Instructions for Fluorescent Immunoassay Analyzer Operation

Beijing Dianotech Sci-Tech Co., Ltd

Contents

Chapter I. Information for Operation

Thank you for selecting the Fluorescent Immunoassay Analyzer of Beijing Dianotech Sci-Tech Co., Ltd. .This device is a fluorescent immunoassay system based on the photoelectric testing principle, and the operation of which needs to have special-purpose fluorescent immunoreagents for supporting. This analyzer has high testing accuracy, excellent stability, fast testing speed and low costs. It could be applied in multiple fields such as disease diagnosis, healthcare, epidemic surveillance and food security.

The present Operation Instructions is suitable for devices of Model FIC-Q100N series.

The present Operation Instructions describes in detail the characteristics of the device and the related information. The illustrated operating steps are convenient for users. Please following this instruction carefully when operating this analyzer.

1.1 Introduction of the Analyzer

1   **Model number/specification: FIC-Q100N**
2   **Basic size:** 280*240*130 (length $\times$ width $\times$ height, unit: mm).

1.2 Fields of application

The Fluorescent Immunoassay Analyzer needs to have a series of supporting fluorescent immunoreagent cards and reagents for general use. It is only suitable for medical laboratory professionals to do in vitro diagnosis (IVD) test. It could be used in the central laboratories of hospitals, outpatient/emergency test laboratories, clinical sections and other medical service points (such as community medical points), physical examination centers of medical institutions, and also could be applies to scientific research laboratories.

1.3   Explanation of product symbols

Number	Symbol	Explanation
1	⚠	Attention, refer to the attached text
2	IVD	In vitro diagnosis
3	☣	Biological risk

Chapter II. System assemblies and the main structure

Please check carefully according to the following standard list for any missing or damaged accessories after unpacking.

Note: When noticing any missing or damaged accessories, please contact Beijing Dianotech Sci-Tech Co., Ltd. and your local sales representatives. For contact details, please refer to Chapter X. of the Operation Instructions.

2.1 Standard configuration list of analyzer

S/N	Name	Qty.	Unit
1	Fluorescent immunoassay analyzer	1	Set
2	Power supply adapter	1	Set
3	ID card	1	Piece
4	Quality control card	1	Piece
5	Printing paper	1	Roll
6	Optical disc	1	Piece
7	Scanning gun (optional)	1	Set

2.2 Main structure

Note: The appearance of the analyzer and its accessories is subject to the physical object.

1 Front side structure diagram:

(Figure I) Front side structure of analyzer

2 Power supply adapter

(Figure II) Power supply adapter

Notes: This accessory is used in coordination with different testing reagents

Chapter III. Basic parameters and operating conditions of analyzer

3.1 Basic parameters of analyzer

Interface   RS232, USB, network interface

Printing   Built-in thermal printer

Repeatability CV≤10%

Stability CV≤10%

3.2 Transportation and storage conditions of Analyzer

After packaging, the Analyzer should be stored and transported in a well-ventilated environment free from condensation or corrosive gas. The temperature should be kept at -10℃ ～ 40℃, with relative humility of 20% ～ 90% and an atmospheric pressure of (86~106) kPa.

Take care to prevent moisture, impact and strong vibration in transportation.

3.3 Operating conditions of analyzer

3.3.1 Positioning and placing requirements

1) The analyzer should be placed in a stable and horizontal table in a room free from heavy dust, direct sunlight and corrosive gas. The worktable must be able to bear a weight above 2.5kg.

2) There should be no strong vibration sources and electromagnetic field exist around.

3) The analyzer must be placed in a well-ventilated position with a spare space over 10cm around to ensure the necessary room for operation and maintenance.

3.3.2 Power supply voltage requirement

This analyzer uses 220V/59Hz AC power supply. The input voltage is

DC 12V. The power of the analyzer is 36VA. Take care to avoid short circuit and electric shock danger during operation! The analyzer connects to ground through power supply adapter.

Note: In all circumstances where the symbol is marked, it is imperative to consult relevant documents.

Chapter IV. Installation of the analyzer

Please use this analyzer under the specified operating conditions (Refer to Chapter III "Operating conditions of analyzer").

1 Place the fluorescent immunoassay analyzer on a stable operating table.

2 Connect the power supply adapter with the power supply interface of the fluorescent immunoassay analyzer.

Power supply interface

3 Switch the power supply to the position "on" to start the analyzer.

Chapter V. Detailed operation steps of analyzer

The operation of this test analyzer relies on fingers to operate the touch screen of the analyzer. First, connect the power cord of the analyzer. Turn on the power supply switch of the analyzer to start the machine. The analyzer goes through self-checking process. After successful starting, the analyzer's parameters display on its interface.
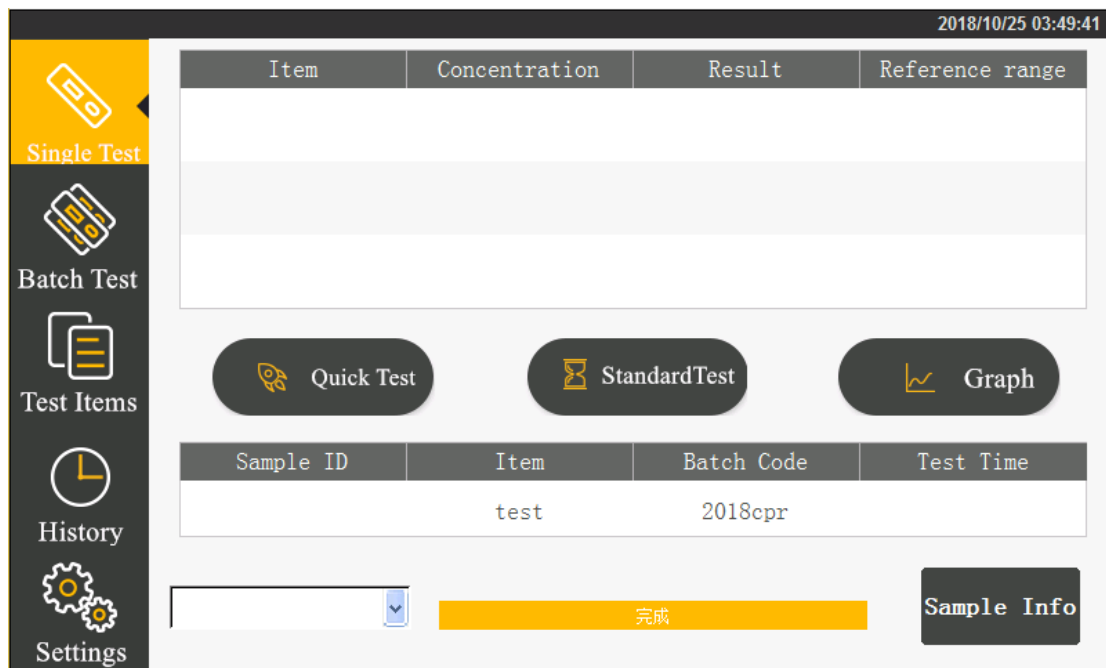
Complete the system setup process according to the operation instruction before sample testing. After that, you can proceed to single sample testing, batch testing, project management and historic record operation.
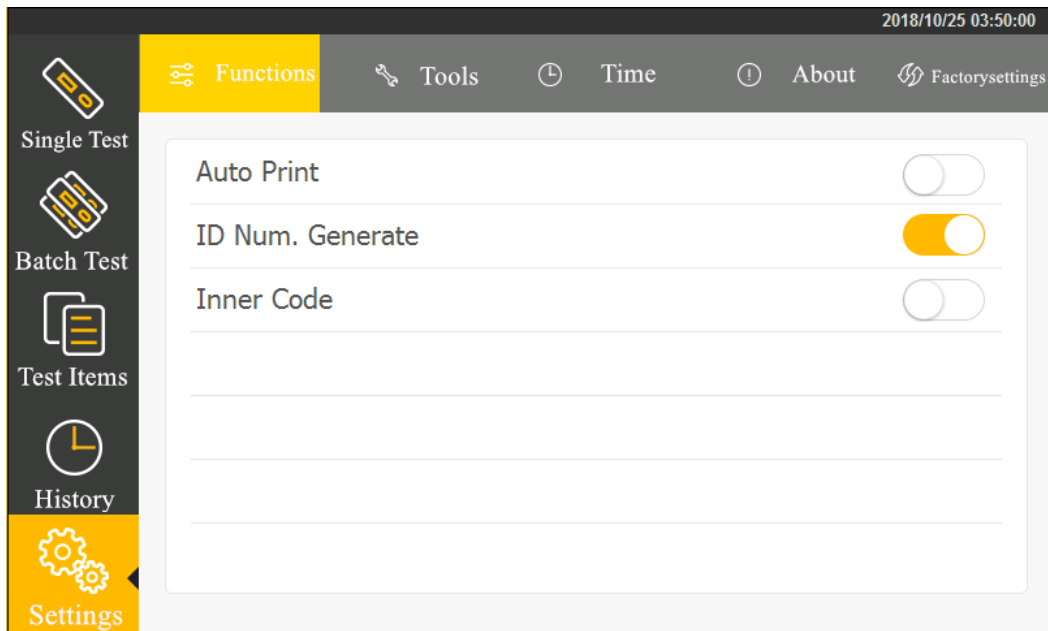
5.1 System setup

Click the "Settings" button to enter into the operation interface, then process to function setup, tools, time setup, about and factory resetting menu.

5.1.1 Function setup

Click "Function Setup" button to enter the following interface. Then click icon corresponding to second level items to select the setup items.

1 Start auto printing:
   on-print the result automatically after testing
   off-print no result after testing
2 Automatic generation of ID number:
   on-generate an ID number automatically according to the edited date
   off-input an ID number manually
3 Start the built-in barcode:
   on-scan built-in barcode to identify the testing item and batch number information
before test
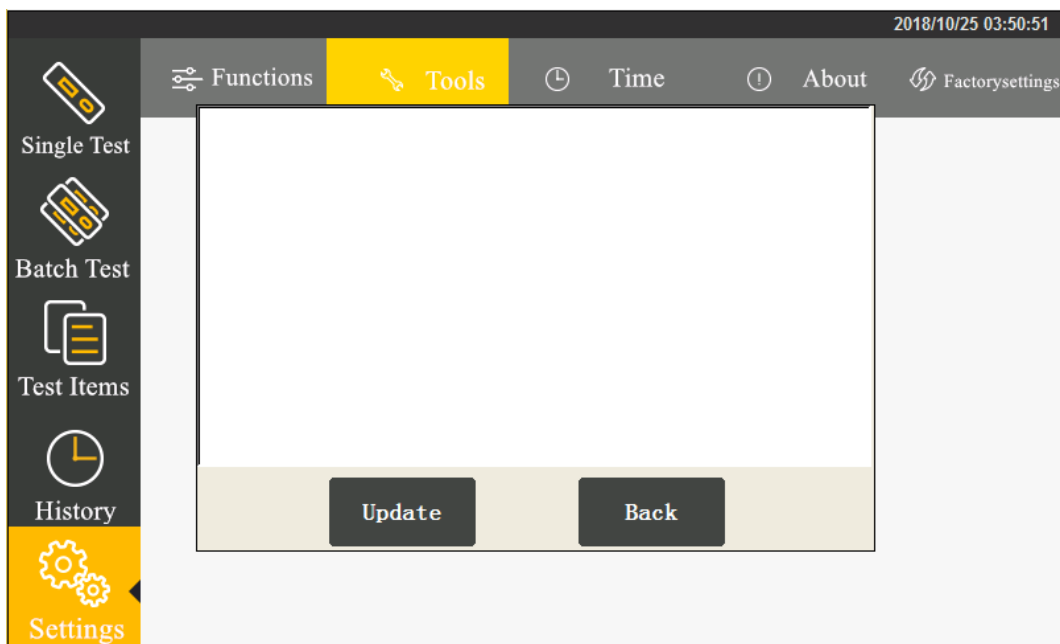   off-test directly without scanning the built-in barcode

5.1.2 Tools

Click "Tools" button to enter the follow interface. The main tools include: updating

program, backlight adjustment, quality inspection, administrator, network

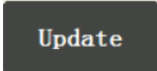configuration, port configuration and network connection.
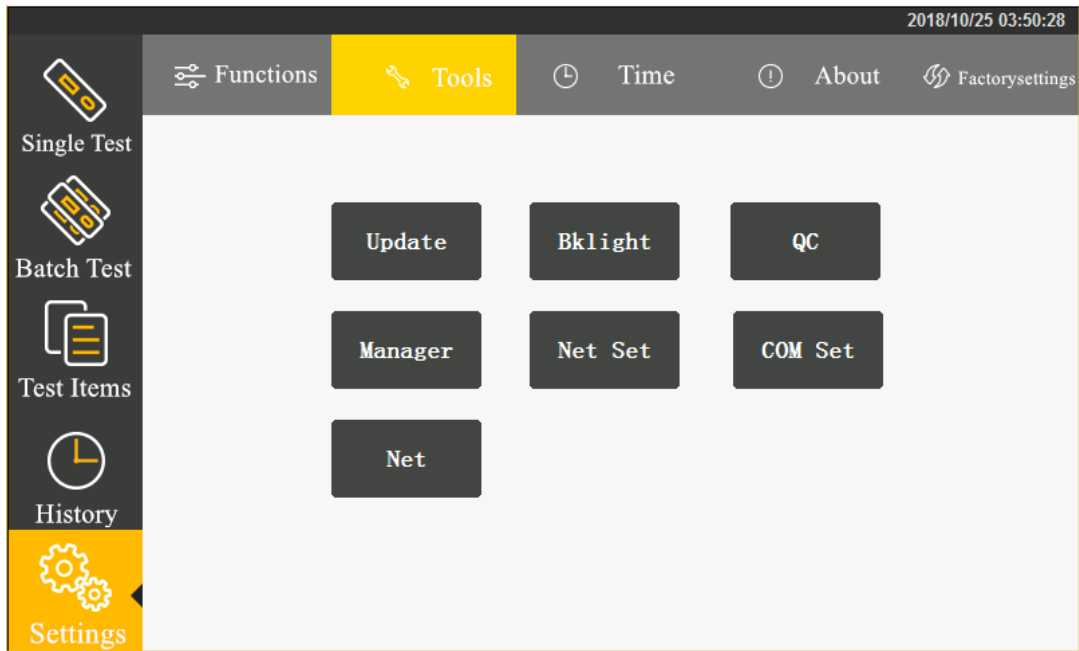
I. Updating program

Click "Updating Program" to enter the following interface.

You can select network updating or u-disk updating.

Click **Update** to copy the updating program package to a U-disk and insert it into the USB port behind the analyzer. The analyzer obtains the program of a new version from the U-disk and updates the system.

After updating, the analyzer restarts.
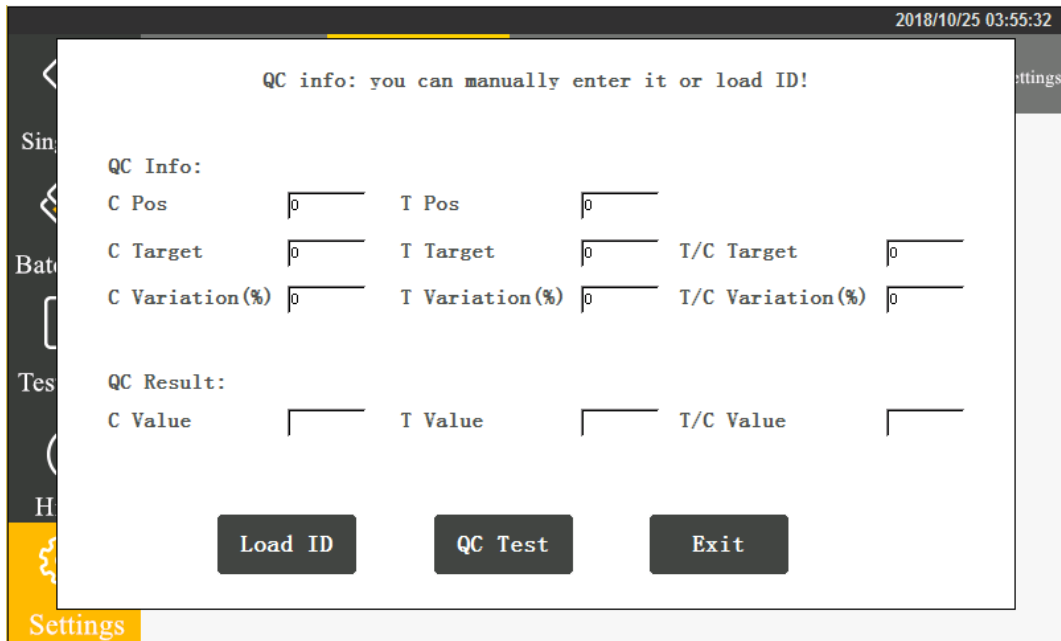
II. Backlight adjustment

Click the "Backlight Adjustment" button to enter the following interface.
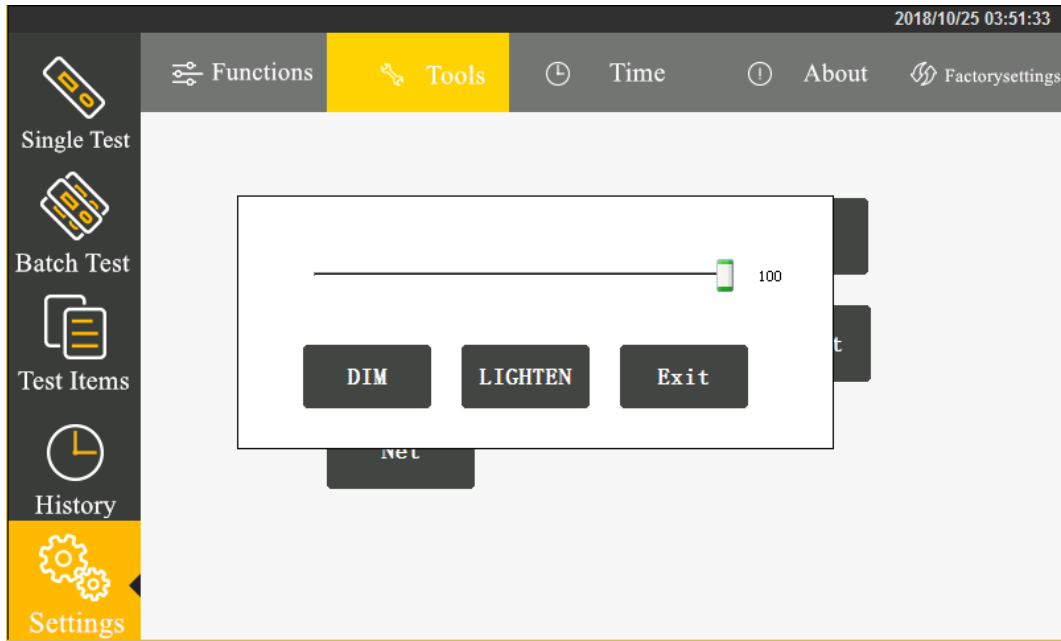
Click [DIM] or [LIGHTEN] to adjust the backlight brightness. Click [Exit] to complete the setup and close the dialogue box.

III. Quality inspection

Click the "Quality Inspection" button to enter the following interface.

QC info: you can manually enter it or load ID!

QC Info:

C Pos	0	T Pos	0		
C Target	0	T Target	0	T/C Target	0
C Variation(%)	0	T Variation(%)	0	T/C Variation(%)	0

QC Result:

C Value		T Value		T/C Value

Load ID   QC Test   Exit

Settings

By scanning the quality inspection 2D code, you can obtain the quality control

information. Click "QC Test" to start quality inspection of the analyzer.
When passing the quality inspection, "quality Inspection successful!" will display
on the screen. When not passing the quality inspection, "quality inspection failed!"
will display. If the quality inspection fails, you have to contact the manufacturer for
analyzer adjustment and the testing result is invalid.

IV. Administrator

The administrator function is available for professional technicians to adjust the machine
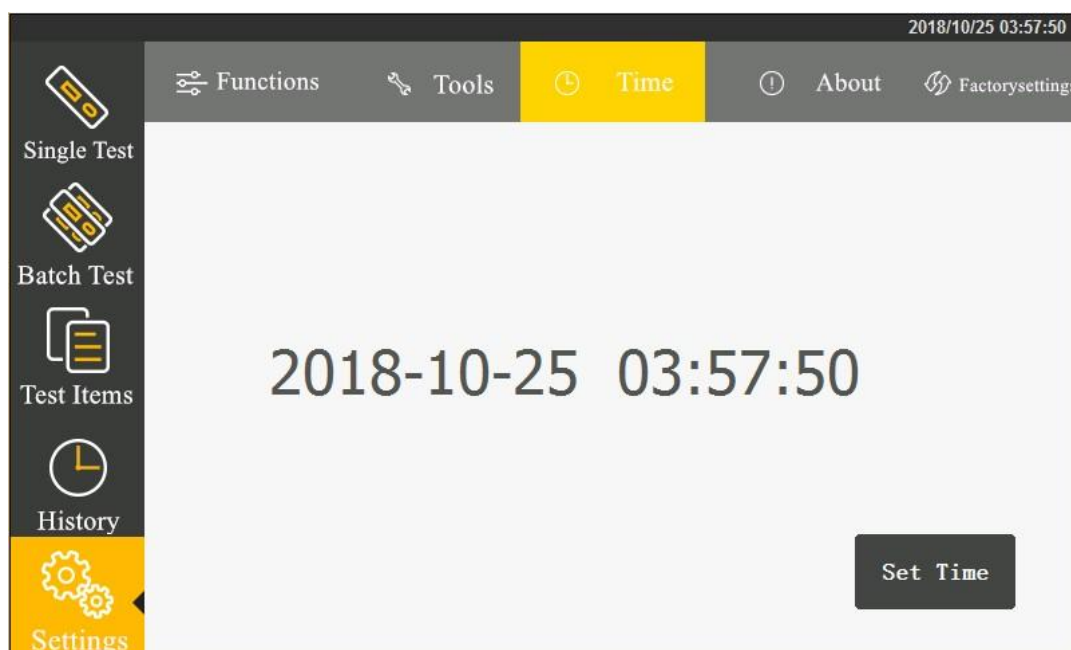only.
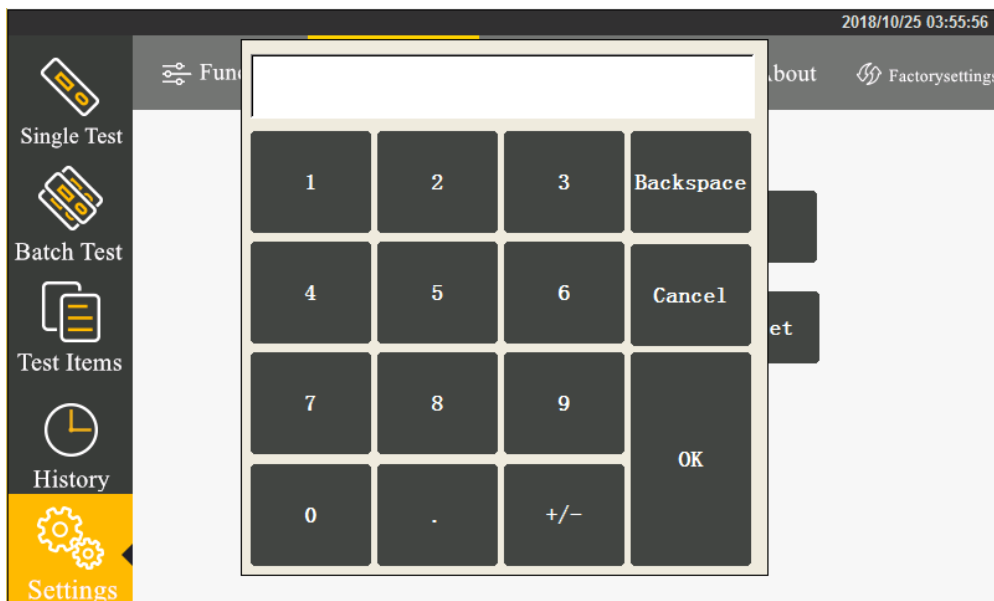
After entering the password, you can set up automatic testing, automatic testing interval.

Besides, the analyzer provides the following new tools: calibration tool, gain adjustment, save data, clear records and about the analyzer.
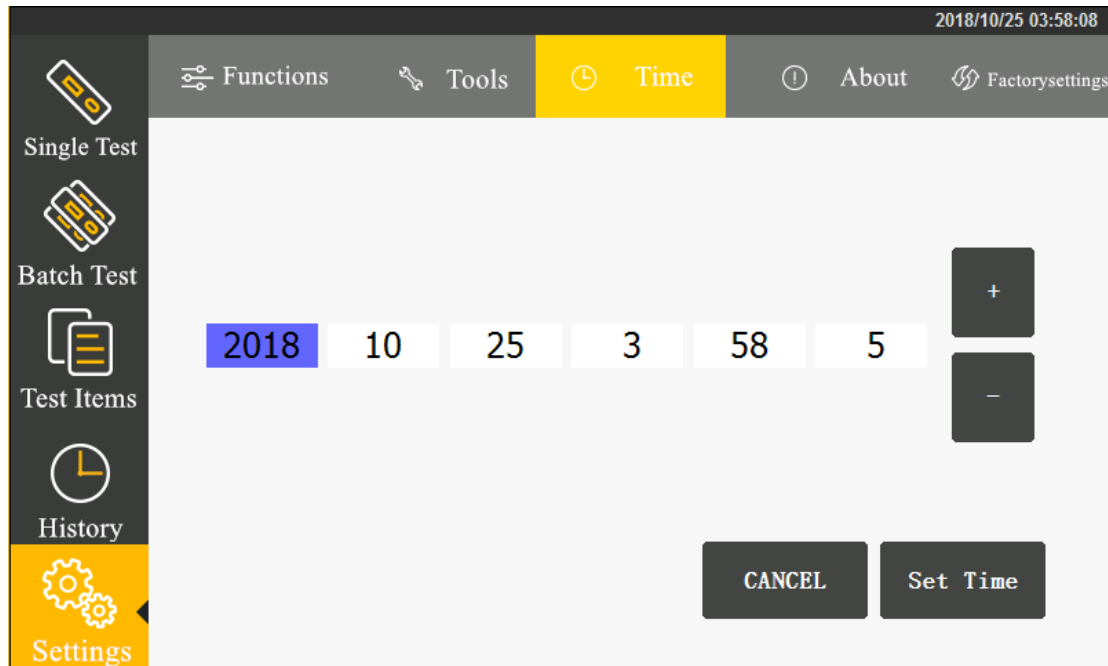
5.1.3 Time setup

Click "Time Setup" button to enter the following interface.

By clicking "Time Setup", you can set up time. Click the field to be modified and

press the signs + or - for adjustment. After modification, click "Time Setup" to confirm the modification. Clicking "Cancel" to cancel time modification.


5.1.4 About the analyzer

Click "About" to enter the following interface, which displays the model number and version information of the fluorescent immunoassay analyzer.
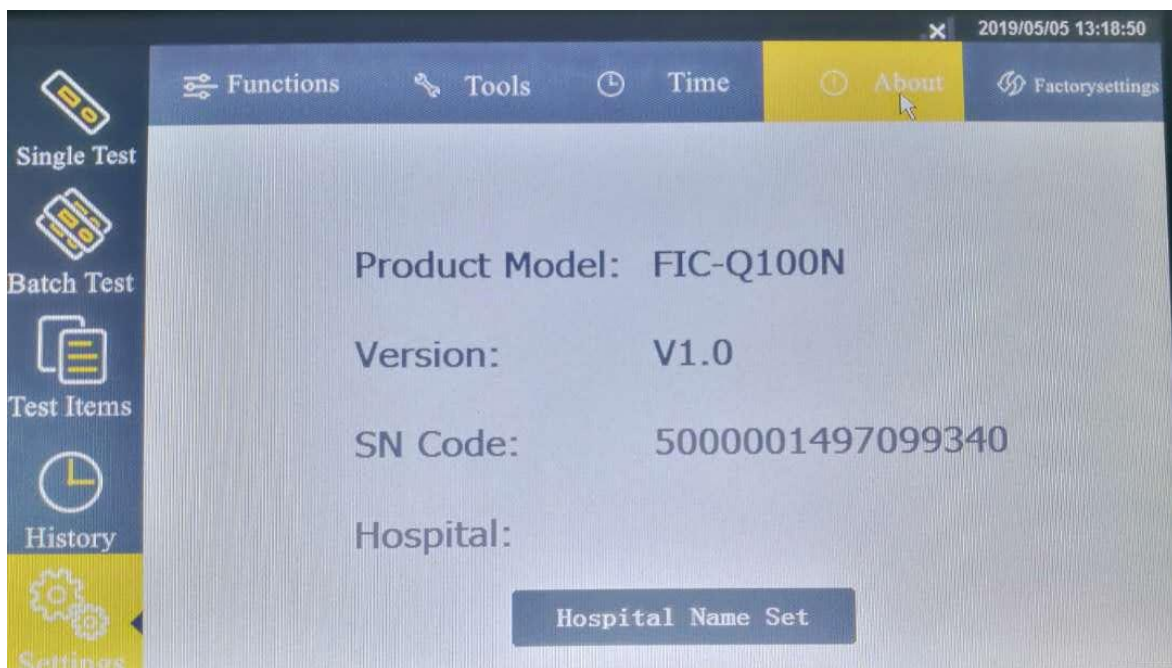
5.1.5　Factory reset

When clicking "Factory Reset" button, a dialogue box will appear. You can clear all data to resume the ex-factory setup.

After resuming the ex-factory setup, the machine restarts automatically.
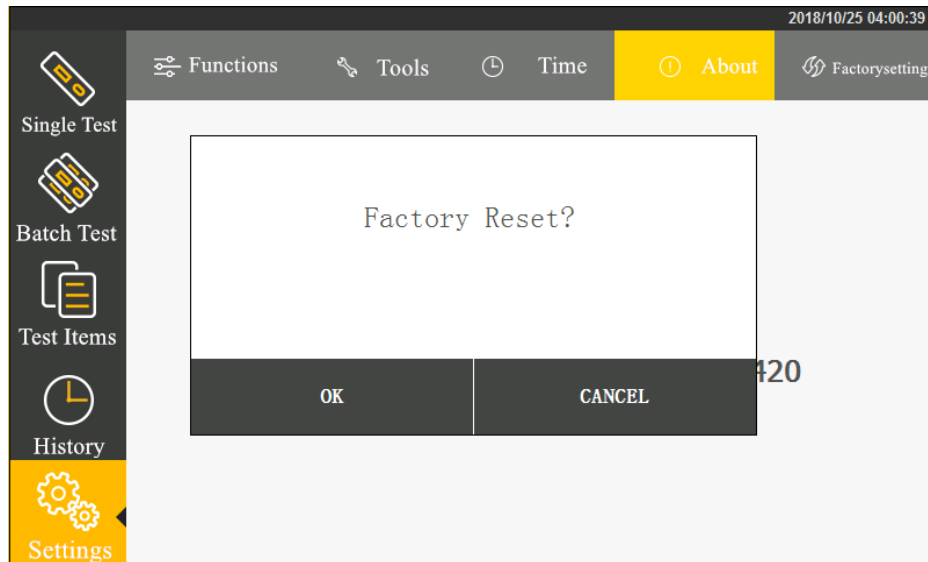
5.2 Project management

Click "Project Management" to enter the following interface. Clicking the corresponding item to select the information appropriate for current test.
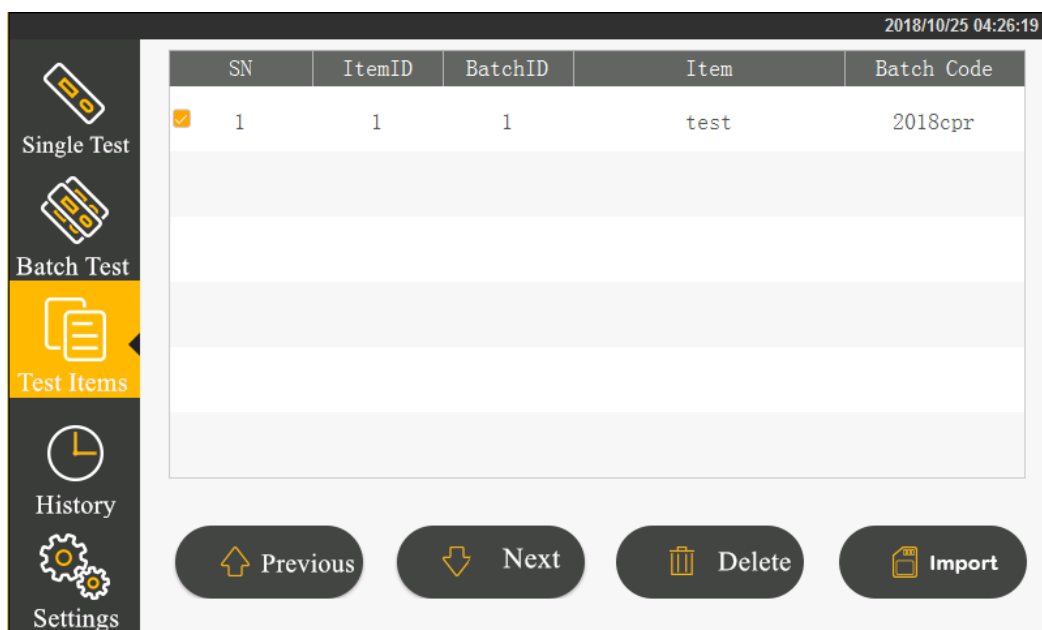
Click "Previous Page", "Next Page" to browse the test items saved by the analyzer.

Click "Delete the Selected" to cancel the information of selected test item.

Following is the ID card import method:

Step 1: Insert the ID card into the D card socket of the analyzer.

Step 2: In the inspecting item management interface, click the button "Import ID Card" to complete the import examination information.

Supplementary notes to ID card import:

1) Each item number and batch number have a unique corresponding examination information data. Setting again will overwrite the original setup information.

2) When inserting the ID card to the analyzer to scan for the matched barcode and complete one test, it will add the current ID card inspecting item to the list.

5.3 Single sample testing

Step 1: Install the analyzer properly and power on to start the device.

Step 2: Click "Single Sample Testing" to switch to the following interface
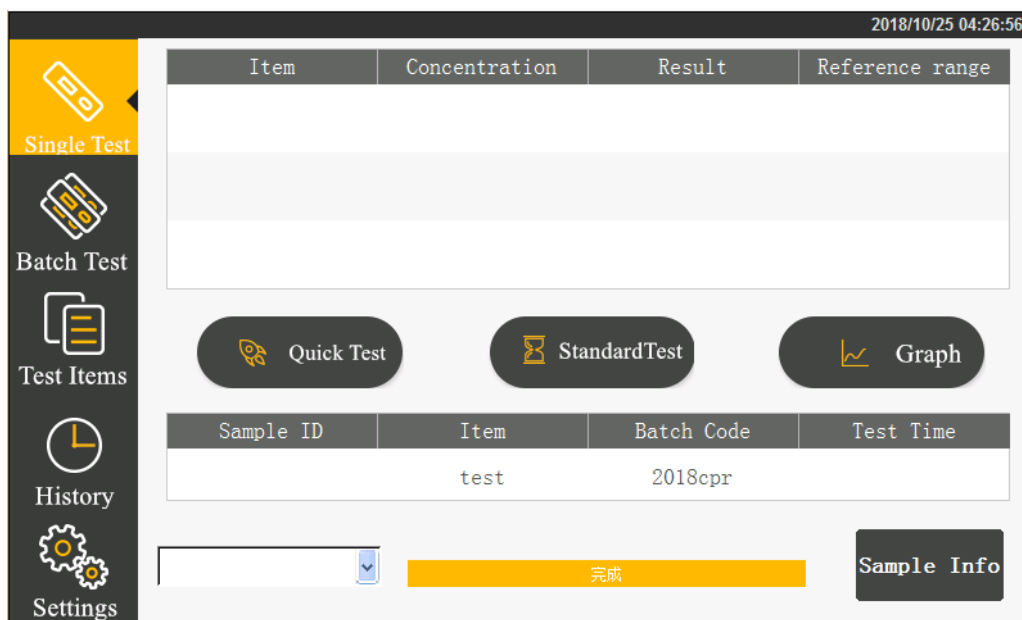

Step 3: Select the sample type to be tested.

Step 4: Confirm the inspecting item and batch number information.
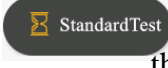
The current testing item and batch number information are set up in the project management. Refer to 5.2 Project Management when it is necessary to change.

Step 5: After obtaining the confirmed information, begin to test.

Click [Quick Test] and the analyzer start the motor to scan the card and begin to test.
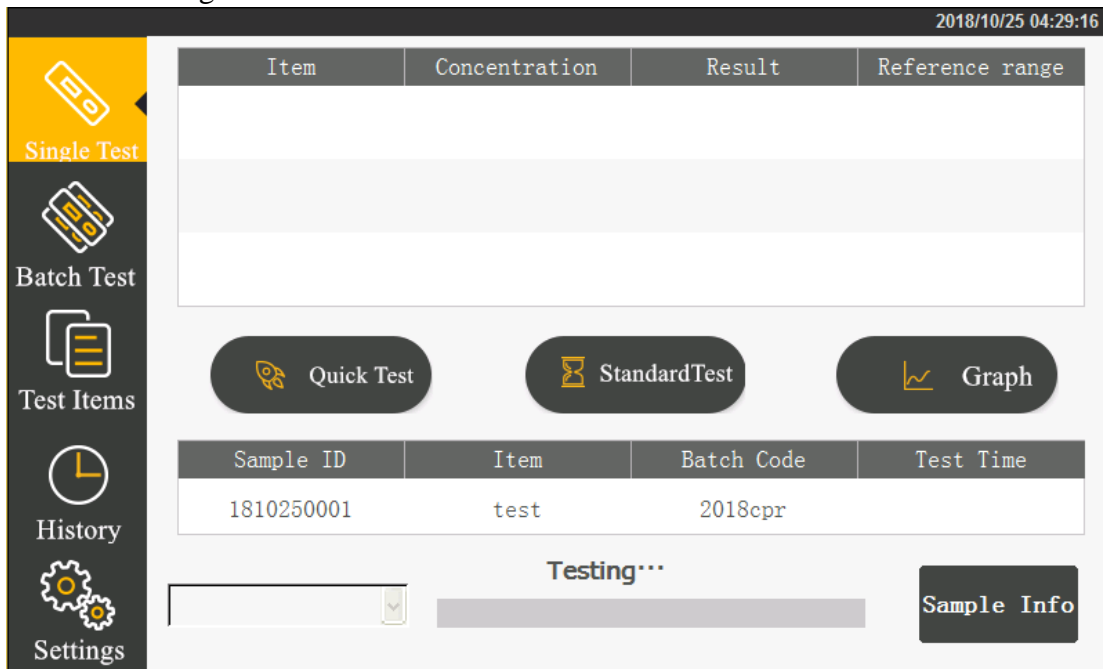
If clicking [StandardTest] the analyzer begin to count the incubation time. The test will start only after incubation is finished.
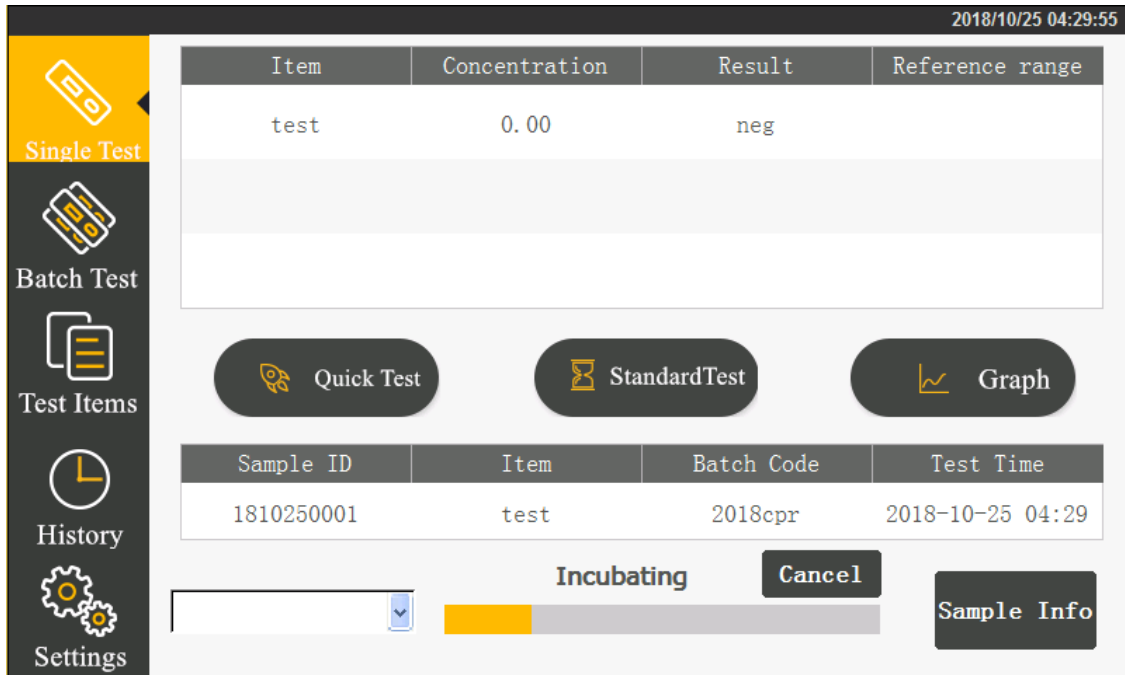
After test is finished, the result will display on the screen.
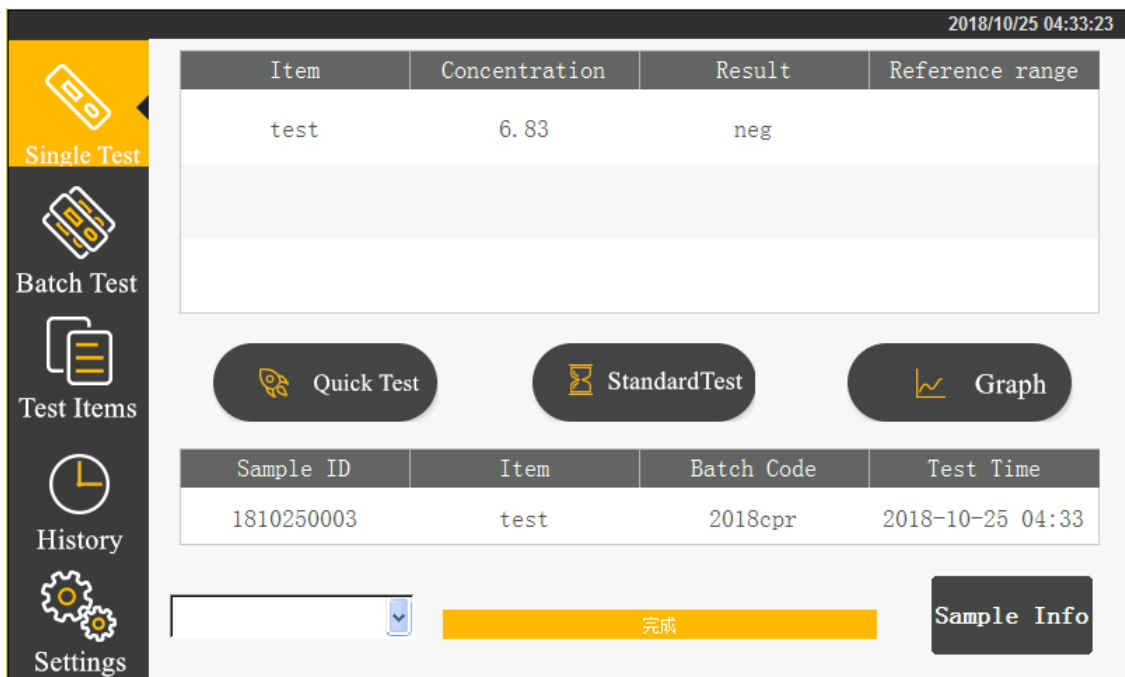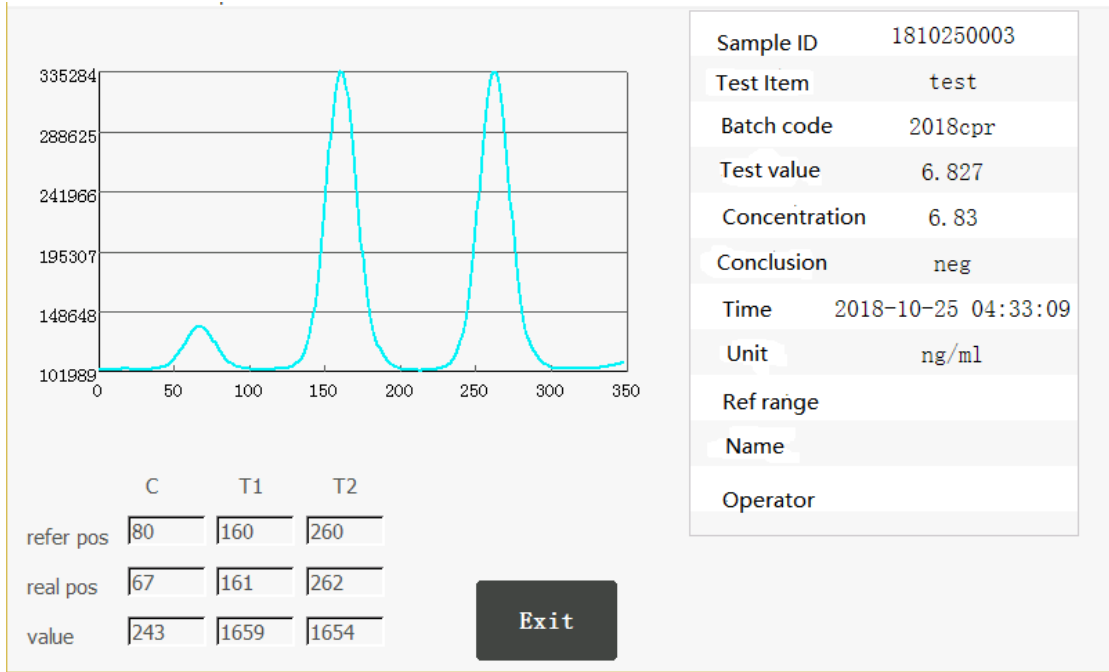

Step 6: Check the Result

When the test is complete, the result will display on the screen. By clicking

, the detailed test result could be checked.

	Sample ID	1810250003
	Test Item	test
	Batch code	2018cpr
	Test value	6.827
	Concentration	6.83
	Conclusion	neg
	Time	2018-10-25 04:33:09
	Unit	ng/ml
	Ref range	
	Name	
	Operator	

	C	T1	T2
refer pos	80	160	260
real pos	67	161	262
value	243	1659	1654

Exit

5.4 Batch testing

Begin to incubate→ during incubation→ inserting a test strip→ testing –〉 pull out the test strip

Click "Batch Testing" to switch to the following interface.

Step 1: Add samples.

Click to complete adding the IDs of all samples to be tested.
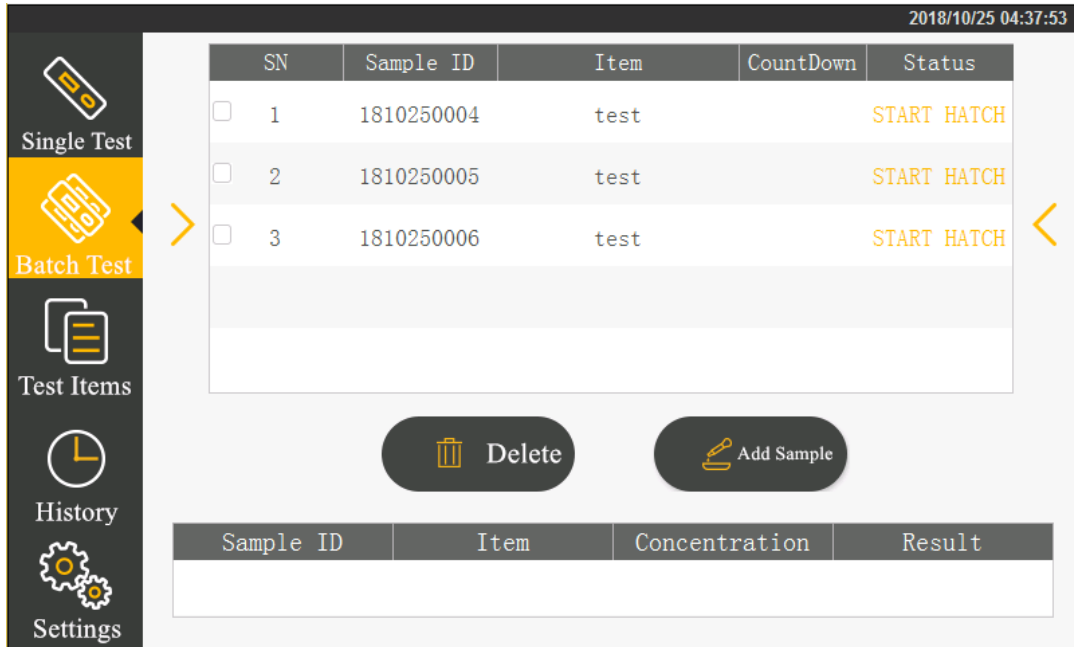
Step 2: Begin to incubate

Add samples to the test strips. Immediately after adding samples, click "Begin to Incubate". The testing state changes and incubation time countdown begins.
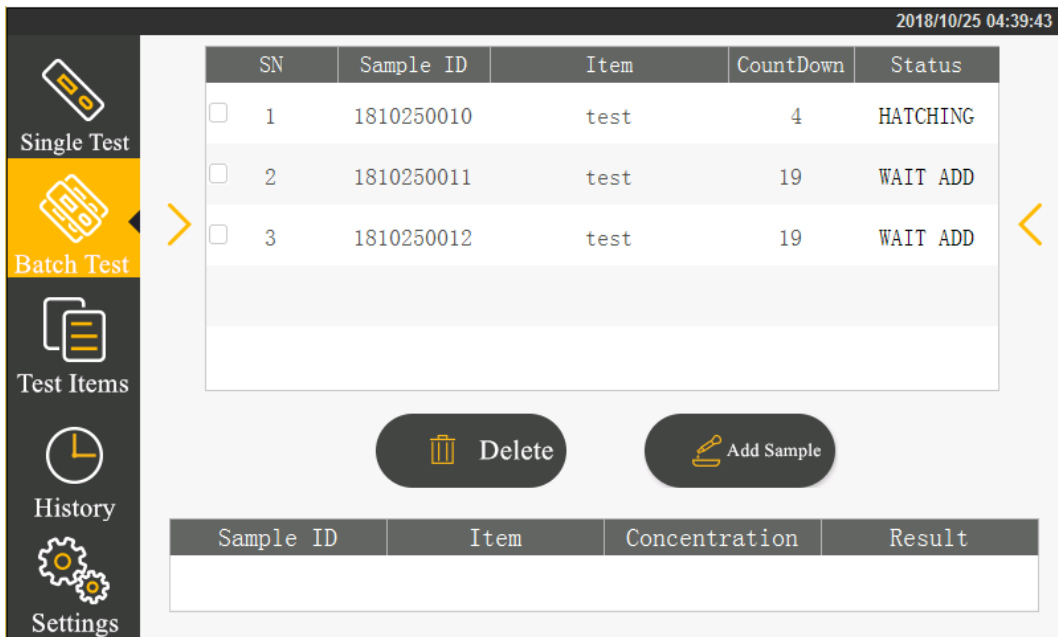
Step 3: Begin to test

When incubation timing is finished, put in the test strip.
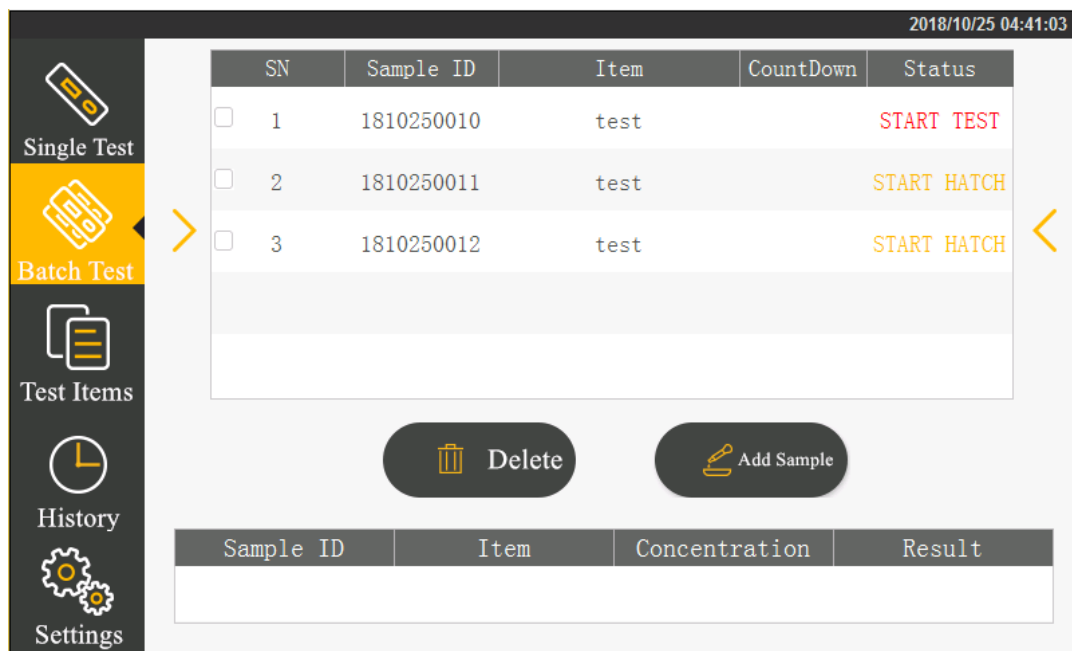
Click "Start Test" to begin testing.
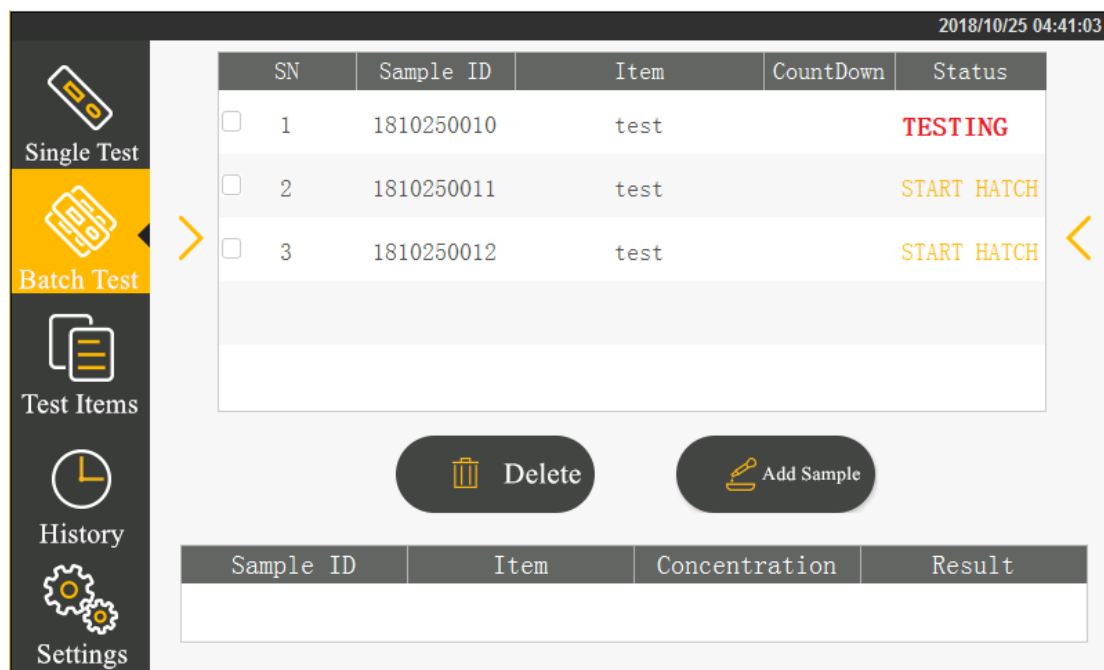
When the test is finished, the test result will display on the screen. The test is completed when no more results displayed.
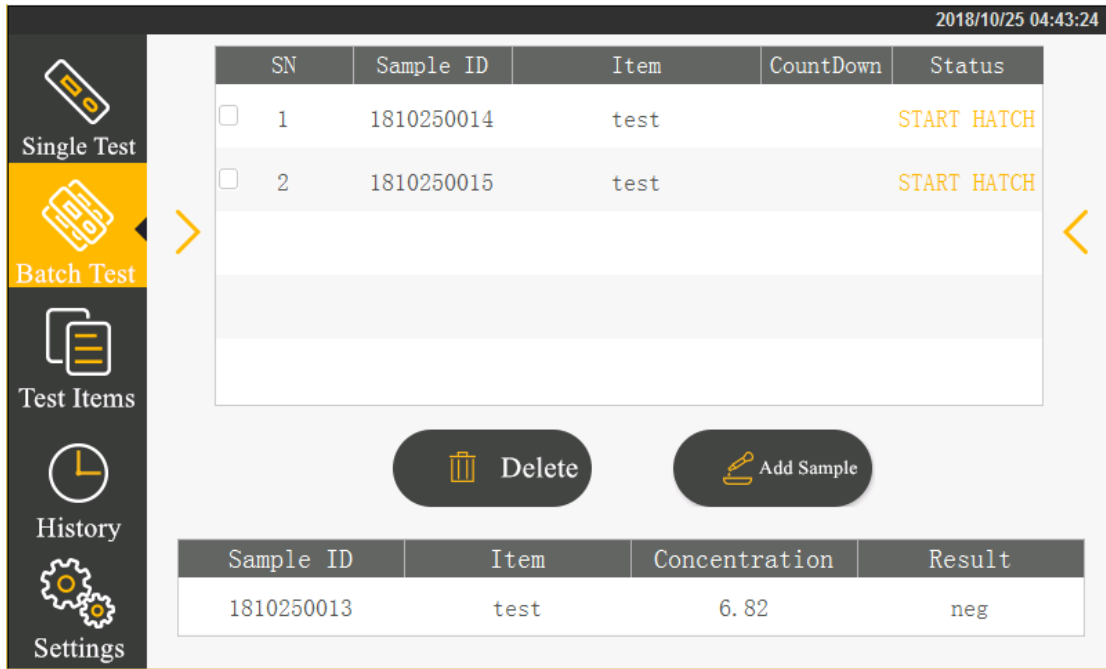
Step 4: Repeat the above operations to test the next strip.

5.5 Historic records

Click the "Historic Records" button on the main menu to switch to the following interface.

The operation records are provided.
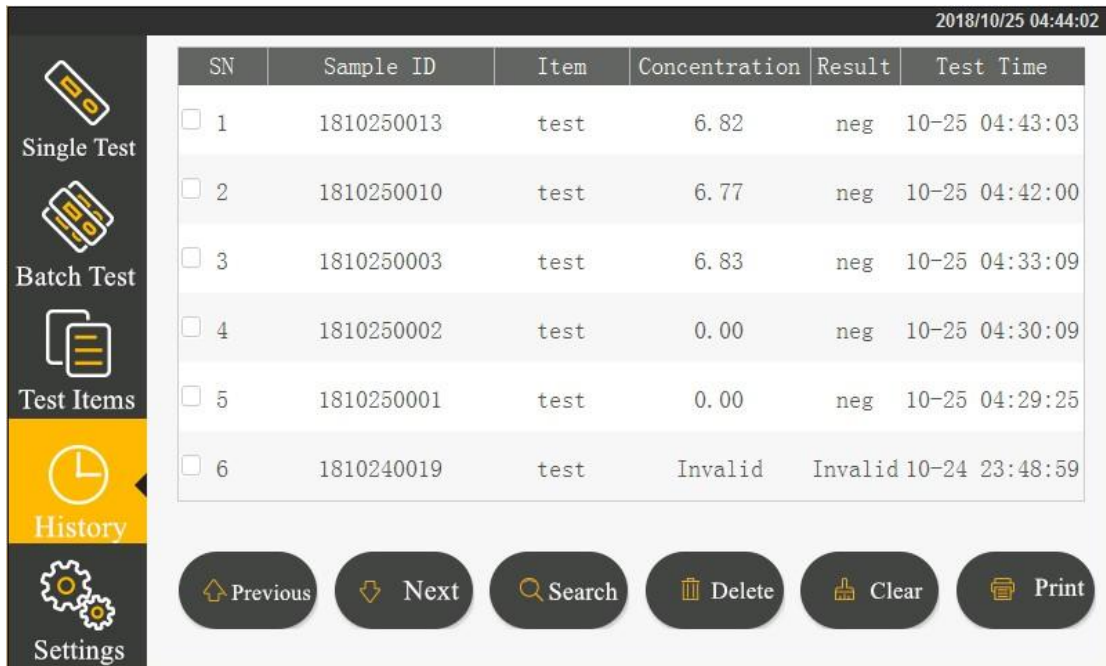
Click or to browse the test records.

Click ![Print button] to print the selected test result through the built-in printer;

Click ![Delete button] to delete a selected test record.

Click ![Clear button] to clear all records.

Click ![Search button] to enter various selecting conditions for record searching.
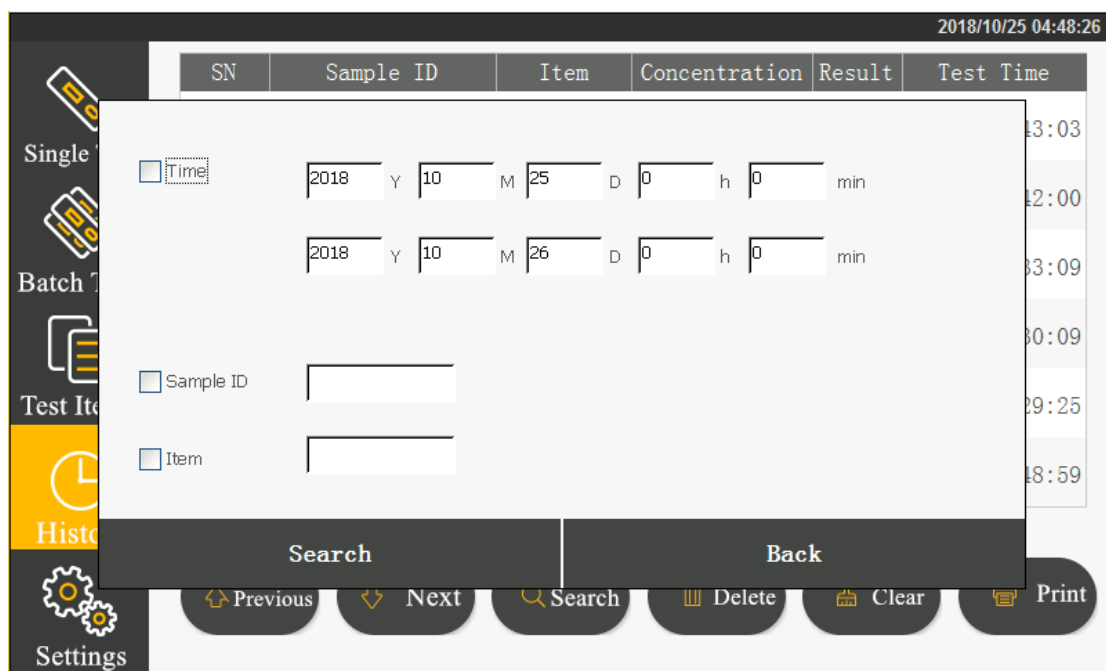
Select time, sample ID, item number and enter the retrieval field. By clicking the "Search" button, you can find the corresponded record.

Chapter VI. Maintenance and Service

6.1 Maintenance

What you have to do is only to keep the external part of the fluorescent immunoassay analyzer clean.

External cleaning and maintenance method: Clean the outer surface of the analyzer with wet cloth and 70% ethanol. Do not use any strong bleaching agent (≥0.5%

solution), as oxidants and solvents may damage the outer surface and touch screen of the analyzer.

Note: Do not use the same method to clean any internal components or internal surface.

⚠ Before cleaning the analyzer, switch off the power and ensure that the power cord plug is in a disconnected state to avoid short circuit and electric shock!

6.2 Maintenance planning

Maintenance item	Weekly	Three months	When necessary
Analyzer dust collection	√		
Change printing paper			When the printing paper is used up

6.3 Attentions for analyzer operation

6.3.1 Do not place the analyzer in a place where it is hard to operate or inconvenient to disconnect the device.

6.3.2 Except the test cards provided by the manufacturer, do not place anything else into the test strip holder.

6.3.3 If any test samples has potential infections, please use protective gloves or take other protective measures to avoid skin contacting with the tested samples.

6.3.4 Please dispose all used reagents and strips according to the Medical Waste Management Regulations to avoid any potential biological hazard.

6.3.5 Please use the analyzer strictly following the Operation Instructions from the manufacturer.

6.3.6 Notes to analyzer data saving and restoring procedures: In the analyzer, the calibration curves related to test items and batch numbers are imported by the manufacturer, and the testing records of users can be saved. When manufacturer

imports through the ID card or transmits through an upper computer any calibration curves, the analyzer will save the curves automatically. The analyzer can save the calibration data for a maximum of 16 items with each item having 3 batches simultaneously. The testing results during normal operation by users will be saved automatically in the analyzer in the record form. The analyzer can save a maximum of 50,000 records. The data saved can resume automatically after power-off without losses. When users select "Factory Reset", the recorded data will be cleared.

6.3.7 Those using and operating the supporting PC software for the fluorescent immunoassay analyzer need to have relevant knowledge: be familiar with such operating systems like windows XP, windows7 and with the installation, unloading of the software installation package in windows XP, windows7.

Chapter VII. Troubleshooting Guide
Steps dealing with device crash

When there is no response to clicking the analyzer interface buttons or analyzer press keys, device crash occurs. 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 power.

Notes to common errors:

1. Unable to perform the "testing" function of analyzer may result from the user interface error. This will not influence the data backup and transmission function. In this situation, you can upload the records backed up to the upper computer software and then return the analyzer to the factory for repairing.

2. The device self application programs error. The possibility for this error is very low. When it occurs, the testing data will lose. However, the historic data backed up in the analyzer will not lose. At this point, power off the analyzer and restart the device to use continually.

3. The system or network resources cannot be used and the testing function and data backup function of the analyzer itself can be used continually. This may influence the record uploading to the upper computer software. As the system or network resources stabilized, the function will resume automatically.

Chapter VIII. Repair and Destroy

As long as you keep the analyzer clean and change printing papers, the fluorescent immunoassay analyzer needs no special maintenance normally. In case of needing any service or repair, please call 400-0536917.

The internal structure of the fluorescent immunoassay analyzer, including those important spare parts and components like circuit boards, optical testing modules, display screen, printer and 1D scanning modules, can only be tested and replaced by our company. No third party service or repair are supported.

When the fluorescent immunoassay analyzer has any trouble or the upper computer software operates abnormally, please call 400-0536917 for consultation. We will provide technical supports online to help customers for troubleshooting. If any analyzer needs repairing, please send the analyzer back for repairing according to the relevant requirements. Normally, the repair period is not beyond one week. If any analyzer does have to be scrapped, the company will provide a new analyzer within the warranty period.

If any user needs to destroy the fluorescent immunoassay analyzer due to any reasons, it is suggested that the user should destroy the device according to the regulations relating to class B electronic analyzers.

The company provides technical support and maintenance to the software, including functional maintenance, corrective maintenance and software error correction or upgrading.

The company declares that the above service guarantees will be available only subject to fully complying with the Operation Instructions from the manufacturer. For any damage other than this, the company will not take any responsibility.

Contact information

Production enterprise (registering person) name: Beijing Dianotech Sci-Tech Co., Ltd.

Registered address: No.1 Zhongli Technology Park, Shangdi 3-Road, Haidian District, Beijing

Production address: No.1 Zhongli Technology Park, Shangdi 3-Road, Haidian District, Beijing

Medical apparatus registration certificate number:

Production license number:

Contact: 400-0536917

Fax: 010-82816022