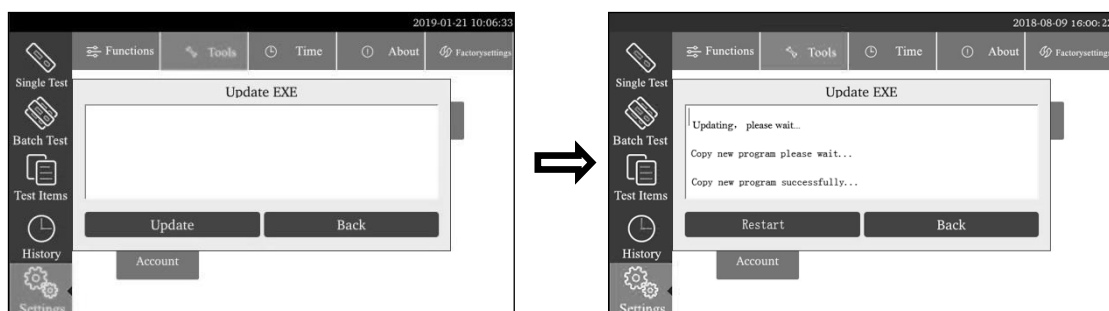


Fig 17

You can select net update or USB flash disk update. Click “ **Update** ” to copy the program update package to an external Flash drive and insert it into the USB port behind the analyzer. The analyzer obtains the program of a new version from the external flash drive (Such as USB drive) and updates the system. After updating, the analyzer will restart.

- **Backlight adjustment**

Click the “ **Backlight** ” tab to adjust the backlight. (Ref Fig 18)

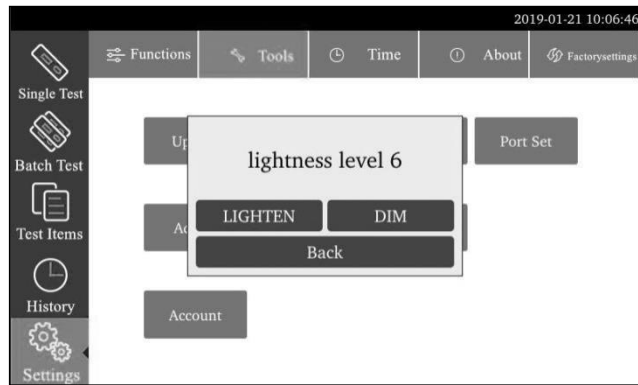


Fig 18

Click “ **DIM** ” or “ **LIGHTEN** ” to adjust the backlight brightness. Click “ **Back** ” to complete the setup and close the dialogue box.

- **Quality Control**

Click the “ **QC Test** ” tab to run QC program. (Ref Fig 19)

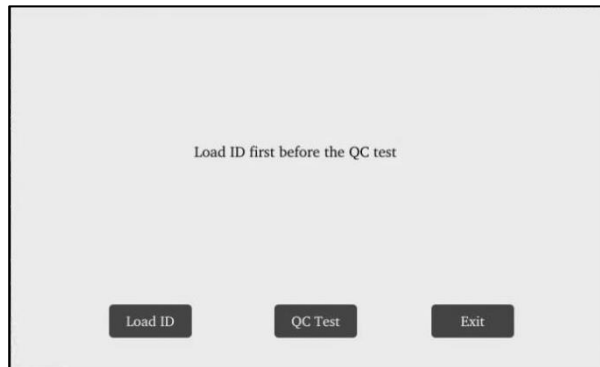


Fig 19

Insert the QC ID card and the information of QC will be filled in the corresponding frames. (Fig 20)

Click “ **QC Test** ” to run the test, after few seconds, the test result will be shown as Fig 21.

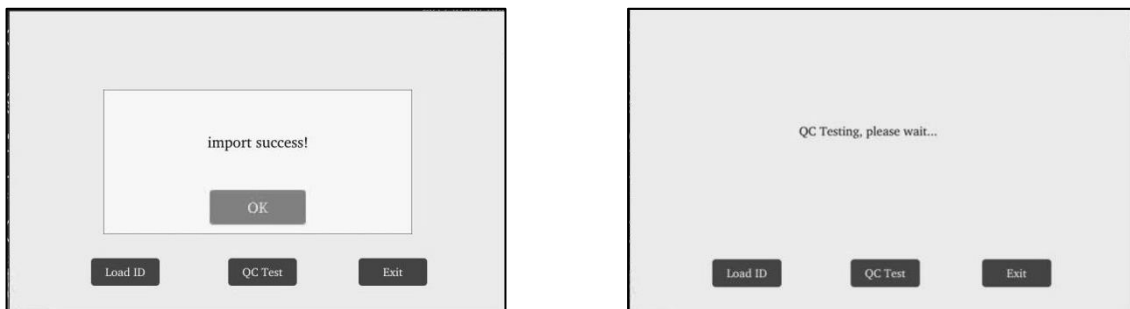


Fig 20

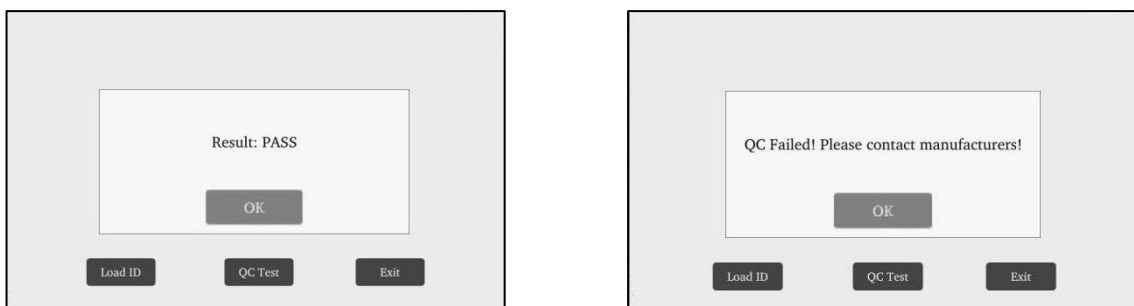


Fig 21

- **Port Set**

Click “ **Port Set** ” to manage port setting for various purpose, such as LIS connectivity. (Ref Fig 22)

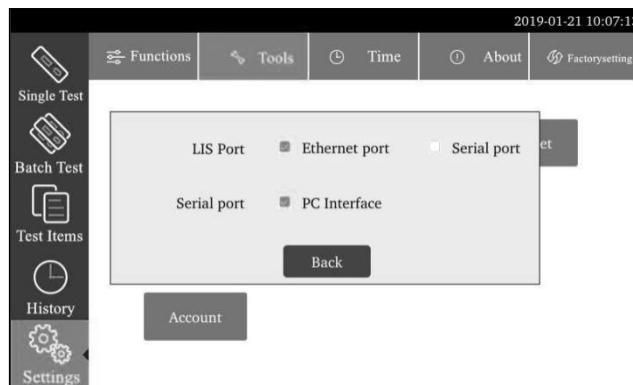


Fig 22

The analyzer can be connected to the LIS by Ethernet port (LAN Port) or the serial port (COM Port).

- **Manager**

The manager function is available for professional technicians to commission the machine only and must be used by trained technicians only. Click “ **Manager** ” to gain access to following tools: LIS, Import, and Export. Display will appear as Fig 23.

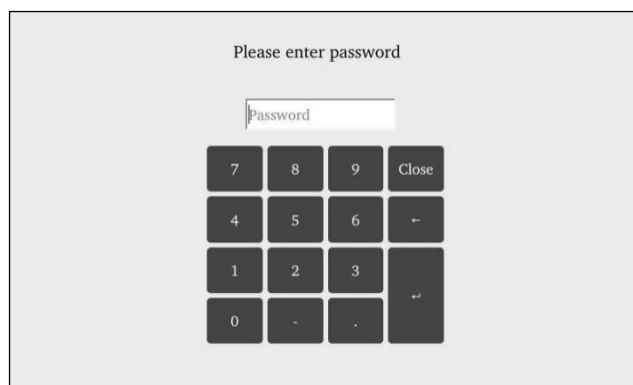


Fig 23

After entering the password, aforementioned functionalities can be accessed.

- **Language**

Click “ **Language** ” to select the target language. (Ref Fig 24)

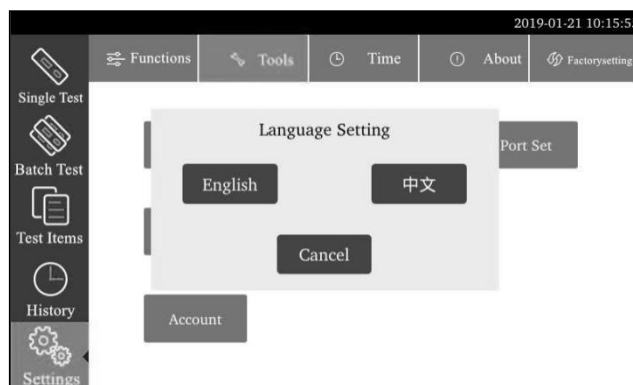


Fig 24

- **Net Set**

Click “ **Net Set** ” to set up the analyzer IP and the server IP. The IP of analyzer would be assigned automatically. (Ref Fig 25) Fill in the information of the Server IP and Server Port. An IT technician's

help may be required. Contact your server administrator for this information.

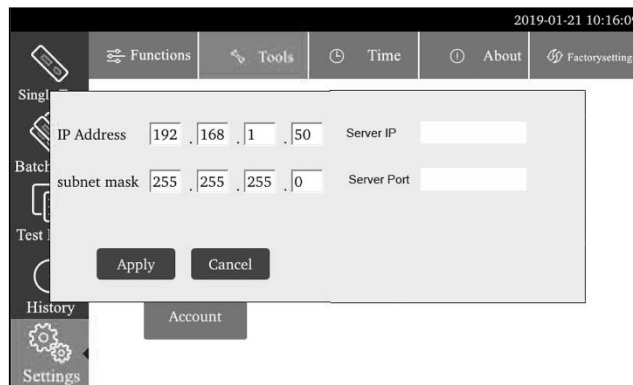


Fig 25

Note: The analyzer IP setup will come into effect after restarting. So, after setting up IP, please switch off the equipment and restart.

- **Account**

Click “ **Account** ”, the interface will appear as Fig 26.



Fig 26

i. Procedure for changing the admin password: Click drop-down button in the top of the window and select admin ->click “ **Modify Password** ”, fill in the original password, new password and confirm password, then click “ **OK** ”. (Ref Fig 27)

Note: The name as admin cannot be changed.

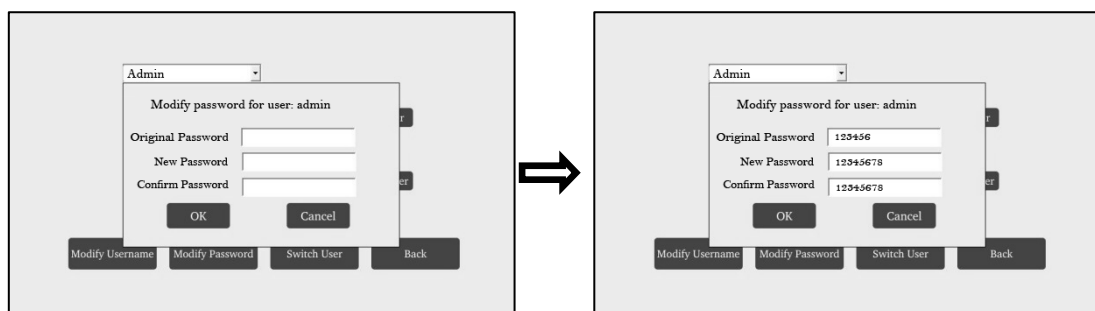


Fig 27

ii. Modify Username: Click “ **Modify Username** ”, fill in the new name, and then click “ **OK** ” to complete the setting. (Ref Fig 28)

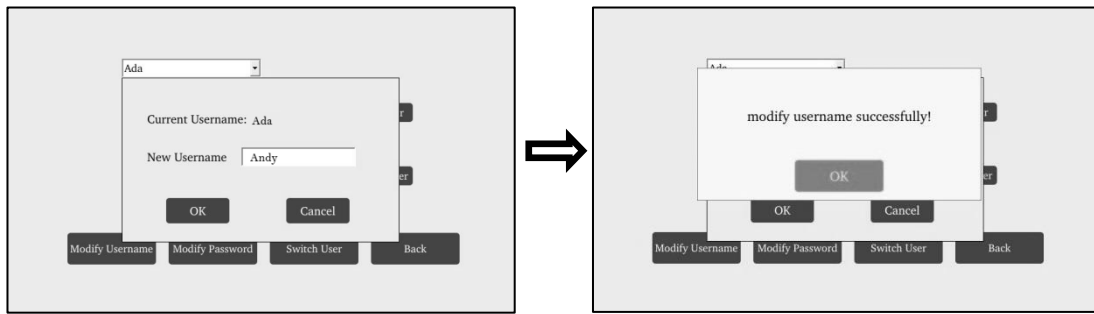


Fig 28

iii. **Add New Users:** Only admin can add new users. Fill in the User name, password and confirm password in the assigned box, click “ **New User** ” to save. (Ref Fig 29)

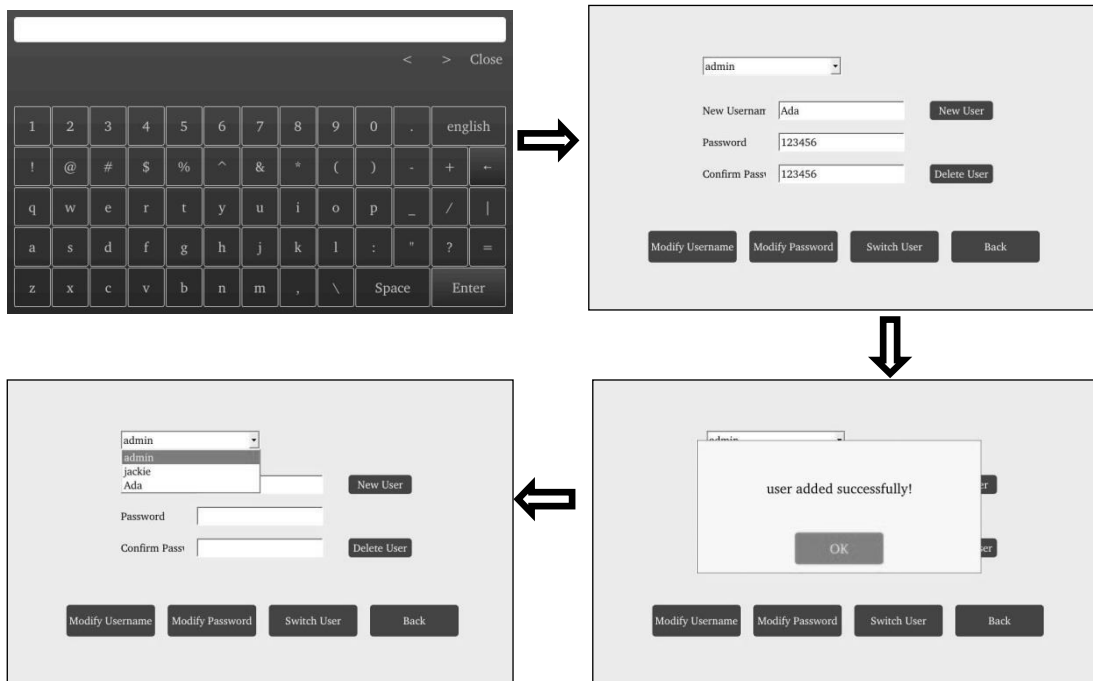


Fig 29

Note: If the password of new user is not set, the user can login the analyzer without the password.

iv. **Switch User:** Click “ **Switch User** ” to enter Fig 30.

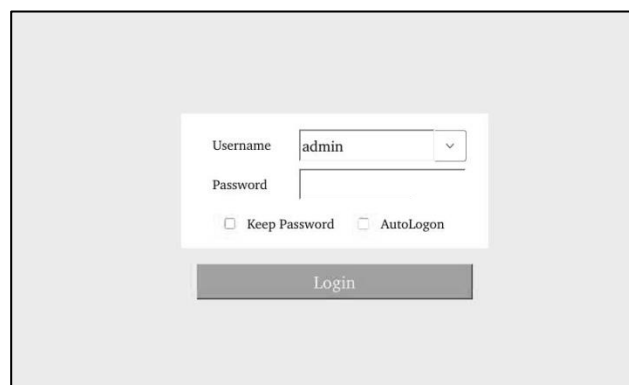


Fig 30

In the interface, you can select the user and fill in the password to login the analyzer. If “ **Keep Password** ” is selected, the password will be remembered. If “ **Auto Login** ” is selected, the interface of Login will not displayed when turn on the analyzer.

- **Export**

Click “ **Export** ” to export the data to U-Disk. (Ref Fig 31)

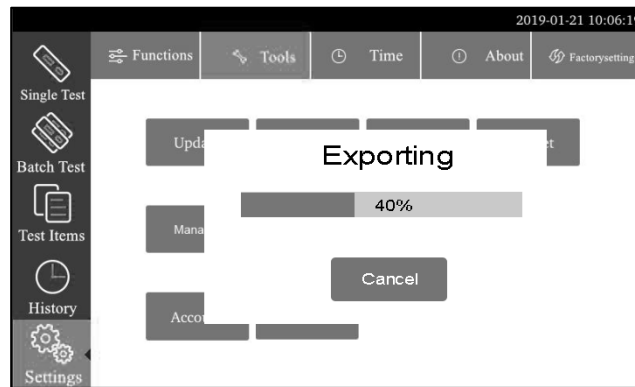


Fig 31

5.1.3 Time setup

Click “ **Time** ” to access the function. (Ref Fig 32)

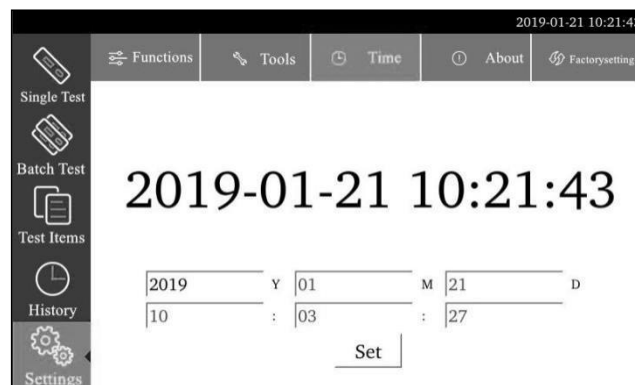


Fig 32

Click corresponding date and time blocks to modify the time. (Ref Fig 33) Click enter menu to save the modification and click “ **Close** ” to cancel. After modification, click “ **Set** ” to confirm the settings.

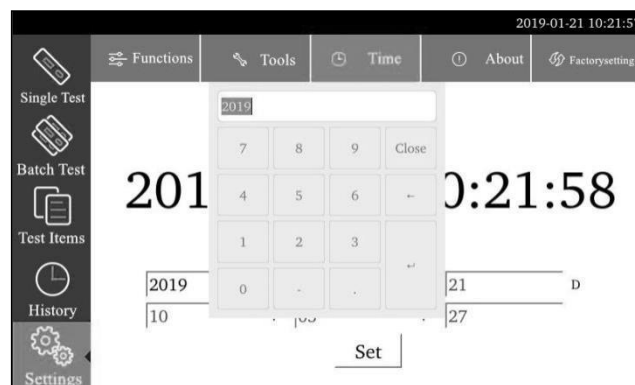


Fig 33

5.1.4 About

Click “ **About** ” to see the model, version information and serial number of the analyzer. (Fig 34)



Fig 34

5.1.5 Factory Reset

When clicking “ **Factory Reset** ”, a dialogue box will appear. (Ref Fig 35) You can clear all data to resume the ex-factory setup.

NOTE: This function will clear all the history and saved data. Therefore, this function must be used in very rare circumstances and any data that needs to be saved should be saved, before going for Factory Reset option.



Fig 35

5.2 History

Click “ **History** ” to browse the records of performed tests. (Ref Fig 36) The test records from different users will be stored separately.

2019-01-21 10:25:43						
SN	Sample ID	Item Name	Concentration	Result	Test Time	
<input type="checkbox"/> 1	201901210003	RD	Invalid	Invalid	2019-01-21 10:04:58	
<input type="checkbox"/> 2		RD	Invalid	Invalid	2019-01-21 10:11:45	
<input type="checkbox"/> 3	201901210001	CEA	19.92	POS.	2019-01-21 10:05:50	
<input type="checkbox"/> 4	201901180024	CEA	19.69	POS.	2019-01-18 17:41:07	
<input type="checkbox"/>						
<input type="checkbox"/>						
<input type="checkbox"/>						

Fig 36

Click “ **Previous** ” or “ **Next** ” to browse the test records.

Click “ **Print** ” to print the selected test result through the built-in printer;

Click “ **Delete** ” to delete a selected test record.

Click “ **Clear** ” to clear all records.

Click “ **Search** ” to search a particular record, such as an analyte. (Ref Fig 37)

Time

2017 01 01 00 00

2017 01 01 00 00

Sample ID

Item Name

Search Cancel

Fig 37

Input time, sample ID, item number information and enter the retrieval field. By clicking the “ **Search** ” button, you can find corresponding record(s).

5.3 Test Items

Click “ **Test Items** ” to enter the interface as Fig 38. Select the corresponding item to have test.

2019-01-21 10:27:56

SN	Item ID	Batch ID	Item Name	Batch Code
<input checked="" type="checkbox"/> 1	3	2	PSA	FPSA18120001
<input type="checkbox"/> 2	2	2	PCT	FPCT8110001
<input type="checkbox"/> 3	5	2	CEA	FCEA18120001
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				

Single Test

Batch Test

Test Items

History

Settings

Previous Next Delete Import

Fig 38

Click “ **Previous** ”, “ **Next** ” to browse the test items saved in the analyzer.

Click “ **Delete** ” to delete the selected test item(s) information.

Click “ **Import** ” to load the standard curve which is in the ID card. Generally, the standard curve will be loaded into the analyzer automatically when the ID card is inserted into the ID card slot.

Note:

- 1) Each item number and batch number have a unique corresponding examination information data. Setting again will overwrite the original data.
- 2) When inserting the test ID card to the analyzer, the corresponding test item information will be saved and displayed in this interface.

5.4 Testing Procedures

5.4.1 Single Test

There are two modes for testing in Single Test Mode.

A. Quick Test Mode: In this mode, the incubation of the test cassette is done outside the analyzer.

B. Standard Test Mode: In this mode, incubation of the test cassette is done inside the analyzer.

Once a new test is selected to be performed here and test cassette is loaded after sample addition (and if required buffer addition) in the test cassette slot, nothing more needs to be done.

The user can walk away from the analyzer and perform other tasks. The results would be

automatically available at the end of the incubation period, when the analyzer reads the results.

Test Procedure

Step 1: Turn on the power switch to start the analyzer.

Step 2: Click “ **Single Test** ” to switch to the interface as Fig 39.

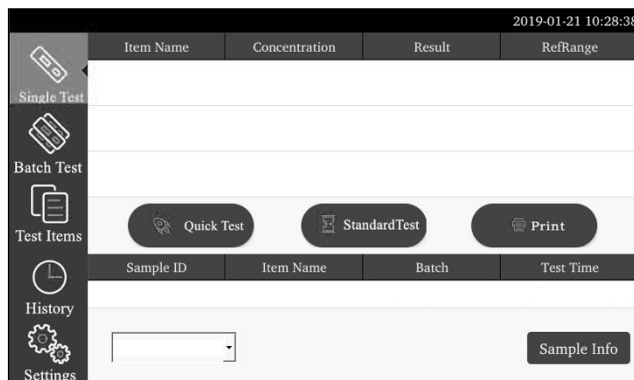


Fig 39

Step 3: Insert the ID card of the analyte (Must be from Test Kit from which test cassettes are to be used. Use of ID card from another test kit may lead to erroneous results)

Step 4: Confirm the test item and batch number. Click “ **Sample Info** ” to fill the information as Fig 40. In this interface, sample ID, patient name, gender, age and operator can be filled or selected.

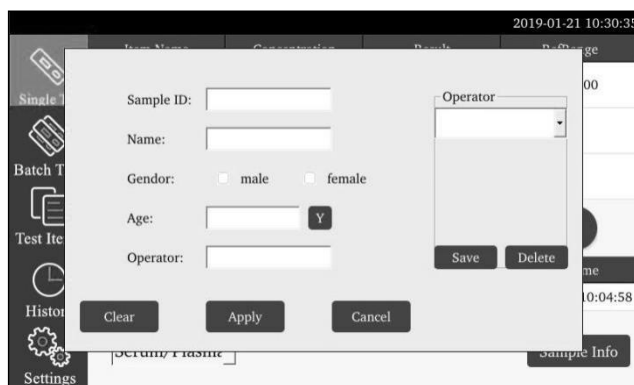
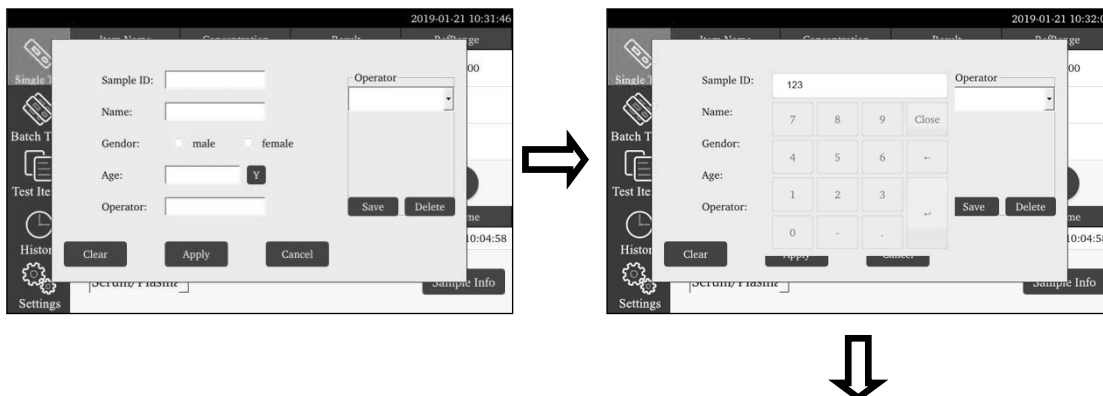
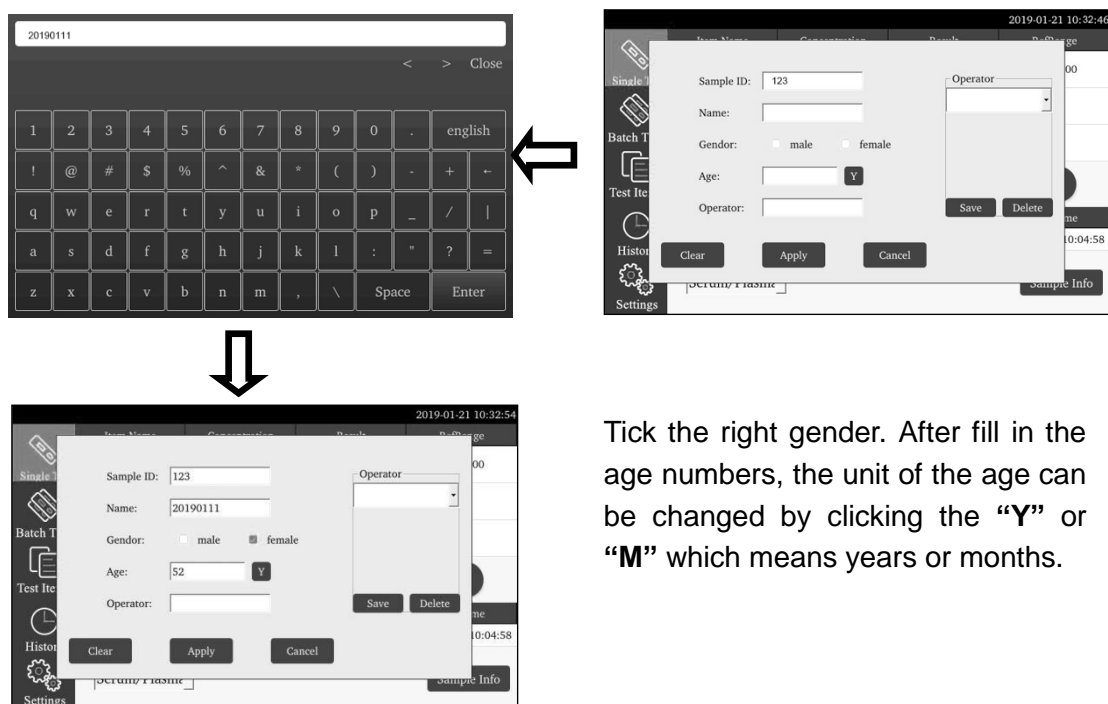


Fig 40

- Fill the information of sample ID Scan the sample barcode with the barcode scanner, the sample ID will be filled in the blank space beside the Sample ID automatically, or click the frame -> key in the information -> apply. (Ref Fig 41)





Tick the right gender. After fill in the age numbers, the unit of the age can be changed by clicking the “Y” or “M” which means years or months.

Fig 41

Note: the operator information should be added to the assigned dialog box on the right side, The test can be performed without sample information. So in cases of emergency, if there is no time to assign the sample information, this step can be omitted. Nevertheless, as part of good laboratory practice, assigning sample information is highly recommended.

- Add and change the operator information (Ref Fig 42):

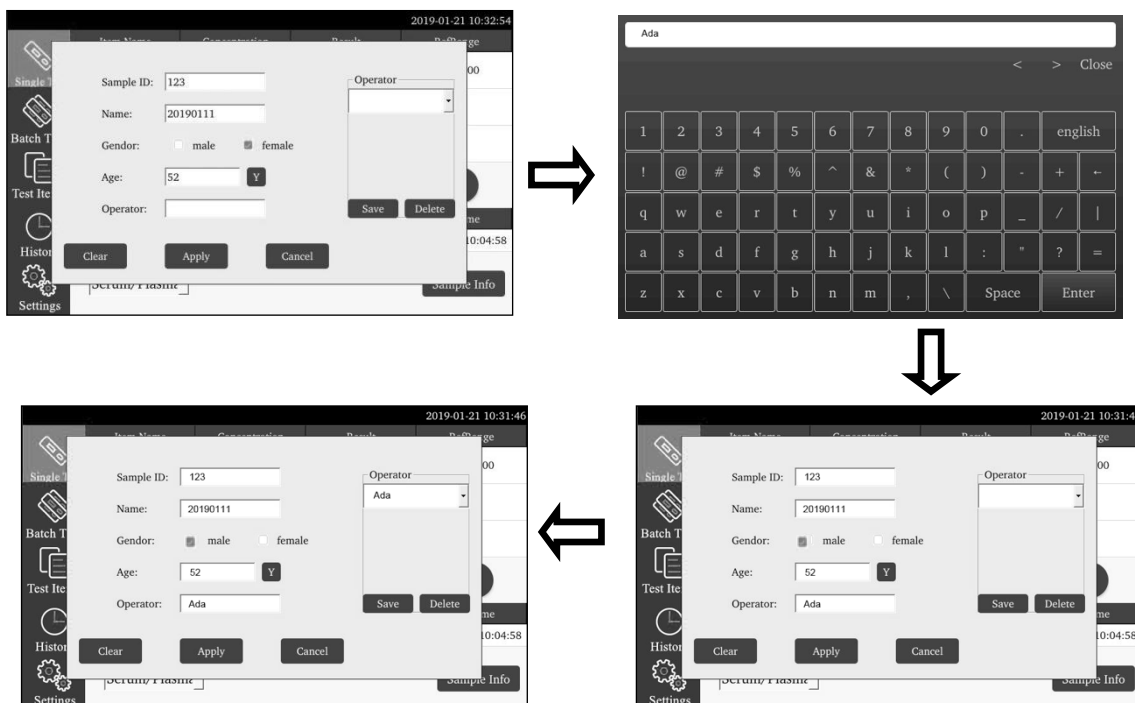


Fig 42

Step 5: After confirming all the relevant information, start the test.

- **Quick Test Mode**

Insert test cassette into the slot **at reading time** (add samples according to the package insert of the

test and place the test cassette on a clean and flat surface by the side of the analyzer for the incubation time mentioned in the package insert), click “ **Quick Test** ” to start testing, test will begin immediately and after a few seconds the test result will be shown. (Ref Fig 43)

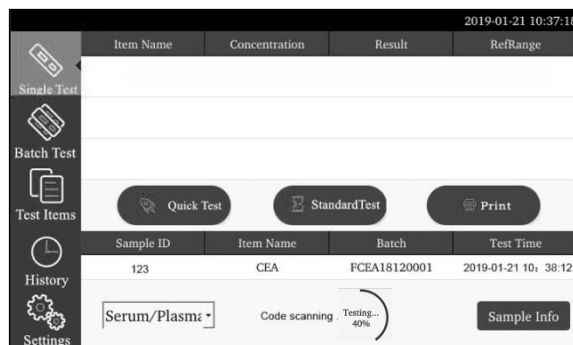


Fig 43

● Standard Test Mode

Insert test cassette into the slot immediately after sample application (add samples according to the package insert of the test), click “ **Standard Test** ” to start Standard Test Mode. The analyzer will start to count down for incubation. Please wait for the pre-determined incubation time for each test. (Ref Fig 44) After incubation, the analyzer will start testing automatically.



Fig 44

Step 6: The results will be displayed in the lower middle of the screen when testing is completed. (Ref Fig 45)

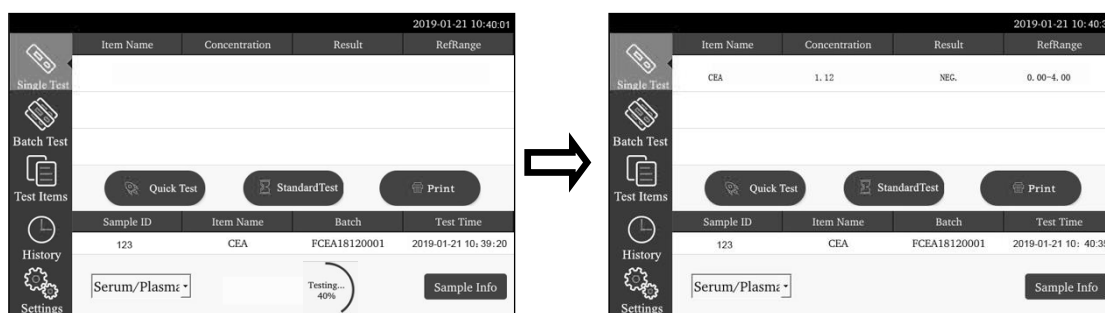


Fig 45

Step 7: Print the result.

If Auto-print is on, the results will be printed automatically after each test (please refer to **5.1.1 Functions setup** for printer setting), or you can also click “ **Print** ” in the interface to print test result also. (Ref Fig 46)



Fig 46

5.4.2 Batch Test

This test mode is recommended for laboratory use. This Mode is suitable, when more than one test is to be performed as incubation time can be utilized for another test too.

The procedure for the batch test follows as below:

Add the test ID which need to be tested -> Add specimen to begin incubation -> Count Down for test -> Insert the cassette which has finished the incubation -> Start the test -> Take out the cassette -> Repeat

Click “ **Batch Test** ” to switch to the interface. (Ref Fig 47)

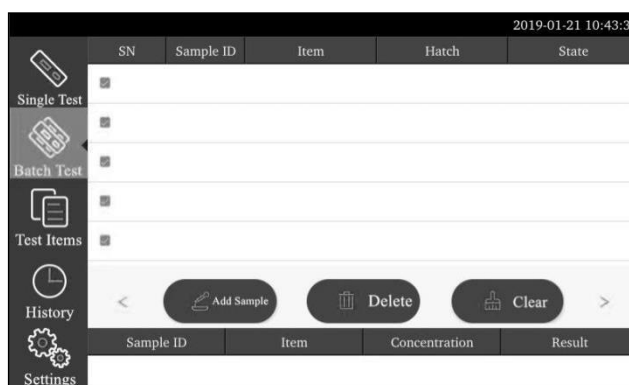


Fig 47

Step 1: Add Samples.

Click “ **Add Sample** ” to add the Sample IDs of all tests to be tested. The sample ID will be generated automatically if the ID number generate function (Ref 5.2.1) is enabled. Otherwise, the IDs should be keyed in manually or scanned by scanner.

Step 2: Test application and incubation

Add the specimen to the specimen well of the test cassette and marked with sample ID. Click “ **START INCUBATION** ” to begin the incubation. The status will change to “ **INCUBATING** ” and incubation countdown begins.

After 20 seconds the Status of the 2nd test will be ready to “ **START INCUBATION** ” and then you can add the 2nd specimen to the sample well and click “ **START INCUBATION** ”. Follow this sequence for rest of the test units.

Step 3: Start test

When incubation time is finished, the status will turn to “ **START TEST** ”, you need to insert relevant test cassette into the slot and click “ **START TEST** ”. (Ref Fig 48)

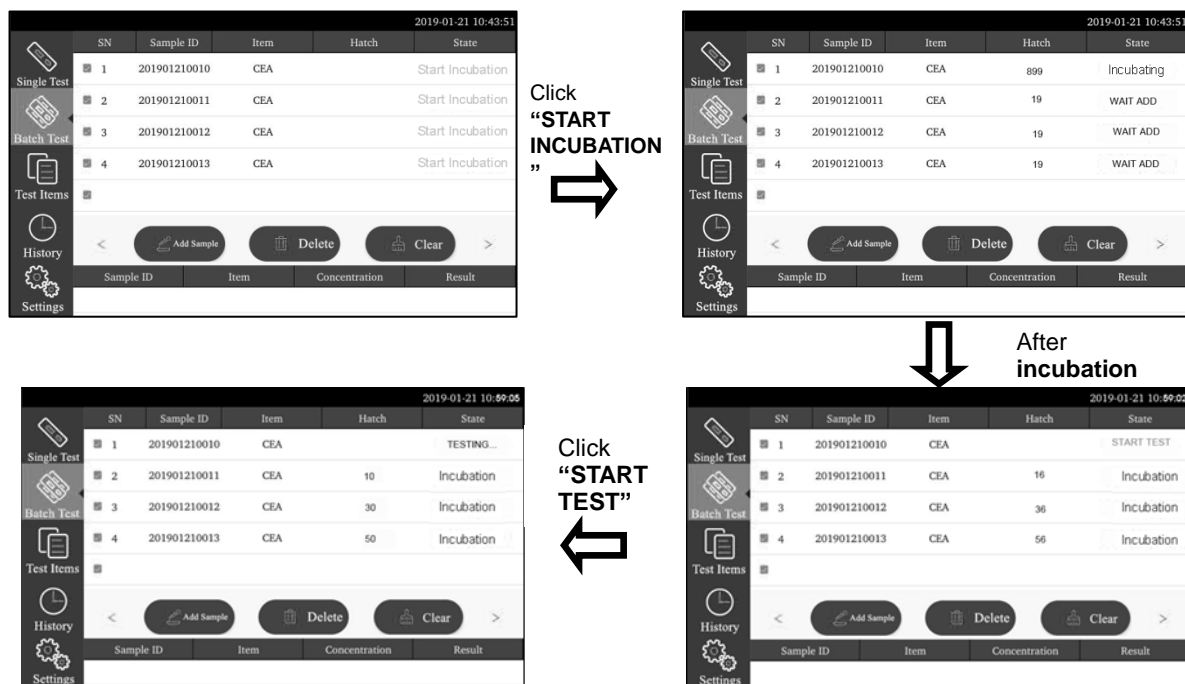


Fig 48

When the testing is finished, the test result will be displayed at the bottom of the screen as Fig 49.

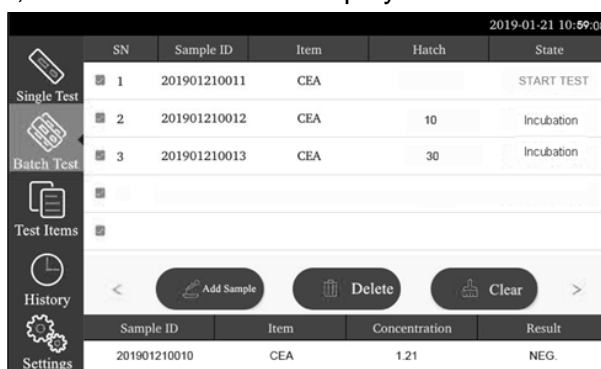


Fig 49

Step 4: Repeat the steps to operate rest of the tests.

You can click "Delete" to delete the selected test items, click "Clear" to delete all the test items.

Note:

- The "Batch test" mode can only be used for the same analyte each time. Analyte cannot be changed. Besides, care should be taken that all the tests in this mode are from the same kit, of which the ID card is used.
- Make sure that there is no test pending in the "Batch Test" mode, when the single test is to be operated.

Chapter 6 Maintenance

6.1 General Cleaning

Keep the exterior of the instrument free of dust at all times. If needed, the exterior may be cleaned using a damp cloth. Do not use any type of solvent, oil, grease, silicone spray, or lubrication on any instrument. Please keep the instrument in switch off mode, while cleaning the screen to avoid any wrong command being recorded.

6.2 Maintenance

Basic maintenance is to keep the exterior 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 analyzer's parts 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!

6.3 Maintenance plan

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

Chapter 7 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 to 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 products 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 50 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 “RESET” to return to factory settings or when the user manually clears the data.

Chapter 8 Troubleshooting Guide

When there is no response on clicking the analyzer interface tabs or pressing any key, the program may have crashed. Please restart the analyzer by following the steps below:

- 1) Switch off the power;
- 2) Plug and unplug the power cord again;
- 3) Switch on the analyzer.

Notes to common errors:

1. A user interface error may result in the analyzer being unable to perform the “Testing” function. This will not influence the data backup and transmission function. At this point, you can export the records to the USB disk and then return the analyzer to the factory for repairing.
2. The application logic itself errs. The possibility for this error is very low. When it occurs, the testing data this time will be lost. However, the historic data backed up in the analyzer will not be lost. At this point, power off the analyzer and restart the analyzer.
3. When the system or network resources cannot be used, the testing function and data backup function of the analyzer itself can be used continually, but this may influence the record uploading to LIS. As the system or network resources become stabilized, that function will resume automatically.

Chapter 9 Service, Repair and Destroy

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's internal parts, including the circuit boards, optical detection modules, display, printer, and one-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 analyzer software 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 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 local regulations.

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.

The fuse included in the adapter cannot be replaced, and a new adapter can be purchased if it is damaged.

Chapter 10 Manufacturer Information

Name : Hangzhou AllTest Biotech Co., Ltd.

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

















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Web: www.alltests.com.cn

Email: info@alltests.com.cn

Index of Symbols

	Instruction for use		Test 1 kit		For <i>in vitro</i> diagnostic use only
	Store between -10-40°C		Catalog #		Authorized Representative
	Manufacturer		CE Mark		Keep dry
	Fragile, handle with care		Keep away from sunlight		Protect from heat and radioactive sources
	Caution		Biological risks		Lot number
	Recycling is handled separately				



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

EC REP

MedNet GmbH

Borkstrasse 10
48163 Muenster
Germany



Number: F145003001
Effective date: 2021-12-22

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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