

MORE Health®

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MORE Health®

**DL300**  
**Fluorescence Immunoassay Analyzer**  
**Operation Manual**

MORE Health, Inc

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## **1. Introduction**

### **1.1 Intended Use**

MORE Health DL300 fluorescence immunoassay analyzer is a point of care device for the processing and analysis of matching MORE Health rapid tests used for various applications, including cardiovascular disease, inflammation, renal function, and rheumatoid arthritis. DL300 analyzer is intended for professional *in vitro diagnostic* use only. This manual contains instructions for the use of DL300 analyzer and general instructions for testing specimens and quality control materials.

### **1.2 Product Description**

MORE Health DL300 fluorescence immunoassay analyzer is used to measure concentration of various analytes in human whole blood, serum, plasma or urine samples. The results can be used as an aid in clinical diagnosis of laboratory and point of care testing.

### **1.3 Product Principle**

The DL300 analyzer is a fluorescence scanning instrument to be used in processing and analysis of matching MORE Health rapid tests. DL300 analyzer uses light-emitting diode (LED) as the excitation light source for illuminating fluorescent molecules on the test cartridge membrane. The fluorescent light is filtered and collected by a photo-electric component. The DL300 analyzer can obtain the intensity of photo-electric signal by scanning the membrane, and the voltage difference between the test line and the background is obtained. This voltage difference is correlated to the analyte concentration, and the result is displayed on the screen of the DL300 analyzer.

## 2. Installation

### 2.1 Unpacking

Take out DL300 analyzer from the packing box and put it on flat surface. Avoid dusts, vibrations, noises and electric interferences. Avoid direct sunshine, exposure to heat and wind. The DL300 analyzer and accessories are packed in a box. Open the packing box and check the packing list

Packing List			
No.	Description	Qty.	Unit
1	Fluorescence immunoassay analyzer	1	Set
2	Power supply adapter	1	pc
3	Data Cable	1	pc
4	Printing paper	1	pc
5	Operation manual	1	pc
6	Product Qualification Certificate	1	pc
7	Barcode Scanner	Optional	pc

### 2.2 Product Components

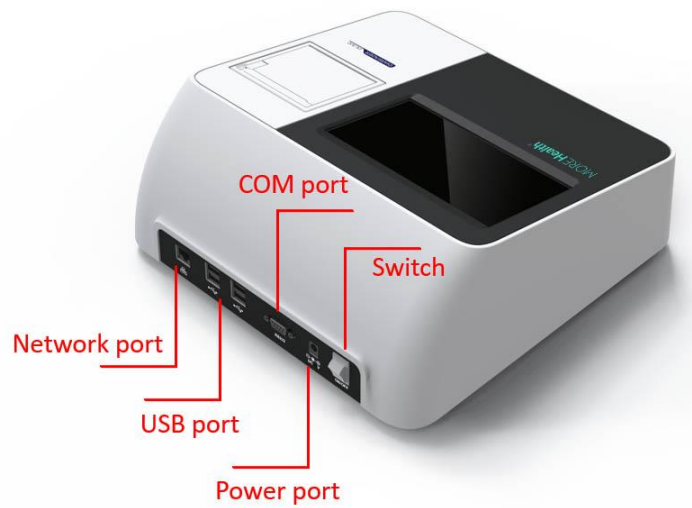
**Front side structure diagram:**

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## Back side structure






## Power supply adapter



## ID card



### Explanation to product symbols

Number	Symbol	Explanation
1		Attention, refer to the attached text
2		Vitro diagnosing apparatus
3		Biological risk

## 2.3 Instrument Specifications

Touch screen	7-inch touch screen	
Communications	USB port for barcode scanner, RS232 computer interface port for PC	
Data storage	10,000 data	
Dimensions	300mm x 305mm x 120mm	
Weight	9.23 pounds (4.20kg)	
Operating Environment	Temperature	+20°C ~ 25°C
	Relative humidity	20% ~ 90%
	Air pressure	86.0kPa ~ 106.0kPa

Storage	Temperature	-10°C ~ +40°C
	Relative humidity	≤ 93%
	Air pressure	50.0kPa ~ 106.0kPa
Power Supply	AC 100~240V, 50~60 Hz; DC 12V 5A	

## 2.4 Setup

### 2.4.1 Power on

a) Use the adapter packed together with the DL300 analyzer.

Supply voltage: AC100V~AC220V, Frequency: 50~60Hz.

b) Connect power with DL300 analyzer through the AC/DC adapter.

c) Switch on the device.

### 2.4.2 Loading printing paper

Open the printer cover, place the printing paper into the printer with the carbon sensitive surface facing down to the screen. Pull out approximate 2 cm of paper from the roll, then close the cover of the printer.

### 2.4.3 Barcode Scanner Connection (optional)

Connect the barcode scanner via USB port on the back of the instrument (see details in appendix).

## 3 Startup

### 3.1 Self Check

Each time the instrument is turned on, it will conduct a self-check. The system will check its hardware automatically. After self-check is finished, the system will enter the main interface, as shown in Fig.1.

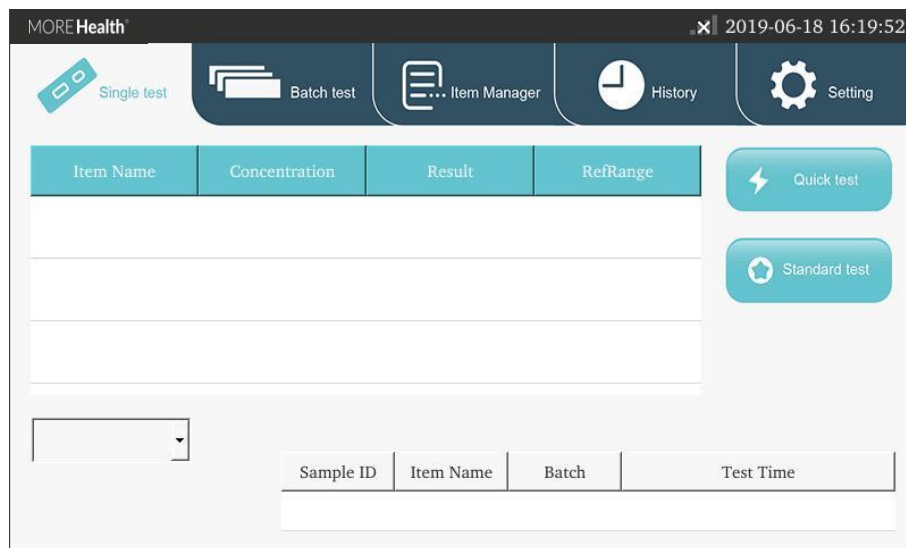


Fig.1 Main Interface

### 3.2 QC Test

To ensure the accuracy of the measurement and the comparability of the measured data, optical part of the instrument need to be tested (optional). (see details in part 4.3.2).



## 4. Operating

### 4.1 Preparations before Power On

Before turning on the device, make sure the device is ready to be used. Check the system in following steps:

- a) Check whether the power supply is connected safely.
- b) Check whether the printing paper is enough.
- c) Check the temperature of test environment is  $+20^{\circ}\text{C} \sim 25^{\circ}\text{C}$

### 4.2 Power On

Press the switch to turn on the device.

### 4.3 System setup

Complete system setup before operating the analyzer.

Click the “Setting”, a second-level interface appears: Function, Tools, Time setting, About, Reset.

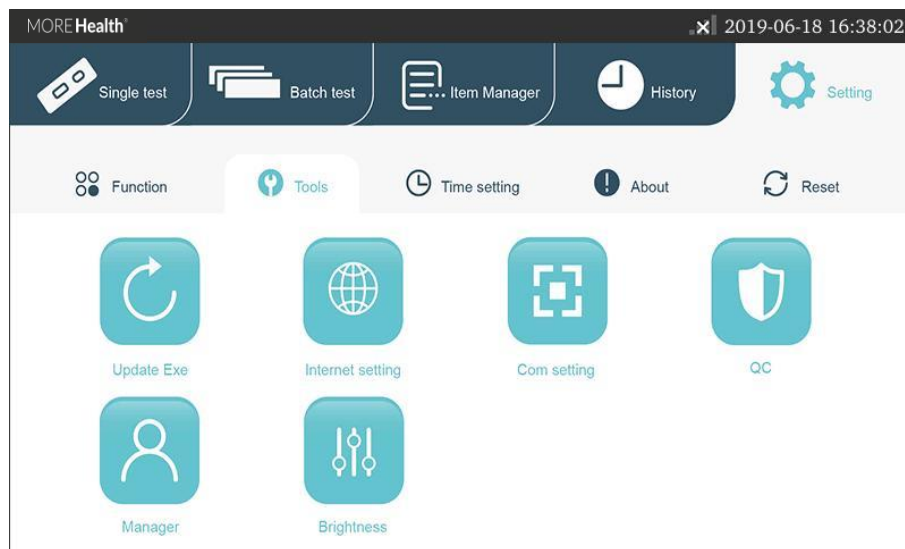


Fig. 2 Setting interface.

## 4.3.1 Function setup

Click "Function" to enter the following interface. Click the icon behind each column to enable/disable the function.

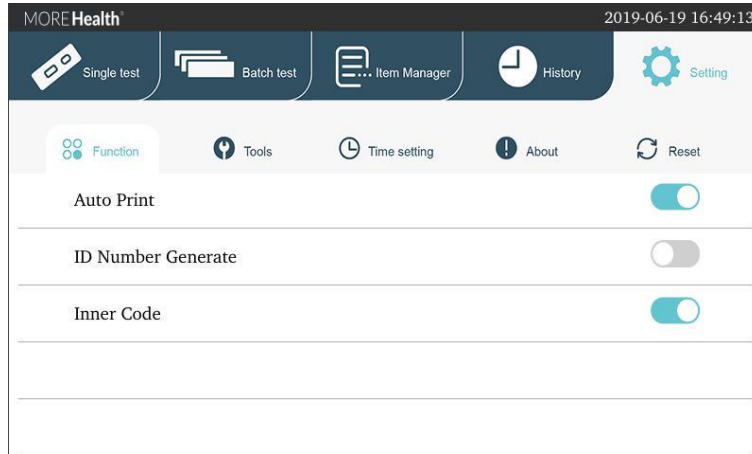


Fig. 3 Function interface

### a) Auto Print:

on-- print the result automatically after testing

off—don't print after testing

### b) ID Number Generate:

on-- generate an sample ID number automatically according to the date encoding

off-- manually input an sample ID number when testing

### c) Inner Code:

on-- scan barcode on cartridges to identify the test item and Lot number of test

off-- test directly without scanning the barcode

## 4.3.2 Tools

Click "Tools" to enter the following interface. The main tools include: Update Exe, Internet setting, Com setting, QC, Manager, Brightness.

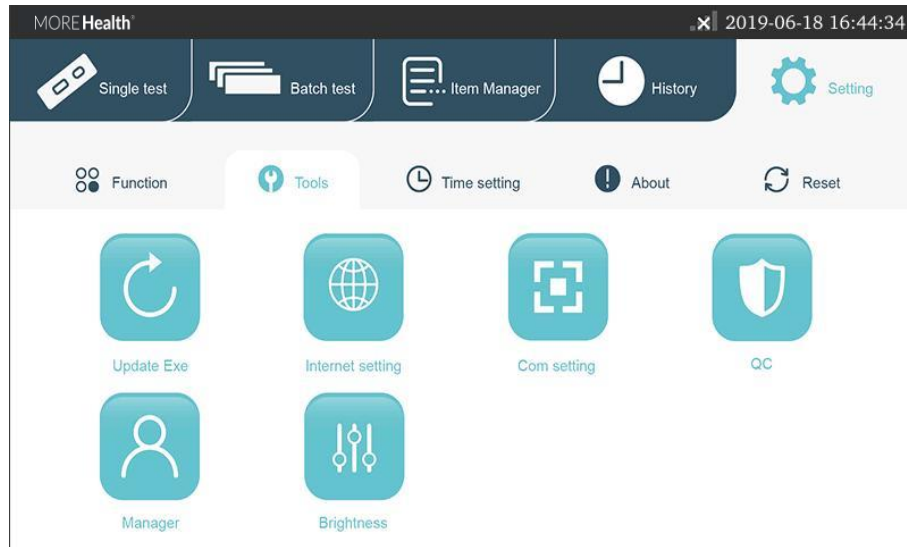


Fig. 4 Tools interface.

## a). Update Exe

Click “Update Exe” to enter the following interface.



Fig. 5 Update Exe interface.

Copy the updating program package to a U-disk and insert it into the USB port behind the analyzer. Click “ Update”, the analyzer loads the program and updates the system.

After updating, the analyzer restarts.

## b). Brightness

Click the “Brightness” button to enter the following interface.

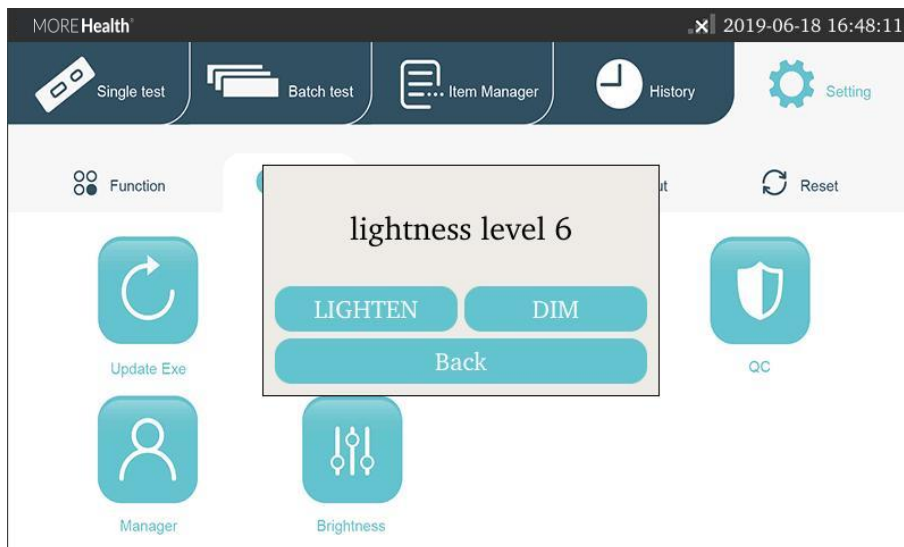


Fig. 6 Brightness interface.

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

## c). QC

Click the “QC” to enter the following interface.

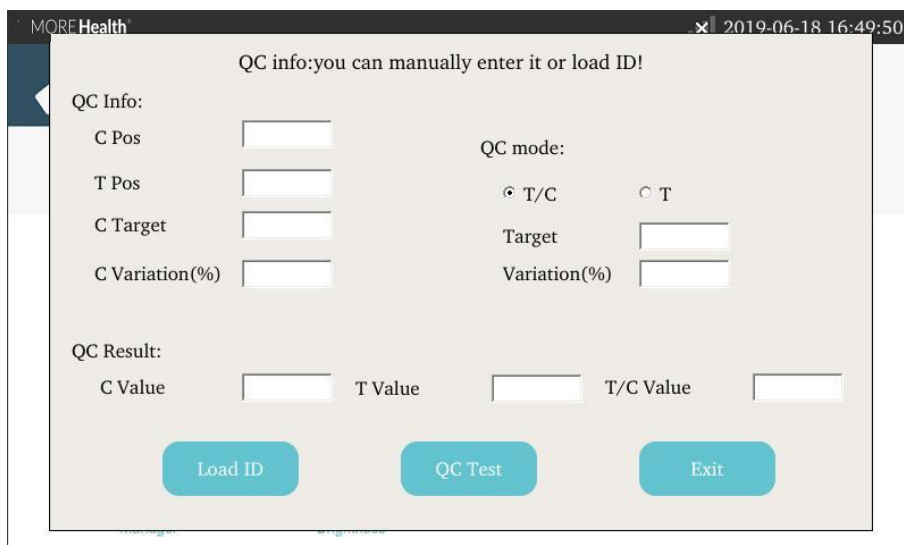


Fig. 7 QC interface.

Insert the QC ID card into ID port of the analyzer, click “Load ID”, QC info can be loaded. Insert the QC cartridge into Card input port of the analyzer, click “QC Test” to start analyzer quality inspection.

When passing the quality inspection, “quality Inspection Successful!” will display.

When not passing the quality inspection, “quality inspection failed!” will display.

If the quality inspection fails, please contact the manufacturer.

## d). Administrator

The administrator function is available for professional technicians only. Click “Manager” and entering the password to manage the analyzer.

## e). Network configuration

Clicking “Internet setting”, you can set up the analyzer IP. The analyzer IP setup will be effective after restarting. You can set up the computer IP address. After proper setup, you can connect the computer by clicking “Connect”.

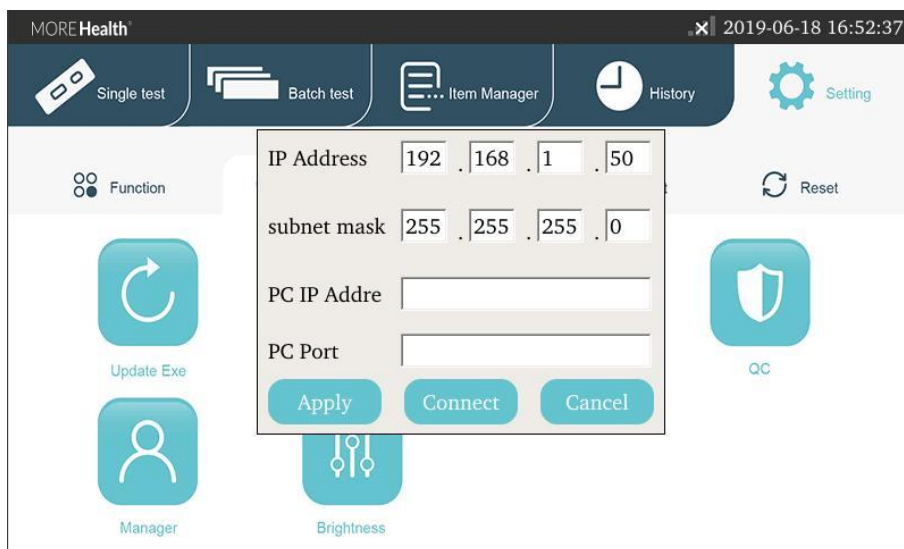


Fig. 8 Internet setting interface.

## f). Com setting

Clicking “COM setting”, you can set up the port of the analyzer to connect Lis.

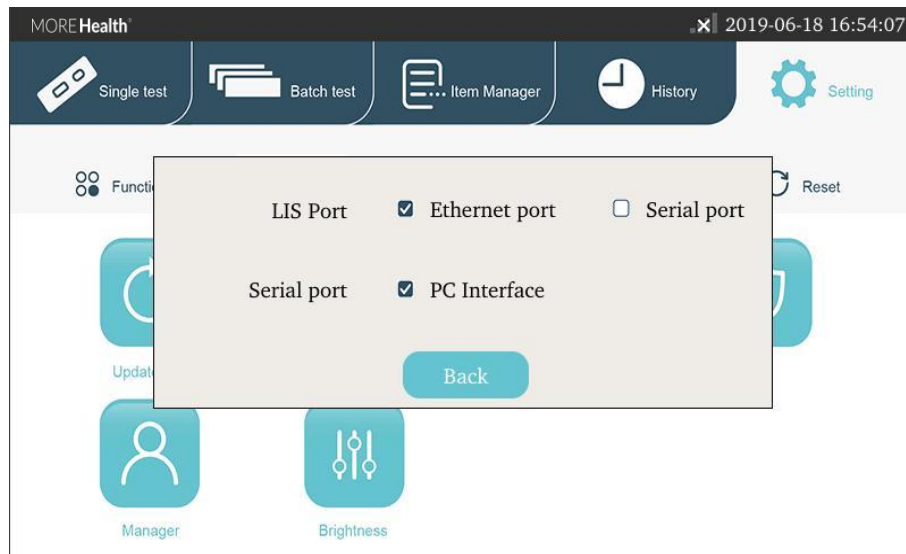


Fig. 9 Com setting interface.

### 4.3.3 Time setting

Click “Time setting” to enter the following interface.

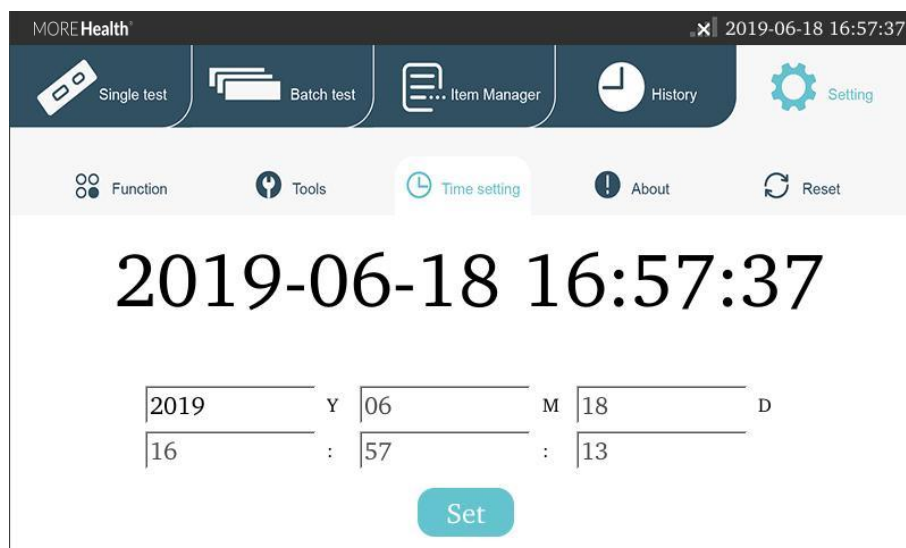


Fig. 10 Time setting interface.

After adjustment, click “Set” to confirm time change. Clicking other button to cancel time modification.

## 4.3.4 About the analyzer

Click “About” to show the system information of the analyzer.

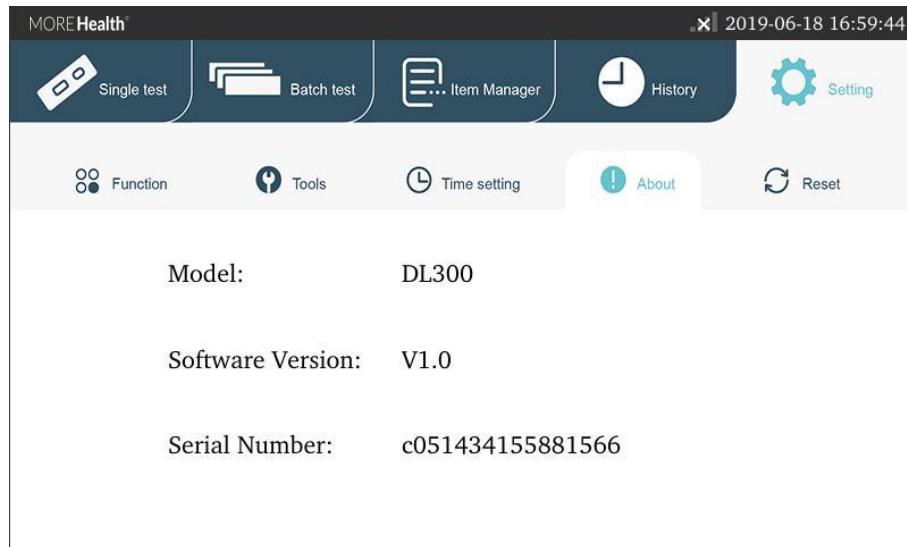


Fig. 11 About interface.

## 4.3.5 Reset

Clicking “Reset”, you can clear all data to resume the ex-factory setup. After resuming the ex-factory setup, the machine restarts automatically.

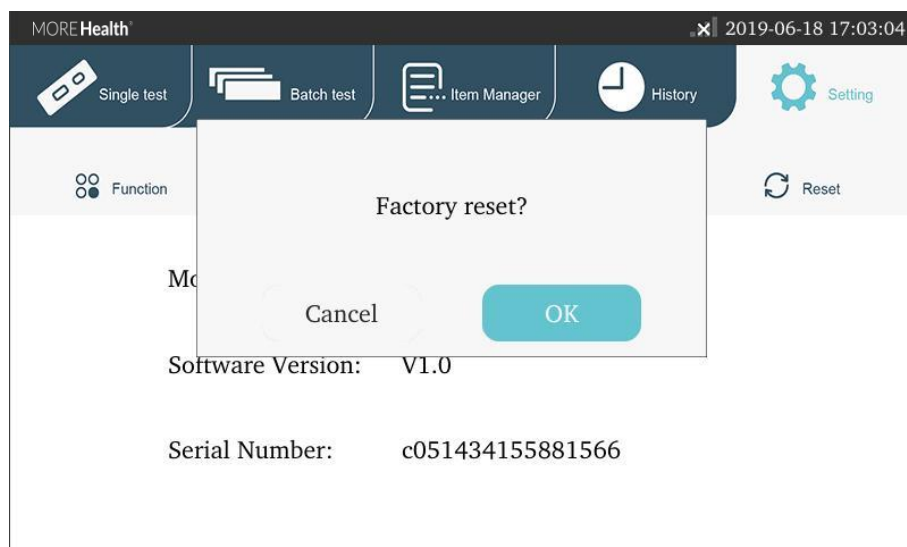


Fig. 12 Reset interface.

## 4.4 Measure Item management

Click “Item manager” to view measure item info that is loaded previous. Click “Page up” or “Page down” to browse the measure items. By selecting a measure item, you can click “Delete” to delete it. By insert the ID care into the ID port of the analyzer, you can import measure items.

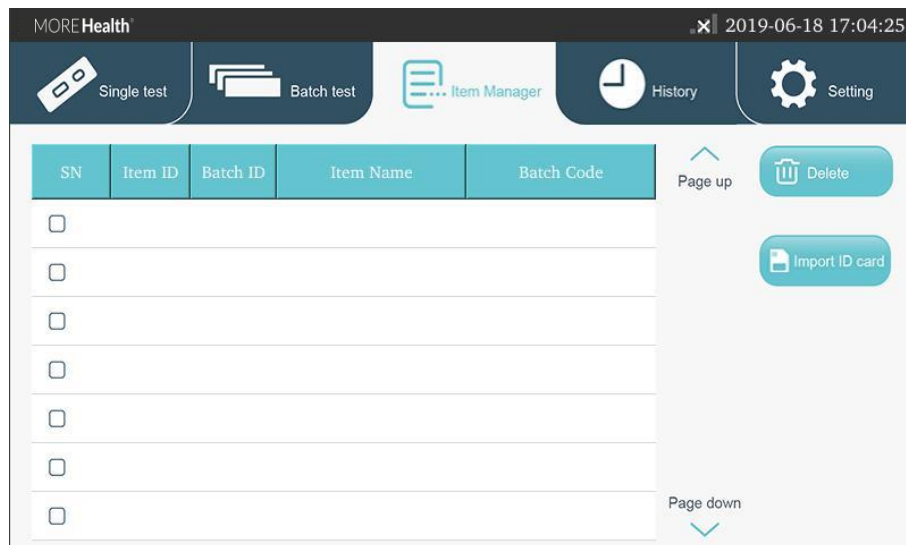


Fig. 13 Item Manager interface.

## 4.5 Sample testing

There are three types for sample test: “Standard test”, “Quick test”, and “Batch test”.

### 4.5.1 Preparation before test

- Make sure that the environmental temperature for test is 20°C to 25°C (Room temperature). (Important! If the environmental temperature is out of this range, test results may be incorrect.)
- If cartridges and/or test specimens are taken out of the fridge, allow them to reach the room temperature by leaving them in the room for approximately 30 minutes.
- Preparing a pipette (10-100uL or 20-200uL volume range), tips, and a timer, if needed.



- d). Switch on the DL300, and make sure that the measure item and lot# on cartridge packages match those on the ID card.
- e). Insert the ID card into the “ID port” of the DL300, the instrument will automatically read the calibration info. The analyzer makes a sound ‘Ding’ when it finishes the loading, and you can also find the calibration info on the “Item manager” interface.

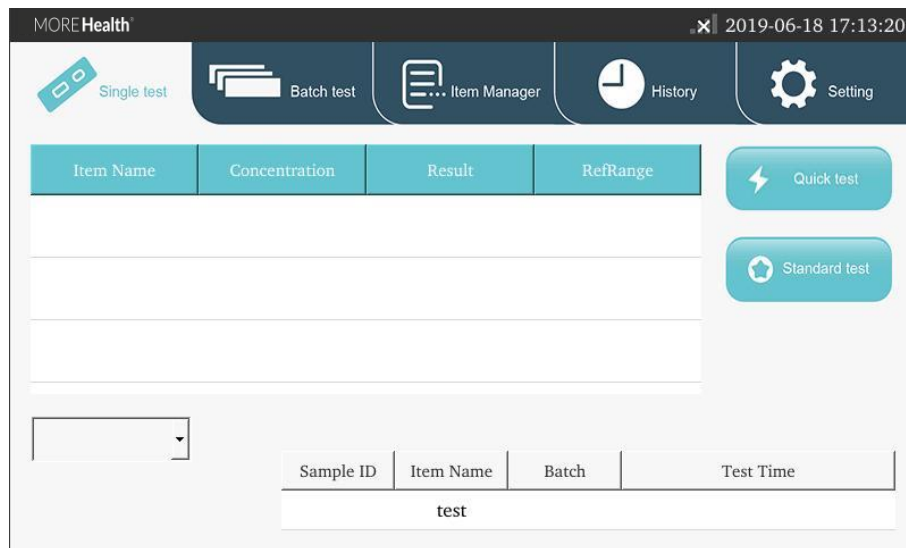


Fig.14 Single test interface.

## 4.5.2 Standard test for single specimen test

- a). Open cartridge package, taking out the cartridge and put it on a table horizontally. (Important! After opening the package, the cartridge should be used within 1 hour, otherwise the test result may be incorrect.)
- b). Click “single test”, switch to the “single test” interface. Then select an appropriate specimen type.
- c). Using a pipette, pipetting 80ul out of test sample and load it into the sample well on the cartridge.
- d). Insert the cartridge into the “Card Input” port of the DL300, and Click “Standard test”, the incubation time countdown will appear.
- e). The test will automatically start when countdown is finished, and the test result will be shown and printed automatically.

f). After finishing the test, take out the cartridge. The cartridge and pipette tips should be discarded by an appropriate method in accordance with relevant local regulations.

### 4.5.3 Quick test for single specimen test

a). Open cartridge package, taking out the cartridge and putting it on a table horizontally. Using a timer, setting countdown time of the test according to the reaction time in the [Test Procedure] section of the test instruction. (Important! After open the package, the cartridge should be used within 1 hour, otherwise the test result may be incorrect.)

b). Using a pipette, pipetting 80ul out of test specimen and load it into the sample well on the cartridge.

c). Starting countdown.

d). After finishing the countdown, insert the cartridge into the “Card Input” port of the DL300. Then select an appropriate type of the test sample. Click “Quick test”, and the test starts. The test result will be shown/printed automatically. (Important! After finishing the countdown, the cartridge should be read by DL300 within 5 min, otherwise the test result may be incorrect.)

e). After finishing the test, take out the cartridge. The cartridge and pipette tips should be discarded by an appropriate method in accordance with relevant local regulations.

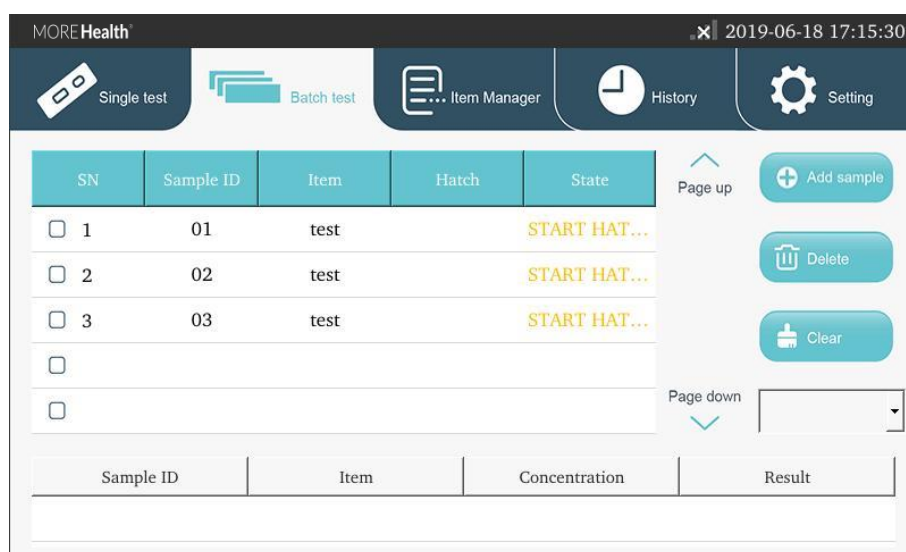


Fig.15 Batch test interface.

## 4.5.4 Batch test for multiple specimen test

- a). Applicable situation: multiple-specimen test with one measure item. (Important! The maximum number of samples that can be processed for batch test at one time can be calculated. For example, if a test needs reaction time of 15min, maximum number of samples that can be processed for batch test at one time would be  $n = 15 \text{ min} \times (60 \text{ sec} / 20\text{sec}) = 45 \text{ samples}$ . A 20 sec interval is required for a single specimen processing.)
- b). Open cartridge packages as required, taking out cartridges and putting it on a table horizontally. Near sample well on cartridges, marking each cartridge with one corresponding specimen ID. (Important! After open the package, the cartridge should be used within 1 hour, otherwise the test result may be incorrect.)
- c). Click “Batch test”, switch to the “Batch test” interface. Then select an appropriate type of the test sample. Click “Add sample”, input a corresponding sample ID. Repeat click “Add sample” and input another corresponding sample ID. until all sample’s ID is loaded.
- d). Using a pipette, pipetting out 80ul of test specimen and load it into the sample well on the corresponding cartridge. In the corresponding specimen info column on the “Batch test” interface, click “Start Hatch”, the test starts countdown. Waiting for about 10 sec, then pipetting out 80ul of another test specimen and loading it into the corresponding cartridge, click corresponding “Start Hatch” button. Repeat those procedures, until all samples are loaded.
- e). When a test finishes the countdown, the analyzer makes sounds ‘Ding Ding Ding’ that reminds you a cartridge can be tested. Insert the corresponding cartridge into the “Card Input” port of the DL300. Click corresponding “Start test” button, and the test starts. The test result will be printed automatically.
- f). After finishing a test, take out the cartridge. And waiting for another sound of ‘Ding Ding Ding’ and starts another test. Repeat those procedures until all tests are finished.
- g). After finishing the test. cartridges and pipette tips should be discarded by an

appropriate method in accordance with relevant local regulations.

## 4.6 Historic records

Click the “History” on the main menu to browse and process previous records.

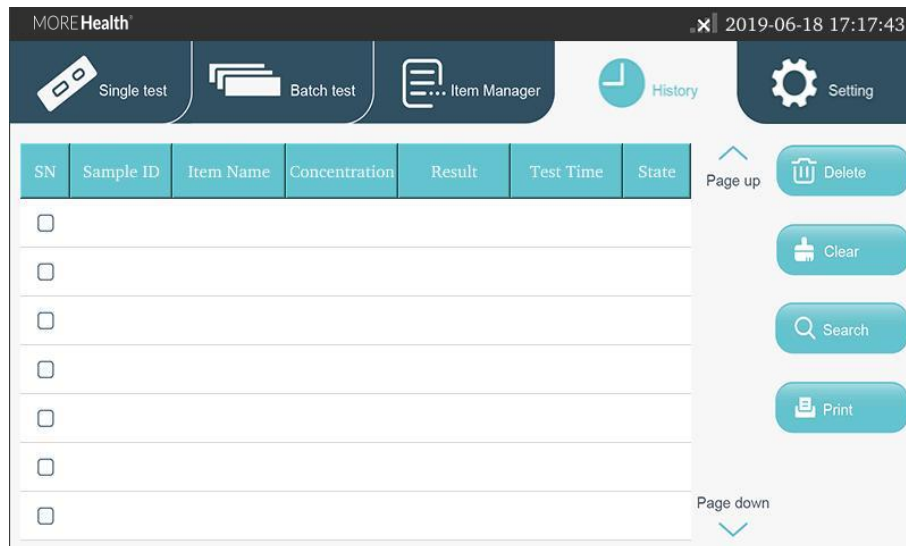


Fig. 16 History interface.

Click “Page up” or “Page down” to browse records. Select a record, click “Delete” or “Print” to delete or print the test record. Click “Clear” to clear all records. Click “Search” to search a specific record.

## 5. Instrument Maintenance and Troubleshooting

### 5.1 Instrument Maintenance

- a). Please operate the instrument following the requirements of the user manual, to ensure the reliable long-term performance.
- b). Calibrate the device periodically with QC card to ensure the accuracy of the results.
- c). Equilibrate the device at room temperature for 5 minutes before testing to ensure the accuracy and reliability of results.
- d). Device should be placed in a dry place with a stable temperature and humidity.
- e). Wipe the surface of device gently with a clean dry cloth regularly.
- f). Do not disassemble the device. Operation done by unqualified people may damage the device.

### 5.2 Troubleshooting

When there is no response in clicking the analyzer interface buttons or analyzer press keys, 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. 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 upload the records backed up to the upper computer software 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 lose. However, the historic data backed up in the

analyzer will not lose. At this point, have the analyzer power off and restart 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 become stabilized, that function will resume automatically.

## **6. Appendix**

### Testing Procedure with Barcode Scanner

- a). Turn on the device and connect the barcode scanner to DL300 rapid Reader via USB.
- b). Do the tests according to the steps described in the previous content.