IVD CE

Immunofluorescence Analyzer

（WS-Si1500）

User Manual

WESAIL

Declaration

This manual describes the main structure, specification, installation, operation, maintenance, storage, and safety precautions of the product. Please refer to the corresponding chapters for more details.

Contents

1 Overview

1.1 Product Name

Immunofluorescence Analyzer

1.2 Product Model

WS-Si1500

1.3 Intended Use

The Immunofluorescence Analyzer should be used along with WESAIL reagents for qualitative or quantitative detection of human samples to be tested.

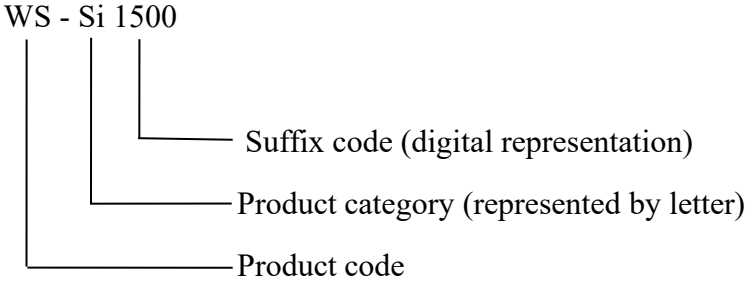
Intended User: Suitable for use by clinical medical professionals.

1.4 Software Information

(1) Basic information:

1. Software name: WS-Si series Immunofluorescence Analyzer software
2. Software model: WS-Si1500

   Model and designation：



3. Released version of the software：V1

4. Complete software version：V1.0.0.1

Software Version Naming Rules：VA.B.C.D

V: Abbreviation for the word Version.

A: Major version number, the value is ≥1. This field is incremented by 1 when there is a major enhancement update or major network security update to the software.

.：spacer. This field does not change when the release version changes.

B：Minor version number. Starting from 0, this field is incremented by 1 when a minor enhancement class update or minor network security update occurs to the software.

C：Build (0-99). Start from 0.

D：Revision number (0-99). Start at 1.

(2) Operating environment:

Hardware Configuration：four-core ARM-A55 64-bit processor，2.0GHz

Storage：2G RAM,16G ROM

Software Environment: Android 11

Network conditions: WIFI

1.5 Contraindications

Immunofluorescence Analyzer is in-vitro diagnostic medical device with no requirement for contraindications.

1.6 Product Lifetime

1. Production date: printed on the product label
2. Product lifetime: 5 years

2 Main Parameters

Table 1 Product Specification

Repeatability	CV≤ 5%
Accuracy	The relative deviation should be within ± 15%.
Stability	The relative deviation should be within ± 5%.
Linearity	Linear correlation coefficient r should be ≥ 0.990.
Temperature Accuracy	Temperature deviation should not exceed 18.5°C ± 0.5°C.
Temperature Fluctuation	Temperature fluctuation does not exceed ±1.0°C.
Clinical Programs	It is suitable for 9 types of clinical tests: experimental diagnosis of myocardial diseases; immune function determination; bleeding and coagulation test; hormone determination; sugar and its metabolites determination; vitamins, amino acids and blood drug concentration determination; experimental diagnosis of renal diseases; experimental diagnosis of liver disease; protein and peptide test.
Test time	The duration from insertion of test cassette to display of test results is less than 1min.
Product size	Length × Width × Height : 182mm×93mm×63mm
Weight	Net weight: about 1.0 kg Gross weight: about 1.5 kg
Storage conditions	temperature：-20℃～55℃ relevant humidity ： 10%～93%

3 Points for attention

For safety and convenience, please read this user manual carefully first, and operate the analyzer according to the demands. If the analyzer is not used according to the requirements specified by the manufacturer, the protection mechanism of analyzer may become invalid. Please keep this user manual properly after reading, so that you can refer to it at any time you need.

3.1 Danger of Power Supply

1 Do not use a power adapter that is not supplied by the original factory.

2 Do not plug or unplug the power cord with wet hands, otherwise you may get an electric shock.

3 A well-grounded power outlet must be used, otherwise an electric shock may result when the analyzer leaks.

4 Do not damage the power cord, do not stamp, twist or pull the cord. If damaged power cords are used, electric shock or fire may happen.

5 If any abnormal operation or malfunction happens, you should stop the operation immediately, turn off the power and unplug the power cord, and contact the dealer or manufacturer. Do not open the device without authorization, connect the power supply, or turn on the power of the device, so as to avoid secondary equipment damage and danger to the human body.

6 If there is any inadvertent flow of liquid into the analyzer during the operation or the analyzer emits smell of burning or smokes, stop the operation immediately, turn off the power, unplug the power cord, and contact the dealer or manufacturer.

7 Turn off the power and unplug the power cord after use or when it is not in use for a long time.

3.2 Protection against Biochemical Hazards

1. While this analyzer is operated, please follow the recognized laboratory rules, thoroughly clean your hands, wear disposable gloves and lab coats, avoid exposing any parts of the body to the splashing or spilling infectious solution. All surfaces in contact with biological fluids should be considered as the areas with biological hazard.
2. When the analyzer is out of use, it is necessary to disinfect the analyzer to reduce biological hazards before transportation or scrapping.
3. The manufacturer reminds that all parts of the analyzer may be in direct contact with human plasma, serum and urine and must be treated as a potential infectious agent.
4. If the sample comes into contact with the skin, please follow the operators' working standards or consult a physician to take remedial action.
5. Once the hands or clothing come into contact with the reagents, please clean with soap and water thoroughly.

6. If the reagent gets into your eyes, please rinse with plenty of water immediately and consult a physician for further processing.

3.3 Liquid Waste Disposal

1 The wastes generated during the analyzer operation such as test cassettes, quality controls and samples are subject to pollution regulations and discarding standards. They shall be disposed of in accordance with local regulatory requirements and the relevant manufacturer must be consulted.

2 After the use of the analyzer, the remaining test samples and their appurtenances should be disposed of properly before discard so that it can comply with national regulations and the requirements of local environmental organization.

3.4 Other Precautions

1. This analyzer is limited to the operation and use by the professionally trained medical and health inspectors, doctors or laboratory technicians. For retraining, please contact the dealer or manufacturer. All parts and components of the analyzer can only be inspected or supplied by the dealer or manufacturer.
2. When testing, push the test cassette to the bottom of the carrier slot, making sure that the cassette cannot be moved further forward.
3. When the analyzer starts testing, do not touch the test cassette or put your finger into the channel to avoid the reagent card falling and blocking the channel when the test slot is sent out, damaging the analyzer, or pinching your fingers. This process should be operated, only if the operator has been warned of potential hazards and has been taught how to operate the analyzer as safe as possible.
4. Please read the User Manual of each kit carefully before testing.
5. The use of the kit should be stopped if the single package is damaged or the marking is not clear, otherwise it may lead to incorrect test results.
6. Before using the kit, check whether the kit is within the validity period, and prohibit the use of expired kits.
7. It is strictly forbidden for users to disassemble and repair the analyzer without authorization. They should contact the dealer or the manufacturer and arrange for a

professional maintenance engineer to check and repair the analyzer.

8. If a screw or metal object falls into the analyzer, stop the operation immediately, please contact the dealer or the manufacturer, and ask professional maintenance personnel to remove the metal object and check that the analyzer can operate normally before starting the operation. May cause analyzer failure.
9. Please place the analyzer on a level surface to avoid collision, otherwise it will affect the analyzer test results.
10. Do not put liquids such as reagents and water on the analyzer table to prevent liquids from leaking into the analyzer and causing damage to the analyzer.
11. Manufacturer's statement that the analyzer and its internal parts are designed and manufactured to avoid hazards to operator safety.
12. It is the user's responsibility to ensure the electromagnetic compatibility environment of the equipment so that the equipment can work normally. It is recommended to evaluate the electromagnetic environment before using the equipment.
13. Do not use this equipment near strong radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the normal operation of the equipment.
14. This product is designed and tested according to Class A equipment in CISPR 11 In a domestic environment, this equipment may cause radio interference, requiring precautions.
15. This product complies with the emission and immunity requirements specified in EN IEC 61326-1 and EN IEC 61326-2-6, see Appendix A.
16. When the exposure of moving parts in normal use is unavoidable, please pay attention to the entrance and exit of the parts next to the movement warning label on the instrument to prevent accidental injury.

4 Installation and use

4.1 Out Of Box Audit

When unpacking for the first time, please check whether there is physical damage to the outer box of the analyzer. If there is any damage, please contact the dealer or manufacturer immediately. If not, unpack according to the following steps:

1. Stand the packing case upright.
2. Use a tool to open the packing tape on the case, take out the packing list to check whether the contents are complete, if anything missed, please contact the dealer or manufacturer immediately.
3. Remove the upper fixing foam cover, take out the analyzer from the packing case and place it on a steady table.
4. Check the outer surface of the analyzer for any damage, such as nicks, dents, scratches, etc. Then check all objects. If there is any damage, please contact the dealer or manufacturer immediately.

4.2 Installation Requirement

Table 2 Installation Instructions

Item	Requirements
Basic environment	The ambient temperature should be 10℃~30℃, the relative humidity should be ≤ 85%, no condensation. For indoor use, the installation environment should be kept dry and ventilated, and free from direct sunlight, large amount of dust, mechanical vibration, loud noise source and power supply interference as much as possible. Do not place the device close to a strong electromagnetic interference source, so as not to affect the normal operation of the device.

	Do not place the device in a position where it is difficult to unplug the device. Do not put the device near brush-type motors, flashing fluorescent lamps, or frequently switched electrical equipment.
Space requirements	Considering enough heat dissipation, the ease use of the power switch and multiple interface on side of the analyzer, the installation must meet the following requirements: The space reserved between the left and right sides of the analyzer and the walls should be ≥ 20cm. The space reserved between the analyzer back panel and the wall should be ≥ 20cm.
Reserved space for power plug	There should be enough space for the power cord where it is plugged into the power supply (100-240V, 50Hz/60Hz), ensuring that the lower power plug can be quickly removed from the power outlet in case of emergency.
Desktop requirements	A horizontal, flat and steady desktop.
Altitude requirements	The altitude does not exceed 2,000m.

4.2.1 Printer assembly

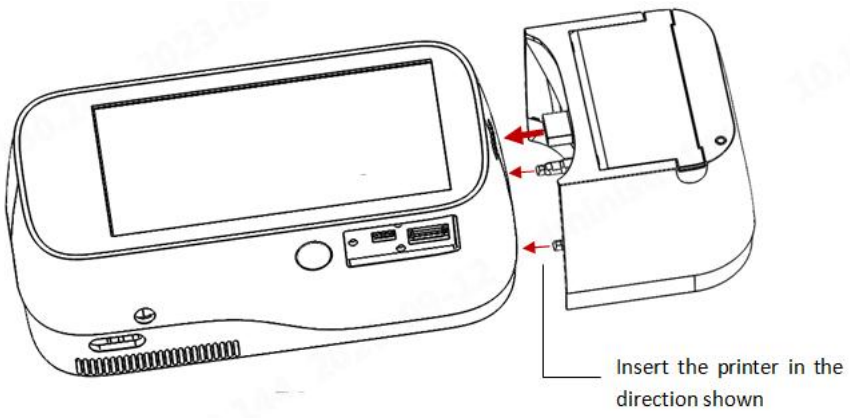


Figure 1 Printer Assembly Diagram

4.2.2 Power adapter assembly

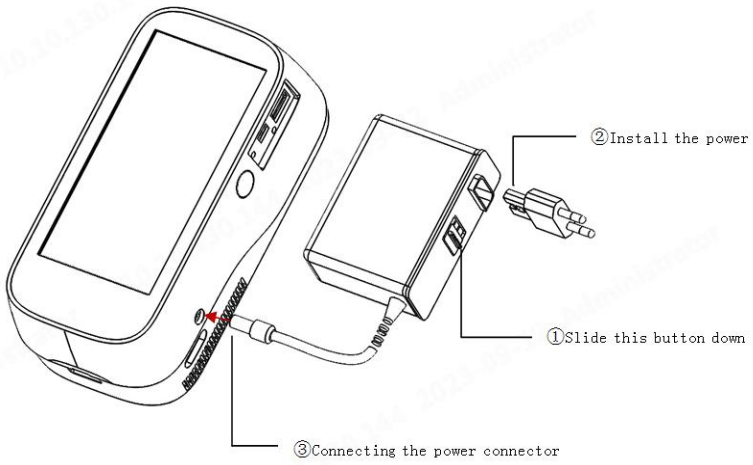


Figure 2 Power adapter assembly

4.3 Power Environment

Adapter Input: 100-240V~ 50/60Hz, 1.7A; Output: 12V, 5A; Instrument Input: DC12V, 60W;

Note：The analyzer shall be protected against dust and shock, away from strong electromagnetic interference and corrosion. In addition, the analyzer has no strong electromagnetic interference to the power grid supply and other equipment.

4.4 Operating Environment

The conditions of normal operation of the analyzer should meet the following requirements:

1. Adapter Input: 100-240V~ 50/60Hz, 1.7A; Output: 12V, 5A;
2. Instrument Input: DC12V, 60W;
3. Battery type: lithium battery；
4. Ambient temperature: 10℃～30℃；

5. Relative humidity: ≤85%，no condensation；
6. Atmospheric pressure: 86.0kPa～106.0kPa；
7. Altitude: ≤2000m；
8. Keep away from interference sources of strong electromagnetic field
9. Avoid direct sunlight.

5 Detection Principle and Structure Composition

5.1 Detection Principle

Immunofluorescence Analyzer is used along with WESAIL reagents. During the detection process, the analyte in the sample and the fluorescent labeled antibody form an immune complex. The immune complex and the fluorescent labeled antibody are captured in the detection area and the control area respectively after chromatography. The excitation light source scans the detection area and the control area, excites the captured fluorescent immune complex, and the emitted light is collected and converted into an electrical signal. The strength of the electrical signal is related to the number of fluorescent molecules. The analyzer automatically calculates the content of analyte in the sample to be tested based on the signal obtained from the reading.

5.2 Structure and Components

The Immunofluorescence Analyzer is mainly composed of main unit and power adapter. The main unit consists of a photometric unit, test cassette loading unit, battery, incubation unit and electronic control unit.

5.2.1 Overall structure

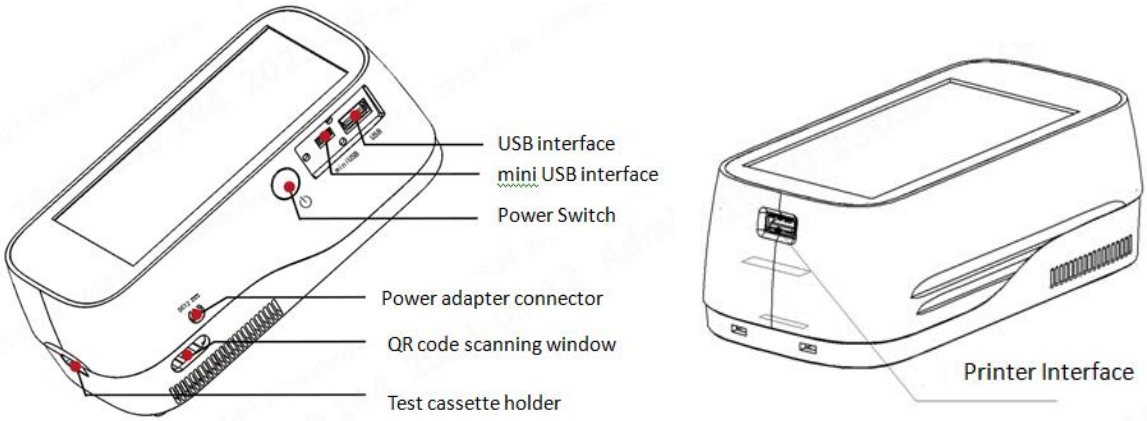


Figure 3 Analyzer Overview Diagram

5.2.2 Photometric unit

The photometric unit is used to provide excitation light and collect fluorescence information, and mainly consists of a light source, a signal acquisition module, an optical component mount, and an adjustable mounting bracket.

5.2.3 Test cassette loading unit

The test cassette loading unit is used for loading and positioning of test cassettes. The test cassette loading unit mainly consists of a test cassette holder, an elastic press, a linear screw motor, a motor mount, a slot, a photoelectric sensor and so on.

5.2.4 Incubation unit

The incubation unit is for constant temperature incubation of test cassettes. The incubation unit mainly consists of heat sinks, cooling pads, and incubation card slots.

5.2.5 Electronic control unit

The electronic control unit mainly includes the main control board, display screen, barcode scanner, cooling fan, thermal printer and so on.

6 Operation Instructions

6.1 Startup

1. Before each power-on, the operator should check whether the battery power of the host is sufficient to ensure that the system can work normally.
2. Long press the on/off button on the right side of the instrument to turn on the power, the analyzer will start and carry out the initialization and self-inspection process (including testing basic software, hardware functions and temperature for normalcy), after the self-inspection passes, it will directly enter the login interface (Figure 4 below).

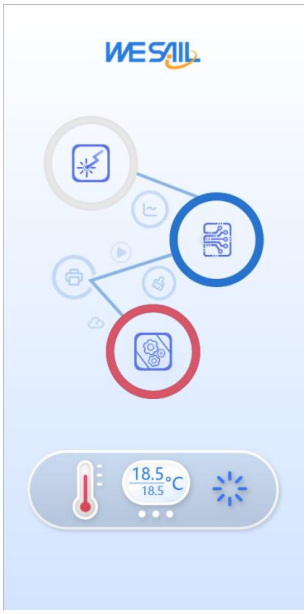


Figure 4 Self-inspection interface

6.2 Interface function

6.2.1 User Access Definition

This analyzer has user access control function. User name and password are required to log in after the power-on self-inspection is complete. After logging in, you can set different

privileges by user level.

There are three levels of permissions: Administrator, Supervisor and Operator. The level of users can be identified via the account name and password, including:

(1) Administrator: all operation permissions.

(2) Supervisor: the basic permissions and Operator accounts creation permission.

(3) Operator: the basic permissions.

6.2.2 Login interface

After the self-inspection is completed and the result is correct, enter the login interface (Figure 5 below)

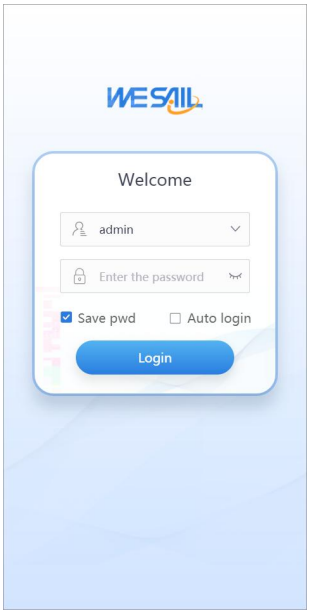


Figure 5 Login interface

1. Login successfully and enter the main interface (Figure 6 below).
2. If the user who logged in before the last shutdown of the analyzer is the default user, and "Save password" and "Auto login" are checked during the login, the analyzer will enter the main interface directly after the self-inspection is completed and there are no errors.

6.2.3 Main interface

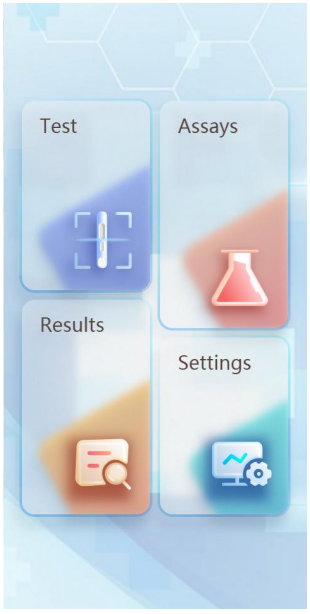


Figure 6 Main interface

After the analyzer enters the main interface, click the buttons in the main interface to enter the sub-interface of the corresponding function.

6.2.4 Main buttons Description

Table 3 Module Description

Button icon	Name	Function
	Test	Enter the Test interface
	Assays	Enter the Assays interface
	Results	Enter the Results interface
	Settings	Enter the Settings interface

6.2.5 Function description

Table 4 Description of Main Functions

Button	**Main functions**

name	
Test	View information about the test items corresponding to the sample, edit the sample number, select the sample type, operate the test and print the test results
Assays	Manage project information with the ability to import, view lists and view project details
Results	View information about the test items corresponding to the sample, results transfer, test item data analysis, query, view, export, print and other functions
Settings	1. Quality control operation 2. Function settings: barcode settings, network settings, language settings, serial port settings. 3. User settings: You can enter the user settings interface to add, edit, delete and logout users. 4. Institution: You can set information on the name of the institution and the name of the hospital department. 5. Help: Display helping documents and FAQ. 6. About: Display the current software version information

6.2.6 Functional Detailed Explanation

6.2.6.1 Test

1. After the power-on initialization is completed or after clicking the [Test] button on the main interface, enter the main test interface (Figure 7 below).
2. Test

   Please import the parameters of the corresponding test item before the test.

   1) Insert the test cassette, the instrument automatically scans the QR code information of the test cassette, and the test cassette is pushed out after the scanning is completed.
   2) To enter information, enter the sample number and select the sample type.Click on the sample number increment button  , and it turns into  . Switch to automatic number accrual and the number is automatically reset back to 0001 at 00:00 each day.
   3) The sample is added dropwise to the sample well of the test cassette, and when sample adding is complete the sample is pushed into the test cassette again for incubation and the page countdown starts.

Note: Before adding samples for testing, please read the instructions for the immunofluorescence test kit in detail and operate as required.

4) After the incubation is completed, the instrument automatically performs the test, and the test cassette is pushed out at the same time during the test.

Note: The number must not be null when testing.

5) Click the Print button  to print the results when the test is complete (Figure 8 below).

6) After completing the test, keep pressing the On/Off button on the right side of the instrument to turn it off.

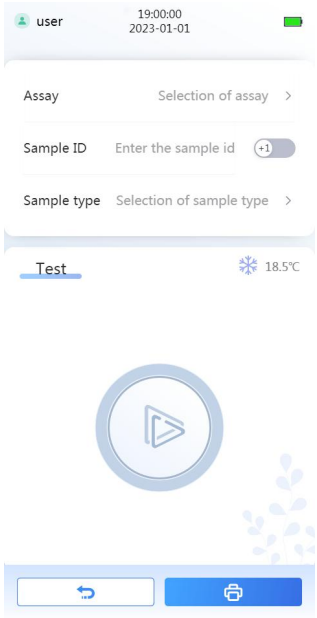


Figure 7 Testing interface

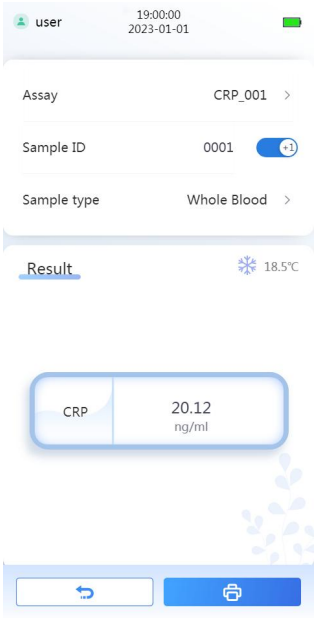


Figure 8 Testing results

6.2.6.2 Assays

1. After clicking the main interface button  , you will enter the assays interface (Figure 9 below).

2. Click the scanning button  , the instrument opens the function of reading two-dimensional code, align the two-dimensional code of the laboratory table that needs to be imported with the scanning window on the right side of the instrument, and when the scanning is successful, the instrument will emit a "D" sound, and at the same time, the screen will display the information of the scanned item, and it will prompt whether it needs to be imported into the instrument or not.

3. Click the delete button  , the selected item can be deleted.

4. Click the  button, to view the current assay details.

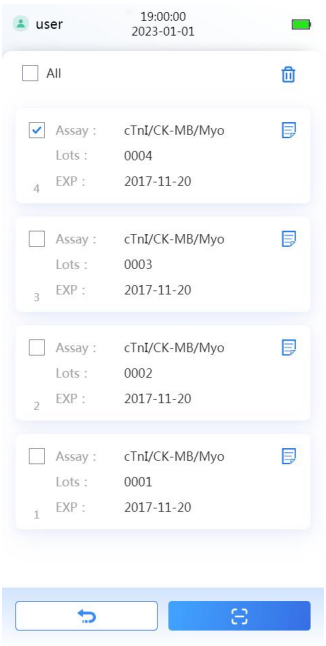


Figure 9 Assay List Interface

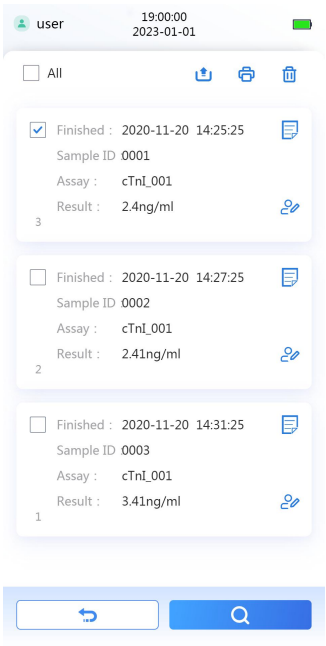


Figure 10 Result List Interface

6.2.6.3 Result

1. After clicking the main screen button  , you will enter the results interface (Figure 10 above).
2. Clicking the  button brings up the search dialog box, which searches for results on a number of dimensions, such as project, number name, age, gender, and start/end time, and after clicking on the query, a list of results is displayed.
3. Users can delete  , export  , print  , detail view  , information supplement  and other functional operations on the results.

6.2.6.4 System

1. After clicking the main interface button  , you will enter the system interface. In this interface, you can set the system functions and quality control.
2. Click the Function Setting button  , in the System Function Interface to enter the Function Setting Interface (Figure 11 below), and set the barcode, network, language and serial port respectively.
3. Click on the bar code  , you can choose to close or open, if you click on the open, the instrument detection is first scanning the reagent card QR code after the success of the

card back to add samples, the second insertion of the reagent card after the incubation test, closed directly to the incubation test.

4. Click the User Management button in the system function interface to enter the user management setting interface, where you can perform management and logout operations.
5. Clicking on the Create button + in the Management button allows you to create, edit, and delete users.
6. Click the Logout button to logout the current user.
7. Click the Institution button, in the system function interface to enter the Institution setting interface, you can operate the Institution name and section.
8. Click on the Help button in the System Functions interface to enter the Help interface for a quick start guide to the instrument.
9. Click on the About button in the System Functions interface to enter the About interface.

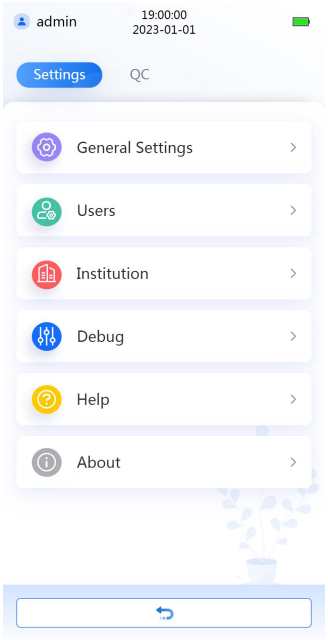


Figure 11 System Function Menu Interface

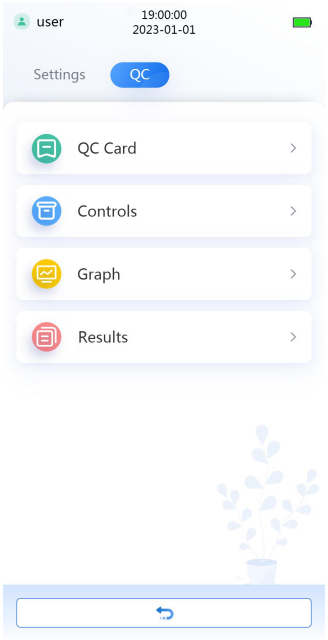


Figure 12 QC menu interface

10. Click on the QC button 质控 in the system interface to enter the QC Settings interface (Figure 12 above).
11. Click the QC card button in the QC interface to enter the QC card operation interface (Figure 13 below), which has the function of detection. After inserting the QC card, the corresponding QC information is automatically filled into the filling box, and then the testing process begins.

12. Click the control material button  in the QC interface to enter the control material operation interface (Figure 14 below). After selecting the control material, the corresponding target value and target value range are automatically displayed.

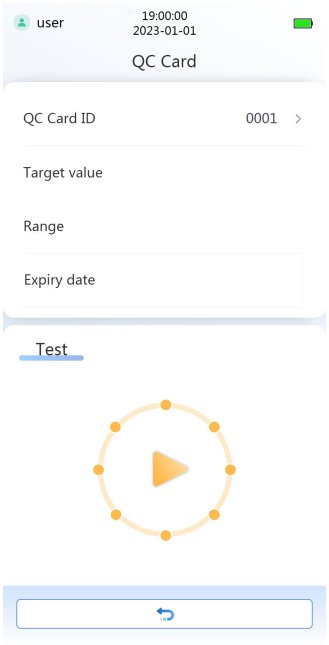


Figure 13 QC card testing interface

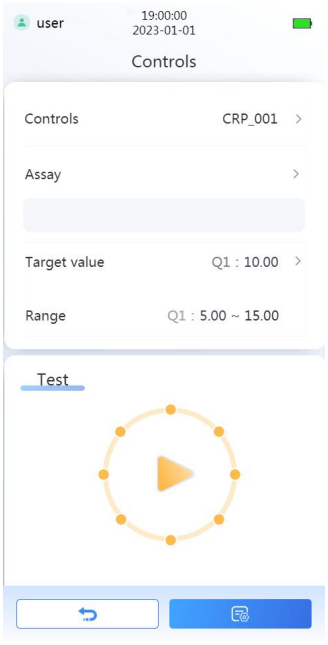


Figure 14 control material testing interface

13. Click the button  in the control material testing interface to enter the control material setting interface, where you can perform management operations such as adding and deleting control material items.

14. Click the QC chart button  in the QC interface to enter the QC chart operation interface (Figure 15 below).

15. Click the Search button  in the QC chart interface to select the time range of QC cards or control materials within the QC chart.

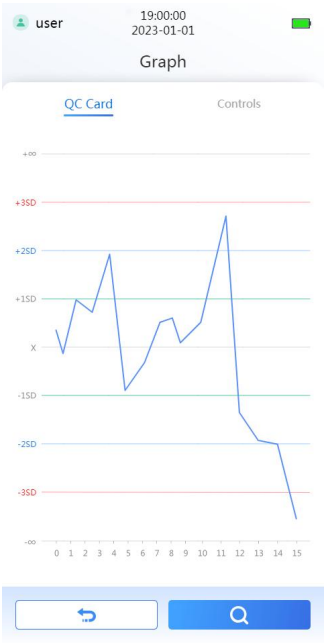


Figure 15 Quality control chart interface

16. Click on the QC result button  in the QC interface to enter the QC result operation interface (Figure 16 below), you can search for the results of the control materials or QC card, and the result list will pop up after searching, and you can print/delete the results according to your needs.

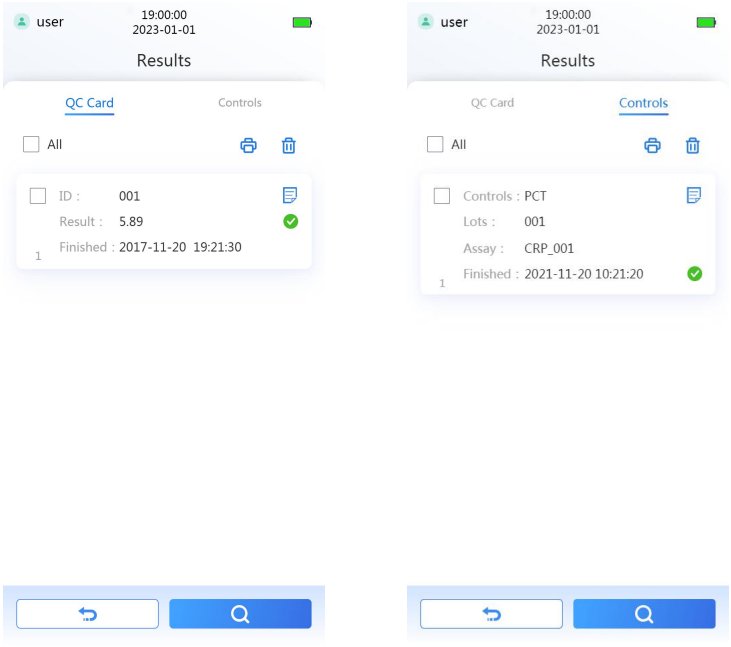


Figure 16 QC results interface

6.2.7 Data transportation and Device (System) Interface

The data interface is a transmission protocol, and the test results of the analyzer can be sent to the LIS system through the Mini USB using the HL7 (Health Level Seven) protocol.

Network Security Feature Configuration: No network connection required, configured via IP.

Data backup: The data will be backed up in the instrument system.

Disaster recovery: When the data fails catastrophically, the data can be obtained from the USB interface of the instrument or the instrument can be restarted to recover.

7 Product Maintenance

7.1 Daily Maintenance

1. Before cleaning the analyzer, make sure the analyzer is turned off and unplugged from the power source before proceeding.
2. Clean the analyzer at regular intervals. When cleaning, the operator must wear disposable gloves.
3. External cleaning: Turn off the power, disconnect the power cord to avoid electric shock to ensure safety, using water or 75% ethanol, wipe the external surface of the device. If necessary, use a dry rag to wipe off excess ethanol and leave it to air dry, prohibit the use of strong bleach and other chemical detergents to prevent damage to the external surface of the analyzer and the screen and other devices.
4. When cleaning, avoid liquid from flowing into the analyzer, which may cause damage to the analyzer.
5. Do not use chemical reagents such as turpentine oil or benzene to clean stains on the outer surface of the analyzer, as they may cause discoloration and deformation.
6. During each power-on self-inspection, the instrument automatically detects the temperature information transmitted from the temperature sensor through the software, and will stop powering on the instrument when the temperature information is

abnormally unable to reach the predetermined temperature range, thus providing temperature protection.

7.2 Regular Maintenance

Regular Maintenance: The analyzer does not contain components that can be maintained by the operators. To avoid electric shocks and damage to the analyzer, regular maintenance must be performed by an authorized maintenance technician.

8 Troubleshooting Guide

This list shows the faults that may occur during the use of the analyzer and the Prompts message on the screen. Please refer to the solutions provided in this list to determine and resolve the fault.

Table 5 Troubleshooting guide

Fault code table				
Fault code	**Fault type**	**Problems**	**Reasons**	**Solutions**
E203	Operational fault	There is no content in the list of testing items in the instrument	Test items are not imported	Import test items according to the user manual.
E201	Integrated fault	Failed to identify the QR code on the Calibration card	No Calibration card was inserted	Please insert the Calibration card
			The QR code of the Calibration card is damaged	Please replace the Calibration card
			The inserted Calibration card is out of position	Please insert it at the bottom
			QR code Scanner Malfunction	Contact the dealer or manufacturer
E221	Integrated fault	Failed to identify the QR code on the test cassette	No test cassette inserted during testing	Please insert the test cassette.
			The QR code of the test cassette is damaged	Please replace the test cassette
			The inserted test cassette is out of position	Please insert it at the bottom
			QR code Scanner Malfunction	Contact the dealer or manufacturer

E204	Operation fault	No corresponding test items were retrieved	The test item for the tested test cassette does not exist	Please import the corresponding test item
E202	Integrated fault	The current test item has expired	Trigger to instrument judgment failure conditions	Contact the dealer or manufacturer
E222	Operation fault	No sample number was entered during analysis	The analyzer cannot test without the sample number	Please enter the sample number
E206	Integrated fault	The test result is invalid	The area of the quality control line is less than the set threshold	Replace the test cassette for detection
			Analyzer signal link anomaly	Contact the dealer or manufacturer
E208	Operation fault	User name or password input error	No such user name	Please create a new user
			Username and password do not match	Please enter the correct password
E219	Operation fault	The identified assay table does not correspond to the instrument version	The assay table format is incorrect	Contact the dealer or manufacturer
E102	Instrument fault	Motion mechanism failure	Carrying slot is not movable	Contact the dealer or manufacturer
E107	Operation fault	Unsuccessful export of data results	No USB flash drive presence detected during export	Please insert the USB flash drive

9 Product After-sales and Maintenance

1. A one-year standard warranty is provided for the product
2. The warranty period begins with the “Acceptance Date” specified on the “Warranty Card” accompanying the product. The Warranty Card is the sole document for calculating the warranty period. If not specified, the warranty period will be calculated 60 days later than the “Ex-factory Date” identified on the packing case. The warranty card needs safekeeping.
3. During the warranty period, the product is provided with free after-sales service. Upon the expiration of the period, the manufacturer may continue to provide paid maintenance service.
4. During the warranty period, if the product needs to be repaired due to the following reasons, the manufacturer will provided paid repair service and you need to pay the maintenance fee and accessories fee.

1) Artificial damage or improper use.
2) Grid voltage is beyond the specified scope of the product.
3) Irresistible natural disasters.
4) Replace or use components, accessories and consumables that are not approved by the manufacturer.
5) Instrument failure caused by the maintenance performed by personnel not authorized by the manufacturer.
6) Other failures not caused by the product itself.

10 Storage and Transportation

1. Storage conditions of packaged analyzer：
   1) Temperature：-20℃～55℃
   2) Relative humidity：10%～93%
   3) Atmospheric pressure：86.0kPa～106.0kPa
   4) non-corrosive gas
   5) Well-ventilated room
2. Transport conditions of packaged analyzer
   1) General transportation is acceptable
   2) Need protection against moisture, sunshine and shock in-transit

Appendix A: Schedule of Electromagnetic Compatibility

Note

1. The Immunofluorescence Analyzer complies with the emission and immunity requirements specified in EN IEC 61326-1: 2021 and EN IEC 61326-2-6: 2021, see the table below.
2. It is the user's responsibility to ensure the electromagnetic compatibility environment of the equipment so that the equipment can work normally.
3. It is recommended to evaluate the electromagnetic environment before using the equipment.

Note

1. The Immunofluorescence Analyzer is designed and tested according to the Class A equipment in CISPR 11. In a domestic environment, this equipment may cause radio interference, requiring precautions.
2. Do not use this equipment near strong radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the normal operation of the equipment.

Table 6 Electromagnetic Emission

Emission		
Emission Test	**Basic standard**	**Conformity**
Radiated Emission	EN IEC 61326-2-1:2021 EN IEC 61326-2-6:2021 CISPR11:2015+A1:2016+A2:2019	Class A
Conducted Disturbance	EN IEC 61326-2-1:2021 EN IEC 61326-2-6:2021 CISPR11:2015+A1:2016+A2:2019	Class A
Harmonic Current	EN 61000-3-2:2019	N/A
Voltage Fluctuation and Flicke	EN 61000-3-3:2019+A1:2019	N/A

Table 7 Electromagnetic Immunity

Electromagnetic Immunity			
Immunity test item	**Basic standard**	**Test value**	**Performance criterion**
Electrostatic Discharge	EN 61000-4-2:2009	Contact Discharge：±2kV、±4kV Air Discharge： ±2kV 、 ±4kV 、	A

		±8kV	
Radiated	EN 61000-4-3:2006+A1:2007+A2:2010	3V/m, 80MHz~6000MHz, 80 %AM	A
Electrical Fast Transient/Burst	EN 61000-4-4:2012	=±1kV(60s,5kHz)	A
Surge	EN 61000-4-5:2014+A1:2017	line-to-ground: ±1kV line to line: ±0.5kV	A
Conducted Susceptibility	EN 61000-4-6:2014	Power cord: 3V/m, 0.15 MHz～80MHz，80%AM	A
Power Frequency Magnetic Field Susceptibility Test	EN 61000-4-8:2010	3A/m，50/60Hz	A
Voltage Dips and Interruptions Test	EN 61000-4-11:2004+A1:2017	50/60HZ test cycle 0.5/0.5,test level 0%； 50/60HZ test cycle 1/1, test level 0%； 50/60HZ test cycle 25/30, test level 70% 50/60HZ test cycle 250/300, test level 0%	A C C C

Appendix B: Graphical Symbols

Table 8 Description of Graphical Symbol

Graphical Symbols	Description	Graphical Symbols	Description
	Caution		Fragile, handle with care
	Consult User Manual		This way up
	Serial number		Keep dry
	IVD medical device		Protection against Sunshine
	Symbol of separate disposal of discarded electrical and electronic equipment (please comply with local laws and regulations)		Biohazard
	Stacking Layer Limit		Prevents hand pinching
	High Temperature Warning		Functional grounding
	Power On/Off Button	12V ⎓	12V DC input
USB	USB flash drive interface	**Mini USB**	Data interface
PRINT	Printer Interface	/	/

Appendix C: Product Configuration

1. List of product configuration

Table 9 List of product configuration

No.	Category	Items	QTY	Unit	Replacement cycle	Replacement method
1	accessories	Analyzer	1	set	5 years	Contact the manufacturer
2	accessories	Power Adapter	1	set	/	Contact the manufacturer
3	optional accessories	Printer	1	set	/	Contact the manufacturer
4	appendage	User Manual	1	copy	/	/
5	appendage	Quick-Start Guide	1	copy	/	/
6	appendage	Qualified Certificate	1	copy	/	Contact the manufacturer
7	appendage	Warranty Card	1	copy	/	Contact the manufacturer
8	appendage	Packing List	1	copy	/	Contact the manufacturer

Appendix D: Registration Information

Guangdong Wesail Biotech Co., Ltd.

Address: 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China

Tel: 400-900-1339

E-mail: customer@wesailbio.com

Website: http://en.wesailbio.com

EC REP MedPath GmbH

Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Tel: +49(0)89 189174474

E-mail: info@medpath.pro

Website: www.medpath.de

Revision Date: 2023-07-27

Version：0001

Approval Date: 2023-07-31

Date of Issue: 2023-08-01