

Immunofluorescence Analyzer

Operation Manual


Model: FIA-680

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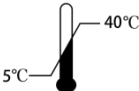






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Index of Symbols

Read all contents of this Manual carefully prior to use.

 If the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

The following symbols are used on the Immunofluorescence Analyzer, related components and accessories, labels or in the text of this user manual:

	Caution
	Consult Operator's Manual
	WEEE (Waste Electrical and Electronic Equipment)
	Keep Dry
	Operation Temperature Limitation
	Storage and Transportation Temperature Limitation
	Keep away from Sunlight
	For <i>in vitro</i> Diagnostic Use only
	Manufacturing Date
	Serial Number
	Catalogue Number



Manufacturer



Authorized Representative



Direct current



Magic Biotech



The Detection Apparatus model



Not to be tipped



Stacking layers Limitation



The Way Up



Fragile

Section I *Intended Use and Principle*

Intended Use:

The Detection Apparatus and instrument are for in vitro diagnostic use only. This instrument is suitable for laboratories with professional testing ability in medical institutions, such as central laboratory, door/emergency laboratory, clinical department and physical examination center.

Immunofluorescence Analyzer is equipped with a built-in Detection Apparatus Holder. The Detection Apparatus Holder will appear through the opening on the front surface of the instrument.

The Power ON/OFF Switch, located on the left of the instrument, which powers the Immunofluorescence Analyzer. The instrument has a built-in printer.

This instruction is developed, designed, manufactured and sold by Magic Biotech Corporation, the instrument is compact, portable, and easy to operate for fluorescence detection to quantify concentration of various kind of analytes in veterinary blood, urine or feces.

This instruction for use introduces the performance and related information of the product, and contains graphical procedures for your convenience. Please refer to the instruction for use before testing.

Test Principle:

Immunofluorescence Analyzer uses an LED as the Excitation Light Source. The emitted light from the fluorescence microspheres is collected and converted into an electrical signal with the help of photosensitive receiver. The signals are closely related to the amount of fluorescing dye molecules present on the spot under examination.

After a sample is applied to the Detection Apparatus, the Detection Apparatus is inserted into **Immunofluorescence Analyzer** and the concentration of the analyte is calculated by a pre-programmed calibration process. **Immunofluorescence Analyzer** can only accept Detection Apparatus that are designed specifically for use with this instrument. The Detection Apparatus are disposable, so there is no need to worry about the cross infection.

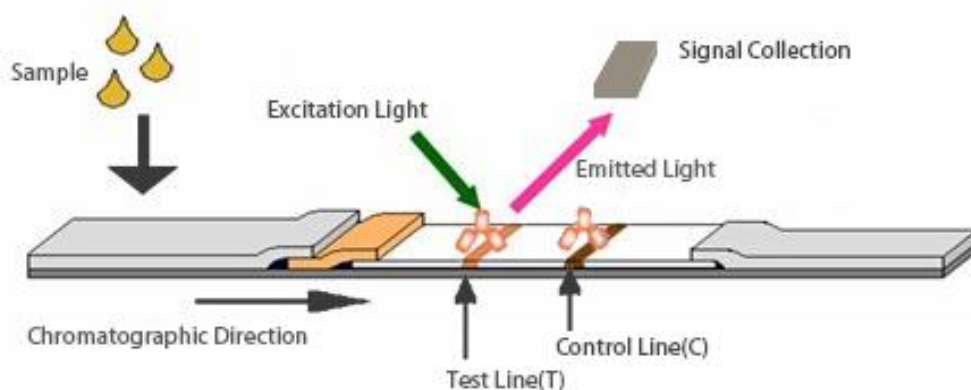


Figure 1.1 Working Principle

High resolution, narrow band SMD LED was used as light source in the **Immunofluorescence Analyzer**.

The central wavelength λ_0 of the excitation spectrum is 365 nm. The response band of photosensitive receiver is 320-1000nm, central response wavelength is 610nm, sensitivity is 0.4, the Photometric linearity and accuracy were shown as below:

Spectral response

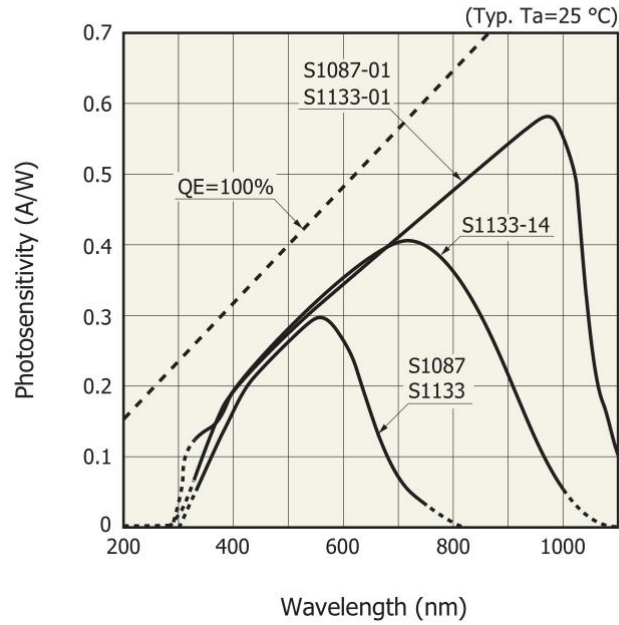


Figure 1.2

Unpacking

After opening the package box, please check to ensure that the content listed below are included.

If any item is missing, please contact your sales distributor or **Magic Biotech**.

Detailed contact information is mentioned in **Section K**

Contents

1. Standard contents:

No.	Name	Quantity
1	Immunofluorescence Analyzer	1
2	Power adapter for instrument (including the power cord)	1
3	Printer paper (roll)	1
4	Operation manual	1
5	Certificate of qualification	1
6	Warranty card	1
7	Packing list	1

2. Materials required but not provided

- Detection Apparatus: rapid quantitative detection reagent (immunofluorescence chromatography)



Figure 2.1 Structure Chart of Immunofluorescence Analyzer- Front View



Figure 2.2 Immunofluorescence Analyzer Features - Back View

Power switch, Ethernet Port, USB Interface, Serial Interface, Power interface.

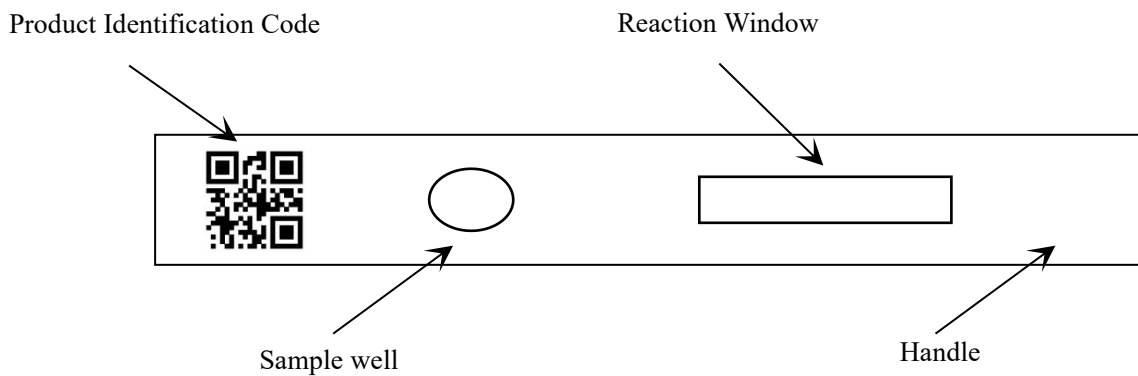


Figure 2.3 Detection Apparatus Features
(Remark: You shall purchase the Detection Apparatus separately)

Section III Specifications and Operation Conditions

Basic Specification

Model No.	FIA-680
Excitation light source	LED
Excitation spectrum	Center wavelength $\lambda_0 = 365\text{nm}$
Absorption spectrum	Center wavelength $\lambda_1 = 610\text{nm}$
Test Specimen	Whole blood, serum, plasma, urine and feces
Interface	Serial Port, USB, Ethernet network
Built-in Printer	Thermal printer
Size	280*240*130mm \pm 5mm
Weight	<2kg
Repeatability	CV \leq 15%
Stability	CV \leq 15%

Operating Environment

Temperature	5°C~40°C (41°F~104°F)
Humidity	10%~80% (No condensation)
Atmospheric pressure	700hPa~1060hPa
Power supply voltage	AC100-240V
Power supply frequency	50/60Hz
Power Input	24 VA
Location	Dry, clean, flat, horizontal surface, with the front surface at least 10 cm inside of the table edge, away from direct sunlight, mechanical vibration, and strong electromagnetic interferences.

Storage and Transportation Environment

Temperature	-10°C~+50°C
Humidity	\leq 85%

Performance (In an example of cCRP)

Precision	CV \leq 10%
Accuracy	Relative Deviation \leq 10%

Section IV Initial Installation Procedure

1. Power Requirements

Immunofluorescence Analyzer will work on household power line. If you are uncertain of your power line, consult with your utility manager. The **Immunofluorescence Analyzer** can only be used with the power adapter (including the power cord) provided. If the replacement for Power Adaptor is required, please consult with your sales distributor or **Magic Biotech** .

2. Installation

Please be noted that **Immunofluorescence Analyzer** should only be used at 5°C~40°C (The recommended operational temperature of Detection Apparatus is 25°C) and Relative Humidity of 10%~80% conditions (Detailed information is mentioned in **Section III**).

- ①. Connect the **Power Cord** with **Immunofluorescence Analyzer** to the wall power outlet.
Note: The meter shall be connected to a mains socket outlet with a protective earthing connection. The mains outlet shall be located in a user accessible position for easy unplugging in emergency. The mains plug of the power cord set is a disconnect device of the instrument. In order to completely disconnect the instrument from the supply mains, the mains plug of the power cord set should be unplugged from the mains outlet.
- ②. Press and hold **Power ON/OFF Switch** about 3 seconds of **Immunofluorescence Analyzer** to carry out power startup and shutdown. (See **Figure 4. 1**)

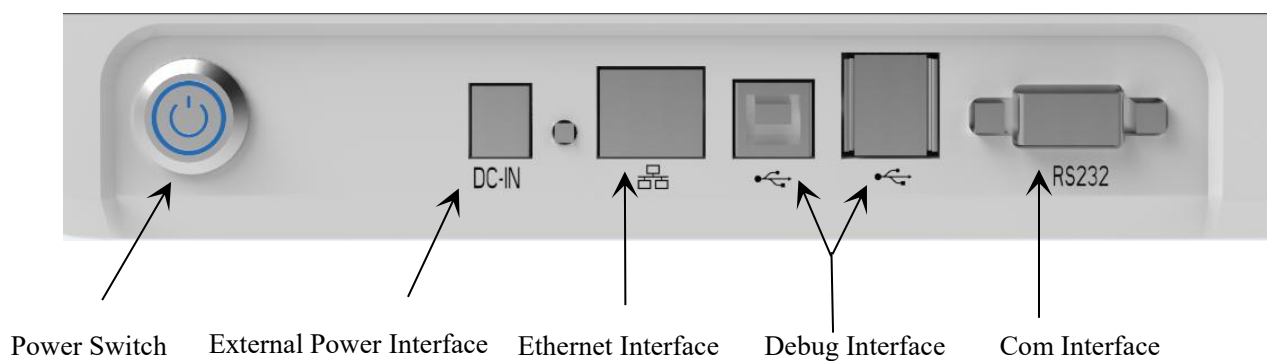


Figure 4.1

***Caution:**

Keep the power cord for the **Power Adapter** in suitable place. Power cord without good maintenance could render hazardous to connect/disconnect the **Power Adapter**.

Section V Operation Instruction

Immunofluorescence Analyzer provides two test modes, including **Standard Test** and **Fast Test**. Under the standard test mode, the instrument as an incubation place reaction of test item to provide required standard countdown. Under the fast test mode, the test item should be completed incubation prior, the user can directly conduct testing.

Immunofluorescence Analyzer can be operated through LCD screen with finger touch or touch pen, also can be operated through with a mouse and keyboard.

V.1 Start

V.1.1 Press and hold **Power ON/OFF Switch** about 3 seconds of **Immunofluorescence Analyzer**. (See **Figure 5.1**)

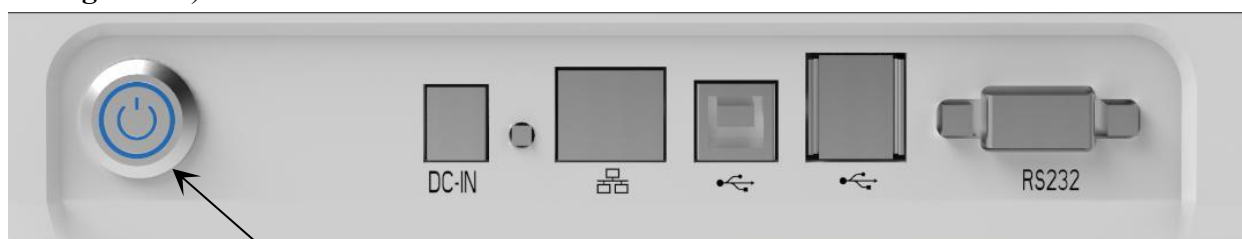


Fig 5.1

V.1.2 The instrument will load the test system.

V.1.3 Waiting for about 10 seconds, the instrument will show the initial screen.

V.1.4 **Fast Test** interface will be showed by default when you turn on **Immunofluorescence Analyzer** at the first time. After that, the power-on interface will show the test mode, which was selected by the user when the instrument was turned off last time. (See **Figure 5.2**)

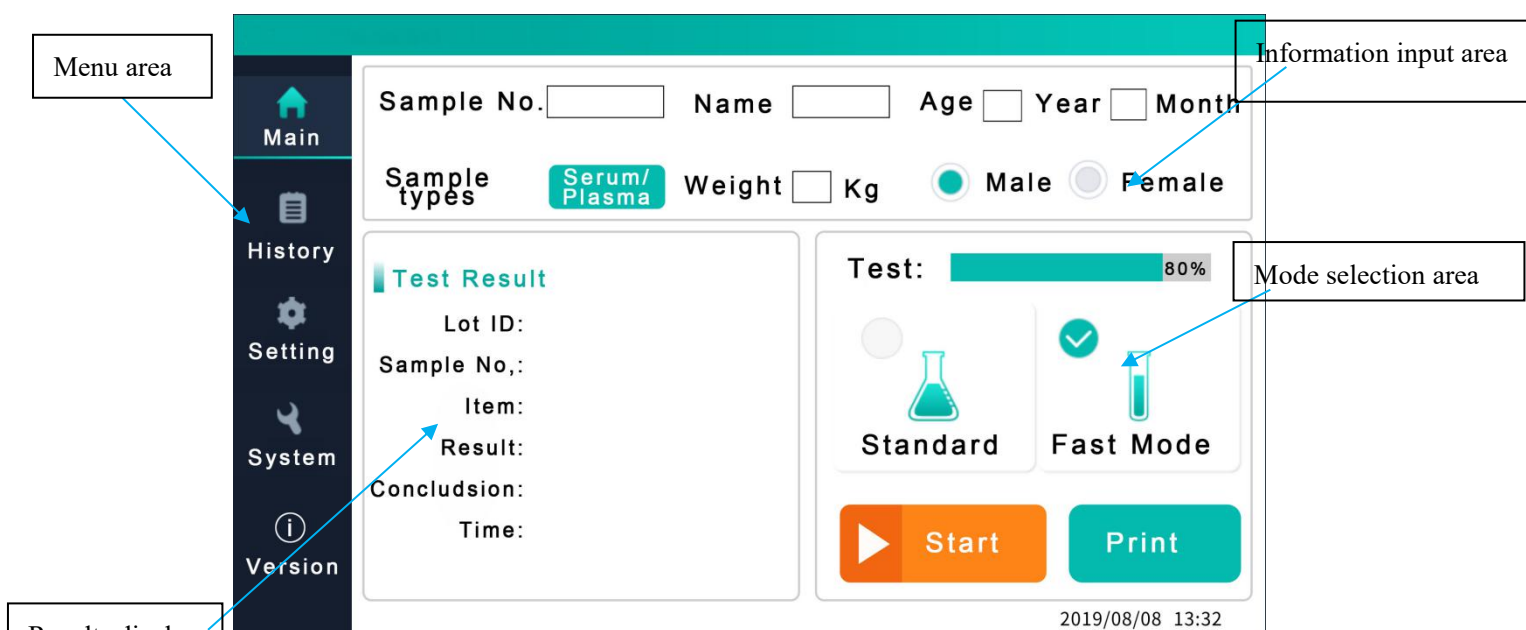


Fig 5.2 Fast Test interface

Menu area - Touch the button to achieve the corresponding function.

Information Input area - Input Sample number and Sample type.

Results Display - Display test Lot number, item, test results and reference range.

Pattern selection area - Choose test mode.

The functions of menu area from top to bottom as following:

【Main】 To carry out testing of test item.

【History】 Inquire historical record.

【Setting】 Conduct relevant Settings such as time, instrument LIS, WIFI and etc.

【System】 reagent management, instrument self-check, maintain.

【Version】 System version.

***Caution:**

*If the initial interface doesn't show after more than 3 minutes please turn off the **Power** and restart the instrument. If failure continues, please contact your sales distributor or Cervino Corporation.*

V.1.5 Software version

Click “Version” to show the current software version (See **Figure 5.3**)

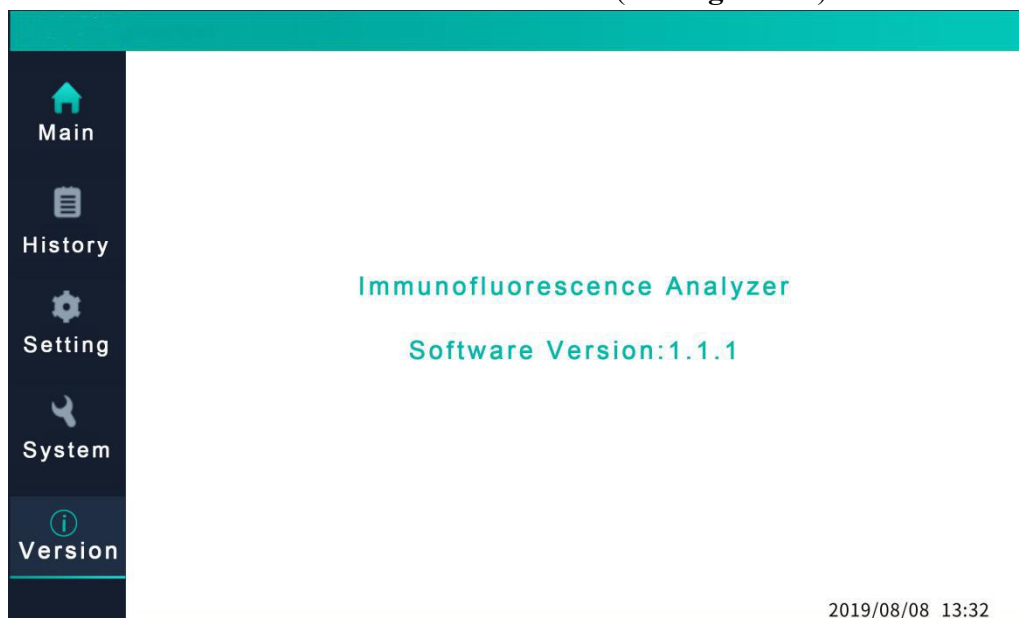


Figure 5.3

V.2 Test Operation

Please insert the ID card of corresponding test item before clicking “**Main**”, Under the initial interface of **Immunofluorescence Analyzer**.

Immunofluorescence Analyzer enter the initial test interface after booting, you can freely choose “Standard Test” mode or “Fast Test” mode according to different needs. (See **Figure 5.4**)

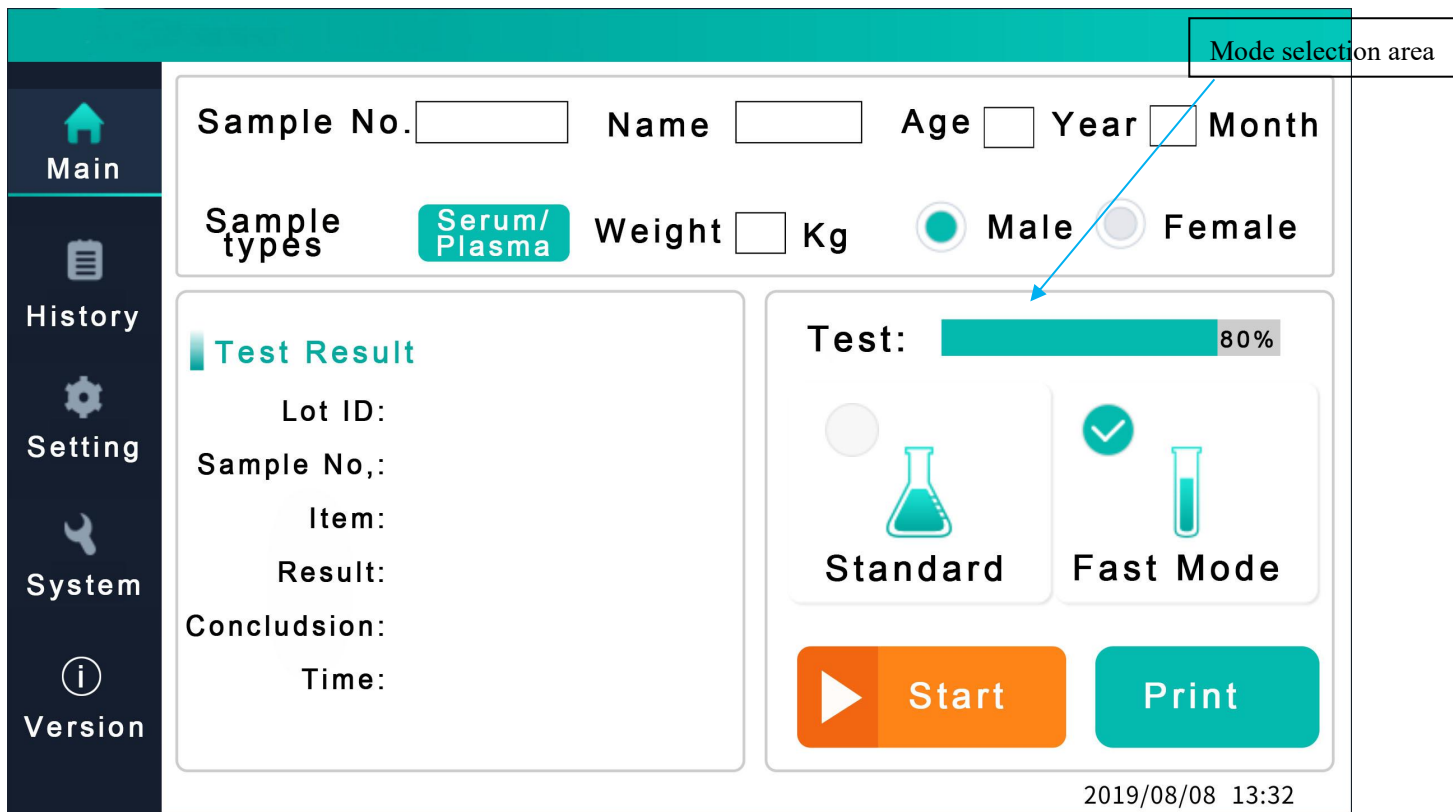


Figure 5.4

***Caution:**

It is recommended to insert ID card after successful boot!

Operation steps:

2.1 Choose Test mode (**Standard Test** or **Fast Test**).

2.2 Input basic patient medical information, including sample number and sample type and etc. (The serial number will be automatically generated by system). (see **Figure 5.5**)

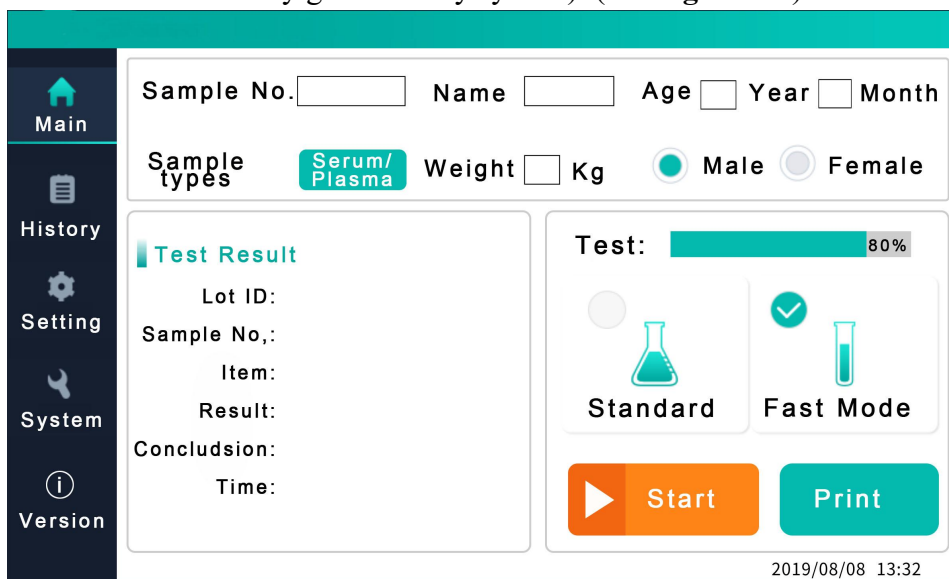


Figure 5.5

2.3 According to Instruction for Use of specific Detection Apparatus, it is possible to add sample to the

buffer first and mix well.

***Caution:**

Please carefully read relevant Instruction for Use of specific Detection Apparatus before adding sample to test, and operate the test according to requirements.

2.4 Prepare a Detection Apparatus and apply sample or sample-buffer mixture onto the sample well of Detection Apparatus (Refer to the Instruction for Use of specific Detection Apparatus).

2.4.1 If you choose **Fast Test** at step 2.1, insert the Detection Apparatus that is completely reacted into the Detection Apparatus Holder of **Immunofluorescence Analyzer**, and click “**Start**”.

2.4.2 If you choose **Standard Test** at step 2.1, immediately insert the Detection Apparatus into the Detection Apparatus Holder of **Immunofluorescence Analyzer**, and click “**Start**”.

2.5 Immunofluorescence Analyzer will scan and analyze the reagent card automatically, collect data and analyze the test results.

***Caution:**

If the lot number of the **ID card** does not match with the lot number of the Detection Apparatus when use the specific Detection Apparatus at the first time, the instrument will show “**Lot ID mismatch**”. Please check the lot number of ID card and Detection Apparatus if they are mismatched.

2.6 The test result will be showed under the “Result” of the screen. (See **Figure 5.6**)

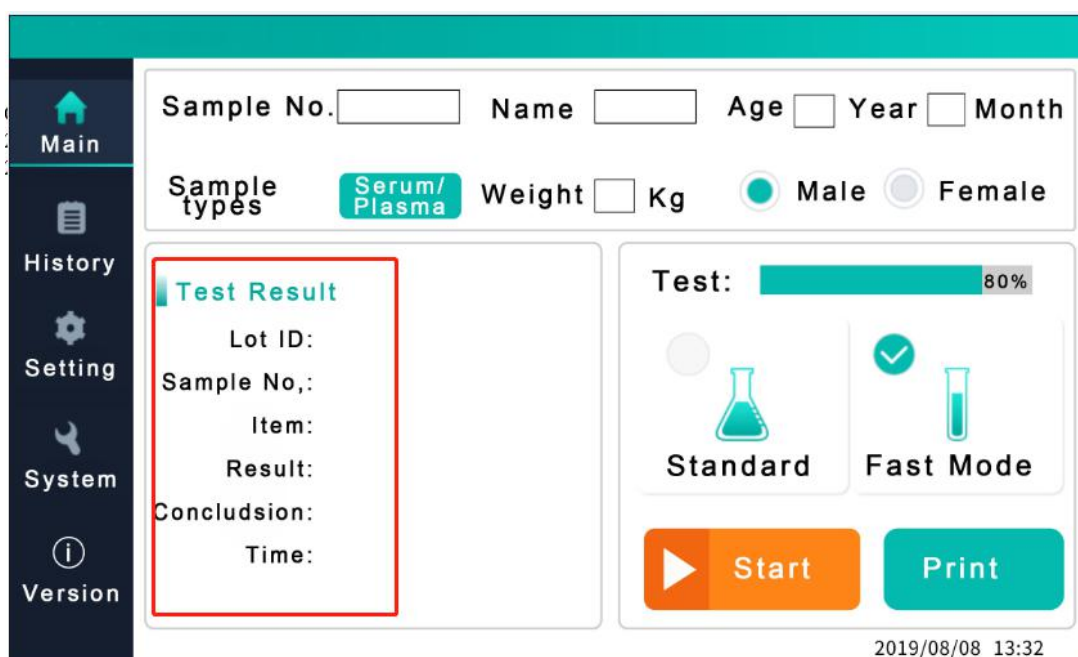


Figure 5.6

2.7 Click “**Print**” to print the test result.

***Caution:**

The test result will be printed automatically after ticking “**Print automatically**”.

2.8 Take out the reagent card. Insert the next reagent card that is completely reacted for the next testing.

2.9 When the screen show main page and testing is not executing, insert **ID card** and **Immunofluorescence Analyzer** will read and keep the ID card information.

***Note:**

Caution: If the Lot No. is tested at the first time, then users should insert the ID-card and read it before test, after this, users don’t need to read the ID-card when they test the Detection Apparatus of the same Lot No. Users can also pre-read the ID-card whenever they like: Insert the ID-card, when the analyzer reads the information from ID-card successfully, users do not need to read ID-card when they test the Detection Apparatus of the same Lot No. Afterwards.

V.3 History record Operation

“**History**” function provides the user with a function of conditional filter, view the history of test records. There are Search, Delete and Print buttons to carry out operation of query, delete and print test results under the interface of “**History**”.

3.1 Click “**History**” on the left of the instrument to enter the query interface, the test results will be listed. (See **Figure 5.7**)

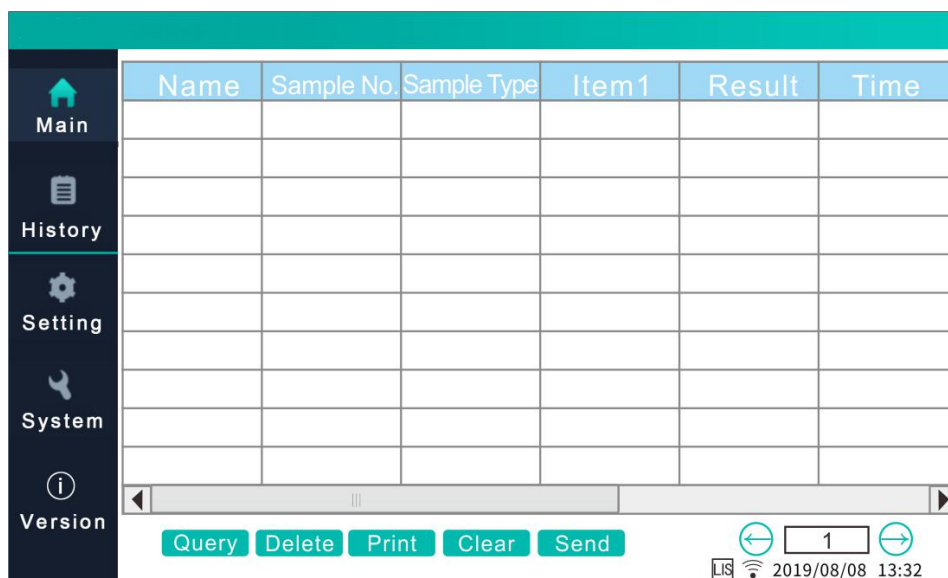


Figure 5.7

3.2 Click “**Query**” under the “**History**” interface, then input the search conditions, Immunofluorescence Analyzer will filter out the test results that match the search conditions to conduct fuzzy query.

3.3 Tick a specific data record, click “Delete” under the “History” interface, the selected records can be deleted.

3.4 Tick a specific data record, click “Print” under the “History” interface to print a selected record.

3.5 Click “Clear” under the “History” interface, Immunofluorescence Analyzer will delete all of recorded saved.

3.6 In the case of the LIS system was connected, select specific data record, click “Send” under the “History” interface to send test result to LIS system.

V.4 Setting Operation

“Setting” function provides the user with setting function for the machine function parameters, including Time setting, LIS setting, temperature control setting, item parameters setting and WIFI setting

4.1 Time setting: Users can set the time of the analyzer here. (See **Figure 5.8**)

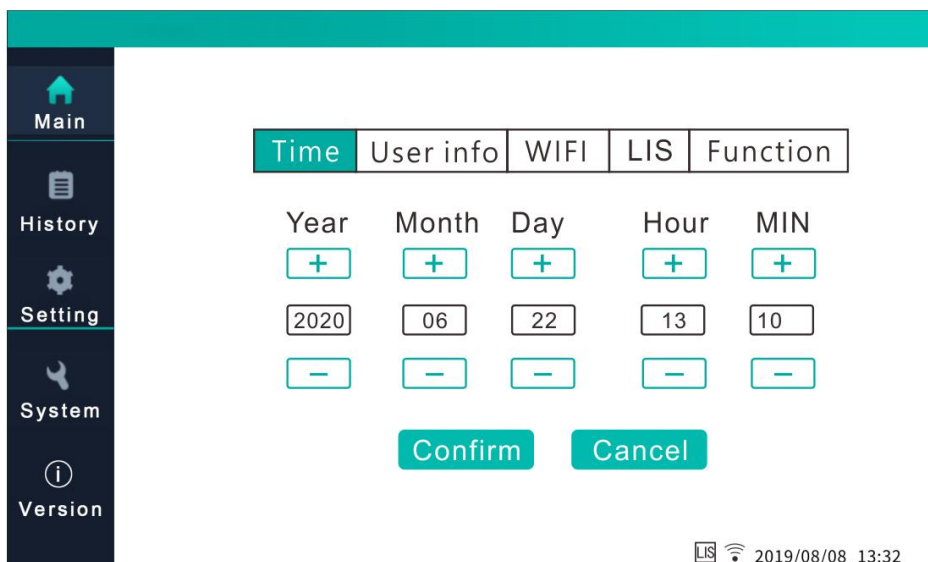


Figure 5.8

4.2 User info setting: In this page, user can input the tester’s information; the information will be print into the test report.

4.3 LIS setting: The instrument can be connected to LIS server through network cable. After setting up the server and the local IP address and port, the data can be transferred to the server. See section XI for details.

4.4 WIFI setting: the users search for and connect to nearby WIFI. WIFI is used to send the information to the server finally.

4.5 Function setting: setup the “Auto Print”,” Beep” and etc.

V.5 System function

System functions can provide instrument information, reagent management and software update, firmware update and instrument self-test and other functions.

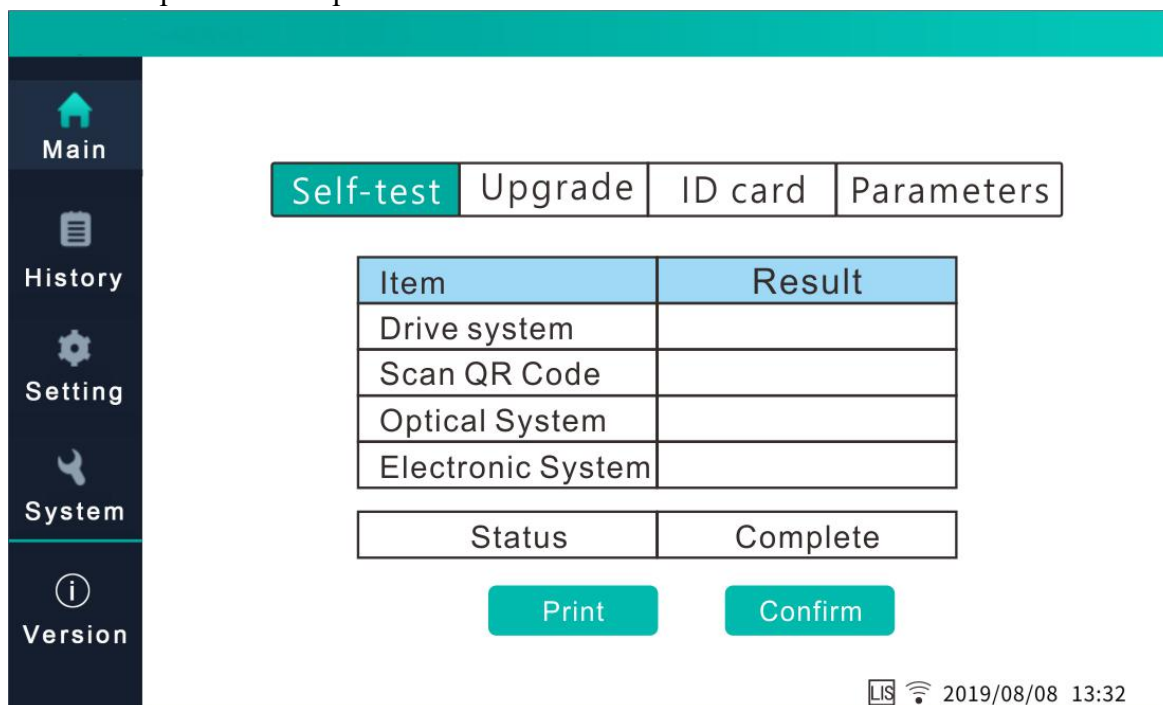
***Note:**

Caution: This function is only available to administrators. Please keep your password carefully.

5.1 Instrument self-test: The users can self-test the transmission system, Barcode system, optical system and circuit system of the instrument and print the self-test results

- **Self-test step:**

1. Insert the quality control card, press “Start” button.
2. The analyzer will display the self-test result, after test.
3. Users can press “Print” button to print the self-test result. The analyze will print the self-test result if the “Auto print” be setup.



5.2 Update: Software updating, Skin updating, Font updating, etc.

- **Software updating:**

1. Put the update file into the USB flash drive from PC.
2. Insert the USB flash drive into the analyzer.
3. Click “firmware updating” button, it can automatically complete the updating, restart the machine is ok after updating.

- **Skin updating**

1. Put the new skin files into the USB flash drive from PC.
2. Insert the USB flash drive into the analyzer.
3. Click “skin updating” button, it can automatically complete the updating, restart the machine is ok after updating.

- **Font updating**

1. Put the new font files into the USB flash drive from PC.
2. Insert the USB flash drive into the analyzer.
3. Click “font updating” button, it can automatically complete the updating, restart the machine is ok after updating.

5.2 Reagent management: Click “ID card” on the top of the instrument to enter the interface, the users can view and delete local saved ID card information.

Select the particular ID card information, press “Delete” button, then the selected ID card

information will be deleted.

Click the “Clear” button, then delete all of the ID card information saved.

This section introduced the operational instruction of **Immunofluorescence Analyzer** connect with server.

VI. 1 Outline

Transfer Protocol Instruction:

Immunofluorescence Analyzer sends data to outside by TCP/IP, click “**LIS**” when the test is completed every time, the current test data will be sent out.

Preset initial IP address of **Immunofluorescence Analyzer**: 192.168.0.2

Preset initial subnet mask of **Immunofluorescence Analyzer**: 255.255.255.0

Preset initial default gateway of **Immunofluorescence Analyzer**: 192.168.0.1

Preset initial receiving IP of PC (server): 192.168.0.88

Subnet mask of PC: 255.255.255.0

Default gateway of PC: 192.168.0.1

PC port: 50000

VI.2 Immunofluorescence Analyzer to connect with server system (PC port).

LAN (Local Area Network) (This method is recommended)

Use a standard network cable that can make normal PC access the Internet, connect one end of the network cable to the **Immunofluorescence Analyzer**'s Ethernet port, connect the other end to the Laboratory LAN (Insert LAN devices such as router and switchboard etc.). (See **Figure 6.1**)

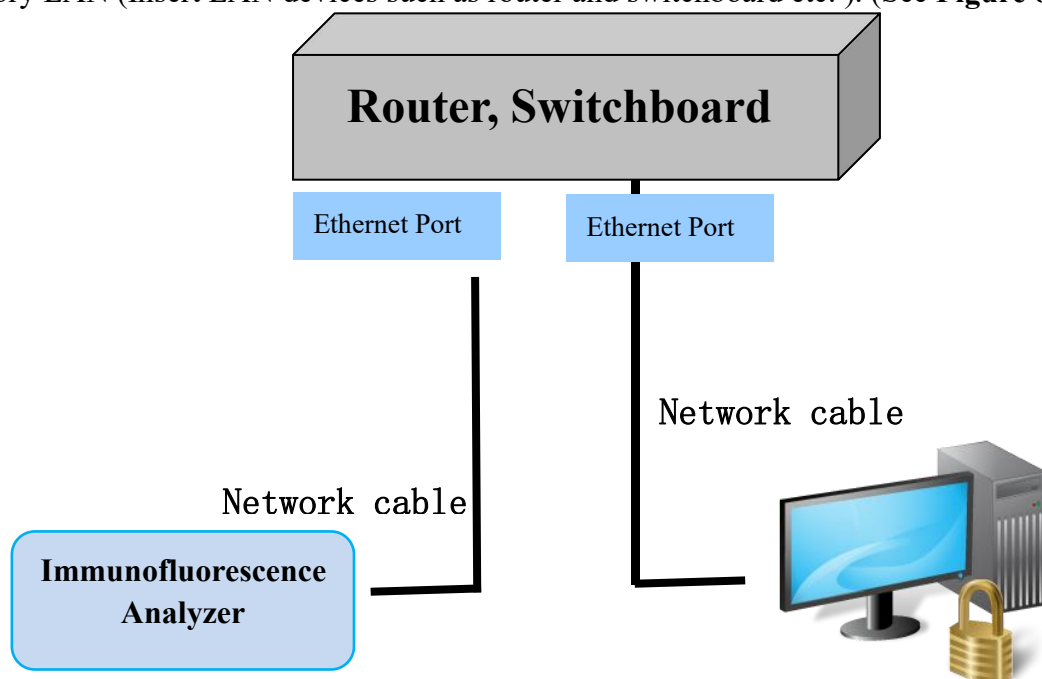


Figure 6.1

Click “Start” -> “Routine”-> “Attachment”-> “Communication”-> “Network”; double click “local connection” and enter to “Local Area Connection Status”.

Don't change primary IP address of PC. Example: Primary IP address: 192.168.1.6.

1) Click “Advanced”, enter to “Advanced TCP/IP settings” (See **Figure 6.2**)

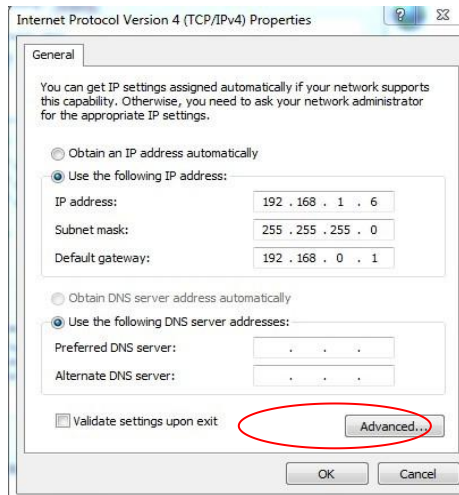


Figure 6.2

2) Click “Add” under “IP address”, enter to “TCP/IP address”. (See **Figure 6.3**)

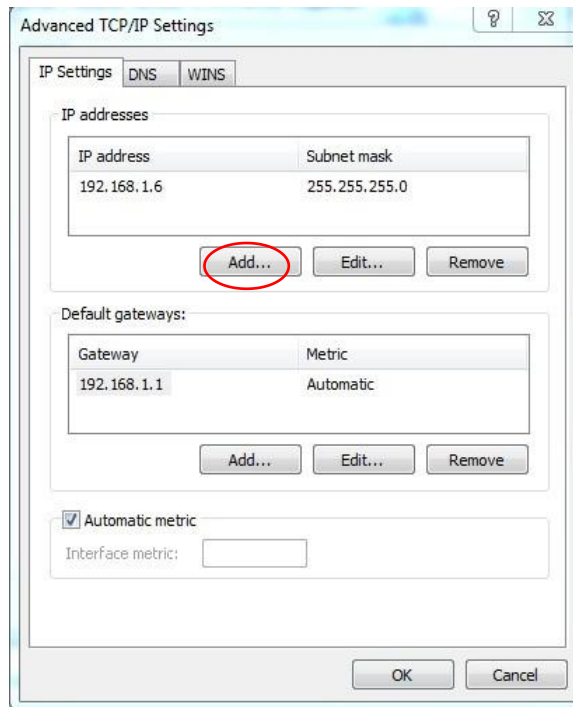


Figure 6.3

3) Add IP address: 192.168.0.88, Subnet mask: 255.255.255.0. After inputting the IP address and the Subnet mask, click “Add” to return to “Advanced TCP/IP setting” (See **Figure 6.4**)

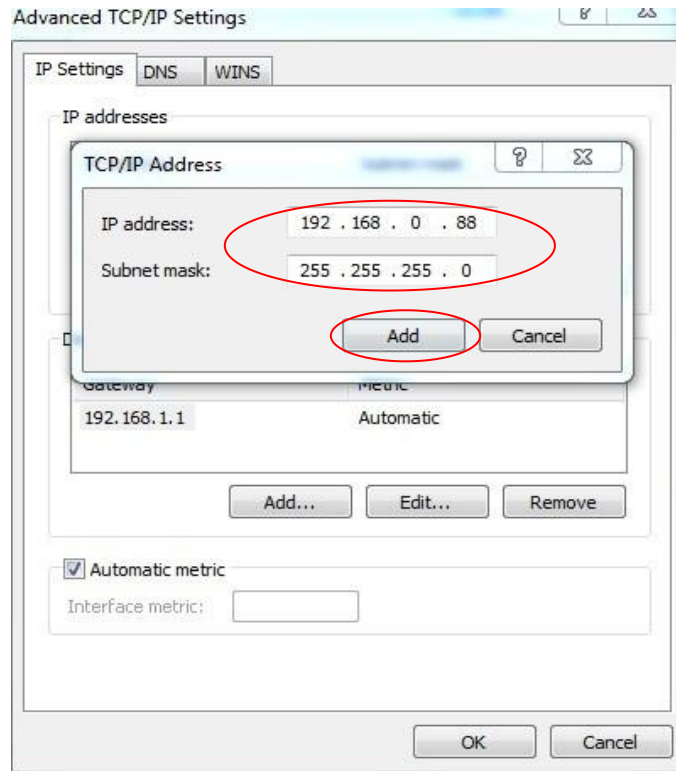


Figure 6.4

5) Click “Add” under “Default gateway”, enter to “TCP/IP Gateway Address”. (See Figure 6.5)

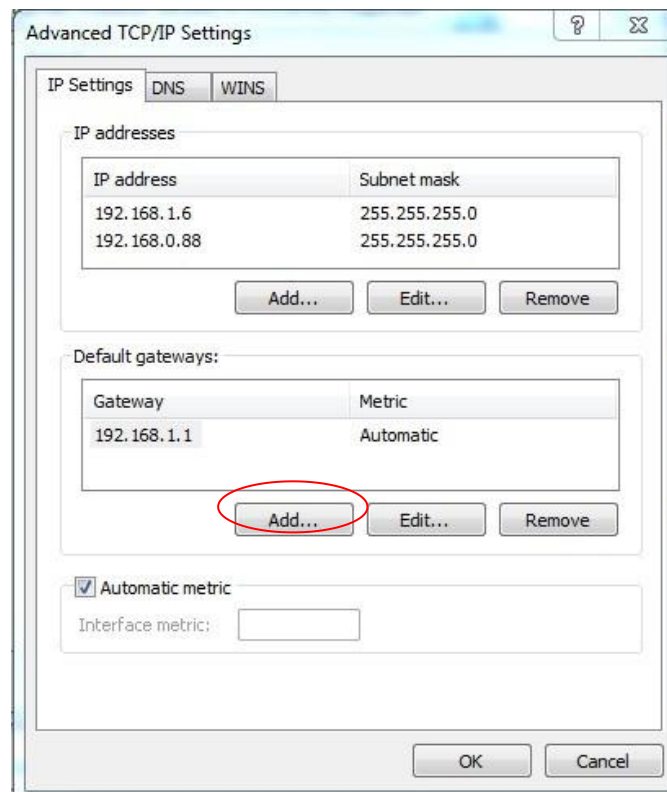


Figure 6.5

6) Input Gateway: 192.168.0.1, click “Add” after finishing, return to “Advanced TCP/IP settings”. (See

Figure 6.6)

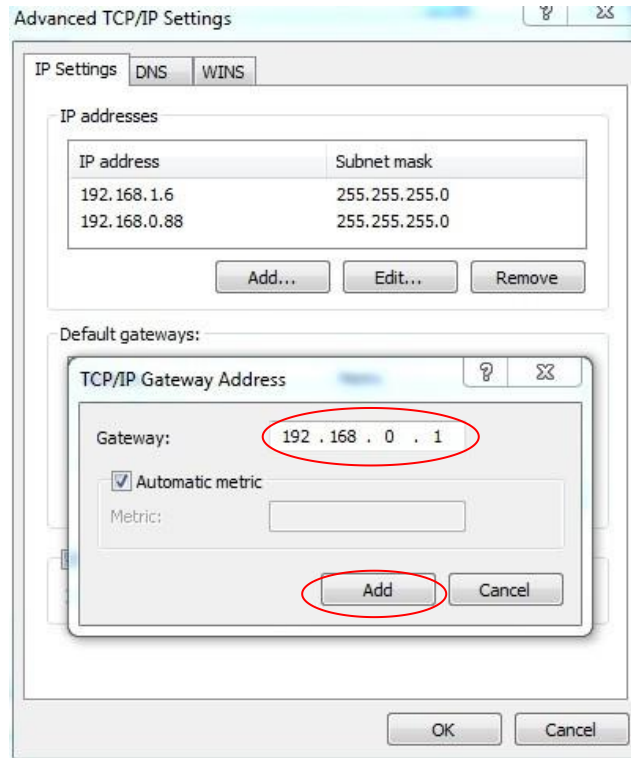


Figure 6.6

7) Click “OK”, return to IP address setting menu, then click “OK” to exit IP setting, run the corresponding server software on the computer after setting successful. (See Figure 6.7)

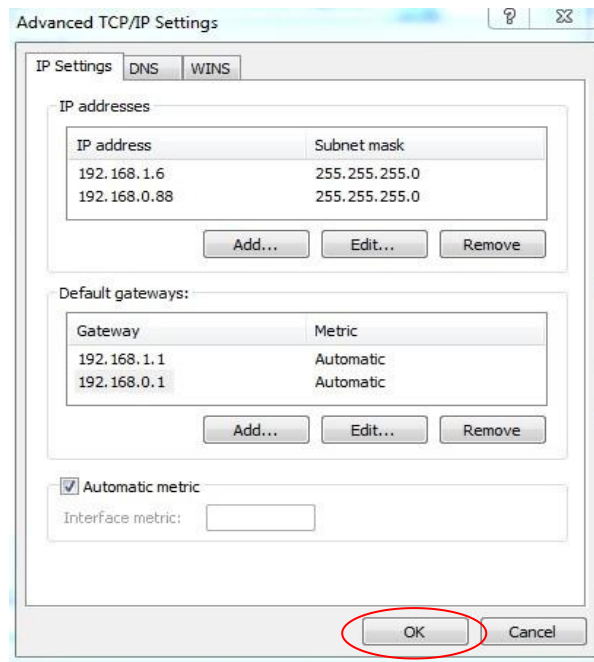


Figure 6.7

VI.3 Instrument terminal IP setting steps

1) Enter "LIS Settings" interface, input the corresponding IP address with computer: "192.168.0.88"and

port number: 50000.

- 2) The Immunofluorescence Analyzer can access the corresponding LAN port through the network cable. So far, IP and port Numbers of PC port and instrument port have been set up. After each successful test, the immunofluorescence analyzer will automatically send the current test results to the computer (on condition that the LIS system is connected). The user can also select to send records in the history and click send. The receiving software of the server will receive the corresponding test result.

Section VIII Warning, Precautions and Limitations

Caution in using the Detection Apparatus

- The test sample should be applied to the Sample well, as shown in **Figure 2.3** of **Section II**.
- When inserting the Detection Apparatus into the **Detection Apparatus Holder**, orient the Detection Apparatus in such a way that the Sample well should be upward, and Product Identification Code toward **Immunofluorescence Analyzer**.
- Push the Detection Apparatus all the way into the Detection Apparatus Holder until the Detection Apparatus comes to a stop. Push the Detection Apparatus holder by only using your thumb or the index finger. Don't use excessive force on the Detection Apparatus, or it will result in a mechanical failure.
- The used Detection Apparatus should be treated as a potential bio-hazard and should be disposed according to the local standard procedures and relevant regulations observed by microbiological hazard materials. We recommended high temperature autoclaving by incineration.
- Gloves, masks and other protective measures should be used when handling potential infectious materials.

Caution in Use with the Immunofluorescence Analyzer

- Do not insert anything other than a Reagent Card provided by the manufacturer into the Detection Apparatus Holder.
- Do not spill any liquid on **Immunofluorescence Analyzer**. This may disable the system.
- Do not drop or crash **Immunofluorescence Analyzer**.
- Do not subject **Immunofluorescence Analyzer** to mechanical shocks heavier than light taps with hands.
- Do not dismantle **Immunofluorescence Analyzer** without written authorization from Magic Biotech or its representative.
- Do not place heavy objects on **Immunofluorescence Analyzer**. This may damage the optical alignment to result in degraded performance or in mechanical damage.
- The mains outlet for **Immunofluorescence Analyzer** shall be located in a user accessible position for easy unplugging in emergency.
- Please make sure power outlet properly grounded. Improper grounding may cause electrical shock and systematic damage.
- Use only the **Power Adapter** (including the power cord) provided with **Immunofluorescence Analyzer**.
- Use **Immunofluorescence Analyzer** only in environment as specified in **Section III**.
- **Immunofluorescence Analyzer** malfunction due to maintenance, processing or transporting damage, please contact customer service representative.
- Use the test result as a pre-screening guide. The result should be interpreted by trained medical

personnel only.

- The Immunofluorescence Analyzer shall be operated by professional person.
- If the **Immunofluorescence Analyzer** is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

Cautions should be taken to use **Immunofluorescence Analyzer in Settings meeting the requirements specified in **Section III** of this manual and in observance of the warning in **Section VII**. Otherwise, the built-in safety features of **Immunofluorescence Analyzer** may be compromised to present severe electrical, mechanical or biological hazards to the user.*

Section VIII Service, Maintenance and Disposal

If any service or maintenance were to be required, **Immunofluorescence Analyzer** should be sent to Magic Biotech. No Special maintenance other than paper replacement and periodic cleaning is required for the instrument. Occasional cleansing of the exterior with a mild-dry cloth is sufficient to assure the instrument operation. The instrument shall be separated from mains supply prior to cleaning.

External cleaning

Use a damp cloth with 0.5% bleach, 70% isopropyl alcohol or 70% ethanol to clean the external surface of instrument. To prevent damages of screen or other surface device, strong bleach (bleach concentration more than 0.5%), oxidizing substances and solvents are prohibited.

Decontamination

If the instrument needs maintenance or replacement after clinical use, decontamination and **disinfection** should be done before repacking and transporting. Use disinfectant (e.g. bleach concentration lower than 0.1%) and a cloth to scrub external surface of instrument completely. To prevent damages of inner devices, spray-washing or clean any internal parts and inner surface with disinfectant is prohibited.

Maintenance

In addition to regularly cleaning or replace paper, **Immunofluorescence Analyzer** generally does not require special maintenance, with a soft, dry cloth to wipe the external surface of the instrument to ensure the normal operation of **Immunofluorescence Analyzer**.

***Caution:**

Instrument does not contain any serviceable components by operator. To avoid electric shock, regular maintenance must be executed by authorized technical service personnel.

Power Supply

Use only the AC/DC power supply provided with the instrument. In case the power adapter needs replacement, you should contact **Magic Biotech** or its designated representative.

Return Procedure

If **Immunofluorescence Analyzer** happened to malfunction, please contact **Magic Biotech** or the local distributor at first. If it was determined that the unit will be returned to the manufacturer, a return authorization number will be issued, then **Magic Biotech** will send an **Immunofluorescence Analyzer** for replacing. The user is expected to utilize the packaging supplies accompanying the replacement to ship the malfunctioning unit in. Verify the return authorization number on the package and send the unit to **Magic Biotech** upon receiving the replacement **Immunofluorescence Analyzer**.

Transporting and storing

The original shipping container should be used to ship or transport **Immunofluorescence Analyzer**. The original shipping container is also recommended for storing **Immunofluorescence Analyzer** over an extended period. When transporting or storing **Immunofluorescence Analyzer**, keep it dry in upright position and protect it from sun, mechanical shocks, transportation requirements according to an order under the contract.

Immunofluorescence Analyzer should be stored in a well-ventilated room that has storage temperature of -10°C~50°C, relative humidity is less than 85% and no corrosive gas.

Disposal

Any spent Detection Apparatus should be disposed according to local ordinances regarding the disposal of bio-hazardous materials.



WEEE (Waste Electrical and Electronic Instrument)

This symbol for the marking of electrical and electronics devices is according to the Directive 2002/96/EC. The Immunofluorescence Analyzer, accessories and the packaging have to be disposed of waste correctly at the end of usage. Please follow Local Ordinances or Regulations for disposal.

Section IX *Trouble Shooting*

Phenomena	Probable Cause	Recommended Measures
Immunofluorescence Analyzer does not response	Power Failure	Check the Power Plug.
	Poor Connection between the Power Adapter and the Cord.	Pull out the Cord and Re-connect firmly.
	Main switch is off.	Turn on the main switch.
	Power Adapter is broken.	Call Customer Service.
Run finished but no result returned	Excessive Computation Load	Wait till the computation is finished.
	Computational Abnormality	Turn off the power and start fresh.
Message: Insert the corresponding ID card Message: Reset reagent and test again!	Detection Apparatus or ID card was not inserted.	Insert the Detection Apparatus or ID card.
	ID card is not inserted or the lot of Detection Apparatus is incompatible.	Insert the right ID card.

Section X Contact Information

Magic Biotech Corporation 's expressed and implied warranties are conditioned upon full observance of manufacturer's published direction with respect to the use of Magic Biotech Corporation 's products. Under no circumstance whatsoever shall Magic Biotech Corporation be held liable for any indirect or consequential damages.

For technical assistance, call or send e-mail to us:



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