FIC-Q100N

Dry Immunoassay Analyzer

Operating Manual



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1.Introduction

VETDiagnostix FIC-Q100N Dry Immunoassay Analyzer (the Analyzer) is a high-resolution reader machine for the efficiently qualitative and quantitative interpretation of test results of rapid test kit. It is based on photoelectric detection principle and employs visible spectrum light source. The users can get a more precise result than visual observation. This analyzer is applied as an auxiliary tool to the rapid test under the brand VETDiagnostix for professionals. Please read this manual carefully before use. This manual is only applicable to FIC-Q100N model, which is subject to the actual operation interface.



1.1.Specification

1) Name: VETDiagnostix Dry Immunoassay Analyzer
2) Model: FIC-Q100N
3) Dimensions: 299mm×230mm×150mm (L×W×H)
4) Weight: 2.5KG
5) System version: V1
6) Date of production: See the outer package label.

1.2.Intended Use

The Analyzer is to be used by hospitals, clinics, testing centers and laboratories, as an analystic tool for the qualitative, semi-quantitative or quantitative interpretation of test results by rapid test kits under the brand VETDiagnostix. Please consult the after-sales service personnel for the available rapid test items which can be applicable to the Analyzer.

1.3.Symbols

Table 1.3.1 is a list of symbols used on the Analyzer and in this document.

No.	Symbol	Description
1		Important information; refer to manual
2	IVD	In vitro diagnostic use
3	CE	Conforms to European Union directives

2.Components and main structure

Please carefully check the status of components according to the standard configuration list. In case of any missing or damage, please contact the local after-sales service center or local distributor in time.

2.1.Standard configuration list

Table 2.1.1 Standard configuration list

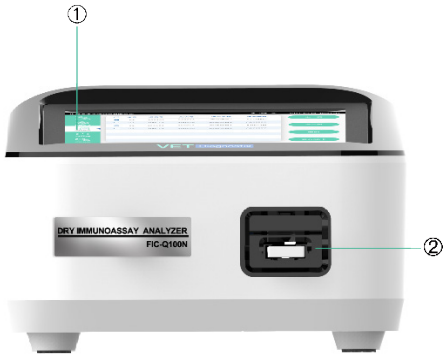
No.	Item	Quantity	Unit
1	The Analyzer	1	set
2	Power adapter	1	unit
3	Power cord	1	unit
4	USB to serial port line	1	unit
5	External code scanner	1	set
6	External code scanner cord	1	unit
7	QC Test card	1	unit

2.2.Main structure

Note: The appearance of the Analyzer and attached accessories is subject to the physical object.

the Analyzer:

Figure 2.2.1 and Figure 2.2.2 show the front and back structural diagram of the Analyzer



(Figure 2.2.1) Front-Panel structural diagram of the Analyzer



(Figure 2.2.2) Rear-Panel Structure diagram of the Analyzer

Table2.2.1 describes the Rear-Panel controls and connections of the Analyzer.

No.	Name	Description
①	Touch screen	Touch screen operation and display results
②	Test card slot	Test card
③	LAN port	Device Port for connecting to Local area network.
④	Power Switch	Turns the Analyzer on and off.
⑤	Power connector	Input connector for attaching the power adapter and power cord to the Analyzer. Input DC 12V.
⑥	COM port	Device Port for controlling the Analyzer from a PC.
⑦	USB port	USB port for attaching the External code scanner to the Analyzer.

The accessories:



Power adapter



Power cord



USB to serial port Line



External code scanner



External code scanner cord



QC Test card

3.Basic parameters and Environmental requirements

3.1.Basic parameter

1) Dry Immunoassay Analyzer interface: USB, USB-COM, COM, LAN
2) Printing method: automatically print a note by the Built-in thermal printer or link to software in PC to print professional report
3) Touch screen: 24-bit 7-inch color LCD.
4) Power supply: host input DC 12V 4A
5) Adapter input: AC 100~240V, 50 Hz~60 Hz.
6) Repeatability CV≤10%
7) Stability σ≤10%
8) Accuracy δ n ≤ 10%
9) Linearity r≥0.99
10) Maximum capacity of record: 1000 records.

3.2.Transportation and storage conditions

After packaging, it should be stored in an environment with-10°C ~ 40°C, relative humidity of 20% ~ 90%, atmospheric pressure of (86 ~ 106) kPa, no condensation, no corrosive gas and good ventilation. Attention should be paid to moistureproof during transportation to prevent impact and violent vibration.

3.3. Working conditions

3.3.1.Installation requirements

1) The Dry Immunoassay Analyzer should be placed on a stable horizontal workbench, and there should be more than 10cm space around it to ensure the necessary space for operation and maintenance.
2) There is no strong vibration source and strong electromagnetic field around the Dry Immunoassay Analyzer.
3) The room should be well ventilated without serious dust, direct sunlight and corrosive gas.

3.3.2.Working Area Requirements

1) Working environment temperature range: 5°C-40°C;
2) Relative humidity range: 10% ~ 80%;
3) Air pressure range: 700 HPA ~ 1060 HPA.

3.3.3.Electromagnetic compatibility requirements

1) The Dry Immunoassay Analyzer meets the electromagnetic compatibility requirements of IEC61326-1/IEC6326-2-6, including emission and noise immunity requirements.
2) Before use, users should evaluate the electromagnetic environment around the equipment to ensure its normal operation.
3) Use in dry environment, especially in the environment containing artificial materials (fabrics and carpets, etc.), may lead to destructive electrostatic discharge of equipment and draw wrong conclusions.
4) Strong radiation sources (such as unshielded wireless power supply) may interfere with the normal operation of the Dry Immunoassay Analyzer.
5) The Dry Immunoassay Analyzer may cause radio interference, so protective measures should be taken.

4.Installation

4.1.Product connections

Accessories connect to the Analyzer through the rear-panel connections
Note: Please install the Analyzer according to "3.3.1. Installation Requirements".
1) Place the Analyzer on a stable horizontal workbench.
2) Connect the Power adapter and Power cord to the Power connector of the Analyzer.
3) Connect the External code scanner to the the USB port of the Analyzer.



Figure 4.1.1 . Accessories connections to the Analyzer

4.2.“Cloud printing client” installation

1) Click to run the software installation package "Cloud printing client" and run the installation program to complete the installation.
2) Click "Edit" in Figure 4 .2.1to add the corresponding serial number of the Analyzer to complete the installation.

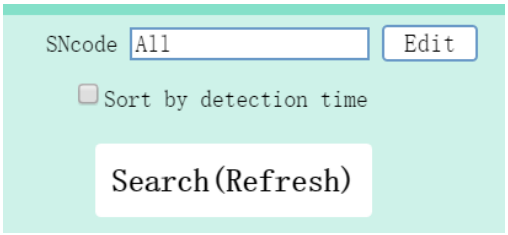


Figure 4.2.1

5.Operating procedure

5.1.Dry Immunoassay Analyzer startup and landing

This Product is operated by touching the Touch screen.

1) Press the power switch on the rear panel to "ON" and display the Initialization interface in Figure 5.1.1



Figure 5.1.1 Initialization interface

2) After initialization, the Analyzer enters into the login interface as shown in Figure 5.1.2, and the user name and password need to be entered.

Note: initial user name/password: admin /12345678.

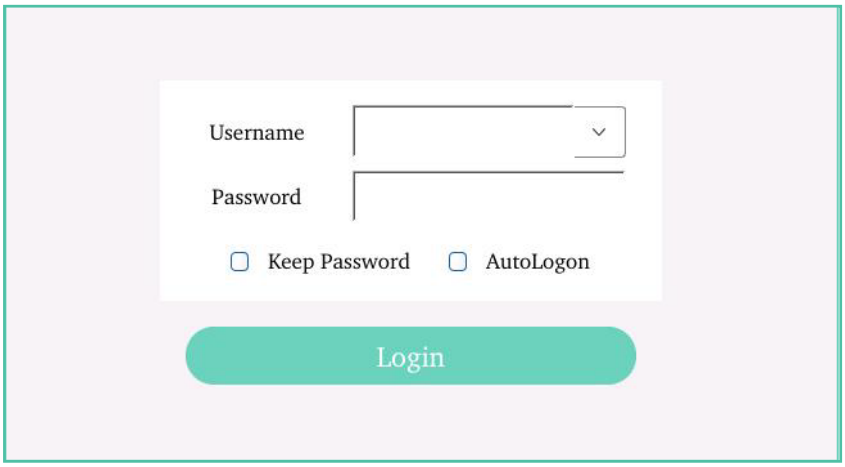


Figure 5.1.2 Login interface

3) After logging in, the Analyzer enters into the operation interface as shown in Figure5.1.3.

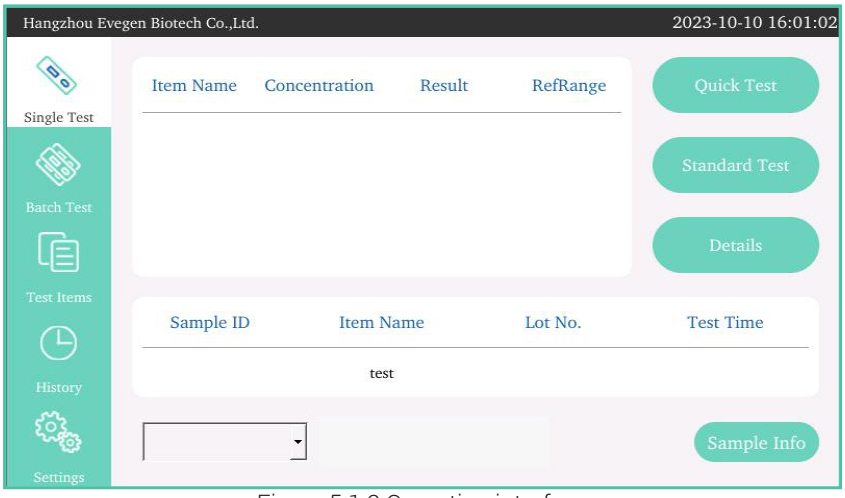


Figure 5.1.3 Operation interface

5.2.System setup

Click the "Settings" on the left side of the operation interface to enter into the system setting interface.

5.2.1.Functions

Click the "Functions" to enter the interface in Fugure 5.2.1.1 , click the the icon on the right of the "Auto Print", "Sample ID Generate", "WLAN" to turn on or turn off the corresponding function.

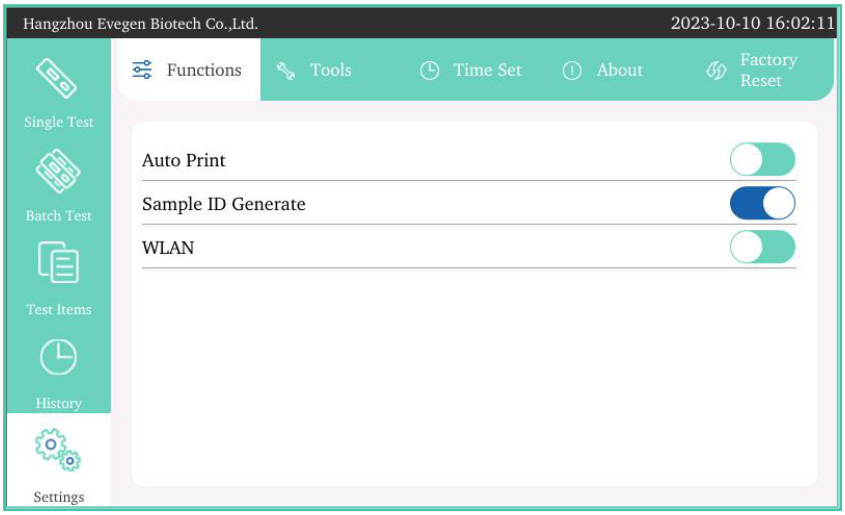


Figure 5.2.1.1

5.2.1.1.Auto Print

Right: the Analyzer will automatically print the real-time test reports after testing.
Left: Test results will not be automatically printed after testing.

5.2.1.2.Sample ID Generate

Right: Sample ID number is automatically generated according to date coding.
Left: Turn off the function of automatic sample ID number generation.

5.2.1.3.WLAN

Right: Allow WiFi network connection.
Left: WiFi network connection denied.

5.2.2.Tools

Click the "Tools" to enter into the interface shown in Figure 5.2.2.1 .

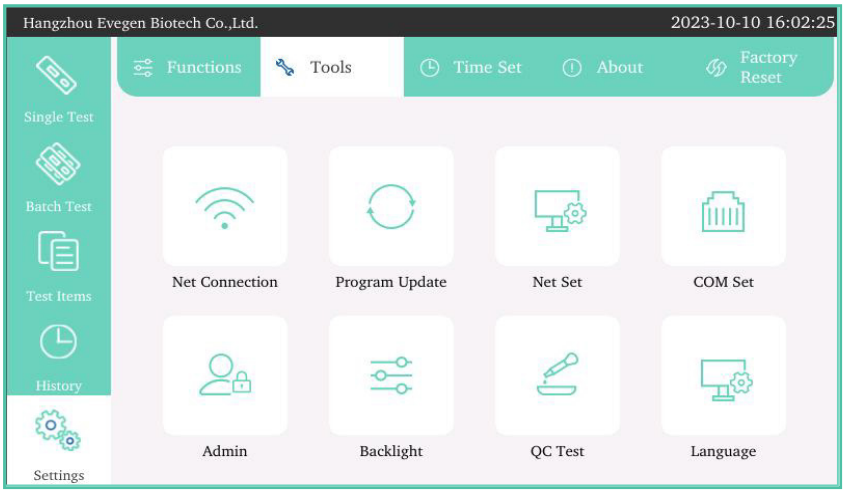


Figure 5.2.2.1

5.2.2.1.Net Connection

Click the "Net Connection" to turn on the WLAN switch. Select the corresponding WiFi and enter the password. Click the "Enter" to connect the WiFi.

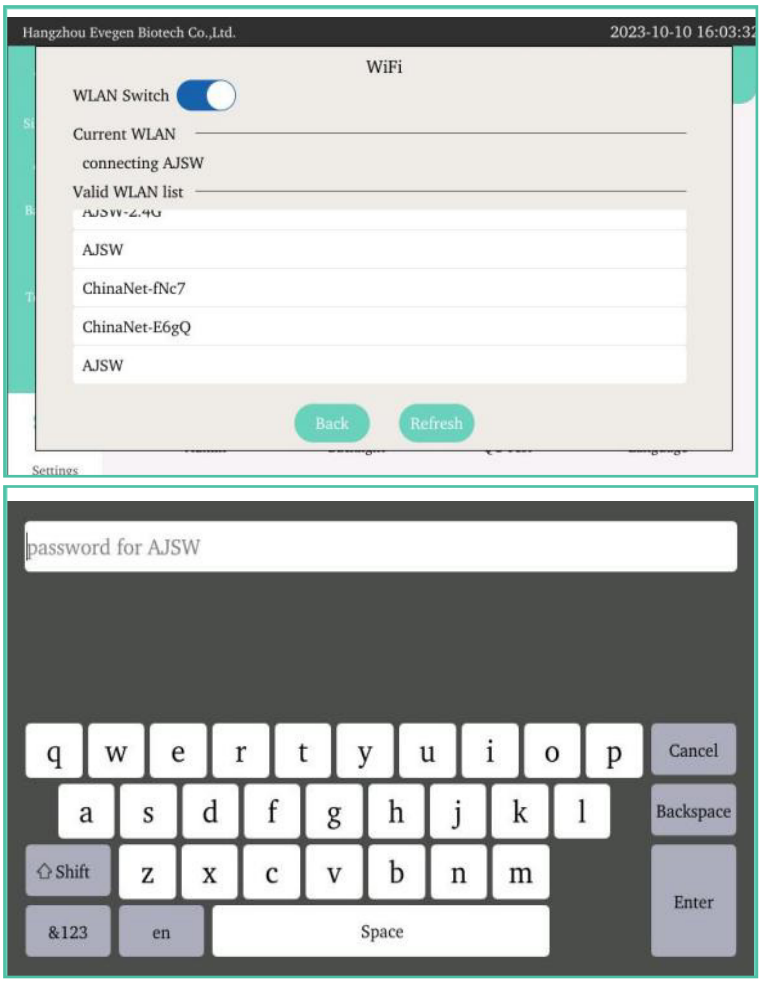


Figure 5.2.2.1.1

5.2.2.2.Program Update

Click the the "Program Update" to enter into the following interface.

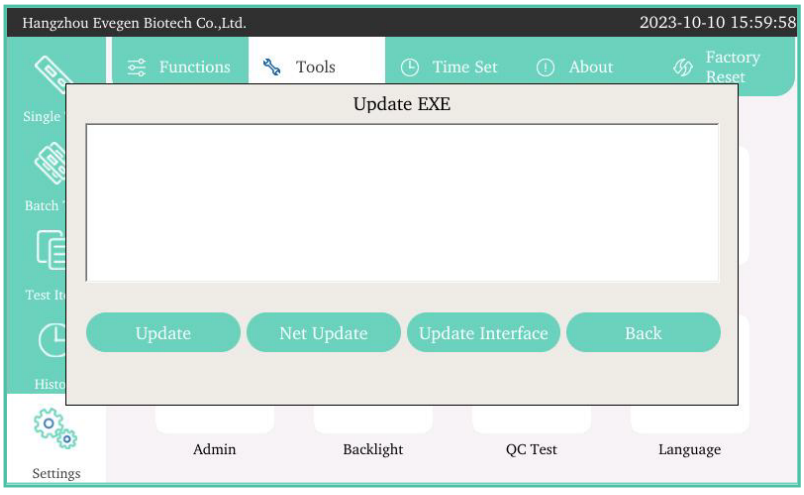


Figure 5.2.2.2.1

1) Update: update with USB flash drive
Copy the update package to the "Update" folder of the USB flash disk, and insert it into the USB port of the Analyzer, then click the "Update". The Analyzer will get a new version of the program from the USB flash drive and update the system. After the update, Click the "Restart" to restart the Analyzer.
2) Net Update: update with network
When the software supports it, Click the Network Update, and the Analyzer will automatically update the program.
3) Update Interface: update the startup interface.
Copy the update package to the "Update" folder of the USB flash disk, insert it into the USB port behind the analyzer, and Click the "Update Interface" to update the Analyzer startup interface.

5.2.2.3.Net set

Click the "Net set" and set up the IP address and gateway as shown in Fugure5.2.2.3.1 .

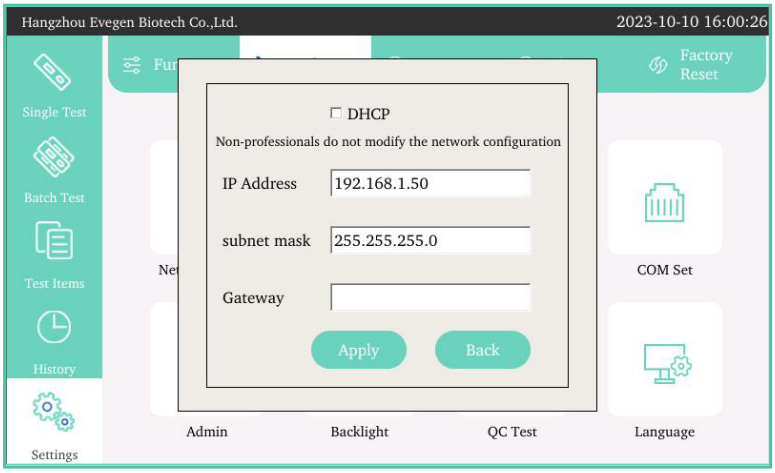


Figure 5.2.2.3.1

5.2.2.4.COM Set

Click the "COM Set" to connect the Lis system, which should be done under the guidance of professionals. If necessary, please contact the after-sales service personnel.

5.2.2.5.Admin

Click the "Admin" and enter the administrator password (initial password 12345678) to enter the following interface:
"CT Gain", "Item Gain", "Batch Gain", "System", "Export" and "Refrange" are only for after-sales maintenance and treatment, please do not open or adjust them.

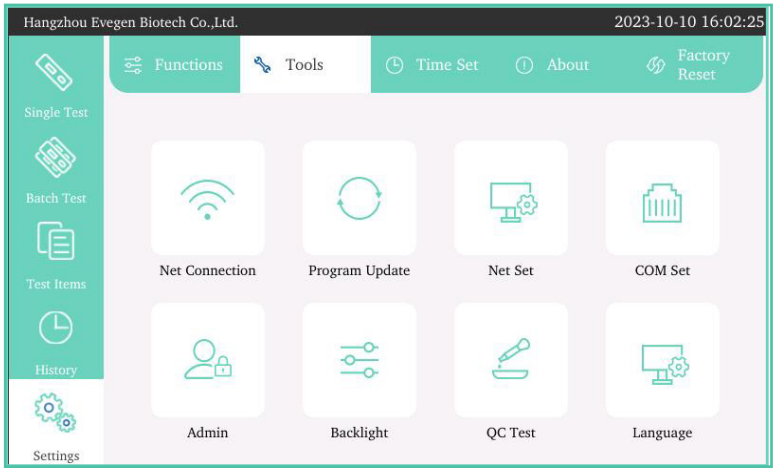


Figure 5.2.2.5.1

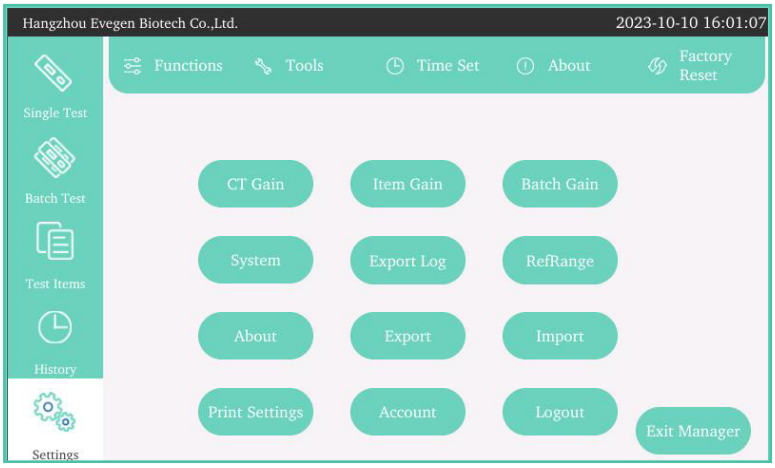


Figure 5.2.2.5.2

1) Click the "About" to display the specific Product model, number and software version number.
2) Click the "Export" to export the historical records of the Analyzer to the USB flash disk.
3) Click the "Import" to import the data records from the USB flash disk to the Analyzer.
4) Click the "Print Settings" and select the information to be printed.

5) Click the "Account" to enter the account management interface, as shown in Fugure5.2.2.5.3 . More user accounts could be created with modified login passwords.

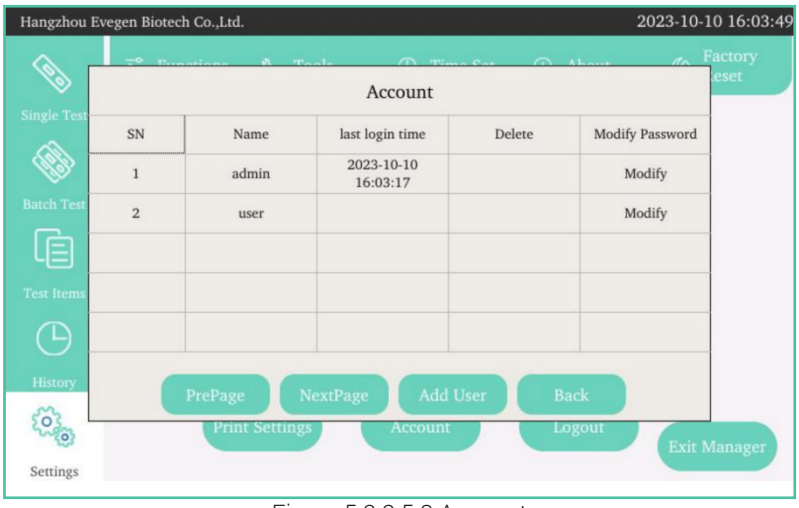


Figure 5.2.2.5.3 Account

5.2.2.6.Backlight

Click the "Backlight" to enter into the following interface in Figure 5.2.2.6.1.Click the "LIGHTEN" or "DIM" to adjust the brightness. Click the "Back" to finish the setup and close the pop-up.

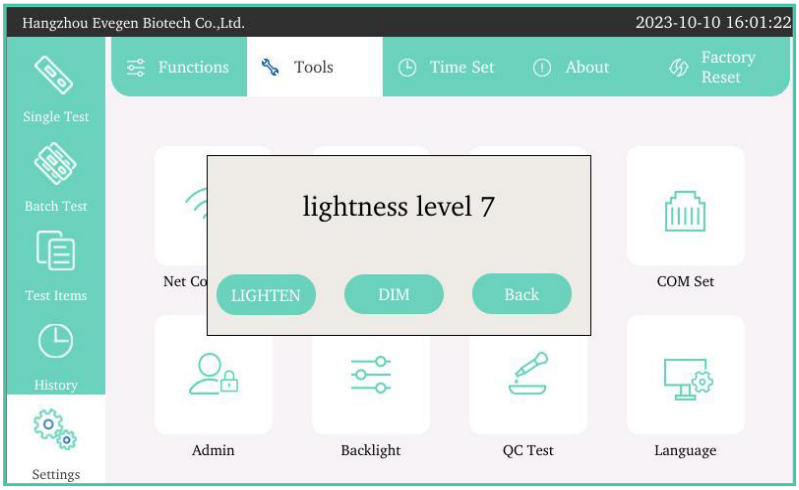


Figure 5.2.2.6.1.Backlight

5.2.2.7.QC Test

Click the "QC Test" to enter into the following interface.

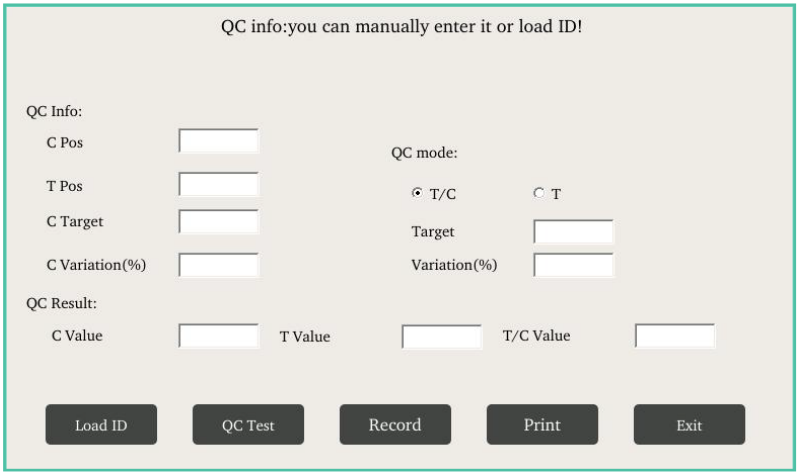


Figure 5.2.2.7.1. QC Test

When the quality inspection is qualified, "quality Inspection Successful!" will be displayed.
When the quality inspection is unqualified, "quality inspection failed!" will be displayed.
If the quality inspection is unqualified, please contact the after-sales service personnel for Dry Immunoassay Analyzer debugging.
NOTES: The QC Test procedure is designed for maintaining the Analyzer. A QC test card is provided together with the Analyzer. It is suggested to maintain the Analyzer every 6 months under the guidance of know-hows. In case of "quality inspection failed", please ask for help from our local distributor in time.

5.2.2.8.Language

Click the "Language" to set up the Analyzer language, which only supports Chinese and English.

5.2.3.Time Set

Click the "Time Set" to dispaly the following interface, enter the date and time to set up the system time.

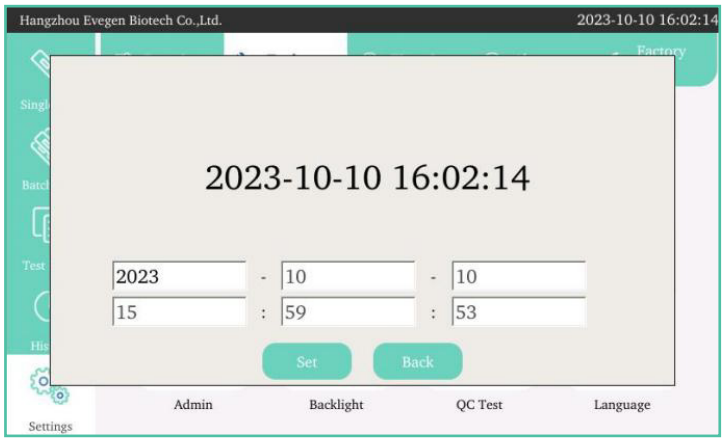


Figure 5.2.3.1

5.2.4.About

Click the "About" to enter into the following interface displaying the model and version information of this Analyzer.

Important Note: The serial number is the only number which can be connected with the software in PC to generate professional reports.

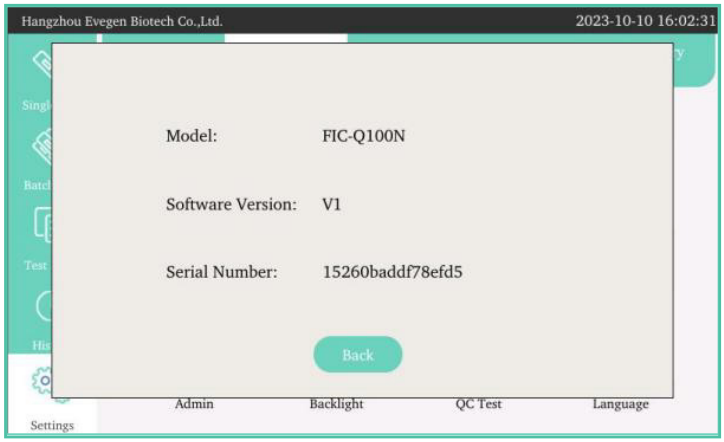


Figure 5.2.4.1

5.2.5.Factory Reset

Click the "Factory Reset" and a pop-up window will appear as shown below in Fiure 5.2.5.1
You can erase all data to restore factory settings. After the factory settings are restored, the Analyzer will automatically restart.

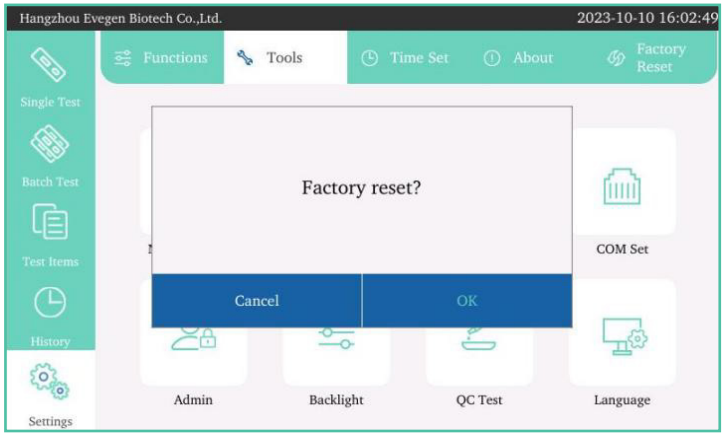


Figure 5.2.5.1

5.3.Test Item

Click the "Test Items" to enter the following interface. Select corresponding item suitable for current detection.

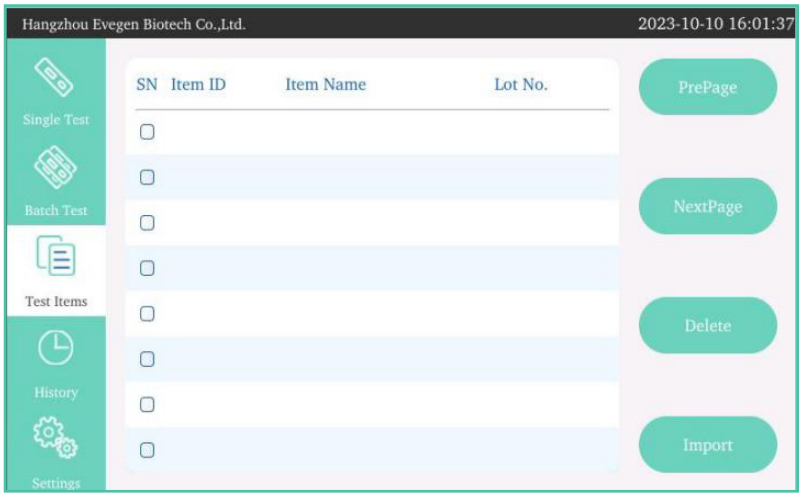


Figure 5.3.1

1) Scan the QR code of the standard curve, and the Analyzer will automatically read the test item information. Supplementary note on importing inspection item information: each item number and batch number has unique corresponding item information data. Setting it again will overwrite the original setting.
2) Click the "Prepage" and "Nextpage" to browse the original saved test items of the Analyzer.
3) Click the "Delete" to delete the selected test information.

5.4.Single Test

Click the "Single Test" to enter into the testing interface as shown in Fugure 5.4.1.

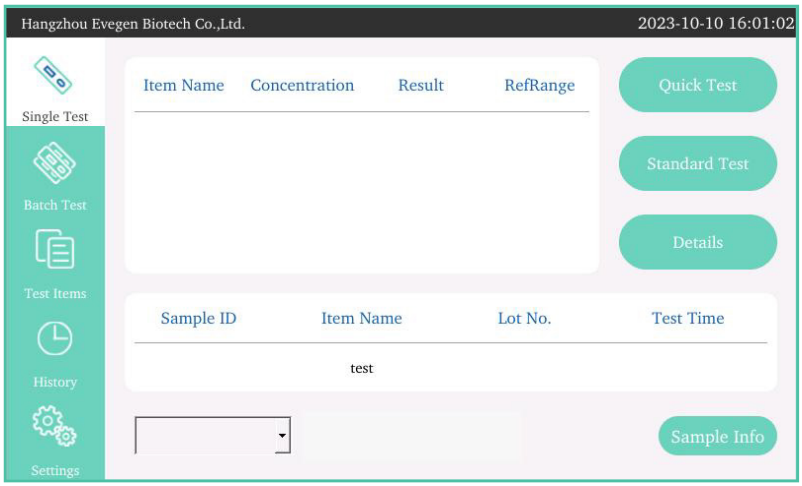


Figure 5.4.1. Single Test

Before testing, please confirm the test item and batch number information. Click the "Sample Info" to check the information of the sample to be tested. If the infomation shows without errors, the test can be started.

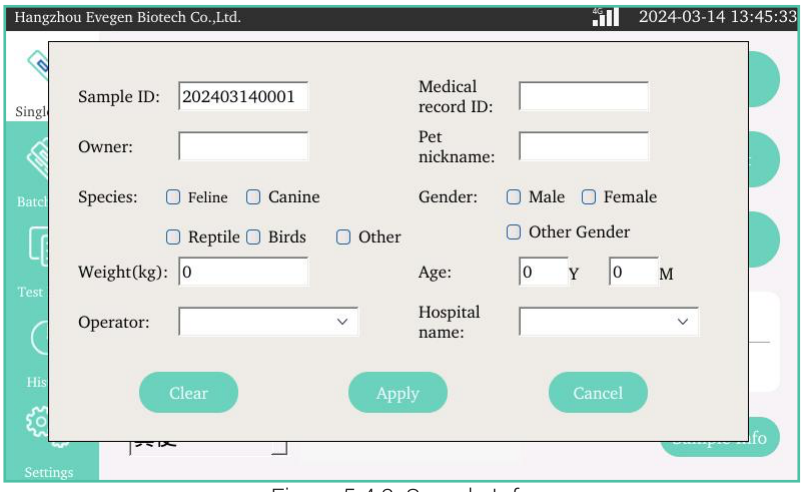


Figure 5.4.2. Sample Info

5.4.1.Qiuck Test

Insert the test card into "Test card slot" and Click the "Quick Test" to immediately start interpreting the results.

5.4.2.Standard Test

Click the "Standard Test" and the countdown will appear. After the countdown is over, the Analyzer starts to interpret the result.

5.4.3.Details

Click the "Details" to view the position of Line C and Line T and the detailed parameters of the test results.

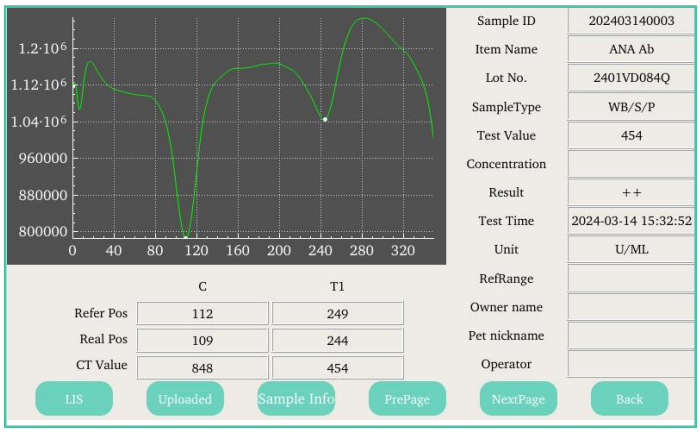


Figure 5.4.3.1 details

NOTE: Details interpretation
Horizontal coordinate: 0-350 points, corresponding to different positions of the detection window from top to bottom
Vertical coordinate: measure the optical signal value reflected by the detected position
Refer Pos: The preset control line and test line positions in the project standard curve
Real Pos: The actual control line and test line position detected by the analyzer.
The analyzer tests the position, width, and signal strength of the lines, calculates the area of the depression, and converts it into the measured values of the control line and test line to be tested.

Example: Actual site 119 detected control line measurement value of 2696, actual site 240 detected test line measurement value of 1064

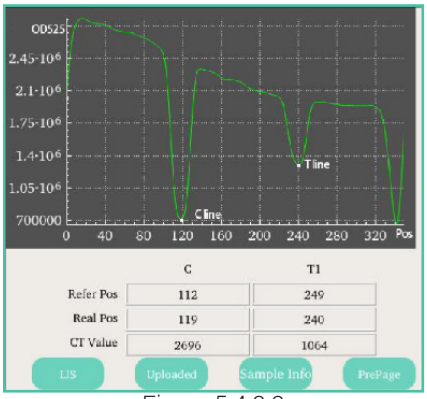


Figure 5.4.3.2

5.4.4.Print test report

After the test is completed, the results will be displayed on the interface list.
You can also print the professional reports corresponding to the record in "Cloud printing client".
Note: Please print the professional reports according to "5.7.Cloud printing client".

5.5.Batch Test

1) Check the items to be tested in "Test Items". If multiple items need to be selected, please tick "Import batch Test" before selecting the items.



Figure 5.5.1

2) Click the "Batch Test" to display the following interface.

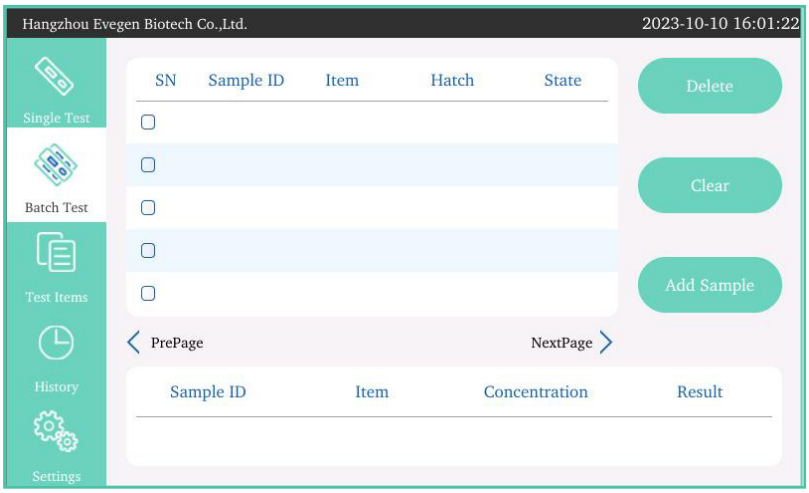


Figure 5.5.2

3) Click the "Add Sample" to input the detection information of the sample to be detected, and Click the "Apply" to add detection items.

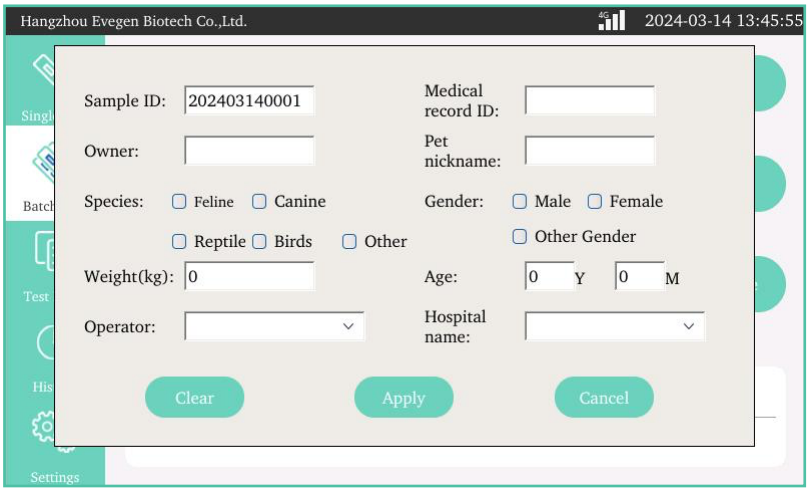


Figure 5.5.3

4) After adding samples, Click the "start" to start the countdown. After the countdown, put the test card into "Test card slot".
5) Click the "start test" to finish the test, and the test results will be displayed.
6) Repeat the above operation to test the next test card.

5.6.History

Click the "History" to switch to the following interface. You can view and delete the completed test records.

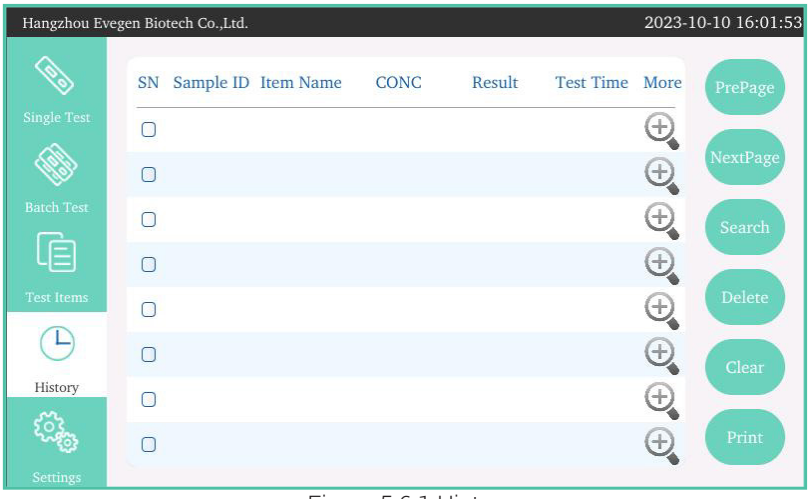


Figure 5.6.1 History

5.6.1.Browse history
Click the "Prepage" or "NextPage" to browse the inspection records.

5.6.2.Print history
Click the "Print" to print the selected test results through the built-in printer.

5.6.3.Delete history
Click the "Delete" to delete the selected test results. Click the "Clear" to clear all records.

5.6.4.Query the local history
Click the "Search" and enter various Filter criteria such as detection time, sample ID, project name, etc. for record search. You can find the corresponding inspection records.

5.7.Cloud printing client

1) Open "Cloud printing client" and click "Search" to synchronize the detection records.

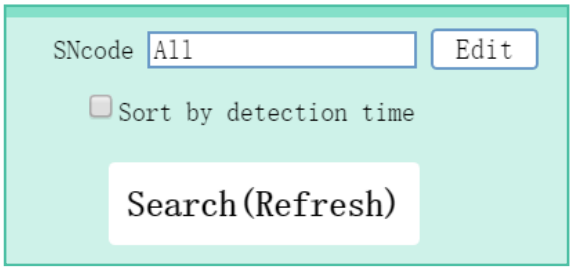


Figure 5.7.1

2) Check the corresponding item and click "Print" in the lower right corner to print the selected item.

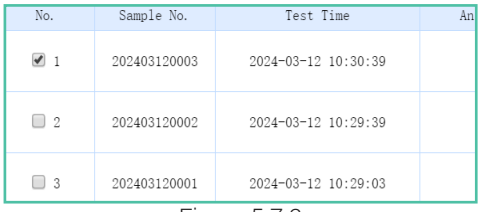


Figure 5.7.2

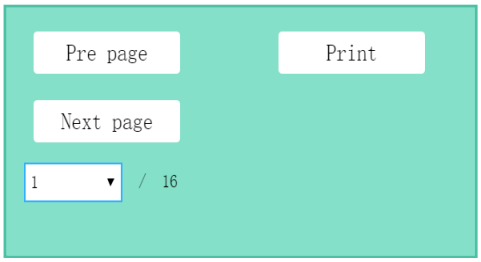


Figure 5.7.3

3) Fill in the sample information and click "Print".

Note: The test records can be found and printed according to the test information and test time in the lower left corner.

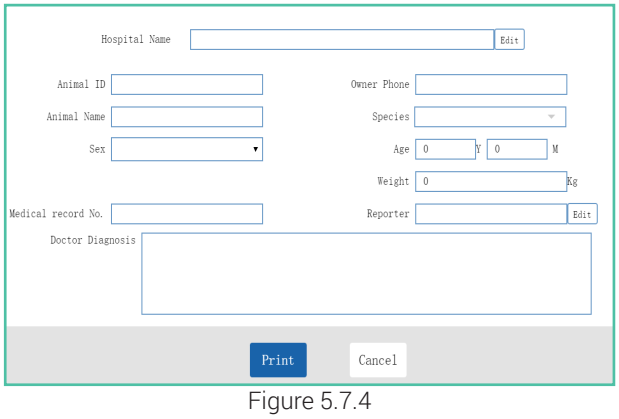


Figure 5.7.4

6.Product Maintenance

6.1.Maintain the Analyzer

Knowhows should regularly check the Analyzer and components. It is suggested to make one time maintenance every 6 months. If there is any problem, please contact the local after-sale service personnel or local distributor to replace the components immediately.

6.2.Clean the Analyzer

You can use a wet cloth and 70% ethanol to clean the external surface. Avoid the use of oxidants and strong decolorants that may damage the shell and touch screen of the Dry Immunoassay Analyzer. Do not clean the internal components and surfaces of the analyzer.

6.3.Troubleshooting

You can use a wet cloth and 70% ethanol to clean the external surface. Avoid the use of oxidants and strong decolorants that may damage the shell and touch screen of the Dry Immunoassay Analyzer. Do not clean the internal components and surfaces of the analyzer.

Errors	Possible causes	Solution
The Dry Immunoassay Analyzer cannot be turned on.	Power cord damaged	Replace the new power cord
	Boot key is damaged.	Contact after-sales service personnel
The screen cannot be displayed normally.	Loose screen connector.	Contact after-sales service personnel
Test result is invalid.	Standard curve transmission error.	Contact after-sales service personnel
	Invalid interpretation of test paper card results.	Contact after-sales service personnel
	Test scan module is damaged.	Contact after-sales service personnel
The Dry Immunoassay Analyzer makes abnormal noise or gets stuck during the test.	Machine operation failure.	Contact after-sales service personnel
Other faults	Other faults	Contact after-sales service personnel

7.Matters need attention

7.1.User

1) Professionals in pet hospitals, pet clinics, veterinary testing centers and laboratories
2) Trained persons who is competent to operate the Analyzer
Attention:In addition to the above users, other person shall not operate the Analyzer; The company does not assume the responsibility of Product damage caused by wrong operation of non-users.

7.2.Limit of toxic and harmful substances

The content of toxic and harmful substances in all homogeneous materials of parts shall be lower than the specified limit in SJ/T 11363-2006 "Requirements for concentration limit of some harmful substances in electronic information products".

7.3.Potential safety maintenance and use restrictions

When using this Analyzer to do interpretation of the result of a rapid test, the potential biological hazards should be disposed of according to the safety requirements of the tested species in the hospital when handling and operating samples. During the testing, please do not put anything except the test card into the "Test card Slot". If an accident occurs when the Dry Immunoassay Analyzer is used correctly, protective measures should be taken for operators and users, and appropriate emergency and corrective measures should be taken; When the Analyzer is used correctly, the probability of accidents is extremely low.

7.4.Necessary monitoring, evaluation and control methods

Under the guidance of a knowhow, use QC Test to check the quality of the Dry Immunoassay Analyzer to evaluate whether the Dry Immunoassay Analyzer works properly. It is recommended to do it once every six months. If users use it frequently, they can also make a quality control cycle according to the actual use.

7.5.Mutual interference and potential harm with other products

Attention:
1) the Analyzer is susceptible to electromagnetic interference, so please use it in an environment far away from strong electromagnetic interference.
2) The Dry Immunoassay Analyzer may emit electromagnetic waves during use, so please use it in an environment far away from electromagnetic sensitive equipment.

7.6.Potential adverse events

This Product is in vitro diagnostic equipment, and no adverse events have been observed. As the test sample may be bio-infectious, please avoid direct skin contact with the test paper card and the sample inlet. Dry Immunoassay Analyzers should be cleaned and disinfected regularly in daily use or before transportation, maintenance and storage to prevent pollution and potential biological hazards.

7.7.Other precautions

1) Diagnosis and treatment can not be based on the test results of this product only, please consider the clinical history and other test results at the same time.
2) Please be sure to use the kit specified by the manufacturer and confirm its applicability.

7.8.Crash handling

When entering into the Dry Immunoassay Analyzer interface or the Dry Immunoassay Analyzer button doesn't respond, please restart the Analyzer according to the following steps:

1) Turn off the power switch;
2) Plug and unplug the power cord again;
3) Turn on the power switch.

8.Service maintenance and destruction

8.1.Repair

The internal structure of this Product includes important components such as circuit board, optical detection module, display screen, printer and bar code scanning module. Components can only be inspected and replaced by manufacturers, and third-party maintenance is not supported.
When the Dry Immunoassay Analyzer runs abnormally, please contact the after-sales service personnel for consultation first, and we will provide technical support.
Contact information:

8.2.Destroy

When the user needs to destroy the Analyzer, it should be destroyed according to relevant local laws and regulations.

8.3.Service

The software services provided by our company include functional maintenance, corrective maintenance and software update maintenance.

8.4.Statement

Our company only provides maintenance service for the faults that occur when the user fully abides by the instruction manual of the Dry Immunoassay Analyzer, and is not responsible for the damage caused by other reasons.

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Date Prepared: July, 2024
Date of Manufacture: See the label
Validity Period: See the label

Registrant/Manufacturer: Hangzhou Immuno Biotech Co., Ltd.