Getein Biotech, Inc.

CE IVD

Getein 1150

Immunofluorescence Quantitative Analyzer

User Manual

Getein Biotech, Inc.

CONTENTS

Symbols

	Manufacturer
	Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*
	Serial number
	*In Vitro* diagnostic medical device
	Catalogue number
	CE Mark
	Authorized representative in the European Community/European Union
	Warning
	Warning; Biological hazard
	This way up
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Stacking limit by number
	Atmospheric pressure limitation
	Humidity limitation
	Temperature limit

Warnings and Precautions

- Immunofluorescence Quantitative Analyzer is only used for in vitro diagnostic analysis of human whole blood, plasma, serum, capillary blood and urine sample.
- Operate the analyzer under the conditions specified in this manual. If the conditions are exceeded, the analyzer may not run properly, the test results will be unreliable, and instrument components may be damaged.
- If the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.
- When the battery shows low power, please connect the adapter in time to charge the battery.
- To avoid fire, electric shock or personnel injuries, cut off the power immediately and disconnect the power plug if any liquid seeps into the instrument, the instrument leaks, emits smoke or a smell. Contact us for technical support when this happens.
- Take proper safeguard measures in accordance with health and safety standards in your local country. Wear protective goggles, gloves, and lab coats when operating and performing maintenance on this instrument.
- Operators or person in charge shall be trained on cautions and operation instructions before operating the analyzer.
- Test kits and consumables should be disposed of after a single use. Proper handling and disposal methods should be established by the laboratory director in accordance with local, status and federal regulations.
- If there are any issues with the instrument, please contact us promptly. Unauthorized personnel are not allowed to inspect or disassemble any parts of the instrument without permission.

1 Product Introduction

This User Manual is applicable to the Getein 1150 Immunofluorescence Quantitative Analyzer. It describes the structure and composition of the analyzer, performance parameters, software operation, daily maintenance, as well as important regulations for safety and proper use. Please read this manual carefully before operating the instrument and keep it properly for future reference.

1.1 Intended Use

In conjunction with dedicated test kits for Immunofluorescence, the analyzer is used for the qualitative or quantitative analysis of biomarkers in human whole blood, serum, plasma, capillary blood or urine samples. The results can be used as an aid in clinical diagnosis of laboratory and point of care testing.
For professional use only.

1.2 Principle of Analysis

1.2.1 Running a Test

Add the patient sample to a test card, insert it into the analyzer, and press the start button. After the automated timed analysis, the test results will be displayed on the screen.

1.2.2 Working Principle

The test card is coated with fluorescent-labeled antibody and capture antibody. When the sample is applied to the test card, fluorescent-labeled antibody binds to the antigen in the sample, forming the antibody-antigen complex. The complex is then captured by capture antibody in the testing area, creating the “double antibody sandwich” complex.

The analyzer’s testing system scans the binding area, receives fluorescence signals, and converts these signals to electrical signals. It then measures and analyzes these signals to quantitatively determined the antigen concentration in the sample.

This analyzer calculates the antigen concentration by measuring the voltage variations during the antibody-antigen reactions. The performance index for each assay is calculated in conjunction with the specific test card

used. Refer to the user manual of the test card for detailed information about the parameters of each assay.

1.2.3 Test Card

Test cards and instrument constitute a system and they must work together.

Warning

- This instrument only works with Getein's *in vitro* diagnostic test cards. Using other test cards may result in unsuccessful measurements or unreliable test results.
- Refer to the label on the package and the enclosed package insert to ensure the correct and safe use of the test cards.
- Observe the labeling on test card packages and follow the instructions for proper storage. Test cards must not be used after the expiry date.
- Each type of test card must be inspected before use. External damage to the card may impair its quality. If the packing case is damaged, check the inner box for any signs of damage. Damaged cards must not be used.

1.3 Instrument Specifications

1.3.1 System Specification

Principle	Immunofluorescence
Operating System	Android
Language	Chinese, English, Spanish
Display	5-inch LCD touch screen, resolution: 1280 × 720
Battery	Rechargeable lithium-ion battery 3.38Ah Standby for more than 48 hours, continuous operation for more than 8 hours
Temperature Control	37℃
Reaction Time	3-15 minutes (depending on the test item)
Data Storage	50000 pieces of result data

Communication Ports	1 USB Type-C interface 1 camera interface Supports Wi-Fi wireless communication Supports 4G network communication Supports Bluetooth communication
Sample Type	Serum/Plasma, Whole Blood, Capillary Blood, Urine
Test Mode	Routine
Dimensions	186 mm (L) × 80 mm (W) × 54 mm (H)
Weight	500 g
Power Supply	AC 100V - 240V ±10%，50Hz ~ 60Hz ±1Hz
Safety Class	II
IP Rating	IPX0
Pollution Degree Rating	2
Operating Conditions	Temperature: 10℃ to 35℃ Relative humidity: ≤ 70% Air pressure: 70.0 kPa to 106.0 kPa No frost, condensation, seepage, rain, sun exposure, etc.

1.3.2 Performance Indexes

Blank Count	Voltage of the blank QC card should be less than 100 mV
Accuracy	Relative deviation is within ±15%
Linearity	r≥0.990 in the detection range from 0 mV to 15000 mV
Repeatability	CV≤2% within range [100, 15000] mV; CV≤5% within range [0, 100) mV
Stability	The relative deviation between test results at the 4th and 8th hours after the instrument is powered on and stabilized, compared to the test result at the initial time of stable operation (using the standard card), should not exceed ±5%

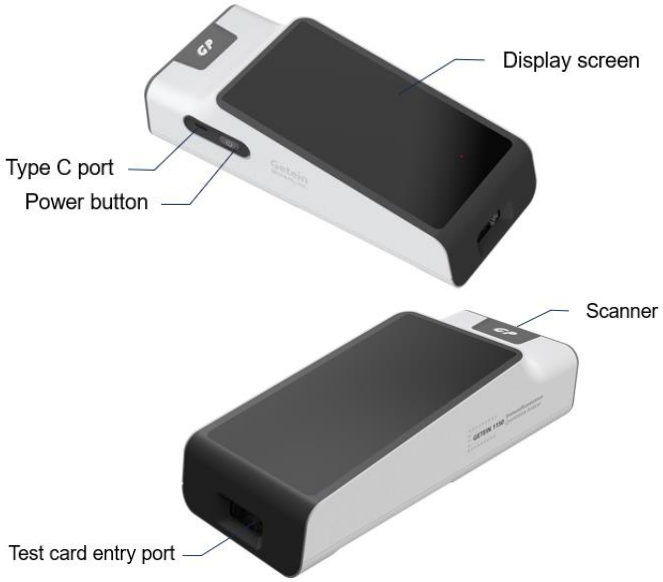
1.4 Structure and Composition

1.4.1 Instrument Composition

The analyzer consists of a single-channel fluorescence detection module, battery, scanning module, signal processing module, temperature control module, and display screen.

- Fluorescence detection module: It detects, measures, and analyze the fluorescence signals.
- Battery: Provides power to the analyzer, ensuring the instrument can operate without an external power source.
- Scanning module: It reads the sample barcode and reagent QR code, ensuring accurate input of sample and reagent information.
- Signal processing module: Receives and processes signals from the fluorescence detection module; amplifies, filters, and digitizes these signals; and transmits signals to the main control system for analysis.
- Temperature control module: Controls and maintains the internal temperature of the analyzer within an appropriate range, ensuring the accuracy and stability of the test result.
- Display screen: Displays the operation interface, test result, system status, and other information, facilitating user operation and data viewing.

1.4.2 Product View



- Display screen - The display screen shows the test menu, system status, test result, operation prompt, etc.
- Type C port – Used for instrument charging and program upgrade.
- Power button – Power on/off the analyzer.
- Scanner – Built-in laser scanner used to scan the test cartridge QR code.
- Test card entry port - The test card entry port is located at the bottom front of the analyzer.

2 Notice for Use

2.1 Safety Prompts

To highlight important information, operation instructions and safety precautions, this manual includes **Note**, **Caution**, and **Warning**. Before using this analyzer, operators must be familiar with safety points in the manual.

Note	Highlight or provide additional information.
Caution	The occurrence **may** cause malfunction, loss of data and damages to the instrument.
Warning	The occurrence **may** cause personal injuries to operators, patients or people around.

2.2 Biological Hazard Description

Operators should follow the instructions below to prevent the risk of potential biological contamination:

- All items (samples, test cards, consumables, wastes, etc.), as well as areas that come into contact with these items, have a potential risk of biological contamination.
- When handling samples and contacting related areas, be sure to follow laboratory safety operating procedures and wear personal protective equipment and gloves. Wash hands thoroughly after handling specimens and reagents.
- Users should prepare dedicated containers for biohazardous wastes disposal. Contents within these containers shall be treated in accordance with the laboratory's biological hazards management protocols.

2.3 Laser

- The barcode scanner of the instrument is classified as Class I laser product. It is labeled with the safety symbol “Warning; Laser beam”.
- Do not disassemble the cover plate at will when using the instrument.
- Do not look directly at the laser source with your eyes when the scanner is working.

- Do not perform maintenance operations on the scanner by yourself. If there is a problem with the scanner, contact Getein's technical support personnel or your local distributor.

2.4 Electrical Shock

- Use only the power cables provided by our company. If you need new power cables, contact us or your authorized local distributor.
- Before performing maintenance or cleaning, power off the instrument and disconnect it from the power source.
- Plug the instrument’s power cord into an adequately rated and grounded electrical socket.
- The switch and power port voltage is AC 100V - 240V, while the port, USB port operates at AC 5V. All connected devices should have safety certifications.

2.5 EMC Description

- In a domestic environment, the instrument may generate radio interference; the user should take protective measures to mitigate the interference.
- Assess the electromagnetic environment to guarantee a secure working environment for the instrument.
- Do not operate this system near strong electromagnetic field sources, such as unshielded intentional RF emitters, to prevent interference with its functionality.

3 Installation

3.1 Shipping and Storage Conditions

1) Transportation
The main unit and accessories are packed and transported in cartons. For long-distance transport, the instrument should be placed in a packing case with quakeproof pad wrapping it. During transportation, personnel in charge should handle shipments according to symbols on the package.

2) Storage
Temperature: -40℃ to +55℃
Relative humidity: ≤ 93%
Air pressure: 50.0 kPa to 106.0 kPa

3.2 Installation Requirements

1) Location
- Dust- free environment with adequate ventilation
- No direct sunlight
- Free from vibration, loud noise and power interferences
- No equipment generating electromagnetic waves nearby

2) Space Requirement

Place the instrument on a stable workbench, and it should have enough space for easy access to the connection ports and for conducting inspections.

3) Power Requirement
Input voltage AC 100V - 240V ±10%, frequency 50Hz - 60Hz ±1Hz, 36 W

3.3 Unpacking

Carefully open the package and inspect the instrument's appearance. For any instrument damage, please report it immediately.

Check the accessories against the packing list. For any missing accessory, contact our company or your local distributor.

Note: Only use accessories and consumables provided by Getein for the analyzer to ensure reliable and accurate results.

3.4 Analyzer Charging

Use the supplied power cable to charge the analyzer. Ensure the battery is fully charged before turning on the analyzer.

Note:

- Only the power cable provided by Getein can be used with the Getein 1150.
- The power plug of the instrument can only be plugged into a socket with a grounding wire.
- Do not use a detachable mains supply cord with inadequate ratings.

4 Test Instruction

4.1 Instrument Startup

Press and hold the power button on the left side of the instrument to turn on the analyzer. After powering on, the system will automatically execute the startup initialization. During this process, each module will perform communication tests and self-checks. The screen will display a progress prompt during initialization, and upon completion, the system will enter the main menu.

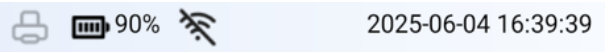
4.2 Instrument Shutdown

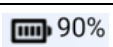
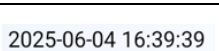
Long press the power button on the left side of the instrument, and select Shutdown from the pop-up menu to power off the instrument.

4.3 Software

The software interface allows users to interact with the analyzer and it consists of the status bar and the operation area.

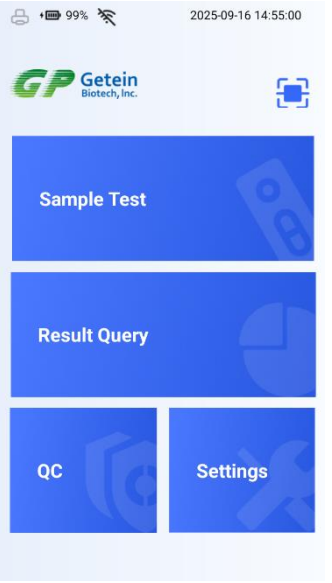
- The status bar displays important status information, including printer connection status, battery level, Wi-Fi connection status, and system date and time.



Icon	Description
	Connection status of the Bluetooth printer
	Battery level
	Wi-Fi connection status
	System date and time in the format yyyy-mm-dd hh:mm:ss.

- The operation area provides operation options based on the selected menu.

4.4 Main Menu



The Main Menu displays upon the completion of initialization. The menu options include Sample Test, Result Query, QC, and Settings.

- Sample Test - Allows users to schedule test tasks and view the test status.
- Result Query –Displays test results and allows users to edit, upload, and print results.
- QC – Enables users to perform quality control tests and view results and curves.
- Settings –Allows users to set basic functional parameters.

4.5 Sample Test

Please read the instructions carefully and follow the steps for the sample test to obtain accurate and reliable test results.

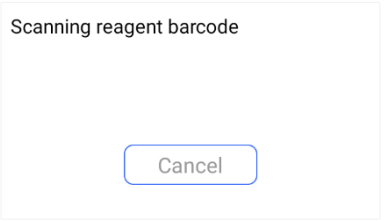
4.5.1 Test Preparation

Ensure the following items are fully prepared before conducting the sample test:

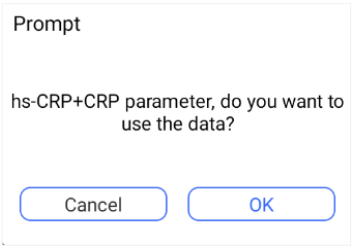
1. Immunofluorescence Quantitative Analyzer
2. Test cards and test cartridge QR code from the same batch
   Note: Each batch of test cards is equipped with a QR code containing the parameters for the test.
3. Sample collector
4. Extraction solution
   Note: Consumables are for single use only and must be disposed of promptly after use.

4.5.2 Sample Test

1. On the main menu, tap , and the system will prompt "Scan reagent barcode." The scanner on top of the analyzer lights up. Align the cartridge QR code with the scanning window to obtain the test parameters.

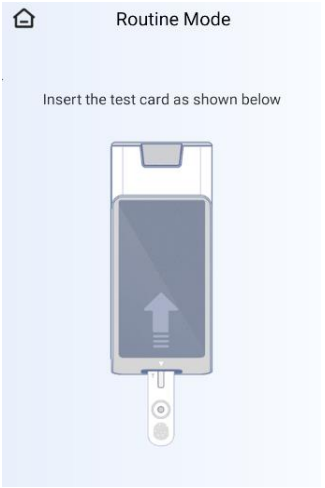


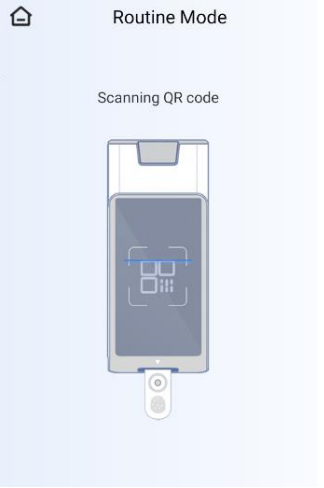
2. After a successful scan, another prompt box will appear, asking whether you want to use the obtained parameters. Tap the OK button.



3. On the main menu, select **Sample Test**, and the system will prompt "Insert the test card as shown below". Insert the test card into the card entry port, and the instrument will automatically scan the QR code on the test card to obtain the test item and lot number.

Note: If the instrument fails to scan the QR code within the specified time, a prompt "Scan timeout" will appear. Tap the Eject Test Card button to eject the test card.

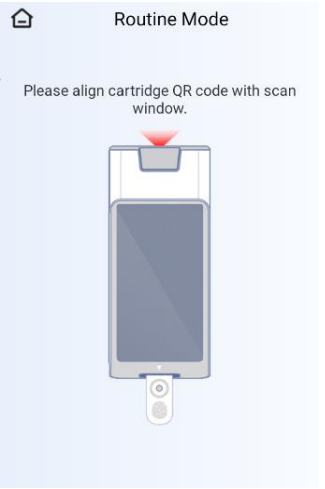




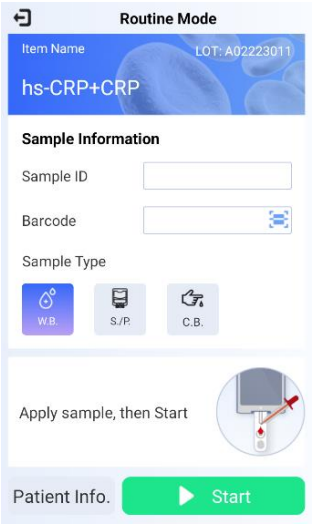
4. After test card scanning is complete, the [Sample Test] screen appears. Routine Mode is displayed by default.

Note:

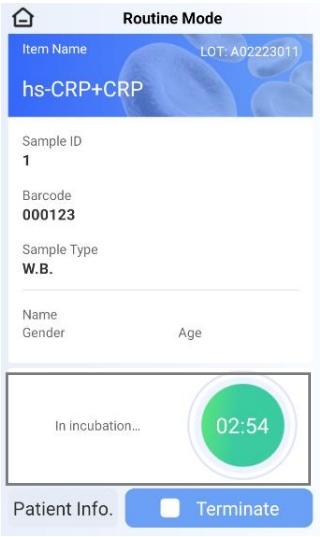
- If the QR code of the cartridge for the current batch has not been scanned or the scan failed, the following prompt will appear after test card scanning is complete:" Please align cartridge QR code with scan window". Follow the instruction to rescan the cartridge QR code. The [Sample Test] screen will then appear upon successful scanning.
- If the QR code scan fails three times in a row, the system will prompt "Scan failed". Tap the Quit button to withdraw the test card.

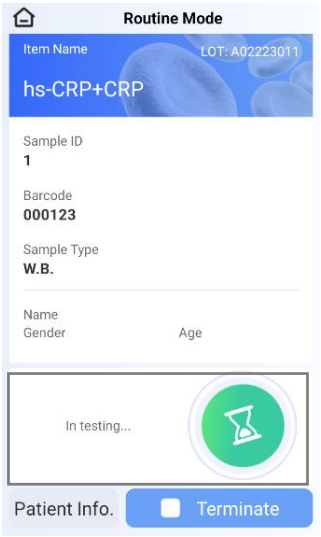


5. Enter sample information.
Sample ID: Manually enter the sample ID, which can be left empty.
Barcode: Manually enter or scan the barcode, which can be left empty.
Sample Type: Use the default sample type or select another one.



6. Take a small drop of the sample and vertically drop it into the sample entry port of the test card. After adding the sample, tap the **Start** button. The test card will be brought into the measurement position, incubation begins, and the remaining time countdown is displayed on the screen.
The Start button switches to the **Terminate** button. Tapping this button can terminate the current test and eject the test card.
Note:
- The required sample volume and dilution ratio may vary for each test item. Refer to the corresponding reagent's IFU for details.
- The incubation time differs among various test items. Refer to the corresponding reagent's IFU for details.





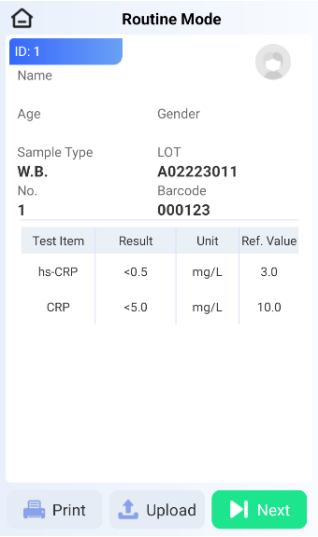
7. When the incubation is in progress, users can edit the patient details. Tap the **Patient Info** button to pop up the [Patient Information] dialog box, which allows users to enter or edit the patient's name, age, and gender.
8. After the test is completed, the test result is automatically displayed, and the test card entry port ejects the test card. Remove the test card and dispose of it in a dedicated waste container.

   If a printer is connected, tap the **Print** button to print a test report.

   If connected to the LIS system, tap the **Upload** button to upload this test result to the LIS.

   To continue testing the next sample, tap the **Next** button to return to the [Sample Test] screen as show in step 1, and repeat the above steps. If the test card is not removed in time when the test is completed, the analyzer will prompt "Please remove the test card" when the Next button is tapped. The user should remove the test card before starting the next sample test.

   To exit the sample test, after removing the test card, tap the icon in the upper left corner to return to the main menu.

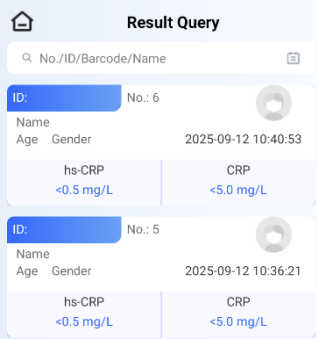


4.6 Result Query

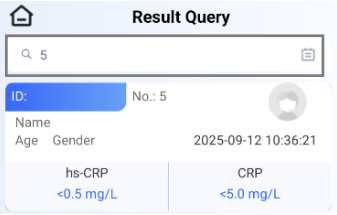
When the test is completed, the result data is automatically saved in the analyzer's memory. The analyzer can store up to 50,000 test results in its memory, and results can be reviewed in order from newest to oldest.

To view test results:

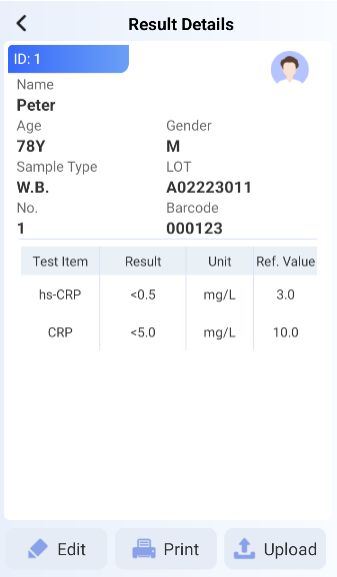
1) On the main menu, select **Result Query** to enter the [Result Query] screen.
2) This screen displays the latest test results, with the sample ID, patient information, test time, and test item. You can scroll up and down to view more result records.



3) **Query by Date**: Tap , select a date range to view the test results within the specified date range.
Query by No./Sample ID/Barcode/Name: Enter a sample No./ sample ID/barcode/patient name in the query criteria box to display test results of the entered sample No./sample ID/barcode/patient name. The query function supports fuzzy search. Enter a number, and those with this number in the sample No., sample ID, or barcode will be displayed.



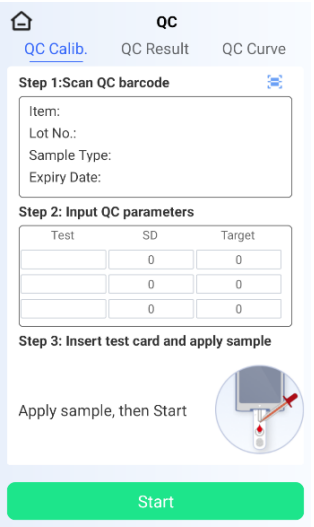
4) In [Result Query], tap on a result record and enter the [Result Details] screen to view the detailed sample information and result.
Edit: Tap this button to edit the test result.
Print: Tap this button to print the test result.
Upload: Tap this button to upload the result record to the LIS.

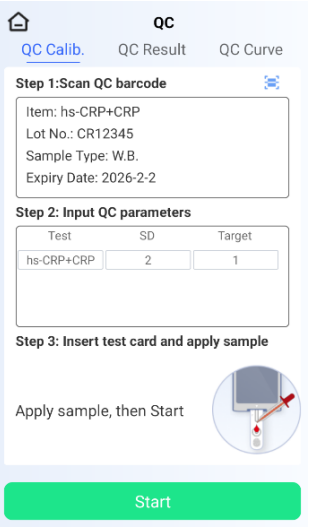


4.7 Quality Control

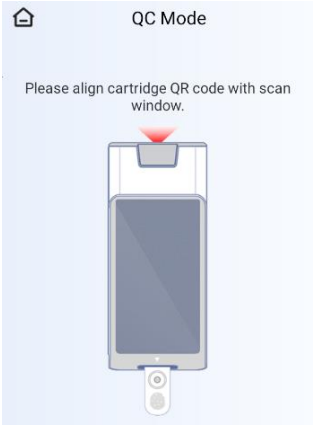
To conduct the quality control test:

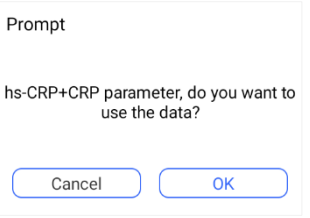
1) On the main menu, select **QC** to enter the [QC Calib.] screen.
2) Follow the steps displayed on the screen. First, align the QC barcode with the scan window, and the system will automatically read and display the QC item, lot No., sample type, and expiry date.
3) Manually input the SD and target value.



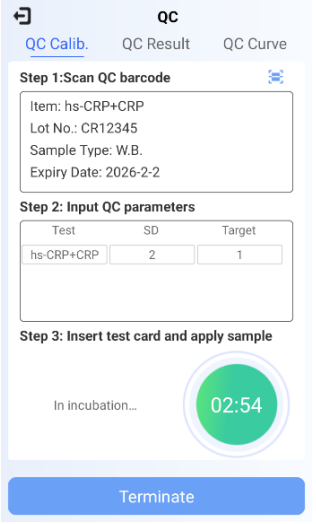


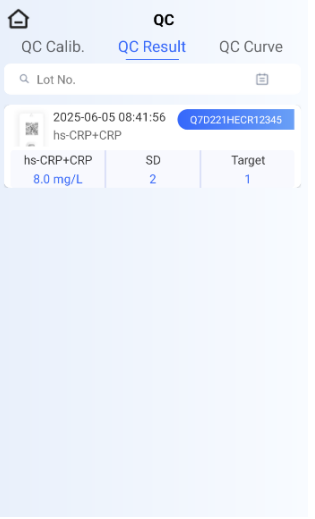
4) Insert the test card into the card entry port, and the test card will be brought to the scan position inside the instrument for QR code scanning. The system will automatically obtain the test item and lot No.
5) After scanning the test card, the system prompts: "Please align cartridge QR code with scan window" and the scanner on top of the analyzer lights up. Scan the test cartridge QR code to obtain the test parameters. After a successful scan, another prompt box will appear, asking whether you want to use the obtained parameters. Tap the OK button.





6) Take a small drop of the control and vertically drop it into the sample entry port of the test card. After adding the control, tap the **Start** button. The test card will be brought into the measurement position, incubation begins, and the remaining time countdown is displayed on the screen. The Start button switches to the **Terminate** button. Tapping this button can terminate the current QC test and eject the test card.
7) After the test is completed, view the QC result on the [QC Result] screen or view the QC curve on the [QC Curve] screen.



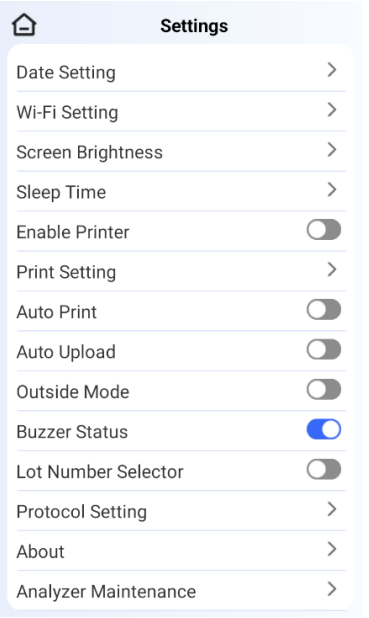


5 Settings

Installation and debugging of Getein 1150 are performed by Getein's technical support professionals after a purchase is made. Operators can customize certain system parameters in Settings to meet the specific requirements of their laboratory.

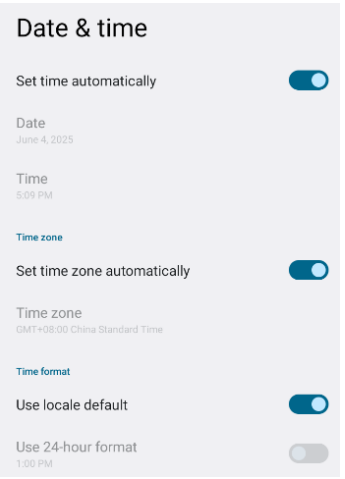
On the main menu, tap **Settings** to enter the [Settings] screen. Setting functions include [Date Setting], [Wi-Fi Setting], [Screen Brightness], [Sleep Time], [Enable Printer], [Print Setting], [Auto Print], [Auto Upload], [Outside Mode], [Buzzer Status], [Lot Number Selector], [Protocol Setting], [About], and [Analyzer Maintenance].

Note: Reset system parameters to your practical operating needs before running sample tests and performing other operations.



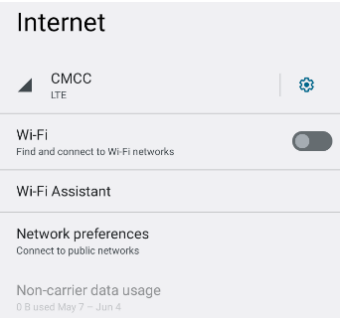
5.1 Date Setting

Tap Date Setting to open the date & time setting screen to set up system date and time.



5.2 Wi-Fi Setting

Tap Wi-Fi Setting to enter the Internet screen, which allows users to enable and connect to a wireless network.

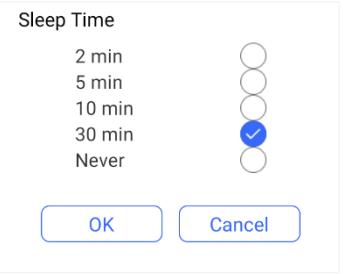


5.3 Screen Brightness

Tap on Brightness to pop up the brightness adjustment box, and the user can slide left or right to dim/brighten the screen's brightness.

5.4 Sleep Time

Tap on the Sleep Time option to pop up the [Sleep Time] dialog box, which allows the user to set the countdown time for the analyzer to automatically enter sleep mode when there is no operation.



5.5 Enable Printer

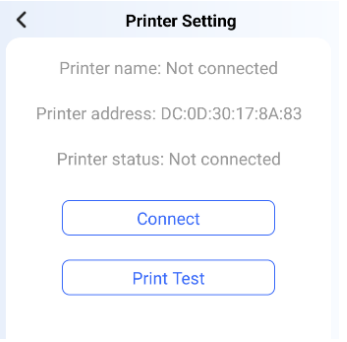
Check the option box to the right of Enable Printer to enable the printer.

5.6 Print Setting

Tap on the Print Setting option to enter the Printer Setting screen.

Connect: Tap this button, a prompt box will pop up, inquiring whether to connect to the last used device. The user can select OK to connect to the last device, or select Re-search to rescan for available Bluetooth printers.

Tap the **Print Test** button, the printer will print a report to test if the print function is working properly.



5.7 Auto Print

When Auto Print is enabled, the test result will be printed out automatically after a sample test completes. If it is disabled, users can print results as needed in Result by tapping the Print button.

5.8 Auto Upload

When Auto Upload is enabled, the analyzer will automatically upload the result data to the LIS after the test is completed; if it is disabled, the user can manually select the data to upload as needed.

5.9 Outside Mode

In the default routine mode, after sample addition, the sample test undergoes the incubation process according to the preset incubation time. If the Outside Mode is enabled, the sample test will skip the incubation and proceed directly to detection following the sample addition.

5.10 Buzzer Status

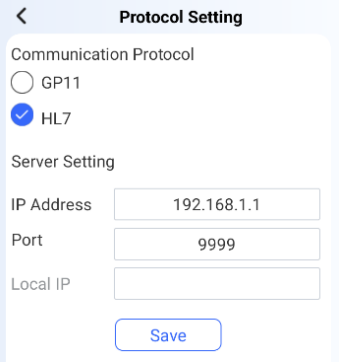
When the buzzer status is enabled, the instrument will emit audible prompts when it is powered, an alarm is triggered, and test results are produced.

5.11 Lot Number Selector

When the lot number selection function is enabled, the system will display the [Lot No. Selection] pop-up window after the user scans the cartridge QR code and inserts the test card. The user can select the required lot number from the list of entered lot numbers. After the selection is confirmed, the interface will automatically transition to the [Sample Test] screen to proceed with testing.

5.12 Protocol Setting

Protocol setting function allows the user to select the data transmission protocol between the analyzer and the LIS, and configure server-related settings.



5.13 About

Tap on the About option to check the program version and serial number of the analyzer.

6 Maintenance

6.1 Cleaning and Disinfection

The instrument only needs to be kept externally clean.
Use a lint-free cloth moistened with 75% alcohol to wipe the surface of the instrument and the card entry port. Be careful not to clean any internal components or inner surfaces.

Note:

- Before cleaning the instrument, turned it off and disconnect it from the power supply to avoid short circuits and electric shock hazards.
- Follow laboratory safety protocols and wear protective equipment such as disposable late gloves. Do not touch areas labeled with biohazard warnings directly with your hands.
- Do not use cleaning agents and disinfectants that may chemically react with the components of the instrument or the materials contained within the instrument.

6.2 Alarms

If an abnormal situation occurs when the analyzer is running, an alarm message will pop up. Follow the instructions to handle the alarms. If the alarm still persists, please the technical support for assistance.

7 Appendix

7.1 Copyright

Getein Biotech Inc.
Product Name: Immunofluorescence Quantitative Analyzer
Model: Getein 1150
Version: V1.1
Issue Date: Sept. 2025

7.2 Statement

- Getein Biotech Inc. owns the copyright to this non-published manual and has the right to take it as confidential information. This manual is provided for operation, maintenance and repair for Getein 1150 only. Anyone has no right to make this manual public.
- This manual contains proprietary information which is protected by copyright law. Copyright of this manual belongs to Getein Biotech Inc. Any content in this manual cannot be copied, reproduced or translated into other languages without the written consent of Getein.
- No warranties of any kind are made by Getein regarding this manual. Getein takes no responsibility for any consequential damages caused by errors in this manual.
- Getein holds the authority of the modification for contents of the manual without informing prior to it.

7.3 Manufacturer's Responsibility

- Getein will only be responsible for instrument safety, reliability and performance in following cases: installation, upgrade, calibration, repair and maintenance are done by personnel assigned by Getein.
- Hospitals or institutions who use this instrument should make a regular maintenance plan and perform strictly, otherwise, inappropriate operations may lead to instrument failure or even endanger people's health.
- Getein will conditionally provide circuit diagram, calibration specifications and other documents required to assist the appropriate personnel to finish maintenance or repair under situations users can do themselves.

- Use only as directed. Getein will take no responsibility for protection failure of the analyzer caused by the analyzer being used in a manner not consistent with the instructions in this manual.

7.4 Instrument Lifespan

The lifespan of Getein 1150 is 8 years under standardized operation and proper maintenance (continuous working time should be no more than 8 hours every day).

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