Product Name: Quantum Dots Immunoanalyzer

Model：AFS-1000

User Manual

CE

Chongqing iSIA Bio-Technology Co., Ltd.

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1. Product Introduction

1.1. Product Main Composition and Structure

Quantum Dots Immunoanalyzer (shored as "analyzer") is composed of photoelectric detection module, bar code scanning module, data processing module, LCD module, shell, power adapter and software.

1.2. Range of Application

Compatible with a specific dry reagent based on fluorescence immunochromatography for immunofluorescence detection of human samples, it is for the purpose of professional medical examiners of medical institutions who perform in vitro diagnostic tests only. It can be used in central laboratories, outpatient/emergency laboratories, clinical departments and other medical service sites(e.g. community health center), physical examination centers, etc.

1.3 Product Technical Characteristics

1.3.1 Main Parameters

- Software information:

Version name: Quantum Dots Immunoanalyzer
Software released version: V 1
Software complete version: V 1.1.1

- Operating environment: Uc/os operating system
- Power parameters: Host input -- 12V⎓4A;
  Adapter input -- 100-240VAC， 50/60Hz;
- Input power: 48VA

1.3.2 Main Performances

- Repeatability: CV≤3%
- Stability: σ≤±3%
- Linear correlation: r≥0.990
- Accuracy: Δn≤±15%

1.3.3Network Security Instructions

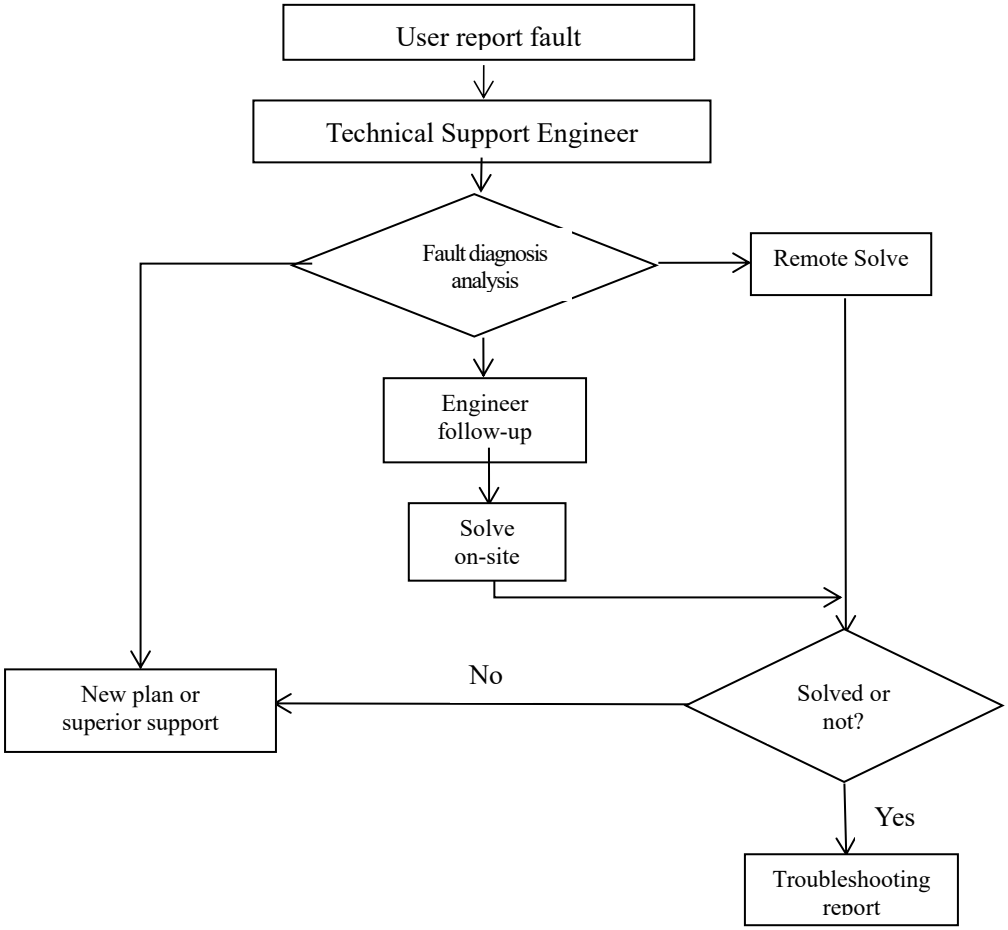
1. Function: Data collection measurement, analysis, management, information transmission
2. Purpose: Applicable to the collection and organization of result data generated from the inspection of this device.
3. Interface type:

a) Interface LIS - Transport Protocol: RS232, for LIS system connection;
b) Interface COM - Transport Protocol: RS232, for code scanning gun connection.

4. Available software (development tools):

Software name	Complete version	Supplier	Operating environment required
Keil 5	MDK5.36	ARM	Multi-platform
Qt	4.8	Qt Group	Multi-platform

Maintenance process for software's (incl. available software) network security updates:



5. Update confirmation: User needs to modify the software's functions realized for various reasons and submits maintenance requests. The maintenance scope covers software bug repair and function optimization only.
The head of the requesting department needs to verify and confirm the detailed situation.
Upon receiving the confirmed maintenance request, maintenance engineers will analyze and propose modification plan to analyze and evaluate the possible risks arising from software update, and propose risk control measures if necessary. The R&D department head shall review the plan to ensure its safety and correctness, analyze the possible risks, and control the risks if necessary, then determine the maintenance method based on the degree of safety and effectiveness impact on the products involved, while ensuring the software maintenance to meet the regulatory requirements.

6. User notification: The maintenance engineer will make modifications according to the plan. After completing the maintenance, if the user software needs to be updated, the user should be notified of the maintenance plan and its main content.

User who request maintenance provides feedback and evaluation on the maintenance results.

1.4 Security Classification of Medical Electrical Equipment

Equipment anti-shock level: I; pollution level: 2; facility category (overvoltage category) : 2.

1.5 Contraindications

Non.

1.6 Precautions

⚠ **Note:** Inaccessible for non-medical institutions professional medical inspection personnel.

1.6.1. Precautions for use in the workplace

⚠ **Warning:**

- **To avoid fire caused by overload, please try not to use the parallel socket;**
- **A 12V/4A power adapter and a effectively grounded socket must be adopted;**
- **There are risks of fire and electric shock in case of using damaged or non-original (modified) power cord; To avoid fire and electric shock accidents, please do not over-bend or crush the power cord;**
- **In case of device loosen or parts fallen or damaged, please contact the company timely;**
- **Do not use this device in unstable environments such as tilting, vibration, impact, etc;**
- **Do not place the equipment in a position hard to disconnect;**
- **No water or debris are allowed entering the interior of the device; In case any foreign objects found, please contact our company timely;**

⚠ **Note:**

- When moving the device, the power supply must be cut off with plug removed;
- When moving the device, vibration should be avoided as far as possible;
- The device shall be placed on the desktop with a bearing capacity of greater than 5kg;
- The device shall not stick tightly to the wall, but leave no less than 20cm space to ensure air circulation and heat dissipation of the device;
- The device should not be covered with any items to avoid blockage of the vent;
- Avoid using the device in the following environments: Places where sunlight shines; High humidity environment; Near water environment; Vibration and tilting places; Strong magnetic field environment; Places where electromagnetic waves and impulse voltages occur; Storage places for chemical drugs and places with corrosive gases;

- This device shall not be placed or used near interference signal sources such as radios, televisions, copiers, fax machines, etc;
- Do not use it in conjunction with other devices (e.g. microwave and other high-frequency equipment) to avoid electromagnetic interference and cause misoperation.

1.6.2. Precautions during use

⚠ **Warning:**

- **Before starting the machine, it is necessary to carefully read this User Manual. Operators must receive professional training and be familiar with this Manual and operating procedures. The device must be managed by a dedicated personnel;**
- **Please set the testing parameters under the guidance of professional personnel;**
- **When handling potential infectious substances (e.g. human samples or reagents), if there is a possibility of skin-contact, protective gloves or other protective measures shall be required;**

⚠ **Note:**

- Confirm whether the device is in normal operation status before use;
- Confirm that all wires are properly connected and safe;
- When using with other devices, it is important to read and acknowledge the operating precautions to avoid danger. Please be careful;
- This device shall be used correctly by professional operators; personnel other than professional operators are not allowed to use this device;
- After the test, confirm the reagent card being removed, reset the card holder, and then turn off the power.

1.6.3. Precautions for faults, storage, and inspection

⚠ **Warning:**

- **When an abnormal situation occurs with the device, it shall be stopped immediately. In case of burning smell or smoke, continue using will cause risks of fire and electric shock. Please turn off the power quickly and unplug, then immediately contact our company or agent;**
- **Except for our company's maintenance personnel or authorized maintenance personnel, no other personnel shall be allowed to disassemble, modify, or repair this device; otherwise it will result in our company being unable to perform normal warranty and maintenance, by which company will not be responsible for any potential personal injury or risk of fire or electric shock caused thereupon.**
- **When being maintained or processed, the device should be immediately stopped from use with confirmation that there are no test cards left inside; Perform routine sterilization and disinfection treatment to the device before maintenance.**

Note:

- The device and its parts shall be checked regularly. In case of damage, cracks and other abnormal conditions, please inform our company for repair or replacement.
- For surface cleaning of the device, a clean soft cloth and non-corrosive detergent should be adopted to prevent scratching the shell and panel;

1.6.4. Precautions related with Electromagnetic Compatibility

Warning:

- **This device is designed and tested based on Category A of CISPR 11. In home environment, this device may cause radio interference, where protective measures should be taken.**
- **Do not use this device near strong radiation sources (e.g. non-shielded radio frequency sources), otherwise the normal operation of the device can be interfered.**

Note:

- User is responsible to ensure the device's electromagnetic compatibility environment for normal operation.
- It is recommended to evaluate the electromagnetic environment before using the device.
- This product meets the immunity and emission requirements specified in this part of content of IEC 61326-2-6, as shown in the table below.

Table 1:

Electromagnetic Immunity			
Immunity Test Item	**Basic Standard**	**Test Value**	**Performance Criteria Met**
Electrostatic discharge (ESD)	IEC 61000-4-2	Contact discharge: ±2kV、±4kV Air discharge: ±2kV、±4kV、±8kV	B
Radio-frequency electromagnetic field	IEC 61000-4-3	3V/m，80MHz～2.0GHz，80%AM	A
BURST	IEC 61000-4-4	Power cord: ±1kV(5/50ns,5kHz)	B
Surge	IEC 61000-4-5	Line to Ground: ±2kV Line to line: ±1kV	B
Radio frequency conduction	IEC 61000-4-6	Power cord: 3V/m, 150kHz～80MHz，80%AM	A
Power frequency magnetic field	IEC 61000-4-8	3A/m，50/60Hz	A

Voltage drop, interrupt	IEC 61000-4-11	1 cycle 0%; 5 cycles 40%; 25 cycles 70%; 250 cycles 5%	B B C C
Performance evaluation: A. During the test, the performance was normal within the specified limits. B. During the experiment, the function or performance was temporarily reduced or lost, but can be restored on its own. C. During the experiment, the function or performance was temporarily reduced or lost, intervention or system reset by operator were required.			

Table 2:

Electromagnetic emission	
Emission test	**Conformity**
CISPR 11 RF Emission	Group 1
CISPR 11 RF Emission	Category A
IEC 61000-3-2 Harmonic Emission	Not Applicable
IEC 61000-3-3 Voltage Fluctuation/ Flicker Emission	Not Applicable

2. Accessories List

No.	Accessory name	Qty	Remarks
1	AFS-1000 Mainframe	1	Standard accessories
2	Quantum Dots Immunoassay Analyzer Software	1	Installed
3	Power Adapter	1	Standard accessories
4	Serial Cable	1	Standard accessories
5	User Manual	1	Standard accessories
6	Product Quality Certificate	1	Standard accessories
7	Product Warranty	1	Standard accessories

8	Thermal Printing Paper	1	Standard accessories
9	QR Code Scanner	1	Standard accessories

3. Installation, Commissioning and Use Instructions

3.1. Installation

3.1.1. Unpacking and inspection

1) Take out the device and accessories gently from the packaging box and keep the packaging materials for future transportation or preservation. Check the attachments according to the packing list.
2) Check the device and accessories for damage.
3) Upon user's acceptance, connect the adapter with the tester.

⚠ **Note:**
For any questions, please contact the sales department of our company or agent instantly.

3.1.2. Installation and debugging procedures

1) The device should be placed in a clean and ventilated room with a temperature of 10℃~30℃ and a relative humidity of 20%~80%, free from condensation, avoiding direct sunlight.
2) Ensure non-blockage of vent openings.
3) Connect the power adapter to the power interface of the dry fluorescent immunoasanalyzer, and turn on the power to start.
4) The device has been debugged before delivery, and can be used directly.
5) To ensure the normal operation of the device, do not place objects on the device at any time.

3.2. Use Instructions

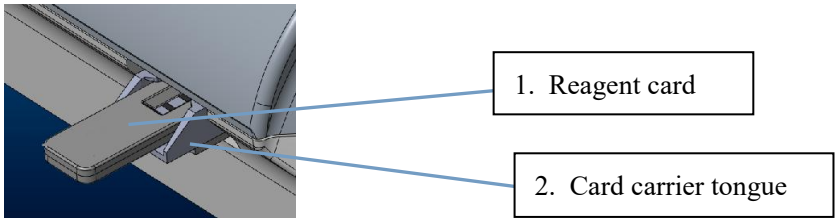
Please use this device in an environment with temperature of 10℃~30℃ (please note that the operating temperature of the test reagent is subject to the *Instruction Manual*), relative humidity of 20%~80%, and without condensate water. Please strictly follow the precautions in this manual. The protection provided by the device can be compromised in case of using the device without following the manner specified by the manufacturer.

3.3. Detailed Operation Procedures

3.3.1. Preparation before use

1) Please make sure the host is placed in a stable place free from direct sunlight or strong electromagnetic interference;
2) Connect the power adapter cord: Insert one end of the power adapter cord equipped with the device into the power socket (a corresponding power identifier is provided on the device body, see "VII. Explanation of the Label Content of Medical Devices" of the *Manual*), and insert the other end into a good grounding standard power socket;

3) Turn on the device power and allow it to perform a self-check (shown as figure below);



1. Reagent Card 2.Card carrier tongue

4) Testing software auto-starts and the main interface auto-appears;

5) For use and storage of reagent, please refer to the *Instructions* equipped with the reagent separately;

6) Place the reagent card containing the sample to be tested on the carrier tongue smoothly and conduct test following the software operation instructions;

3.3.2. Start of test

Conduct test by controlling the actions of device through software.

⚠ **Note:**

- As the card carrier tongue is acting now, please do not approach the outlet of the tongue;
- Do not operate the software during the testing process.

3.3.3. End of test

1) After the test is finished, the reagent card will come out from the card inlet;
2) The card carrier tongue will restore itself to "card loading" position;
3) The test result is shown to end the test.
4) The waste generated during the use of the device should be uniformly disposed of by professional personnel following the State Council Order No. 380 *Regulations on the Management of Medical Waste* and other relevant regulations.

⚠ **Warning:**

- **If there are signs of damage to the device's function or error messages found through the above operation check, it is prohibited to continue testing and please contact our company's after-sales service department.**

3.4. Warning signs

All words with marks of "⚠ **Note**" or "⚠ **Warning**" are warning reminder.

4. Introduction to Software Interface Operations

4.1. Settings

As shown in Figure 4.1.1, start the device and enter into the test interface. Click the [Sys. Setting] button on top of the interface and then enter another interface as shown in Figure 4.1.2.

Figure 4.1.1

1) With [Settings], user can handle operations of [Installation Settings], [Testable Items], [Standard Track Entry]、[Version Info]、[Delete All Results];

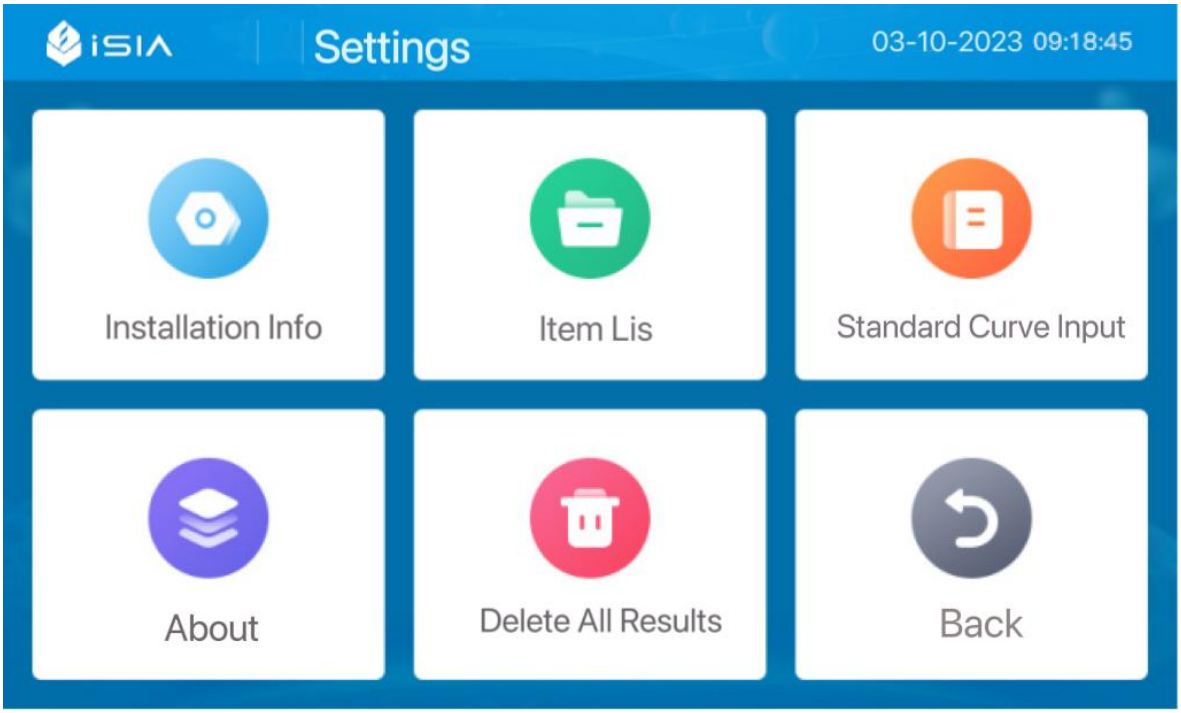


Figure 4.1.2

In Figure 4.1.2 [Installation Settings], users can edit the institute name, machine number, and installation department. After editing the settings, click "save" to automatically return to the settings interface

2) As shown in Figure 4.1.3, with [Work Mode Selection], you can select the printing mode and data transmission method, as shown in Figure 4.1.4. With [Date Settings], date can be edited and entered, as shown in Figure 4.1.5. After saving the information, click Return to back to the settings interface.

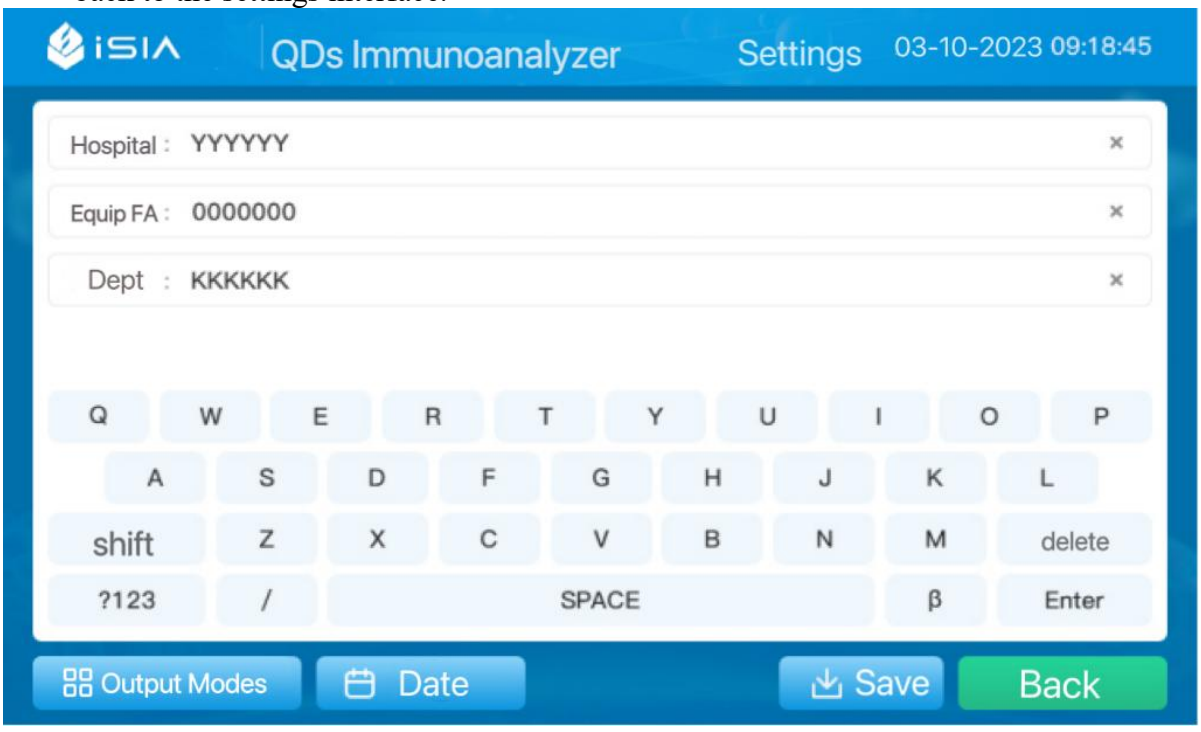


Figure 4.1.3

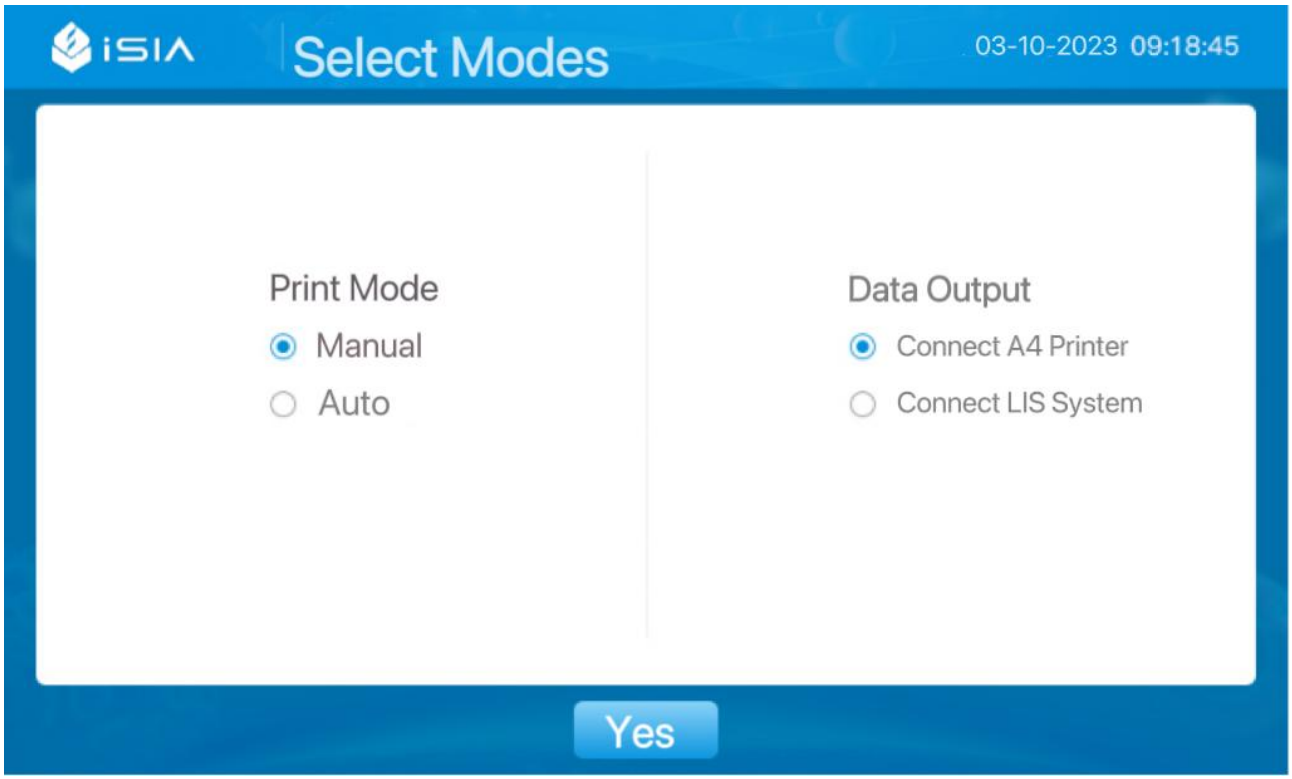


Figure 4.1.4

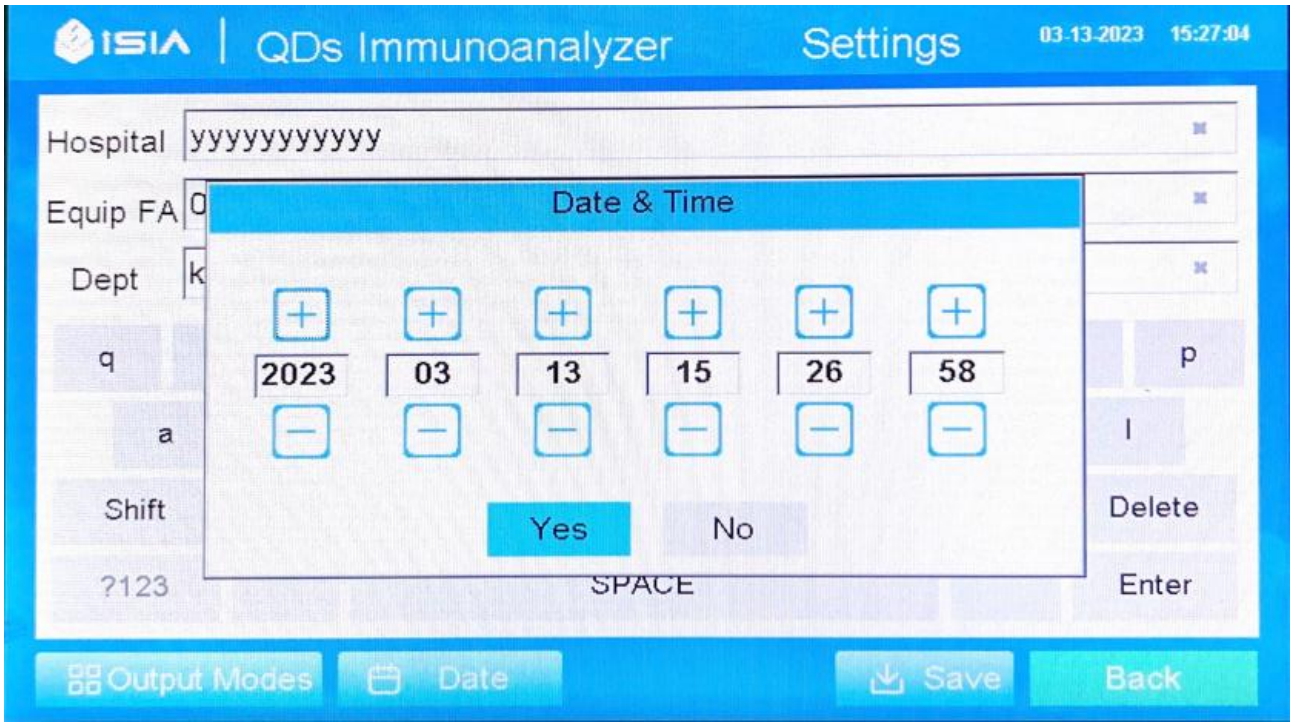


Figure 4.1.5

3) The item name can be checked in [Testable Items], as shown in Figure 4.1.6.

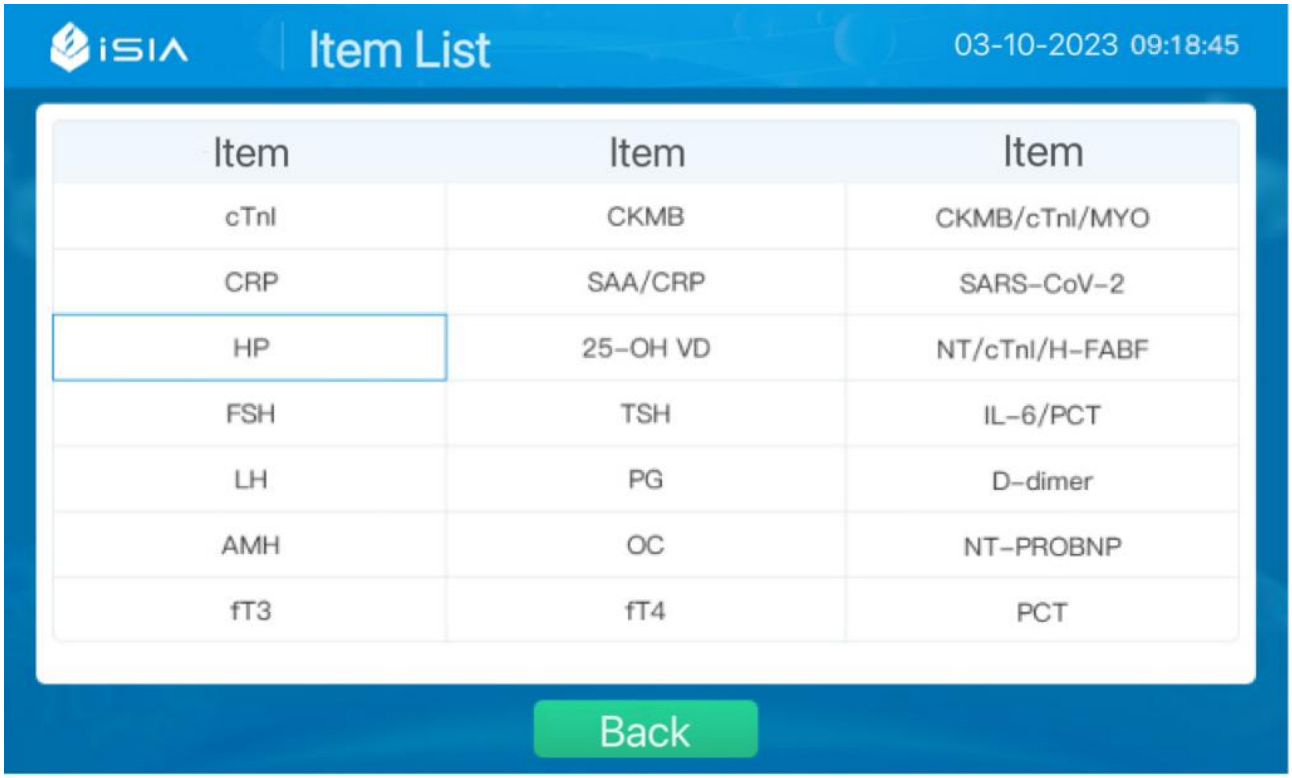


Figure 4.1.6

4) The QR code newly added items can be Checked in [Standard Track Entry], as shown in Figure 4.1.7.

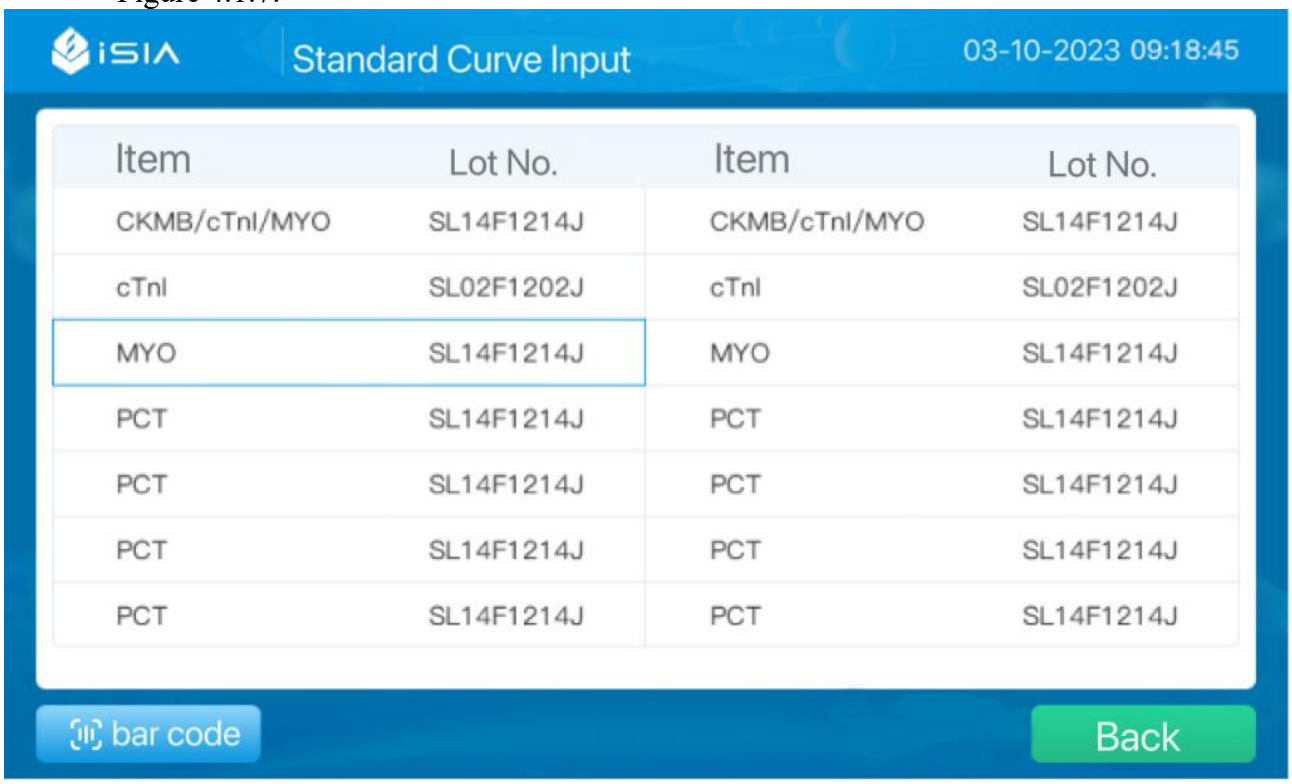


Figure 4.1.7

5) The device version information can be checked in [Version Info], as shown in Figure 4.1.8

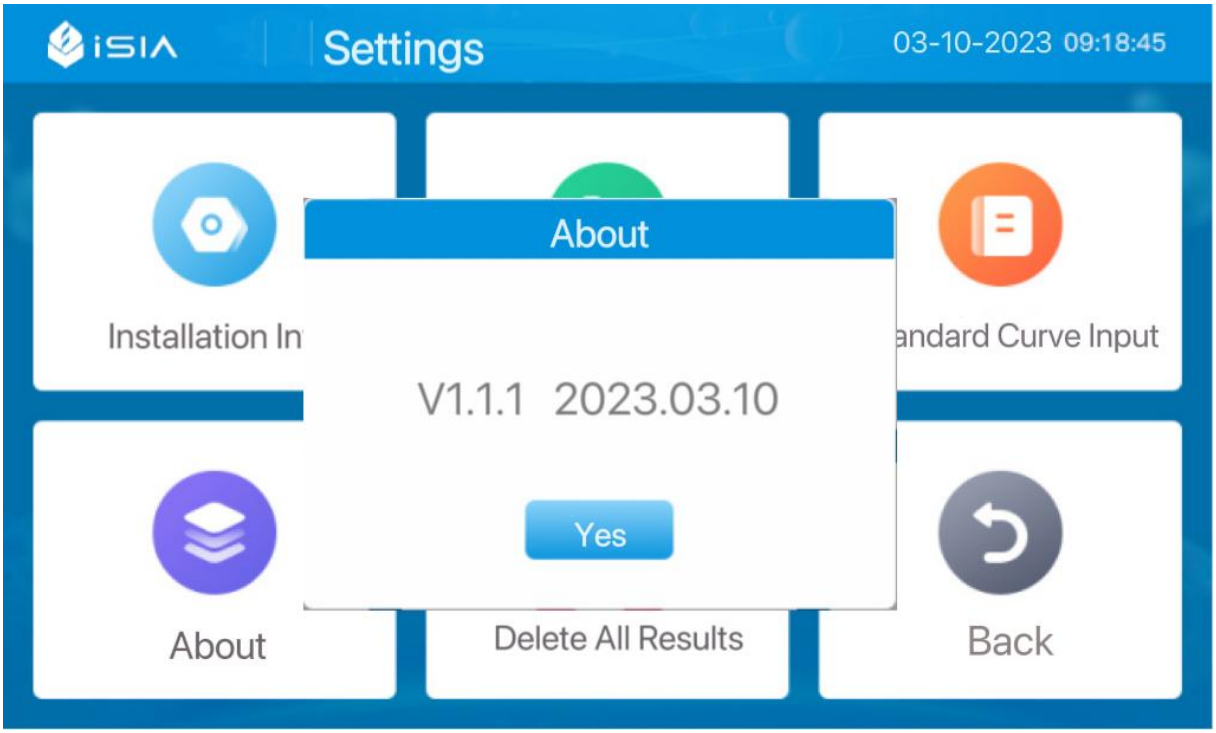


Figure 4.1.8

6) All rusults can be deleted in [Delete All Results], as shown in Figure 4.1.9

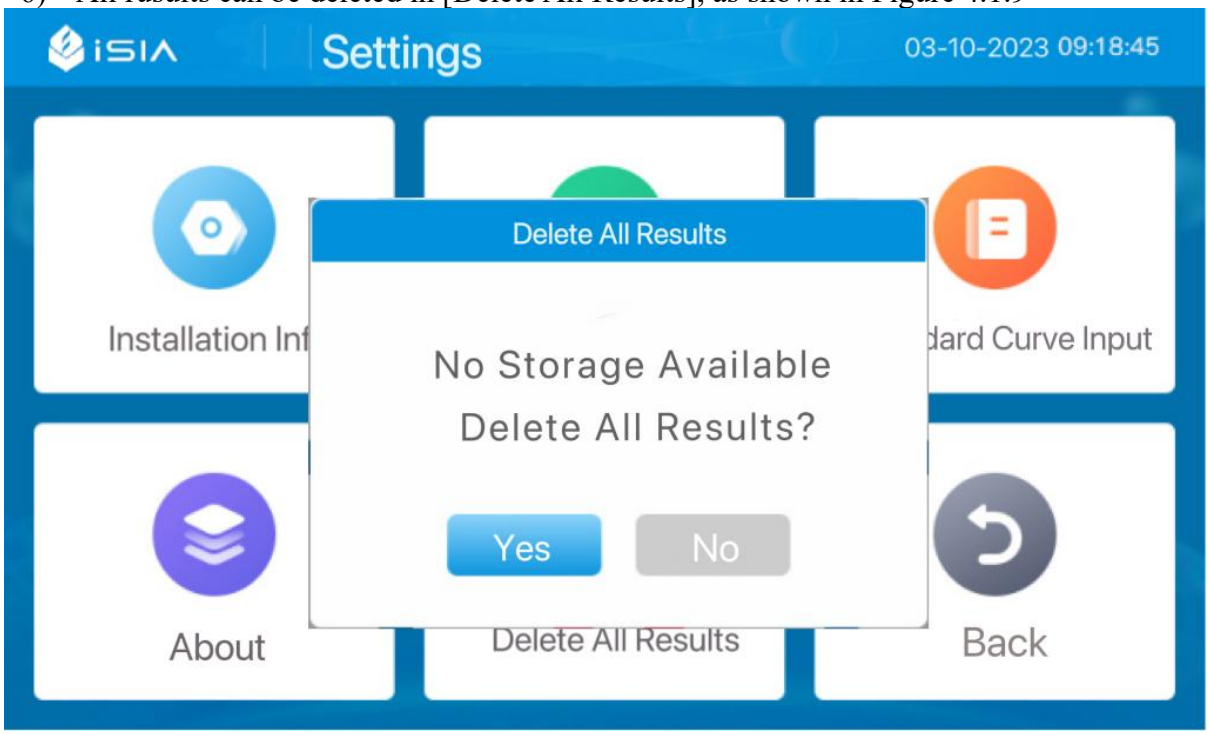


Figure 4.1.9

4.2. Test Preparation

Enter the main interface, user can choose to use instant mode or standard mode by the [Instant Mode] button and [Standard Mode] button in Figure 4.2.1.

Standard test refers to scanning the reagent card for testing and calculating the results after the completion of item's reciprocal reaction time; while instant test refers to immediate testing, scanning, and results calculating.

Figure 4.2.1

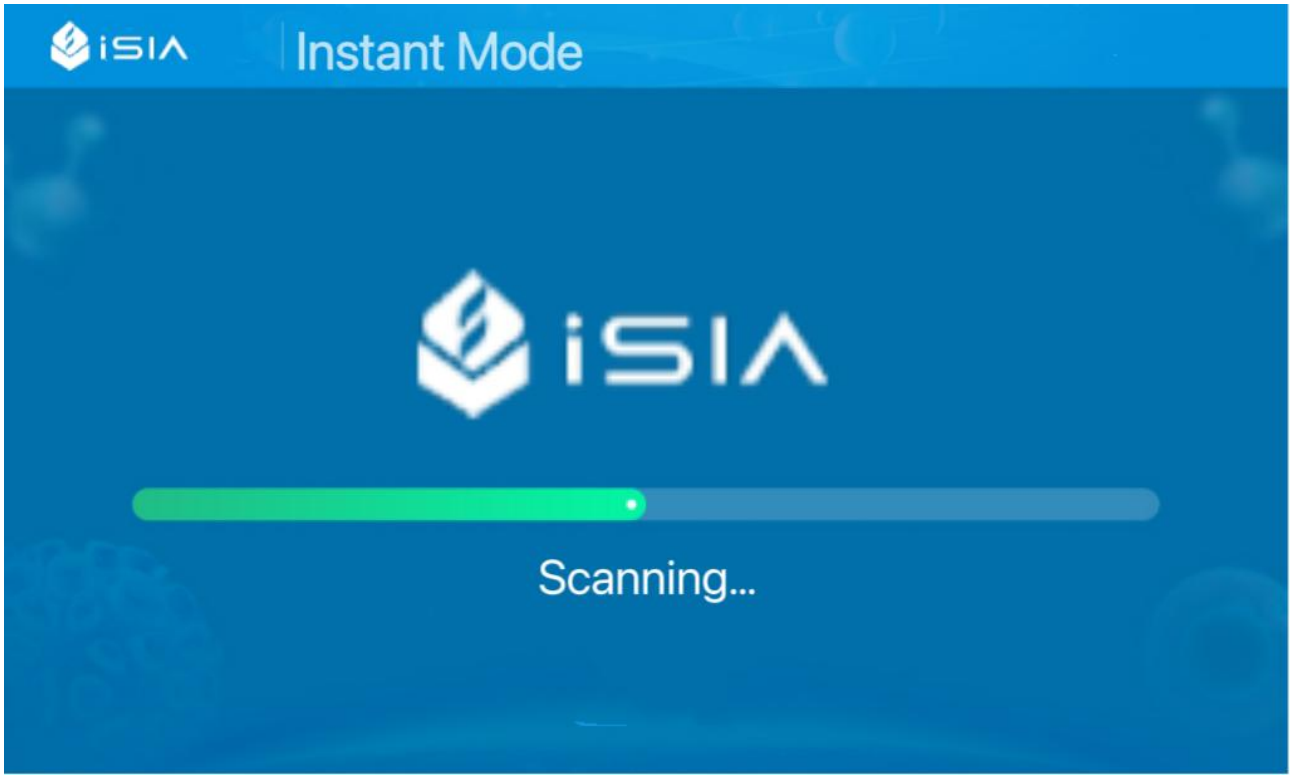


Figure 4.2.2

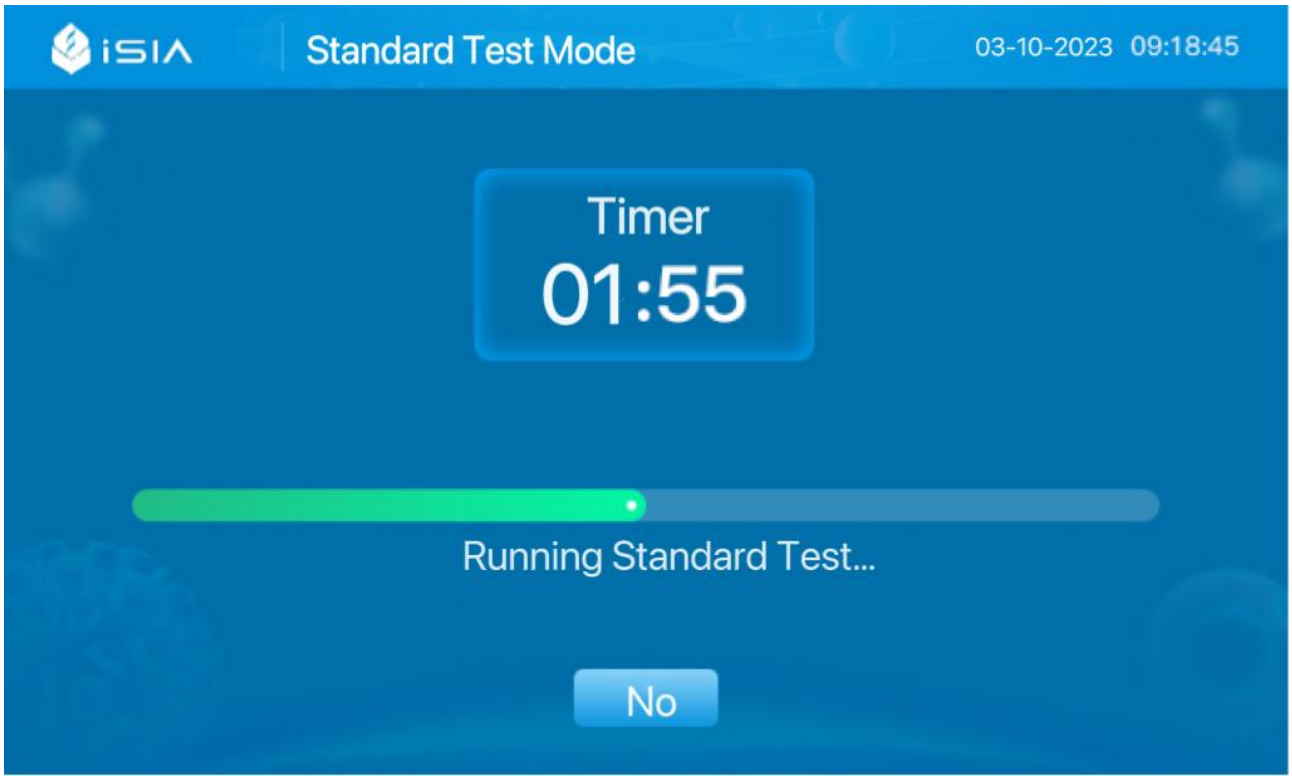


Figure 4.2.3

4.3. Instant Test

1) Enter the test function in the Main Interface, as shown in Figure 4.3.1;
2) Before testing each batch of reagent cards, use a scanning gun to scan the QR code inside the reagent kit to get the corresponding test item, then enter the number with the scanning gun;
3) After entering information, user can switch between the [instant mode] button and [standard mode] button;
4) After inputting all corresponding information, user can choose the [Test] button to conduct text as shown in Figure 4.3.1;
5) After testing each reagent card, a test result window will pop up. Users can choose the [Print] function to print the test report as shown in Figure 4.3.3;

Figure 4.3.1

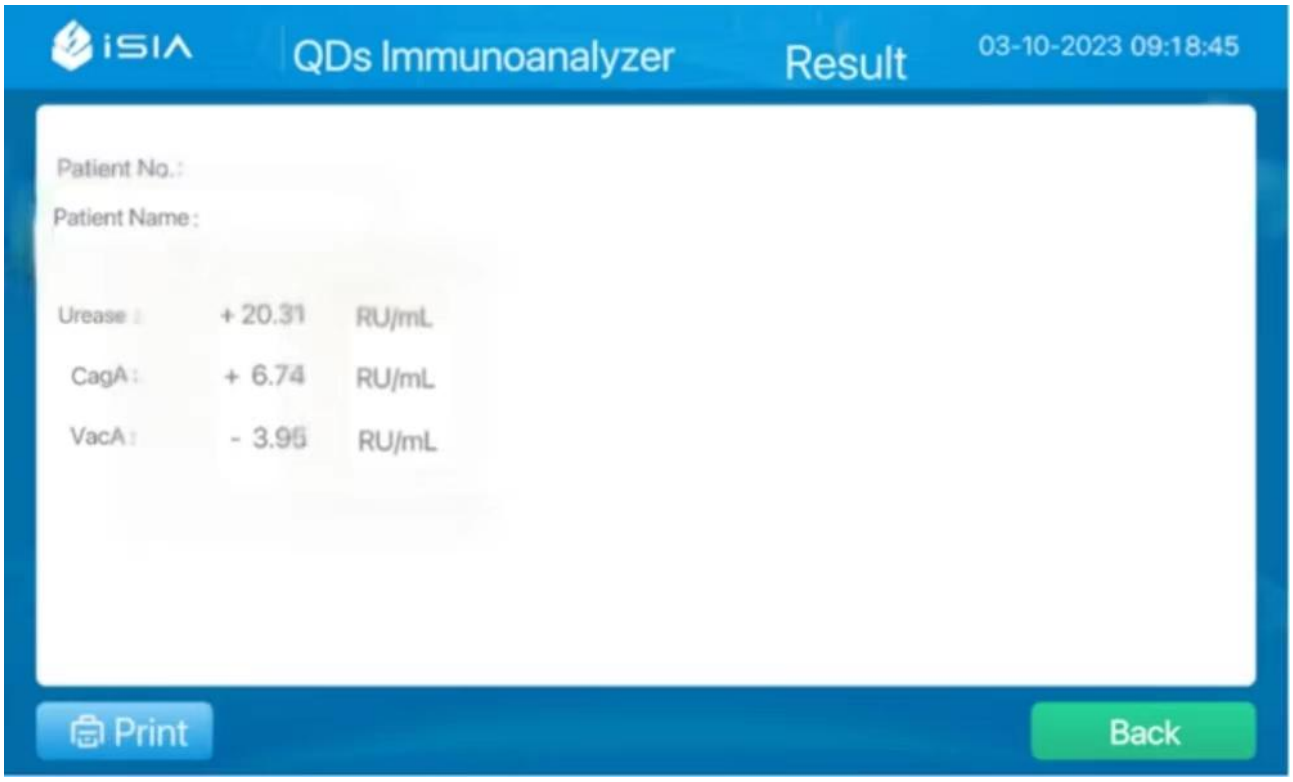


Figure 4.3.2

4.4. Interface of Historical View

1) When each test result is released, the system will auto-save the data to the local, where users can select [Information Query] to check;

2) Click [Upload] in Figure 4.4.1 to upload the selected records or upload all;
3) Click [Delete] in Figure 4.4.1 to delete the selected records or delete all;
4) Click [Print] in Figure 4.4.1 to print the selected records or print all;
5) Click [Search] in Figure 4.4.2 to search by patient's number, item name and date;
6) After selecting the date range in Figure 4.4.2, click [OK] to check the record;
7) After selecting the item number in Figure 4.4.2, click [Search] to screen the corresponding item records;

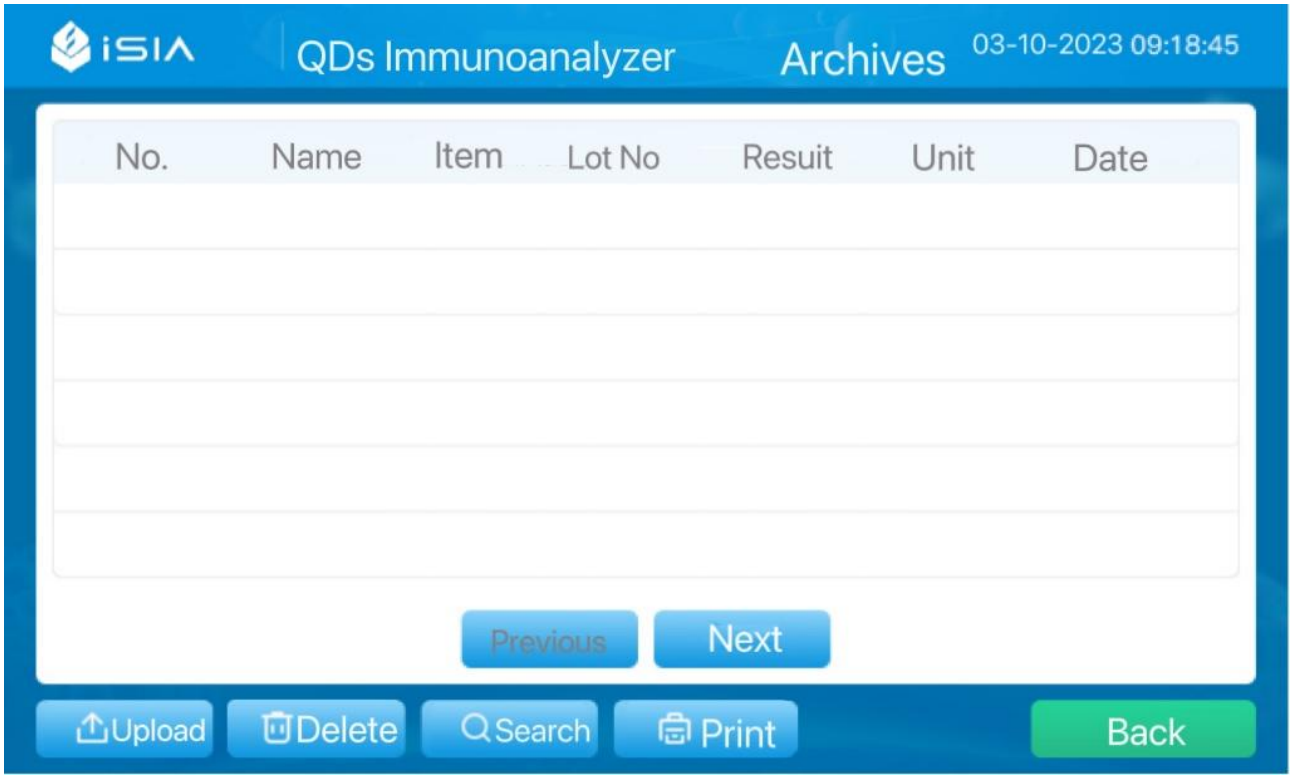


Figure 4.4.1

Figure 4.4.2

5. Quality Control

When booting machine for the first time or every time of booting, quality control can be carried out by the quality control products in the matching reagents for the test. The implementation method of quality control is the same as that of ordinary samples for test.

Compare the reading value of the device with the target value of the quality control product, if the reading value meets the requirements of the target value range of the quality control product, test can be conducted with the device; If it does not meet the target range requirements, the device is prohibited to use! Please contact promptly the after-sales service engineer for factory calibration or repair.

6. Product Maintenance Methods

6.1. Product Regular Maintenance

6.1.1. External cleaning

The basic maintenance of the device is to keep the external clean only, no other maintenance measures needed.

1) Wipe the outer surface of the device with a wrung dry cloth. After cleaning, wipe off the residual water on the surface with a paper towel.
2) For stubborn stains, use a 70% ethanol solution or other mild detergent to apply to the dirty area, and then use a wrung wet cloth to wipe to ensure the detergent is completely removed.

Note:

- Before cleaning the device , the power switch should be turned off and unplugged to avoid risks such as short circuits or electric shock.
- It is prohibited to use chemical detergents with strong oxidation, strong bleaching, and other properties.
- When cleaning, the amount of liquid used should be strictly limited to avoid formation of flowable liquid on the surface of the device; Avoid liquid from dropping or splashing or flowing into the openings of device such as card inlets or power sockets.
- Do not place the instrument in the sun for drying.

6.1.2. Decontamination and disinfection

- Before cleaning this device, the power switch must be turned off and unplugged.
- Use a wrung dry cloth and disinfectant (with less than 0.1% bleach) to scrub thoroughly the device's inlet and other areas at risk of biological contamination.

⚠ **Note:**

It is prohibited to use a spray bottle to wash the device, nor to clean the internal surface or components of the device in case of damage.

6.1.3. Maintenance

1) After adding the sample to the sample hole of the reagent card, wait for the sample to fully soaked into the sample hole before inserting the reagent card into the device to avoid sample splashing.
2) Before inserting the reagent card into the device, remove the liquid splashed on the surface of the reagent card first to keep the outer shell of the reagent card dry from contamination and corrosion of components inside.
3) Do not frequently turn on/off the device's switch.
4) When the device is on, do not unplug the power cord. Please follow the normal steps to turn off the device.

6. 2. Common Faults and Solutions

Fault Phenomenon	Possible Reason	Solution
Device unable to be turned on	Power switch not turned on	Turn on the power switch
	Poor contact of power cord	Check and reconnect the power cord
	Power fuse blown	Please contact the manufacturer for repair
	Electrical fault of device	Please contact the manufacturer for repair
Unable to log on system after device turned on	Device system accidentally stuck	Restart the device and try again
	Device's system fault	Please contact the manufacturer for repair
Device initialization failed	Device's hardware fault	Restart the instrument and try again. If the fault remains, please contact the manufacturer for repair
Fault indicated during operation	Device's hardware fault	Restart the instrument and try again. If the fault remains, please contact the manufacturer for repair

7. Interpretation of Medical Device Label Contents

Label	Interpretation	Label	Interpretation
	Note: refer to files attached		Careful when deliver and transport the package
	In vitro diagnostic device		Max Qty of layers of stacks of the same packaging
	Biological risks		Vertically upward of the packaging during transportation

	Protective earthing		Avoid rain
On	Host power on	Off	Host power off
	Direct current		Alternating current
LIS/COM	Upload LIS data		USB interface
	LANinterface		

8. Product Storage and Transportation Conditions and Methods

8. 1. Storage

The instrument should be stored in the original packing case, in a well-ventilated clean room. The packing case should be high with ambient temperature of -20℃~55℃, relative humidity of no greater than 93%, free of harmful gases, flammable or explosive substances or corrosive gases. If it has been stored for more than 6 months, you need to notify professional maintenance personnel before using it.

8. 2. Transportation

Under transportation and storage conditions, the device should be restored (placed) for more than 24 hours under normal working conditions before being taken out for use. The device should be handled lightly. For moving, better to use the original packaging to prevent damage due to violent vibration. Avoid violent impact during transportation from damage to packaging and the product inside. For shipping of used device, it should be disinfected following the internal regulations of the medical institution before delivery and marked "disinfected", or marked "unsterilized" to remind the personnel who receive the device to be aware of protection.

9. Product Service Life

Please see the nameplate on machine body for Date of Production.
Please see the warranty card for the life of accessories (Note: except for man-made damage).
Discarded instruments and accessories beyond the service life shall be disposed of following the relevant provisions of local laws and regulations.

⚠ Note: If the device being used continuously beyond the service life, it shall be approved by the

biomedical engineer of the hospital, and the performance of which shall be inspected by the hospital engineer regularly in the subsequent use.

10. Contact Method

Product name: Quantum Dots Immunoanalyzer
Product model: AFS-1000
Registered/Manufacturing enterprise: Chongqing iSIA Bio-Technology Co., Ltd.
Registered/Manufacturing address: No.388 Jingdongfang Avenue, Beibei District, Chongqing，China 400714
Tel: +86-20-3214 4996；+86-400 808 8837
Fax: +86-20-3214 4996
E-mail：global@isiabio.com
Website: www.isiabio.com.cn
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