新健康成®

Fluorescent Immunoanalyzer

User Manual

Important information!

Please read and understand this manual carefully before using the instrument. After reading, put this manual in an accessible place.

Sichuan Xincheng Biological Co., LTD

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Preface

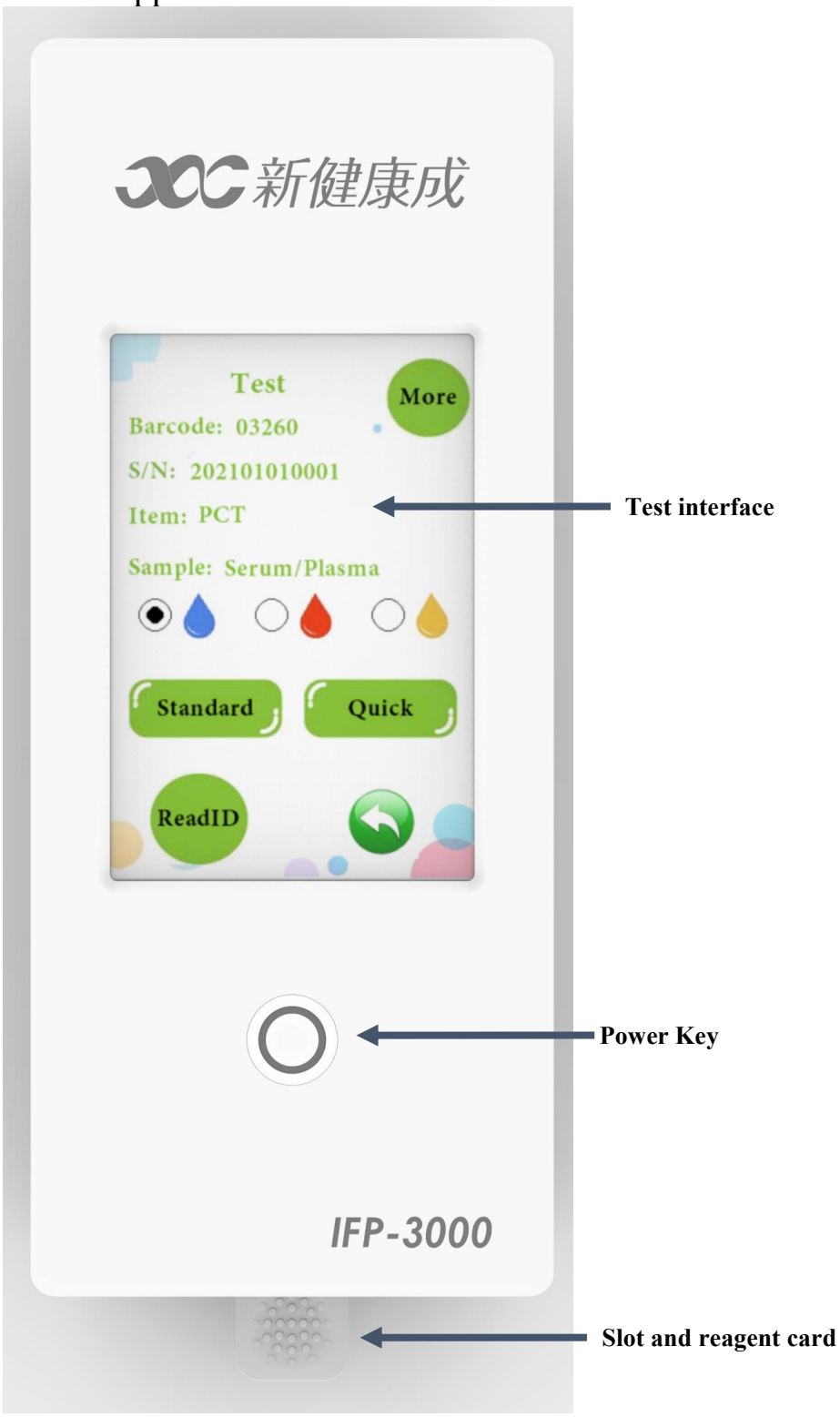
- Dear users, thank you very much for purchasing the Fluorescent Immunoanalyzer of Sichuan Xincheng Biological Co.,LTD (hereinafter referred to as "Xincheng Bio").
- Please read the operation manual carefully before operate, so as to use the Fluorescent Immunoanalyzer correctly. Incorrect operation may affect the accuracy and precision of the test result of the instrument; if the equipment is not used according to the method specified by our company, the protection provided by the equipment may be damaged, or bring danger to your personal safety.
- This manual is only applicable to IFP-3000 Fluorescent Immunoanalyzer produced by Xincheng Bio.
- After reading, please take good care of this operation manual, which can be consulted at any time when necessary.

Important information!

- It is forbidden to copy or reprint the contents of this manual in whole or in part without written permission.
- Without prior notice to the user, the company has no legal obligation to inform if there is any change to the contents of this manual.
- The content of this manual will continue to be improved. If you find any questions, description errors and unknown information, please inform us.

Operation guide

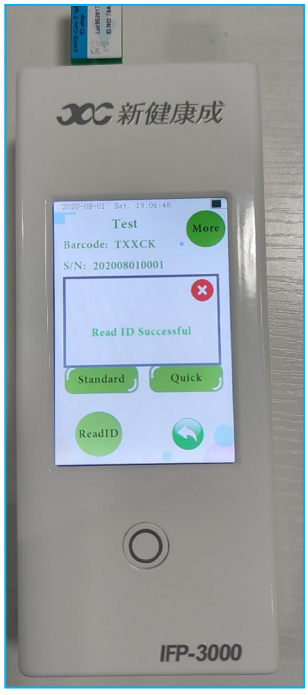
Appearance introduction



Step 1: Power on
Press the power key, the instrument will power on and perform self-test, the motor reset.

Note:

- When the instrument is powered on for the first time or restored to factory settings and powered on again, user name and password are required.
- If you have clicked Remember password and power on again, you will enter the login interface. Click Login to enter the test interface. If you have not click Remember password and power on again, you will need to enter the default user name and password.



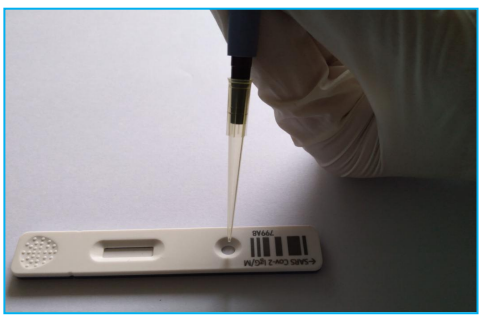
Step 2: Read ID card

① Insert the ID card into the ID interface . Ensure that the test item, batch number and reagent card to be tested are consistent.

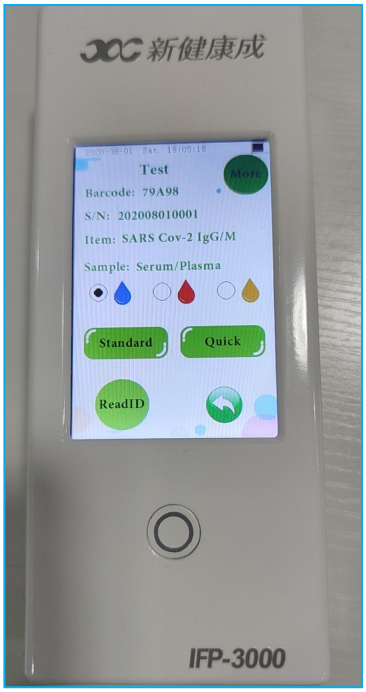
② Click "Read ID" on the test interface, the instrument will automatically read the ID card information and display it.

Note:

- If the test items and ID card information corresponding to batch number already existed in the instrument, it can be tested directly without reading.
- After reading the ID card, the ID card can be taken out.



Step 3: Add sample
Take out the reagent card and add the sample according to the requirements of the reagent manual.



Step 4: Test

① Insert the reagent card after sample adding into the reagent card slot.

② According to the sample type, select "whole blood / serum plasma" in the test interface.

③ Click "Standard Test / Quick Test", and the instrument will test automatically.

④ At the end of the test, the instrument displays the current test results.

Note:

- Standard Test: the instrument will set the reaction time according to the project and enter the countdown. After the countdown, the instrument will automatically detect.
- Quick Test: the instrument tests immediately.
- The waste generated in the weighing process of the instrument should be treated by professionals in accordance with the regulations on the management of medical waste and other relevant provisions.

Step 5: Result query
Enter the “History” interface to query the historical data information.

Step 6: Shut down
After the test, press and hold the power key (about 5 seconds) to pop up the shutdown prompt box and select "√" to shut down.

Step 7: Charging
When the instrument indicates that the power is insufficient, please charge it in time. When charging, plug the charging cable into the USB interface of the instrument, the charging indicator light is on, indicating charging is in progress, and the indicator light is off, indicating that the charging is completed.

1. Safety precautions

Definition of safety precautions words

In this operation manual, the safety precautions are indicated with danger, warning, attention and other words. The meanings of each word are as follows. Please fully understand what these words mean when reading this article.

Precautions Words	Meaning
⚠ DANGER	Indicates a dangerous situation in which death or serious injury will occur if the warning is not followed.
⚠ WARNING	Indicates a dangerous condition that may result in death or serious injury if the warning is not followed.
⚠ BE CAREFUL	Indicates a dangerous situation in which minor or moderate injury will result if the warning is not followed.

Meaning of graphic mark

Graphic Mark	Meaning	Reason
⚠	In this device, this mark indicates that it may cause damage or touch the part that may cause	During the operation of the instrument, avoid touching the reagent card slot in the process of movement, otherwise it will cause personal injury.

	electric shock when the power is turned on.	
	The samples and reagents in the device often touch the parts that the operator may also touch. Please take protective measures.	Samples and reagents used are considered to be potentially infectious.
IVD	In vitro diagnostic device.	The device belongs to in vitro diagnostic device.

Safety precautions

Please follow the following safety precautions when using this equipment.

⚠DANGER	• Avoid using inflammable and explosive dangerous goods around the instrument. • Ignition may cause fire or explosion.

⚠WARNING	• The analyzer must be used under the condition of good grounding, independent power supply shall be used, and the input voltage shall meet the requirements of the instrument. • Do not step on, twist or pull wires and cables. If wires and cables are broken, it will cause fire. • Only touch the designated parts. • If the power is on and the circuit board is touched, it will be shocked. • Do not use wet hands to plug in the power supply, otherwise there is a risk of electric shock. • If there is liquid entering the instrument, please shut down immediately. • During the operation, operators shall wear work clothes, masks and latex gloves as much as possible. During the sample pretreatment, avoid direct contact with the sample, which shall be considered as potentially infectious. • If the sample splashes on the surface of the instrument, reasonable measures shall be taken immediately for disposal.

- Dispose the reagent card according to the instructions provided by the reagent card manufacturer.
- Waste treatment: used samples and reagent cards shall be considered as potentially infectious. Please handle according to relevant regulations of the hospital.
- The instrument shall be operated, regularly maintained in strict accordance with the operation manual, otherwise it may cause instrument failure or affect the accuracy and precision of the instrument.
- When using the instrument, it is necessary to monitor the status of the instrument.

⚠ BE CAREFUL	• The instrument is matched with the dry reagent based on fluorescence Immunochromatography for immunofluorescence detection of human samples. • Please note that the instrument is not suitable for other purposes. • This instrument must be used by professional technicians or trained doctors and experimenters. • The operation and maintenance of the instrument shall be carried out in the specified order. Do not touch other places. • Please do not open the panel, touching the circuit board will damage the IC. • When the instrument is running, please do not touch the reagent card bearing tank. Otherwise, the instrument will be damaged, resulting in the shutdown of the instrument, and may pose a threat to personal safety. • Push all the reagent cards into the reagent card bearing tank until they can not be pushed. When pushing, use your thumb or index finger

to push. Do not use too much force to avoid mechanical failure.

- If the instrument is placed for a long time, dust may accumulate on the surface. Clean the surface with a clean soft cloth or gauze, and use a small amount of detergent if necessary. Cut off the power before cleaning the instrument.
- Please use the instrument under the specified installation conditions.
- Do not make the instrument in the environment of mechanical vibration.
- Do not place heavy objects on the instrument to avoid mechanical damage or performance degradation of the instrument.

2. Product description

2.1 Product Classification

The product is classified according to the classification catalogue of medical devices issued by the State Food and drug administration, and belongs to the clinical test device (classification No.: 22-04-03), and the management category is class II.

2.2 Instrument Model Description

The model of Fluorescent Immunoanalyzer is IFP-3000，I：Immunoassay，F：Fluorescent，P：POCT（point of care testing）。

3. Instrument Introduction

3.1 Summary

- **Brief introduction of the instrument**

IFP-3000 is a small Fluorescent Immunoanalyzer , which is used to analyze the concentrations of various analytes in human samples quickly and quantitatively.

- **Application Scope**

Based on the principle of antigen antibody reaction and Fluorescent Immunoanalyzer, the product is used in combination with the matching reagent produced by our company for the quantitative analysis of the substance to be tested in human samples. It is only for medical laboratory personnel of medical institutions to conduct in vitro diagnostic tests. It can be applied to central laboratory, outpatient / emergency laboratory, clinical department and other medical service center (such as community medical center), physical examination center, etc. of medical institutions, as well as scientific research laboratory.

- **Working principle**

The detected substance in the test sample forms immune complex with the fluorescent labeled antibody, and solidifies in the detection area and the quality control area respectively through the capillary surge process. When the reagent card is

inserted into the Fluorescent Immunoanalyzer detector, the LED excitation light source irradiates the detection area and quality control area of the reagent card, excites the solidified fluorescent immune complex, and the emitted light is collected and converted into an electrical signal. The strength of the electrical signal is strictly related to the number of fluorescent molecules. The detector automatically calculates the content of the detected substance in the test sample according to the scanned signal.

3.2 System Composition

- List of standard accessories

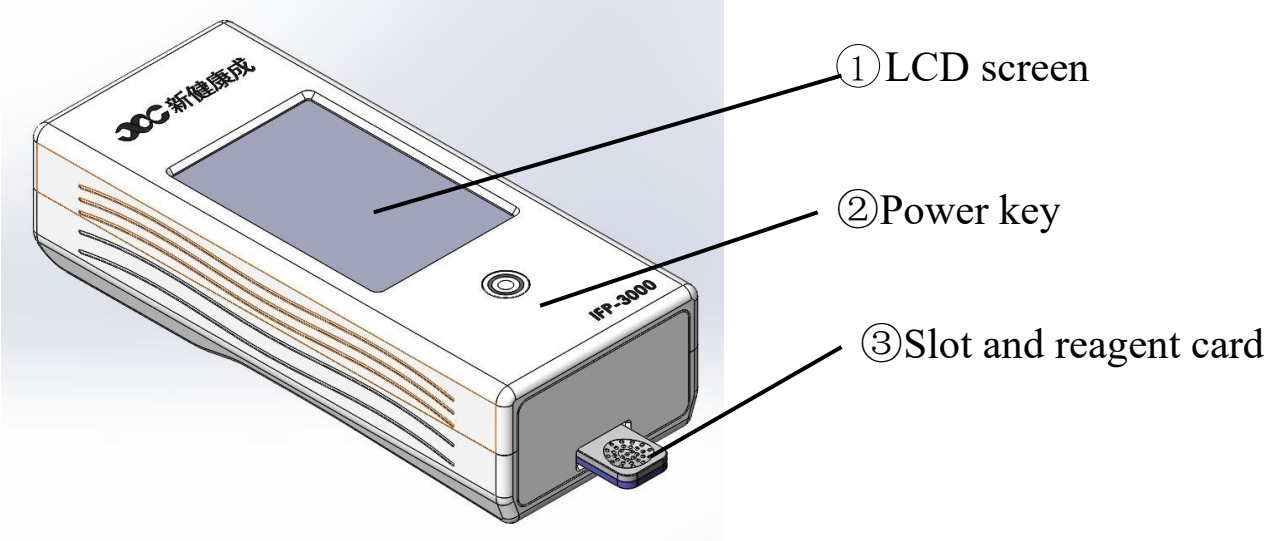
No.	Name	Quantity	Unit
1	Fluorescent Immunoanalyzer	1	set
2	Power adapter	1	set
3	USB cable	1	pc
4	Instruction manual	1	set
5	Warranty card	1	pc
6	Quality certificate	1	pc

3.3 Instrument structure

- **Host part**

The instrument is mainly composed of optical detection module (fluorescence), data processing module, power module and software.

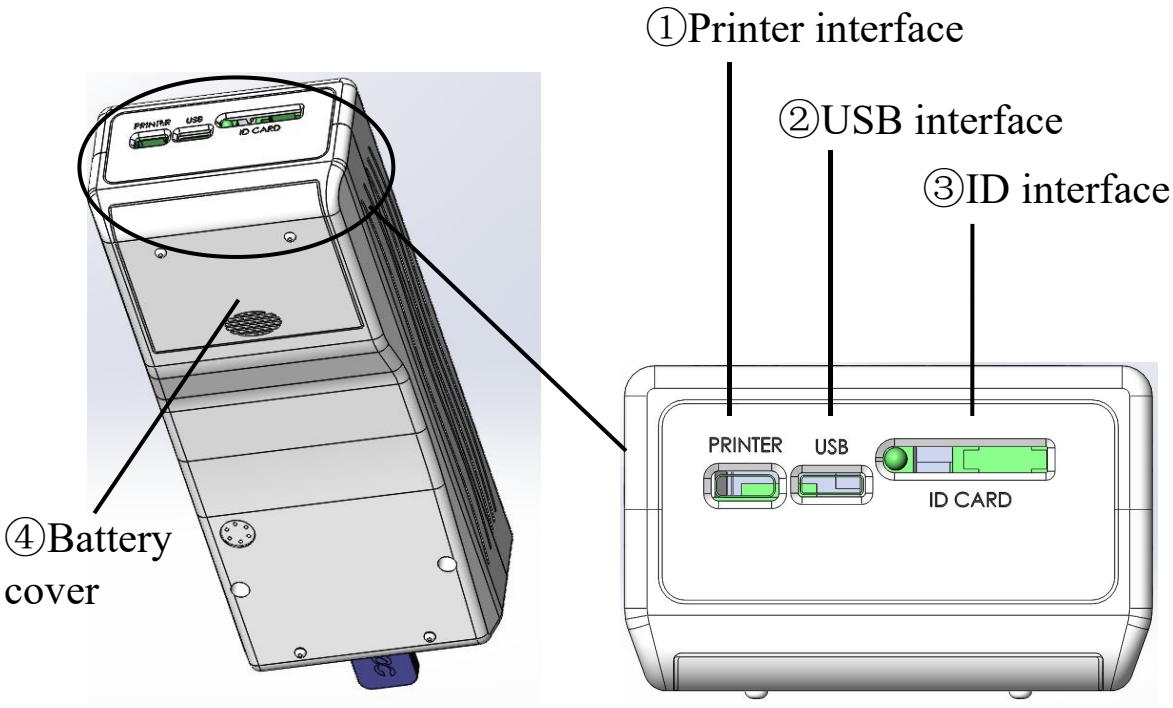
- **Front of instrument:**



As shown in the above figure:

1. LCD screen, human-computer interface.
2. Power key.
3. Card slot: Put the reagent card into manually.

- **Backside of instrument：**



As shown in the above figure:

1.printer interface .

2.USB interface.

3.ID interface.

4. Battery cover and battery installation area.

3.4 Basic parameters of the instrument

Excitation light source: LED

Excitation spectrum: center wavelength λ 0 = 470nm

Receiving spectrum: center wavelength of λ 1 = 525nm

Size: 168mm * 70mm * 44mm (L * W* H)

Weight: about 0.3kg

The shock-proof rating : Level II.

Pollution level: Level 2.

Power supply: Rechargeable lithium battery power supply 3.7V⎓

Adapter input: 110-240V to 50/60Hz 0.3A

Adapter output: 5V 2A (Max)

Waterproof grade: IPX0

3.5 Operation conditions

Ambient temperature: 10 ℃ ~ 30 ℃ (Note: the operating temperature of reagent shall be subject to the instruction)

Relative humidity ≤ 70%

Atmospheric pressure: 86.0 kPa～106.0 kPa

Other conditions: avoiding direct sunlight, violent vibration and strong electromagnetic interference

3.6 Operation steps

3.6.1 Preparation before use

1) Press the power key to start the instrument. the instrument will initialization started, and execute the reset action of the whole machine.

2) The test software starts automatically and enters the test interface automatically.

3) Please refer to the reagent manual for the use and storage of reagents.

3.6.2 Start the test

1)Insert ID card of corresponding item and batch number into ID interface, click “Read ID” to read item information.

2) Put the reagent card which has been added into the sample into the card socket smoothly, and conduct the test according to the software operation guide.

⚠ Be careful:

- If the test item and batch number are the same as the last time, there is no need to insert and read ID card.
- The instrument can only store one ID card information, and reading the new ID card will overwrite the last ID cared

information .

- During the test, reagent card will be moved, do not close to the exit of card slot.
- It is not allowed to operate the software during the test.

3.6.3 Finish the test

1) When the test is finished, take out the reagent card. The results can be viewed by the instrument.

2) Long press the power key to shut down and end the test.

3) The waste produced in the use of the instrument shall be disposed uniformly by professionals in accordance with the regulations on the management of medical waste and other relevant regulations.

3.6.4 Charging

When the instrument indicates that the power is insufficient, please charge it in time. When charging, plug the charging cable into the USB interface of the instrument, the charging indicator light is on, indicating charging is in progress, and the indicator light is off, indicating that the charging is completed.

⚠ **WARING:**

- Through the above operation inspection, if there is any sign that the function of the instrument is damaged or there is an error message, it is forbidden to continue the test, and please contact the after-sales service department of the company.

3.7 Warning tips

The text marked with ⚠ is warning.

3.7.1 Precautions for use place

⚠ WARING：

- Matching power adapter and effectively grounded socket must be used.
- Use of damaged or non-original (modified) power cord may cause fire and electric shock;do not over bend or roll the power cord to avoid fire and electric shock accidents.
- If the instrument is loose or parts fall or damaged, please

contact our company in time.

- Do not use the instrument in unstable environment such as vibration and impact.
- Do not put the instrument in the position where it is difficult to operate the disconnection device.
- There shall be no water or sundries in the instrument. Please contact our company in time if there are foreign matters in the instrument.

⚠ WARNING:

- Avoid using the instrument in the following environments: sunlight; high humidity environment; near water environment; places with vibration and inclination; strong magnetic field environment; places where electromagnetic wave and impulse voltage occur; places where chemicals are kept, places with corrosive gas.
- The instrument shall not be placed near the interference signal source of radio, television, copier, fax machine, etc.
- It shall not be used together with other instruments (such as microwave and other high-frequency equipments to avoid electromagnetic interference and wrong operation.

3.7.2 Precautions during use

⚠ WARNING:

- Before starting the machine, the operator must read the operation manual carefully. The operator must pass the professional training and be familiar with the operation manual and method. The instrument must be managed by a specially assigned person.
- Please set the test parameters under the guidance of professionals.
- When dealing with potential infectious substances (such as human body samples or reagents), if it is possible to contact the skin, protective gloves or other protective measures shall be used.

⚠ CAUTION:

- Confirm whether the instrument is in normal operation before use.
- It is necessary to confirm whether all wires have been connected correctly and safely.
- When using together with other instruments, it is necessary to read and clarify the operation precautions, otherwise there may be dangerous, please pay attention.
- The instrument shall be used correctly by professional

operators, and personnel other than non-professional operators shall not use the instrument.

- Shut down after the test.

3.7.3 Precautions for failure, storage and inspection

⚠ WARNING:

- In case of any abnormal condition of the instrument, the use shall be terminated immediately. In case of smoke and burning smell, there is a risk of fire and electric shock if you continue to use. Please shut down immediately and contact our company or distributor immediately.
- Except for the company's maintenance personnel and the company's authorized maintenance personnel, other personnel are not allowed to dismantle, modify and repair the instrument. If there is any violation, the company will not be able to carry out normal maintenance and repair of the instrument, and the company will not bear any responsibility for the possible personal injury and fire and electric shock risk.

⚠ CAUTION:

- The instruments and components shall be inspected regularly. In case of damage, crack and other abnormal conditions, please inform the company to repair or replace them.

- Clean the surface of the instrument with clean soft cloth and non-corrosive detergent to prevent scratching the instrument shell and panel.

3.7.4Electromagnetic compatibility precautions

⚠ WARNING:

- This instrument is designed and tested according to class A equipment in GB 4824. In the home environment, this equipment may cause radio interference, so protective measures shall be taken.
- It is forbidden to use the equipment beside the strong radiation source (such as the unshielded RF source), otherwise it may interfere with the normal operation of the equipment.

⚠ **CAUTION:**

- The user has the 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.

4. Software operation guide

4.1 Login interface

The instrument is operated by lightly touching the display.

When the device is powered on for the first time or restored to factory settings, it will enter the login interface by default.

(1) In the login interface, you need to enter the following user name and password.

User name:admin

Password:888888

(2) Enter the correct user name(admin) and password(888888) in the login interface, and click "login" to enter the test interface;

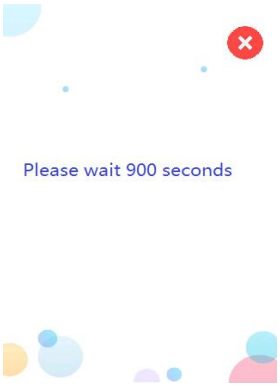
4.2 Test interface

(1) Test interface description

- **More:** Click More to enter the patient name, gender, and age information, as shown below:

- **Sample type:** Choose sample type whole blood or serum/plasma according to the test item;

- **Standard test:** After clicking the standard test, you will enter the standard test interface, the instrument will display the countdown time; you can click the "×" in the upper right corner to interrupt the current test item and return to the main test interface, as shown in the following figure:



- **Quick test:** After clicking quick test, the current test item will be tested immediately (please make sure that the reagent card is in place and the reaction time is correct);

- **Read ID:** After inserting the ID card, the current ID card information can be read correctly. If the ID card is not inserted, it will prompt: Please insert the ID card;
- **Return:** Return to the main interface, this button cannot be clicked during the test.

(2) Test mode and test process

➢ **Standard test procedures:**

a. Take out the reagent card and add the processed sample into the sample hole of the reagent card.

b. Put the reagent card into the reagent card slot.

c. Click "Standard Test" and the instrument enters the countdown.

d. After the countdown, the instrument will automatically start scanning the reagent card information and calculate the test results.

e. After calculating the result, the result will be saved automatically and displayed in the interface.

f. Print the results.

g. Take out the reagent card.

h. Repeat if the next test is required.

i. Press and hold the power key to shut down after the test.

➢ **Quick Test steps:**

a. Take out the reagent card and add the processed sample into the sample hole of the reagent card, and start timing and wait for

sample reagent reaction.

b. After the reaction time required by the instruction manual, put the reagent card into the reagent card slot.

c. Click "Quick Test" and the instrument will automatically start scanning the reagent card information and calculate the test results.

d. After the test, the instrument starts to calculate the test results.

e. After calculating the result, the result will be saved automatically and displayed in the interface.

f.Print the results.

g. Take out the reagent card.

h. Repeat if the next test is required.

i. Press and hold the power key to shut down after the test.

- **Test results**

After the test is completed, the interface will automatically pop up the test result interface, you can click Back to close the interface. If you choose to “print on”in the instrument settings, the printer will print the result directly(Bluetooth or the cable).

4.3 The main interface

Click the back button in the test interface to enter the main interface .The main interface Includes Test, History and Settings. Click each module to enter the corresponding interface.

4.4 History interface

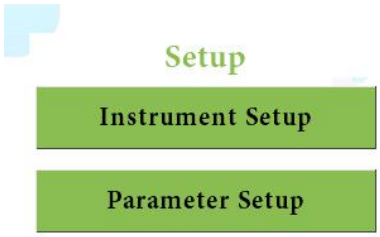
The instrument saves the test results and provides the function of querying, retrieving and printing the historical test results. Steps to view historical data:

- Click "History" in the software interface.
- The details of the test items can be found on the previous page or the next page.
- The record of the current page can be printed by clicking print.

If you configure the Lis Set correctly, click the cloud button, the data will upload to PC

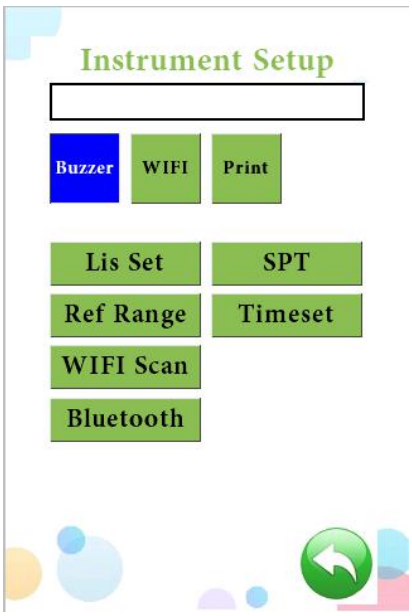
4.5 Setup interface

Click “setup” in the main menu to directly enter the Setup menu, as shown below.



(1) Instrument Setup

Click “Instrument Setup” in the Setup menu to directly enter the Instrument Setup interface. The setting includes Lis Set ,Ref Range ,WIFi Scan,Timeset, etc.



- **Buzzer:** When the buzzer is turned on, in the standard test mode, the buzzer will prompt when the test time is up. If the

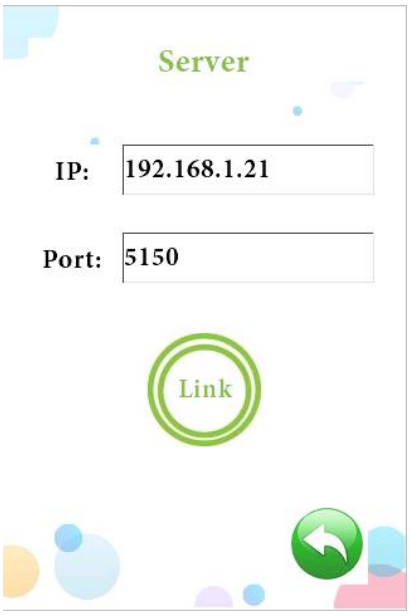
buzzer is turned off, the buzzer will not sound when the standard test time is up;

- **WIFI:** The button can control the network (WIFI/Bluetooth) in the instrument on or off;
- **Print:** After the print is turned on, the external printer (the printer is correctly connected to the PRINTER interface or the printer link to the Bluetooth correctly) will automatically print the test results after the test is over.

- **Bluetooth/WIFI Scan:** Turn on the WIFI or click the WIFI scan/ Bluetooth directly and choose the right name to connect to the network.

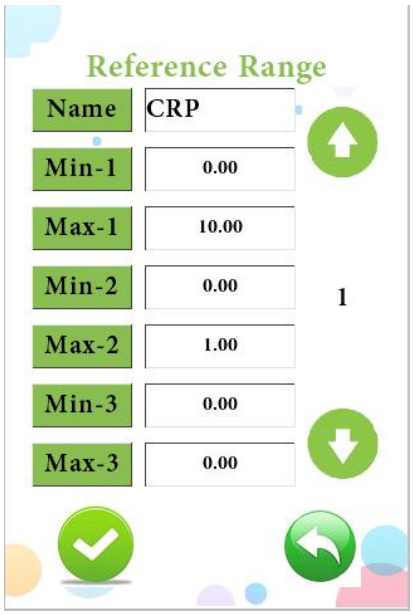
- **Lis Set:** When the WIFI network is configured correctly, Input the correct IP and port, then the test data could upload

to the PC (Make sure the PC and the instrument are on the same Lan).



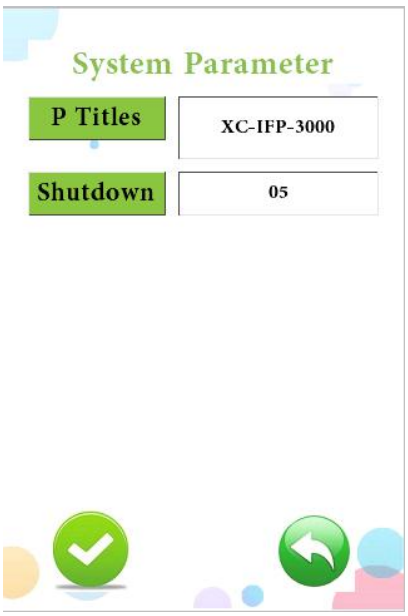
- **Ref Range:** Set the reference range supported by current test item. When the test result is not within the reference range, the test result will be prompted ↑↓ in the printed information. If the current test item contains two sub-items, the Min-1 corresponds to the lower limit of the reference value of ID card sub-item 1, and the Max -1 corresponds to the upper limit of the reference value of ID card sub-item 1. Min-2 corresponds to the lower limit of the reference value of ID card sub-item 2 and the Min -2 corresponds to the upper limit of the reference value of ID card sub-item 2; if there are three sub-items in the test item, the analogy follows. As

shown in the figure below: the reference range of sub-item 1 is 0-10, and the reference range of sub-item 2 is 0-1.



Note： The instrument has nine configurations by default.

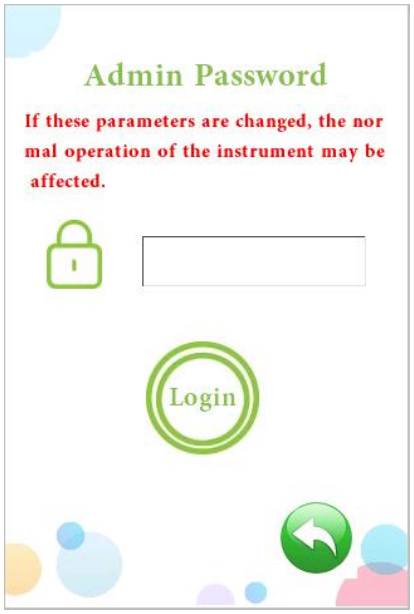
- **SPT:** Click the SPT button to set the print header and automatic shutdown time. When the shutdown time is set to 99, it means never shutdown.

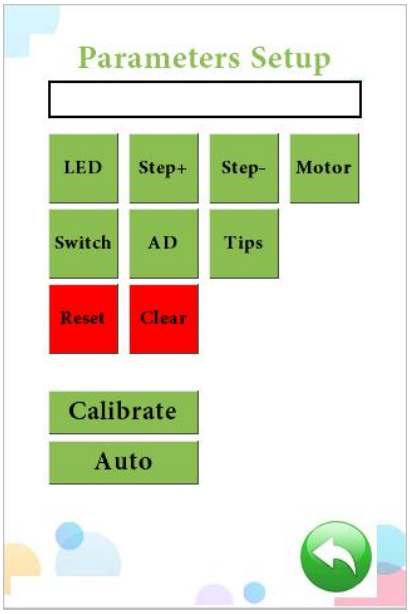


- **Timeset:** Click the Timeset button in the setting interface to enter the set time interface, enter the time that needs to be set, and click "√" to set successfully. Clicking the return button will not save the current set time. Set the current time as shown below the time is 4:08 pm on December 15, 2021

(2) Parameter Setup

Click “Parameter Setup” in the Setup menu to directly enter the Admin Password interface, and input the setting password (666666) to successfully enter the Parameters Setup interface. The setting includes setting LED, setting Motor setting Switch, setting Calibrate, etc.





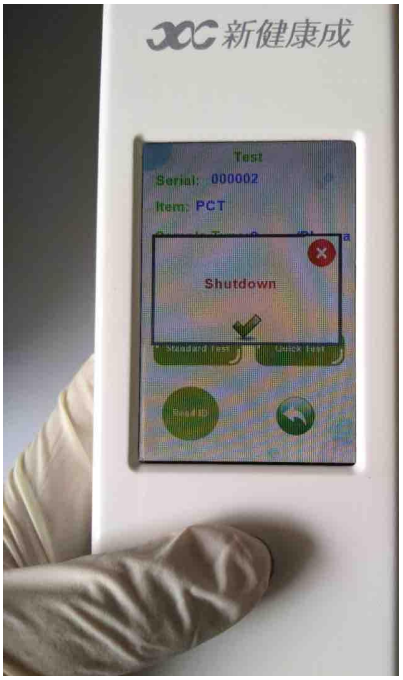
- **LED:** The button can control the LED in the instrument on or off;
- **Step + / step -:** Button are used for production.
- **Motor:** Button are used for production.
- **Switch:** Turn on or off the reagent card detection function
- **AD:** Buttons are used for production ;
- **Tips**: Turn on or off the prompt(Check the Barcode!!!)
- **Auto:** Buttons are used for production.
- **Reset:** Click the reset button to restore to factory settings;
- **Clear:** Click the clear button to clear the current historical data information;
- **Calibrate**: The parameters(offset/Gain/Base/MF)are used for instrument production. If the parameters are modified, it may affect the use of the instrument.

- **Auto:** Buttons are used for production.

Note： The blue background prompts when the setting item is turned on. The red background setting item is executed, it will be prompted whether to confirm the execution, click "√" to perform this operation. Click “X” to not perform this operation.

4.6 Shut down

After the test, press and hold the power button (about 5 seconds) to pop up the shutdown prompt box and select "√" to shut down.



5. Maintenance

5.1 Daily Maintenance

After the daily clinical test, the external surface of the instrument shall be thoroughly scrubbed with inorganic laboratory disinfectant and rag.

⚠CAUTION	• Strong bleach (> 0.5% solution) can not be used, because oxidants and solvents may damage the analyzer's shell and touch screen. • It is not allowed to scrub any internal devices and internal surfaces of the instrument.

5.2 Regular Maintenance

The instrument does not provide an automatic maintenance process. Maintenance shall be performed with the instrument power off. The bearing tank area of the reagent card should be scrubbed regularly to prevent splashing liquid residue.

6. After sales service

6.1 services and destruction

Dear user:

Thank you for purchasing Sichuan Xincheng Biological Co., LTD Fluorescent Immunoanalyzer . You can get the following services provided by our company:

Provide technical consultation at any time.

The complete machine's maintenance is free of charge for one year from the date of purchase. During the warranty period, if the fault is caused by the design and manufacturing defects of our company, it will be repaired free of charge. All components of the equipment can only be inspected and provided by our company or designated agent.

Provide paid services for:

- Products that is out of the warranty period (free warranty period of one year, recommended service life of five years).

- Damage caused by not using according to the instructions.
- Damage caused by unexpected factors and improper use.
- The damage caused by self-repair without the permission of our company.

With the improvement of technology, our company will provide the upgrading service of the analyzer. If you need service or repair, please call 400-6550770 028-87822789

If the user wants to destroy the instrument for any reason, it is recommended that the user destroy the instrument according to the regulations of class B electronic instrument.

6.2 Common Faults and Treatment of Instruments

Fault phenomenon	Reason Analysis	Elimination method
The entire device cannot be powered on	Low power	Connect the charger for charging.
	Software failure	Contact the maintenance department
The display screen does not start	Screen line failure	Contact the maintenance department
	White screen or flashing screen or failed to power on: low battery power	Please charge in time
	No response of touch screen: the	Restart required

	host computer and LCD screen are not synchronized	
	Operating system problems	Contact the maintenance department
Software system failure	Operating system malfunction	Contact the maintenance department
	Test analysis software cannot be started	Contact the maintenance department
	Other prompts appear during the running of the test analysis software	Please record the complete error message code and error message prompt, and then contact the maintenance department
Abnormal sound during the test	The carrier tongue may be stuck	Restart the test unit,let it reset automatically and start working again
Abnormal sound during the test	Mechanical motion failure	Please contact the maintenance department
The test process suddenly stopped	It may be that the power supply of the tester is interrupted	Reopen the analyzer switch and retest
	There is a communication failure	Reopen the analyzer switch and retest
	The problem still exists	Contact the maintenance department

Abnormal test results	Abnormal measurement results	Contact the maintenance department
Other faults	When other faults occur	Please contact the after-sales service department in time

6.3 Transportation and Storage of Instruments

Transportation

- The analyzer shall be transported in the packaging state. During the transportation, the analyzer shall be placed horizontally, and shall be protected from severe collision, rain and exposure to the sun, and shall not be stored with corrosive materials.
- Transportation environment temperature is -20 ℃ ~ 55 ℃, relative humidity ≤ 93%, atmospheric pressure: 86.0kpa ~ 106.0kpa.
- Transport packages contain fragile products, so handle them with care. Once the package is exposed to rain, it will completely deteriorate or be damaged.
- It is not allowed to roll the transport package.
- The number of stacking layers shall not exceed 5.

Storage

- The indoor environment temperature is -20 ℃ ~ 55 ℃, relative humidity ≤ 93%, atmospheric pressure: 86.0kpa ~ 106.0kpa.

- During storage, the objects directly contacted by the packing box shall be and clean without oil pollution, dust and other pollution.
- The number of stacking layers shall not exceed 5.
- No chemicals, corrosive gases and well ventilated environment.

6.4 Description of Electromagnetic Compatibility and Risk Warning

The Fluorescent Immunoanalyzer has passed the electromagnetic compatibility test and meets the requirements of GB /T 18268.26-2010 electromagnetic compatibility requirements of electrical equipment for measurement, control and laboratory use Part 26: special requirements in vitro diagnostic (IVD) medical equipment and GB / T 18268.1-2010 electromagnetic compatibility requirements of electrical equipment for measurement, control and laboratory use part 1: General requirements.

The following requirements shall be strictly followed in use, otherwise electromagnetic interference may be caused to other equipment or the anti-electromagnetic interference ability of the Fluorescent Immunoanalyzer may be reduced, or even the basic performance may be lost.

This equipment is designed and tested according to group I class B equipment in GB 4824-2013. In the home environment, this equipment may cause radio interference, and precautions need to be taken.

Description of portable and mobile radio-frequency communication equipment that may affect medical electrical equipment: portable and mobile radio-frequency communication equipment may affect the normal operation of the Fluorescent Immunoanalyzer . It shall be ensured that the portable and mobile radio-frequency communication equipment and the Fluorescent Immunoanalyzer meet certain space distance. See Table 4 for specific requirements.

Warning 1: In addition to the cables sold by the manufacturer of the equipment or system as the spare parts of the internal components, the use of accessories and cables other than those specified may lead to the increase of the emission or decrease of the immunity of the equipment or system.

Warning 2: The equipment or system shall not be close to or stacked with other equipment. If it must be close to or stacked, it shall be observed and verified that it can operate normally in its used configuration.

Warning 3: It is forbidden to use the equipment near the strong

radiation source, otherwise it may interfere with the normal operation of the equipment.

6.5 Network Security Instructions

6.5.1 Data Interface

1. The instrument transmits data with the outside through USB interface.

2. The instrument can access the external thermal printer through USB interface, and the instrument can transfer data to the external printer for printing correctly.

6.5.2 User Access Control

Before using the instrument, you need to enter the correct user name and password to log in to work properly.

Appendix

Table 1

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</td></tr>
<tr><td colspan="3">The Fluorescent Immunoanalyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment</td></tr>
<tr><td>Launch experiment</td><td>Compliance</td><td>Electromagnetic environment — Guide</td></tr>
<tr><td>Radio frequency emission
GB 4824</td><td>1 set</td><td>The Fluorescent Immunoanalyzer uses radio frequency energy only for its internal functions. Therefore, its radio frequency emission is very low, and the possibility of interference to electronic equipment is very small</td></tr>
<tr><td>Radio frequency emission
GB 4824</td><td>A Class</td><td rowspan="3">The Fluorescent Immunoanalyzer is suitable for all facilities that are not household and not directly connected to the residential public low-voltage power supply network for domestic use.</td></tr>
<tr><td>Harmonic emission
GB 17625.1</td><td>Not applicable</td></tr>
<tr><td>Voltage</td><td>Not applicable</td></tr>
</table>

fluctuation / Flashing emission GB 17625.2		

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
The Fluorescent Immunoanalyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment			
Immunity test	IEC 61326 Test Level Guidelines	Coincidence level	Electromagnetic environment — Guide
Electrostatic discharge GB / T 17626.2	± 4 kV contact discharge ± 8 kV air discharge	± 4 kV contact discharge ± 8 kV air discharge	The floor should be wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%
Electrical fast transient pulse group G	± 1 kV to power line	± 1 kV to power line	The grid power supply should have the quality used in a typical commercial or hospital environment

B / T 17626.4			
surge GB / T 17626.5	± 1 kV line-to-line ± 2 kV line to ground	± 1 kV line-to-line ± 2 kV line to ground	The grid power supply should have the quality used in a typical commercial or hospital environment
Voltage dips, short interruptions and voltage changes on the power input line GB / T17626.11	0% UT for 1 cycle (on Ut , 100% dip) 40% UT, continued 5 cycles (Ut , the 60% of sag) 70% UT, continuous 25 cycles (Ut , the 30% of sag) 5% UT, sustained 5S (in Ut , the 95% of sag)	0% UT for 0.02s 40% UT for 0.1s 70% UT for 0.5s 5% UT for 5 s	The grid power supply should have the quality used in a typical commercial or hospital environment. If the user of The Fluorescent Immunoanalyzer needs to run continuously during the power interruption, it is recommended that the LuxScan Dx24 microarray scanner be powered by an uninterruptible power supply or battery
Power frequency magnetic field (50 /	3A / m	3A / m	If abnormal operation occurs, it is necessary to keep Fluorescent Immunoanalyzer away from the power frequency magnetic

60Hz) G B / T 17626.8			field or install a magnetic shield in the place. The power frequency magnetic field in the intended installation site shall be measured to meet the requirements below the compliance level.
Note: In the voltage sag and short-term interruption test, UT refers to the AC grid voltage before the voltage is applied, one cycle is 20ms .			

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity			
The Fluorescent Immunoanalyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment			
Immunity test	IEC 61326 test level	Coincidence level	Electromagnetic environment - guide
			Portable and mobile RF communication equipment should not be closer to any part of the Fluorescent Immunoanalyzer than the

Radio frequency conduction GB / T 17626.6 Radio frequency radiation GB / T 17626.3	3V (effective value) 150 kHz to 80 MHz 3 V / m 80 MHz to 2.0 GHz	3 V (effective value) 3 V / m	recommended isolation distance. Use including cables. The distance should be calculated using the formula corresponding to the transmitter frequency. Recommended isolation distance d = 1.2 d = 1.2 80 MHz to 800 MHz d = 2.3 800 MHz ～2.0 GHz In the formula: P—— The maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W). d—— Recommended isolation distance, in meters (m). The field strength of a fixed RF transmitter is determined by surveying a of the electromagnetic site, and each frequency range b should be lower

			than the compliance level. Interference may occur near equipment marked with the following symbol 
Note 1 : At 80 MHz and 800 MHz , the formula for the higher frequency band should be used. Note 2 : These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.			
a Fixed transmitters, such as: wireless (cellular / cordless) telephones and terrestrial mobile radio base stations, amateur radios, AM and FM radio broadcasts, and television broadcasts, the field strength of which cannot be predicted theoretically accurately. To assess the electromagnetic environment of fixed RF transmitters, surveys of electromagnetic sites should be considered. If the measured field strength of the Fluorescent Immunoanalyzer is higher than the above RF compliance level, the LuxScan Dx24 Fluorescent Immunoanalyzer should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorienting or relocating the Fluorescent Immunoanalyzer. b In the entire frequency range from 150 KHz to 80 MHz , the field strength should be less than 3 V / m .			

Table 4

Recommended isolation distance between portable and mobile RF communication equipment and Fluorescent Immunoanalyzer			
The Fluorescent Immunoanalyzer is expected to be used in an electromagnetic environment where radio frequency radiation disturbance is controlled. Depending on the maximum output power of the communication equipment, the purchaser or user of the Fluorescent Immunoanalyzer can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication equipment (transmitter) and the Fluorescent Immunoanalyzer			
Maximum rated output power of transmitter W	Isolation distance corresponding to different frequencies of transmitter / m		
	150 KHz to 80 MHz d = 1.2	80 MHz to 800 MHz d = 1.2	800 MHz to 2.0 GHz d = 2.3
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	twenty three
For the maximum rated power of the transmitter not listed in			

the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the transmitter provided by the transmitter manufacturer Maximum rated output power in watts (W) .

Note 1 : At 80 MHz and 800 MHz frequency points, the formula for the higher frequency band should be used.

Note 2 : These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.

[Basic Information]

Name of registrant / manufacturer: Sichuan Xincheng Biological Co., LTD

Address: No. 101, Tianxin Road, Hi-tech Zone, Chengdu, Sichuan, China

After sales service company: Sichuan Xincheng Biological Co., LTD

Contact:

Tel: 0086-28-87822789, Fax:0086- 28-87822689

Zip code:611731 http：// www.xinchengbio.com

Production address:2nd Building (excluding room 1-6 and 1-9) and 1st floor of 3rd Building,No.101,Tianxin Road,High-tech Zone,Chengdu,Sichuan,China

EC REP European Representative:CMC Medical Devices & Drugs S.L

Tel：+34951214054

Fax：+34952330100

Address:C/Horacio Lengo N° 18, CP29006,Málaga-Spain

Term of validity: five years