Getein
Biotech, Inc.

CE

Getein1160

Immunofluorescence Quantitative Analyzer

User Manual

Getein Biotech, Inc.

Warnings, Precautions and Limitations

a. Read this instruction manual carefully to obtain optimum performance from your instrument.
b. Immunofluorescence Quantitative Analyzer is only used for in vitro diagnostic analysis of human whole blood, plasma, serum, capillary blood and urine sample.
c. Only the dedicated test kits mentioned in this manual are allowed. Otherwise the accuracy of measurement cannot be guaranteed.
d. Use only specified replacement parts on the instrument.
e. To avoid fire, electric shock or personnel injuries, cut off the power immediately and disconnect the power plug when any liquid seeps into the instrument, or the instrument leaks, emits smoke or a smell. Contact us for after-sales support when this happens.
f. Take proper safeguard measures in accordance with health and safety standards in the local country.
g. Specimens and reagents may have potentially biological risks of infection, operators should wear laboratory protective clothing and gloves required by the operation regulations of laboratory safety to avoid potential biological infection or contamination.
h. All the 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.
i. Operators or person in charge shall be trained on cautions and operation instructions before operating the analyzer.

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

Label/Symbol Description

	Manufacturer
	Consult instructions for use
	Caution
	Serial number
	This way up
	Fragile, handle with care
	*In Vitro* diagnostic medical device
	Authorized representative in the European Community
	Catalogue number
	Biological risks
	CE Mark
	Keep away from sunlight
	Keep dry
	Stacking limit by number
	Mind your hands
	Atmosphere pressure limitation
	Humidity limitation
	Temperature limit

Contents

1. General Information

1.1 Intended Use

In conjunction with dedicated test kits for Immunofluorescence, the instrument automates the detection and quantification of markers for cardiovascular disease, renal diseases, inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid in a biological sample.

1.2 Safety Instructions

In order to avoid unsafe actions that could potentially result in personal injury or damage to the instrument, all safety cautions should be strictly observed.

1.2.1 Operation Cautions

- Observe all cautionary symbols in the manual and on the instrument.
- Place this instrument in a dry environment with required temperature and humidity. No ventilation facility is required.
- To ensure the accuracy and reliability of results, wait for 10 minutes after startup for the instrument to warm up.
- Under power outage situation, wait for 30 seconds before restarting the instrument.
- Do not look straight into the barcode scanner when the power is connected. Laser from the barcode scanner could cause damage to the eyes.
- During operation, users should wear rubber gloves to prevent from touching residual or dribbled sample directly.
- Do not insert or pull out the test card when the instrument is running.
- When preparing samples, take care not to spill samples onto the instrument.

1.2.2 Electrical Shock

- Unplug the instrument before cleaning and maintenance work.
- Do not immerses the instrument in water or cleaning solution.
- The protective earth wire is connected directly to the instrument to prevent electrical shock and ensure the normal operation of the instrument.
- Voltage of switch and power port is AC 100V - 240 V, voltage of COM port, USB port, and Ethernet port is AC 5V. All connected devices should have safety certifications.
- Verification tests on grounding impedance, continuous leakage current, and dielectric strength at room temperature are conducted on the instrument before delivery to customer and after maintenance to ensure the instrument is in safe working condition.

1.2.3 Biological Hazard Description

Users should prepare dedicated containers for the disposal of biohazardous wastes. Disposal of all materials that have come into contact with specimens and test cards should follow national, international, and regional regulations.

Dispose of all specimens, wastes as infectious waste. Comply with laboratory safety rules; wear disposable, powderless gloves and protective laboratory coats. Wash hands thoroughly after handling specimens and test cards.

1.2.4 EMC Description

- In the domestic environment, protection measures should be taken in case the instrument may cause radio interference.
- Assess the electromagnetic environment to ensure a safe working environment for the instrument.
- In a dry environment, especially in an environment with artificial materials such as synthetic fabric and carpet, using the instrument may cause electrostatic discharge and lead to an incorrect conclusion.

2. Introduction

2.1 Overview

This user's manual contains instructions of operation and maintenance for Getein1160 Immunofluorescence Quantitative Analyzer. To ensure and maintain optimum performance of the instrument, please operate in strict with this manual.

2.1.1 Product Name and Model

Product Name: Immunofluorescence Quantitative Analyzer
Model: Getein1160

2.1.2 Production Description

Getein1160 is used to measure concentration 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.

2.2 Testing Principle

2.2.1 Running a Test

Add the patient sample to a test card, insert the test card into Getein1160 for automatically timed reaction, or place it outside of Getein1160 for a manually timed reaction and then insert it into the instrument to be read. The test results will be displayed on the screen. If configured, the results may also be sent to the built-in printer or transmitted to the lab or hospital information system (LIS or HIS).

2.2.2 Test Card

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

Caution

- This instrument only works with Getein's *in vitro* diagnostic test cards, otherwise, it will not measure successfully or the test results may be unreliable.

- Refer to the label on the package and the enclosed user's manual to ensure the use of test card is correct and safe.
- Observe the labeling on test card packages and follow the instructions to store the test cards. Test cards must not be used after the expiry date.
- Each type of test card must be checked before using. The external damage on the card may impair its quality. In case that the packing case is damaged, check the inner box for any sign of damage. Damaged cards cannot be used.

2.2.3 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 to form the antibody-antigen complex. The complex then is captured by capture antibody in the testing area to form the "double antibody sandwich" complex.

The testing system of the instrument scans the binding area, receives optical signals and converts the optical signal to electrical signal. Then it measures and analyzes the signal to quantitatively calculate the antigen concentration in the sample.

This instrument calculates the antigen concentration by measuring the voltage variation in antibody-antigen reactions. The performance index for each assay is calculated together with related test card. Refer to the user's manual of the related test card for information about parameters of each assay.

3. Instrument Specifications

3.1 Performance Summary

3.1.1 Basic Parameters

Model	Operating Wavelength (nm)	Detection Range (mV)	Resolution (mV)
Getein1160	635±5	0~15000	1

3.1.2 Performance Indexes

Blank Count	Voltage of the blank QC card should be less than 100 mV
Linearity	r ⩾ 0.95 in the detection range from 0 mV to 15000 mV
Repeatability	CV ⩽ 2% within range [100-15000] mV; CV⩽10% within range [0-100) mV
Stability	The voltage variation of the same standard card with a fixed concentration tested within 1 hour should be less than 10%

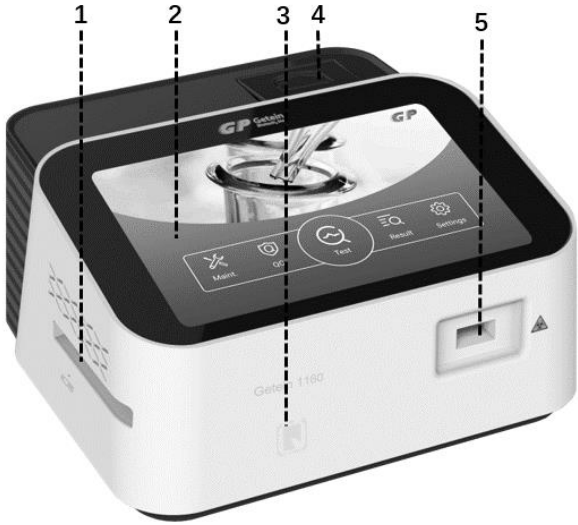
3.1.3 Technical Specifications

Touch Screen	10.1-inch LED touch screen, Resolution: 1280 × 800
Communications	USB port for software update and file copy COM port for PC Ethernet port for LIS
Data Storage	Over 100,000 data
Sampling	Sample Type: serum, plasma, whole blood, capillary blood, urine Sample Volume: 10 ~ 200 µL depending on the assay
Printer	Built-in thermal printer USB printer
Dimensions	299 mm × 276 mm × 152 mm (W × D × H)

Weight	4 kg
Operating Environment	Indoor Use Only Temperature: 10℃ ~ 35℃ Relative humidity: ≤ 70% Air pressure: 70.0kPa ~ 106.0kPa No frost, condensation, seepage, rain, sun exposure, etc.
Storage Environment	Temperature: -40℃ ~ +55℃ Relative humidity: ≤ 93% Air pressure: 50.0kPa ~ 106.0kPa
Power Supply	100 - 240V ~ , 50/60Hz, 60VA
IP Rating	IPX0
Pollution Degree Rating	2
Overvoltage Category	Ⅱ

3.2 Instrument Configuration

Getein1160 is composed of the control system, optical system, display unit, analog signal acquisition system, mechanical driven system and software CD.



1. Card Exit
2. 10.1-inch Touch Screen
3. SD Card Recognition Zone
4. Built-in thermal Printer
5. Card Inlet

4. Installation

4.1 Unpacking

Check the appearance of the instrument after unpacking. Check the accessories with the packing list. If you find any damages during the handling of the instrument or any parts missing, contact Getein's after-sales support or your local agent immediately.

Note: All related accessories and consumables must be provided by the instrument supplier. The use of accessories and consumables from other suppliers may impair the stability and reliability of the testing system.

4.2 Installation Requirements

4.2.1 Location

- The instrument should be installed in a dry and clean area, free from dust, vibration, loud noise and power interferences.
- Keep away from brush type engine, fluorescent light and other electrical equipment that switch on and off frequently.
- Do not place the instrument in direct sunlight or near hot and air sources.
- Place the instrument on a flat and horizontal laboratory table. The carrying capacity of the table shall not be lower than 4 kg/m^2.
- This instrument shall not be placed in a position where is difficult for the operator to press the power switch or remove power plug.
- Indoor temperature and humidity should be kept in the specified range. If temperature fluctuates greatly, it is recommended to install the air-conditioning equipment.

  Note: The test results may be unreliable if temperature and humidity are not maintained within the specified range.

4.2.2 Space Requirement

The laboratory table should provide adequate space for Getein1160. The test card inlet in the front and the card exit on the left should be left with enough space for operation and maintenance. The instrument has ventilation holes on both sides for the emission of heat. Operators must assure clearance space around the instrument to permit ventilation and access to the connection ports on the back of the instrument.

4.3 Analyzer Installation

Note: Installation of the main unit is usually performed by Getein's after-sales professionals.

Loading Printing Paper

a) Open the printer cover.
b) Put a scroll of printing paper into the printer with the carbon sensitive surface facing the thermal head.
c) Pull out approximate 5 cm of paper from the roll, then close the printer cover.

Power Connection

Connect the power plug with an electric outlet of the correct voltage.

Note:

- Only the AC power line provided by Getein can be used on Getein1160.
- Make sure that the grounding wire of the power cord has been connected to the earth meanwhile to the earth terminal of the instrument. The power plug of the instrument can only be plugged in the socket with grounding wire.
- Do not use detachable mains supply cord with inadequate ratings.

External Connections

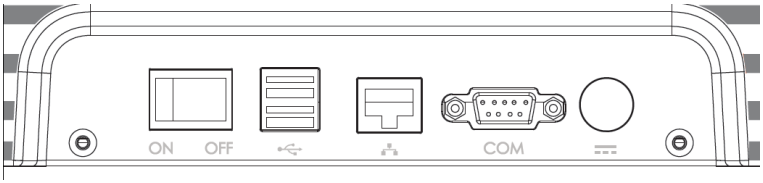


Fig. 4-1 External Connections

- Power Switch - Turn the instrument on/off;
- USB Port - Connect USB devices for software upgrade and barcode import;
- Ethernet Port - Connect network and LIS for communication;
- COM Port - Connect the serial port line for data transmission;
- Power Supply - Connect the power line.

4.4 Transportation

a) Shipment Requirement

The main unit and accessories are packed and shipped in cartons. During transportation, personnel in charge should handle shipments according to symbols on the package.

When the shipment arrives, users should temporarily store the instrument in a cool and clean room with packing case or dust shield covering it (see 3.1.3 Technical Specifications for information on Storage Environment).

b) Carrying Instrument

Getein1160 is a precise laboratory equipment. When lifting the instrument, hold it up from the bottom with two hands. To avoid personal injuries or any damages to the instrument, make sure the instrument is carefully transported. While in long-distance transportation, the instrument should be placed in a packing case with quakeproof pad wrapping it.

5. Test Instruction

5.1 Preparing the Instrument

Please follow these steps to check and confirm that the analyzer is ready for use before turning on the power switch.

- Cable checking: Be sure that there is no broken cable line or exposed copper wire, that the power plug has been safely connected to the qualified electric outlet. Otherwise, change the cable line or use a safe outlet.
- Printer Checking: Be sure that the printing paper is enough and correctly loaded.

Note:

- Do not place the instrument close to the wall or in front of any obstacles that may prevent proper startup and shutdown operations of the instrument.
- If the instrument has problems working after startup, disconnect the power supply and contact our after-sales support.
- Clean and disinfect the card inlet and card exit periodically with alcohol cotton.

5.2 Instrument Startup

a) Turn on the power switch located in the back of the instrument after appearance inspection.

b) The screen displays the initialization interface (Fig. 5-1). Getein1160 automatically checks hardware and optical system.

c) The Main interface appears after system initialization (Fig.5-2).

Fig. 5-1 Initialization Interface

5.3 Instrument Shutdown

Press on the power switch to power off the instrument.

5.4 Main Interface

The system enters the main interface after startup. System functions include Test, Result, QC (Quality Control), Settings and Maintenance.

Fig. 5-2 Main Interface

1. Assays: Working with related test cards, assays this analyzer can carry out include “cTnI”, “NT-proBNP”, “hs-CRP+CRP”, “NT-proBNP/cTnI”, “CK-MB/cTnI/Myo”, “D-Dimer”, “PCT”, “mAlb”, “CysC”, “β2-MG”, “NGAL”, “H-FABP”, “PCT/CRP”, “CK-MB/cTnI/H-FABP”, “HbA1c”, “HCG+β”, “SAA”, etc.
2. Functions Menu: Click on an icon to select the specific function: Test, Result, QC, Settings and Maintenance.
   - Test - It allows users to issue test tasks and view the task queue.
   - Result - Displays test results and allows users to filter results by query criteria as required.
   - QC - Perform quality control; displays control curves and values.
   - Settings - Set basic functional parameters, which include communication setting, print setting, time setting, etc.
   - Maintenance - Debug the instrument and modify system parameters.

5.5 Sample Test

Test screen (Fig. 5-3) allows users to edit patient and sample information, schedule test tasks, view task queue and incubation status, and check system time and temperature.

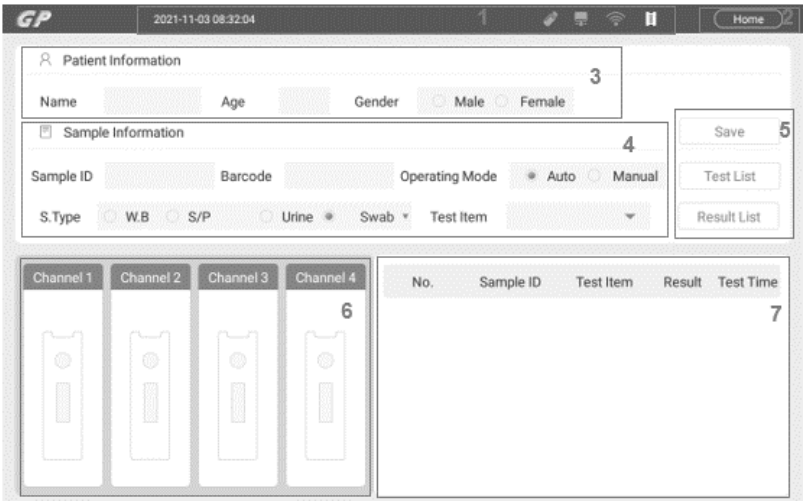


Fig. 5-3 Sample Test

Functions of buttons and icons in Sample Test are described below:

1. System Information Bar: It displays system time and date, as well as the connection status of USB flash drive and network.
2. Home Button: Click this button to return to Main Interface.
3. Patient Information: Edit patient information, including patient name, age, gender, etc.
4. Sample Information: Edit sample information for routine tests and temporary tests. Entered information is for routine tests by default.
5. Function Buttons
   - Save - Click Save to save the entered sample and test item information. Entered information will be displayed in the test task queue.
   - Test List - Click this button to display a task queue which lists all tasks to be tested, as well as the detailed sample and

item information for each test task.

- Result List - Click this button to go to Result for real-time test results.

6. Incubation Area: When the testing process starts, the test card first enters the incubation channel for incubation. The incubation area has 4 incubation positions, which means up to 4 test cards can be incubated at the same time. The incubation time required varies by test type.

   The graphic incubation area displays the test item and the remaining incubation time for the test card in each incubation position.

   Users are allowed to withdraw a test card when it is in incubating process. Long press on a test item, a confirmation prompt displays requesting to confirm the intention to withdraw the test card for this item (Fig. 5-4).

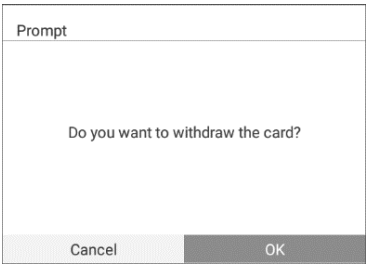


Fig. 5-4 Confirmation Prompt

Press the OK button, the test item will disappear from the incubation channel and the test card will be withdrawn from the card slot.

Fig. 5-5 Card Withdrawing

7. Test Result Display Section: This section display the test result in real time. The result data will be cleared after restarting the analyzer.

5.5.1 Task Scheduler

1. Routine Test

Schedule test tasks in Sample Test. Enter patient information, sample ID, barcode, test item and sample type in routine test mode. Two operating options are available:

- Auto - When a test card is inserted, the analyzer automatically scans the barcode label on the test card and identify the test item.
- Manual - Users select a test item from the dropdown menu of Test Item. The analyzer will not scan the barcode when a test card is inserted.

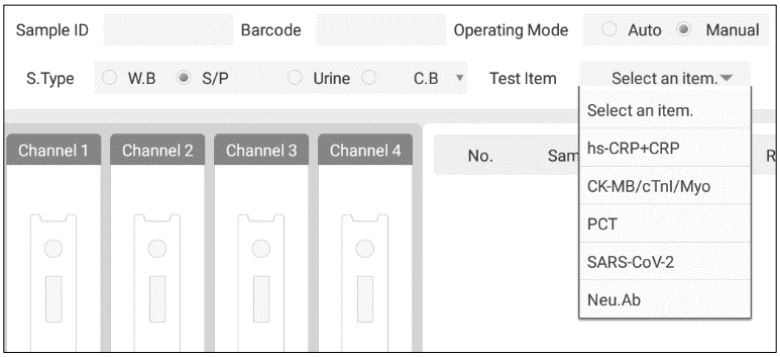


Fig. 5-6 Manually select a test item

After entering the sample information, press the Save button to save the entered information. The test task will be added to the test task queue.

2. Temporary Test

Getein1160 is designed with a temporary test channel. When a temporary test is scheduled, the test card is directly taken to the temporary channel for the rapid test after it is inserted.

Note: The Temporary function button is unavailable to users by default. To enable the temporary channel, go to Maintenance – System Debugging – Temporary.

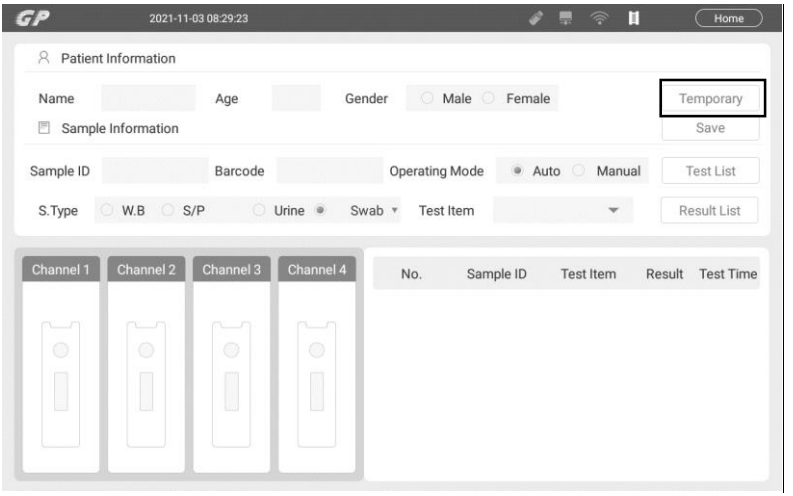


Fig. 5-7 Temporary Channel Enabled

To schedule a temporary test:

a) Press the Temporary button, a confirmation prompt displays requesting to confirm the intention to start the temporary test (Fig. 5-8).

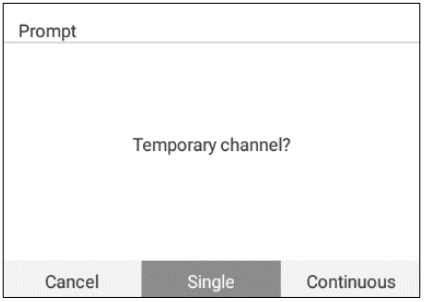


Fig. 5-8 Confirmation Prompt

b) Select a single temporary test or continuous temporary tests.

- Single –Schedule a single temporary test, then the system returns to the routine test mode.
- Continuous –Schedule continuous temporary tests. After the schedule, press the Temporary button to return to the routine test mode.
- Cancel – Click to cancel scheduling temporary tests.

c) After selecting Single or Continuous, the Temporary button turns to red (Fig. 5-9). Enter sample information, select the test item, and insert the test card. The card will be brought to the temporary channel for the rapid test.

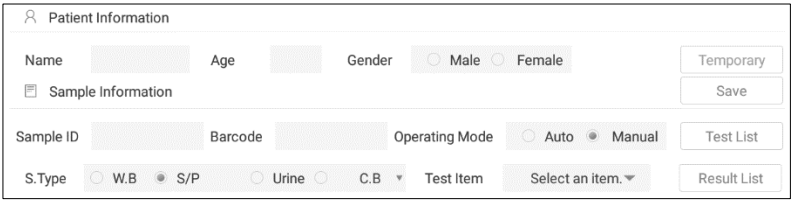
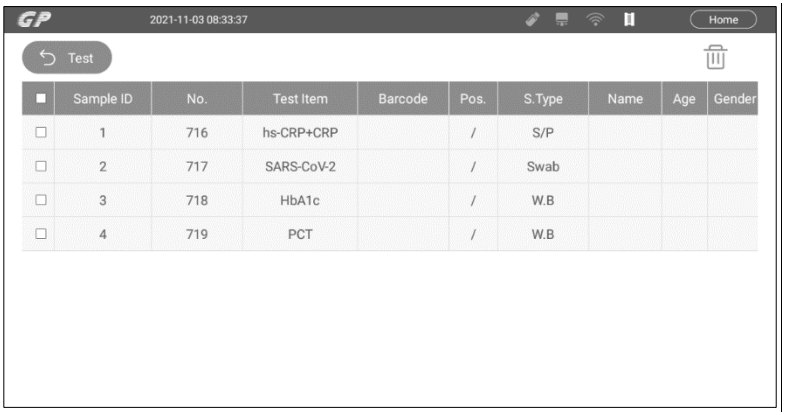


Fig. 5-9 Temporary Test Schedule

5.5.2 Task Queue

After editing patient and sample information, click Save to save the entered information. Then press Test List to display the task queue in Test Task grid (Fig. 5-10).



Sample ID	No.	Test Item	Barcode	Pos.	S.Type	Name	Age	Gender
1	716	hs-CRP+CRP		/	S/P			
2	717	SARS-CoV-2		/	Swab			
3	718	HbA1c		/	W.B			
4	719	PCT		/	W.B			

Fig. 5-10 Task Queue

- Test – Press the Test icon at the top left of the Test Task grid to return to Sample Test to schedule more tests.
- Delete - Users are able to delete a task before the testing process starts. Click the square icon to the left of a task line to select it, then press the Delete icon in the upper right corner to delete the selected task (Fig. 5-11). Users can select multiple tasks to delete.

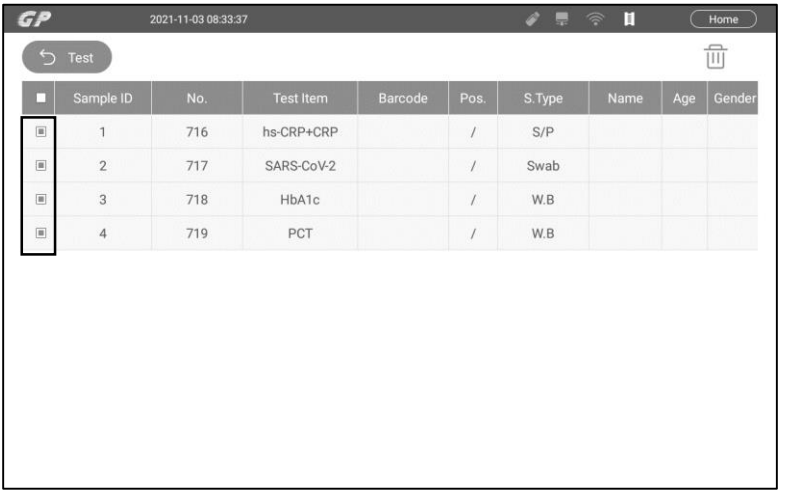


Fig. 5-11 Delete Selected Tasks

- Sample Position – Pos. column in the gird shows 0 for temporary tests representing the temporary channel, and 1 to 4 for routine tests representing the incubation channel.

Sample ID	No.	Test Item	Barcode	Pos.	Sample	Name	Age	Gender
43	213			0	W.B			Female

Fig. 5-12 Temporary Test Position

5.5.3 Test Procedure

The testing process starts when test tasks are issued successfully. Insert the test card into the card slot with barcode facing outward. The card is inserted properly when you hear a snap, and it will be sent to the incubation channel for incubating or to the temporary channel for the rapid test (temporary tests only).

The icon displayed in the system information bar is used to prompt that the test card can be inserted. When the incubation positions are full, the card inlet will be closed and the icon will become , under which circumstance users cannot force more test cards into the analyzer, otherwise, forced operation may lead to instrument failure.

Warning: Do not have direct contact with patient blood or urine specimens.

SD Calibration

Calibration is required when the lot number of test cards changes. Perform the calibration procedure with the attached SD card. Import the item parameters by the following steps:

a) Place the SD card on the SD card recognition zone. A prompt will be displayed on the screen (Fig. 5-13).

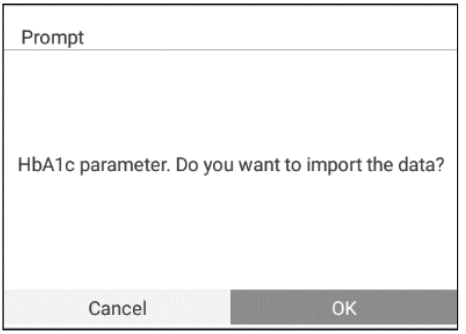


Fig. 5-13 SD Calibration

b) Press OK, the system automatically reads and saves the test parameters.

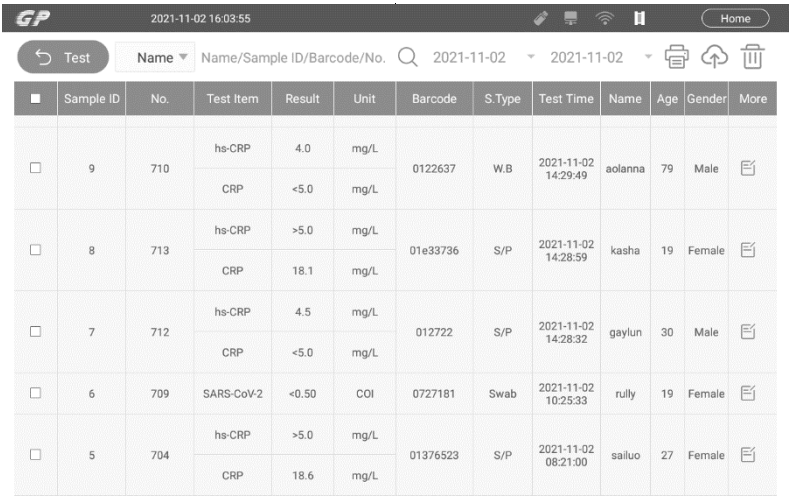
5.6 Results and Results Handling

Click Result in Main Interface to switch to Result interface (Fig. 5-14). Users can also access this screen by clicking the Results List button in Sample Test.

Result screen consists of Test button, search box, function buttons and the Results grid.

Press the Test button to switch to Test screen for tests schedule.

The Results grid lists all test results by date in descending order. The latest test result is displayed on the top and users scroll down to review the previous results. Users are also able to filter results by patient name, sample ID/barcode and date to view results for a specific criterion, and upload, print and delete the selected results or all results.



Sample ID	No.	Test Item	Result	Unit	Barcode	S.Type	Test Time	Name	Age	Gender	More
9	710	hs-CRP	4.0	mg/L	0122637	W.B	2021-11-02 14:29:49	aolanna	79	Male	
		CRP	<5.0	mg/L							
8	713	hs-CRP	>5.0	mg/L	01e33736	S/P	2021-11-02 14:28:59	kasha	19	Female	
		CRP	18.1	mg/L							
7	712	hs-CRP	4.5	mg/L	012722	S/P	2021-11-02 14:28:32	gaylun	30	Male	
		CRP	<5.0	mg/L							
6	709	SARS-CoV-2	<0.50	COI	0727181	Swab	2021-11-02 10:25:33	rully	19	Female	
5	704	hs-CRP	>5.0	mg/L	01376523	S/P	2021-11-02 08:21:00	sailuo	27	Female	
		CRP	18.6	mg/L							

Fig. 5-14 Result

5.6.1 Results Inquiry

Enter the inquiry criteria in the search box, then click the lookup button to display test results for the entered criteria in the Results grid.

Inquiry criteria: Name, Sample ID/Barcode/No. and Date.

- Name: Enter a patient name to view test results for this

patient in the Results grid (Fig. 5-15).

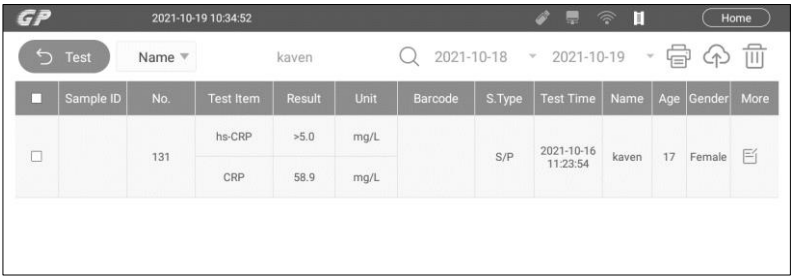


Fig. 5-15 Results Inquiry by Name

- Sample ID/Barcode/No.: Enter a sample ID, barcode or number to view test results for this sample ID, barcode or number in the Results grid (Fig. 5-16).

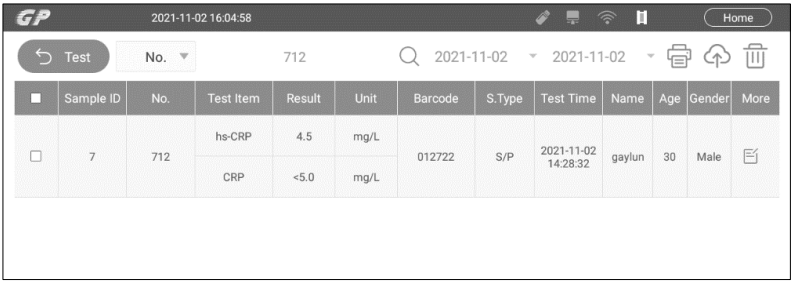


Fig. 5-16 Results Inquiry by No.

- Date: Click the date icon to select a date range in the prompt to view test results for the specific date range (Fig. 5-17).

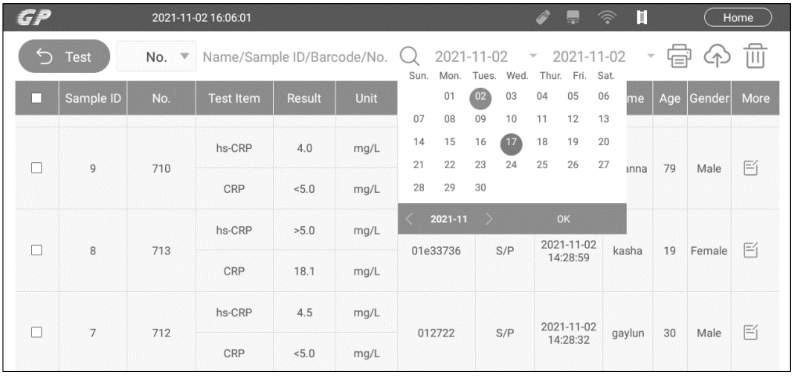


Fig. 5-17 Results Inquiry by Date Range

5.6.2 Results Handling

Result screen allows users to print, upload and delete result lines.

- Select one or multiple result lines in the results grid and click this button to print the selected results.

- Select one or multiple result lines in the results grid and click this button to upload the selected results. Users can select how results are uploaded in Communication Setting.

- Select one or multiple result lines in the results grid and click this button to delete the selected results.

5.6.3 Results Grid

The Results grid lists the detailed test results information saved in the system. The icon to the upper right corner of the No. column indicates the temporary test.

Click the icon in More column, a pop-up window will display which allows users to view sample information (Fig. 5-18).

If the user wants to edit the patient and sample information displayed on the report, edit in this window. Click Save to save the edited information.

Fig. 5-18 Sample Edit

5.7 Waste Disposal

Wasted cards, consumables and other wastes including instrument at the end of life, are considered as medical waste, industrial waste or source of infection. Please dispose of wastes properly in accordance with the disposal policy of your institution and local authorities.

Biological risks

- Follow and obey lab safety rules and guideline. Wear protective goggles, surgery gloves and laboratory coat to avoid the potential biological pollution risks.
- Users are obliged to abide by state and local regulations regarding the disposal of medical waste.

6. Quality Control

6.1 QC/Calib.

Users perform quality control and calibration as needed. Control Materials and calibrators are available from Getein. Scan the barcode on the control material/calibrator, item information will be displayed on the QC/Calib. Screen (Fig. 6-1). Enter the target value and SD value, then insert the test card to start the testing process.

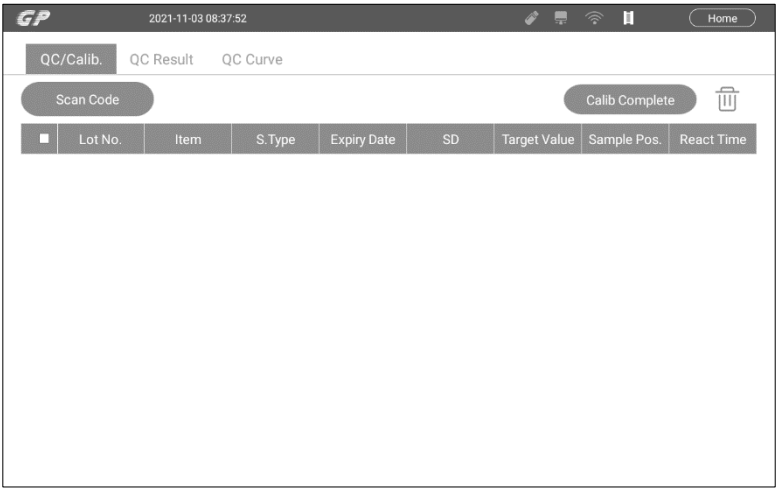


Fig. 6-1 QC/Calib.

6.2 QC Result

Control results will be displayed in QC Result (Fig. 6-2) in real time. Users select a lot number and/or a date range to view corresponding control information.

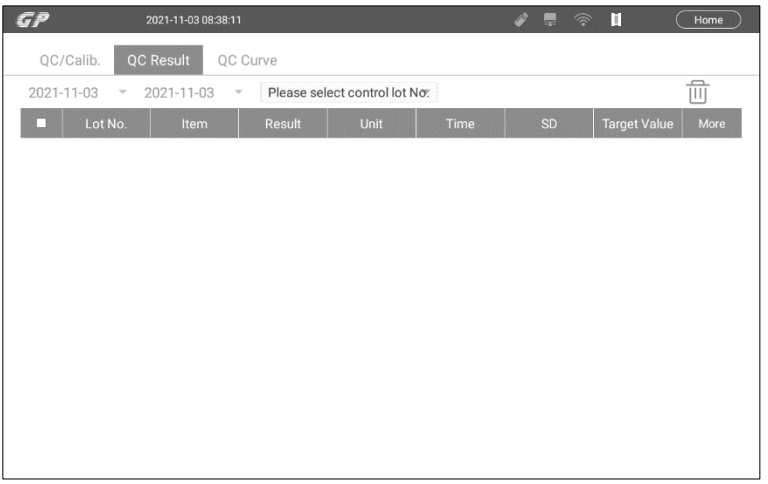


Fig. 6-2 QC Result

6.3 QC Curve

Click QC Curve Tab to switch to QC Curve (Fig. 6-3). Select a date range and a lot number to view the curve and check whether the values tested in the specific date range are outside the ±3SD limit. Click on a measurement point, the target value, standard variance, average value, points, status and result of the current measurement point will be shown beneath the curve.

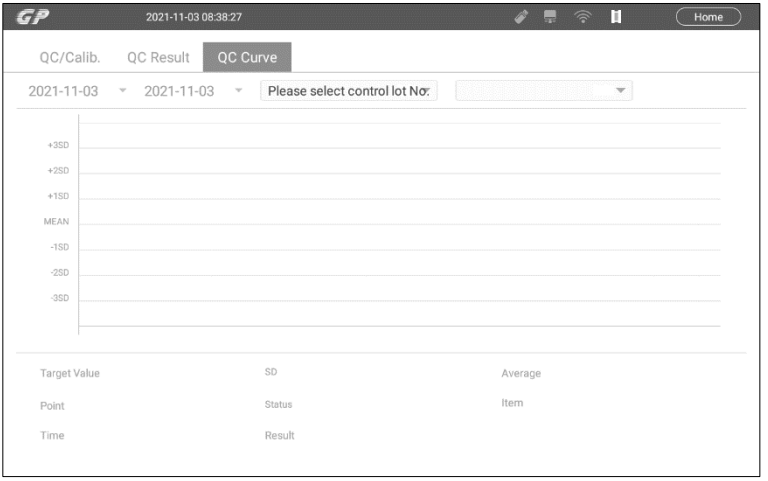


Fig. 6-3 QC Curve

QC Curve describes the chart of test results of a lot of QC materials over a period of time. Getein1160 system adopts Westgard rules.

12s (1-2s): One of one point is outside of +-2-sigma control limits; Warning

13s (1-3s): One of one point is outside of +-3-sigma control limits; Out of control

22s (2-2s): Two of two points outside +-2-sigma control limits; Out of control

R4s (R-4s): Two adjacent points on opposite sides of +-2-sigma; Out of control

31s (3-1s): Three of three points outside +-1-sigma control limits; Warning

41s (4-1s): Four of four points outside +-1-sigma control limits; Out of control

7x (7-x): Seven of seven points on one side of center line; Warning

7T (7-T): Seven of seven points in a trend increasing or decreasing; Out of control

8x (8-x): Eight of eight points on one side of center line; Warning

9x (9-x): Nine of nine points on one side of center line; Warning

10x (10-x): Ten of ten points on one side of center line; Out of control

7. System Setting

Installation and debugging of Getein1160 are performed by Getein's sales and after-sales professionals after a purchase is made. Operators can reset certain system parameters in Settings to meet your laboratory's specific requirements. Click the Settings icon in Main Interface to access Setting screens including: Communication Setting, Print Setting, Time Setting, System Setting and System Version.

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

7.1 Communication Setting

Communication Setting allows users to enable/disable Auto-upload function, select communication mode and communication protocol, perform communication test and barcode scan test.

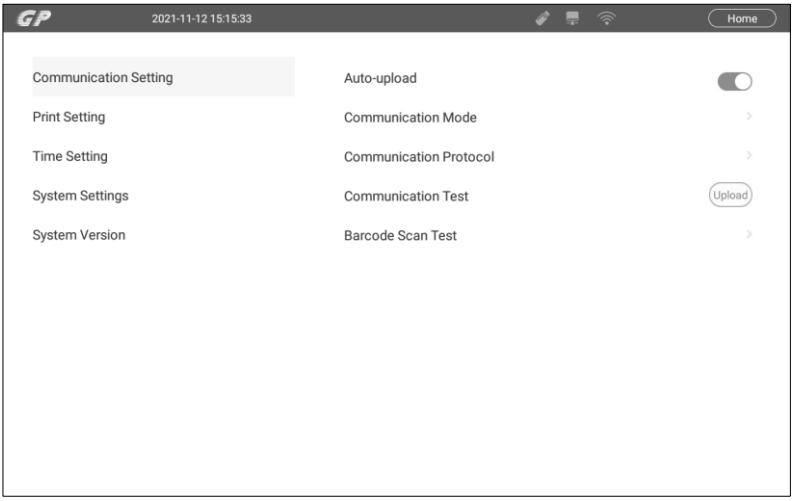


Fig. 7-1 Communication Setting

- **Auto Upload** - If Auto Upload is enabled, the test result will be uploaded to LIS automatically after the completion of a test. If it is disabled, users can upload results as needed in Result by clicking the Upload function button.

- **Communication Mode** - Select Serial Port or Ethernet Port.
- **Communication Protocol** - Select the protocol with the assistance of professionals.
- **Communication Test** - Click Upload button to send test data to the configured communication port to check whether the receiving system is successfully connected to the analyzer.
- **Barcode Scan Test** – This is used to test the barcode scanning function.

7.2 Print Setting

Print Setting allows users to enable/disable Auto Print, perform print test and set printing format (Fig. 7-2).

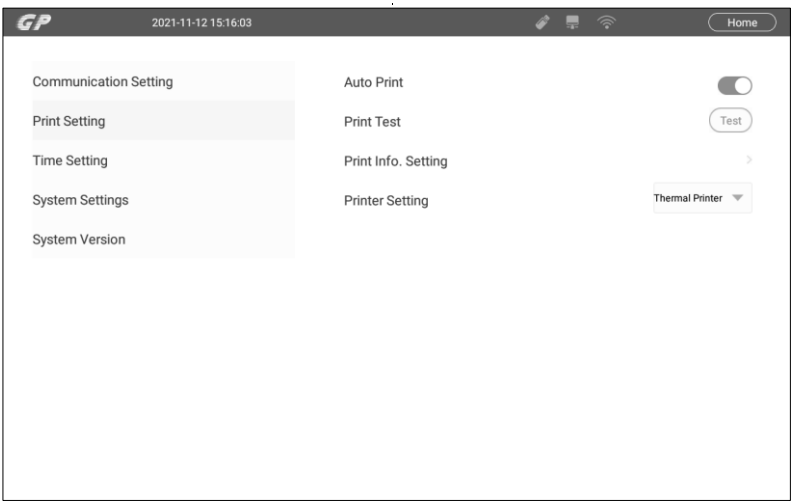


Fig. 7-2 Print Setting

- **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 clicking the Print button.
- **Print Test** - Click the Test button to print out a report template to verify the working status of the printer.
- **Print Information Setting** - Set what will be displayed on the report template and test report.

- **Printer Setting** – Select to print the report through the built-in thermal printer or the connected USB printer.

7.3 Time Setting

Click Time Setting to adjust the system date, time, time zone and date/time format (Fig. 7-3). System date/time can be set up based on the real-time clock. The time change takes effect immediately. Click Date and Time Setting on the top left to return to Setting interface.

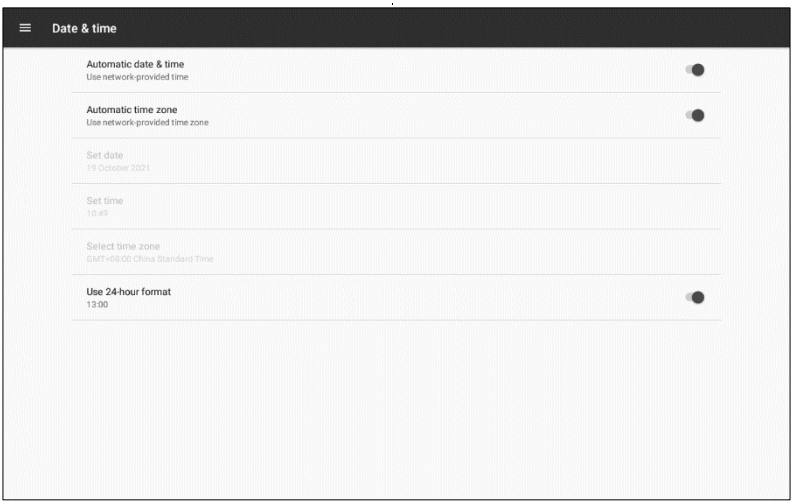


Fig. 7-3 Time Setting

7.4 System Settings

System Setting allows users to adjust the screen display brightness, select language and set up buzzer (Fig. 7-4).

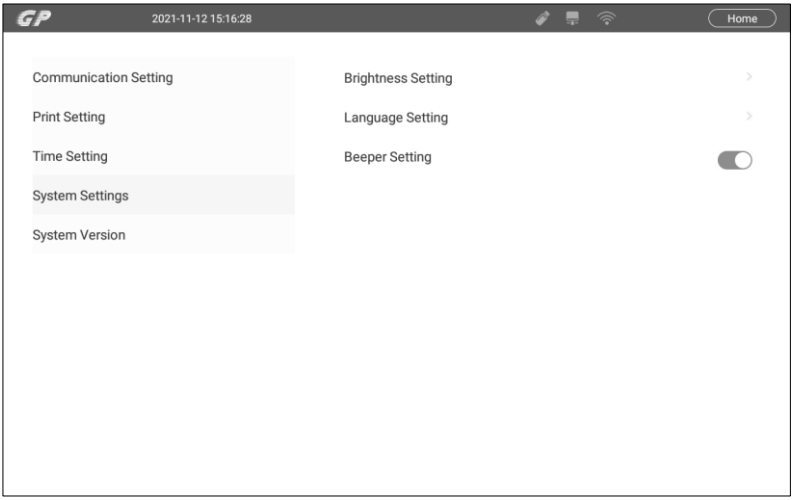


Fig. 7-4 System Setting

- **Brightness Setting** - It allows users to adjust screen brightness as needed.
- **Language Setting** - It allows users to select the display language. Users can select Chinese or English as needed.
- **Buzzer Setting** - It allows users to turn on/off the buzzer. When the buzzer is open, the system will beep when the SD card information is successfully imported.

7.5 System Version

This screen displays the version number for motor board, APP, BSP and SN (Fig. 7-5).

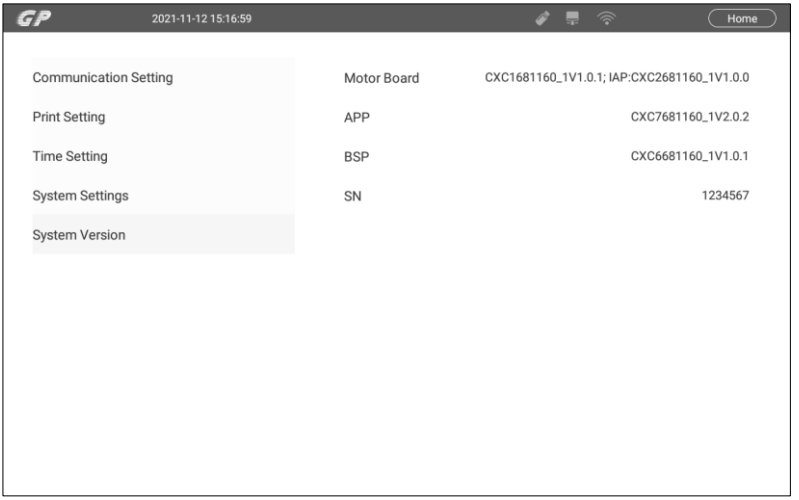


Fig. 7-5 Version Setting

7.6 Maintenance

Maintenance screens are for Getein's after-sales support to debug the instrument and only authorized personnel should have access to all the maintenance screens. To avoid system parameters being modified by accident, screens that users are not granted the access are encrypted. A prompt box will pop up requiring users to enter the password (Fig. 7-6).

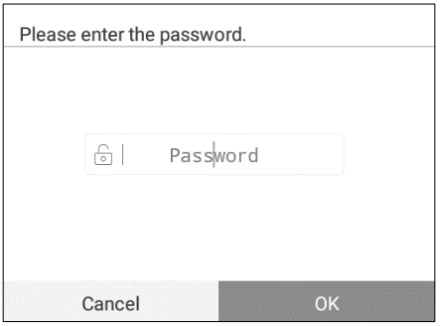


Fig. 7-6 Entering password

8. Communication (Optional)

8.1 Overview

GP Information Management Software can receive and read data transferred from the analyzer and display the real time test state. The management software can also build the user database, allows users to modify, save, query, browse data and backup database. When users are in the middle of automatic testing process of markers, they can observe the real time test state and receive test data; when the testing process is complete, users can enter patient information to browse and print the test report.

8.2 Software Name and Version

Software Name: GP Information Management Software
Version: Refer to the practical

8.3 Environment Requirement

Hardware Environment

a) CPU ≥ Intel Core II ; Internal Storage ≥ 2GB ; Hard Disk ≥ 100GB

b) Display: Resolution ≥ 1024 × 768

c) Printer: Resolution ≥ 600 × 600 dpi

Software Environment

Windows XP Professional, Windows 7, Windows 8, Windows 10 and its compatible machines

8.4 Software Installation and Instructions

Details refer to GP Information Management Software User Manual.

9. Maintenance

The instrument shall be cleaned and sanitized regularly. Users should not attempt any maintenance except for cleaning the external surface.

To clean the external surface:

Use a soft cloth with 70% alcohol to clean exterior of Getein1160. Wipe the external surface and test card slot only.

Caution

- Turn off and unplug the instrument prior to cleaning. Do not clean the ports on the back of the instrument.
- To avoid the risk of infection, wear protective gloves for all maintenance work. After completion of the work, wash hands thoroughly with water.
- Contact us immediately on any instrument problems. Getein will not be responsible for any consequences if unapproved personnel inspect, dissemble or replace any parts of the instrument without permission.
- All accessories, components and detachable parts must be obtained only from the manufacturer or authorized supplier.

10. Appendix

10.1 Copyright

Getein Biotech Inc.

Instrument Name: Immunofluorescence Quantitative Analyzer

Model: Getein1160

Production Date: Details refer to name plate

10.2 Statement

1. 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 Getein1160 only. Anyone has no right to make this manual public.
2. 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.
3. 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.
4. Getein holds the authority of the modification for contents of the manual without informing prior to it.

10.3 Manufacture Responsibility

1. 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.
2. 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.

3. Getein will conditionally provide circuit diagram, calibration specifications and other documents required to assist the appropriate personnel to finish maintenance or repair under situations uses can do themselves.
4. 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.

10.4 Instrument Lifespan

The lifespan of Getein1160 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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Pursue excellence

Deliver health