Automatic Coagulation Analyzer
ALTHEA

User Manual

Linear Chemicals, S.L.U.
Joaquim Costa 18, 2ª planta.
08390 Montgat, Spain

Rev 2.0

How to use this Manual

Thank you for purchasing the ALTHEA Automatic Coagulation analyzer. Before using it, please be sure to read this manual carefully. To achieve the best effect, you must be familiar with our equipment and its performance before making the clinical diagnostic test. In this manual, we will introduce Linear ALTHEA automatic Coagulation analyzer to you about its installation, daily use, maintenance and other contents.

Different versions or configurations of the instruments may have different functions.

Please keep all packing material for future storage, transport and retrofit.

If you have any question, please contact your dealer.

Tag Meaning

Warning: It means that if you ignore this tag to result in the misuse of this instrument, it may lead to the casualties, serious injuries or property losses.

Note: It means that if you ignore this tag to result in the misuse of this instrument, it may lead to personal injury, incorrect output or property losses.

Diagnostic Cautions

Note: This equipment is used for clinical examination. The clinical diagnosis based on test result should be made by doctors according to clinical symptoms and other test results.

Statement

Linear has the final right to construe this manual.

The illustrations provided in the manual are only for a reference, which may not be exactly consistent with the actual display on the product, taking the actual item as the standard. Don't use it for other purposes.

Without the written permission of Linear, any person or organization may not copy, modify or translate the contents of this manual.

Only in circumstances of meeting all requirements should Linear be responsible for the safety, reliability and performance of products, namely:

- Assembly operations, re-commissioning, expansion, improvement and maintenance should be provided by the approved personnel of Linear.
- The product is operated in accordance with this Manual.
- The related electrical equipment meets national standards.

Note

- This equipment must be used by the professional medical testing personnel, trained doctors, nurses or lab assistant.

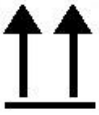
Warning

- If the using unit can’t perform a satisfactory maintenance\repair plan, it could cause the abnormal equipment failure, and may endanger human health.
- Make sure that the equipment is used under the conditions specified in the Manual, and if the using conditions can’t be met, it can cause the analyzer can’t operate normally, resulting in the unreliable measurement results and the damage to instrument components and personal safety.

Main icons

Temperature Limit
It shows that the transport package should be kept under this temperature limit.

Fragile
The fragile is contained in the transport package, so please handle with care when transporting.



Straight up
It shows that the transport package should be placed straight up.

Avoid raining
Packing cases can't stand raining.

Keep out of direct sunlight
Packing cases should be kept out of direct sunlight.

Forbid rolling
Don't roll the transport package.

Biological pollution.

Note, please refer to the accompanying documents.

Users should operate the equipment following the instructions under the sign; otherwise, it may cause personal injury.

In-vitro diagnostic equipment

Warning and Safety Tips

This equipment is only applicable for in-vitro diagnostic. Please read the following warnings before use, which must be strictly observed.

Warning: Please read the following notes before using this equipment.

- **If it has sent out unusual odor, smoke or unusual sound, you must cut off the power immediately, and unplug the power plug from the power outlet. At this point, you should immediately apply the inspection for dealer and agents of Linear. If you continue using the equipment under this circumstance, it may result in fire, electric shock or casualties.**
- **Avoid blood, reagents, staples and other metal pieces going into the equipment. Otherwise, it easily causes a short circuit, fire or smoke. If an exception occurs, you must cut off the power immediately, and unplug the power plug from the power outlet. At this point, you should immediately apply the inspection for dealer and agents of Linear.**
- **Operators can't touch electronic circuits in the equipment, particularly, it has more possibility of electric shock if you touch it by your wet hands.**
- **You must wear rubber gloves during the maintenance and inspection, and use the required tools and spare parts. After the operation, please wash hands with the disinfectant. Otherwise, the skin contacting with blood might be infected or result in electric shock or burns.**
- **Be careful to handle specimens. You must wear rubber gloves, otherwise, it may cause infection. If the specimens accidentally go into the eyes or wound, you must immediately rinse with plenty of water and ask doctors for examination.**

How to use and handle reagents

- **Avoid the reagents contacting with the skin and clothing during the operation.**
- **If the specimens accidentally go into the eyes or wound, you must immediately rinse with plenty of water and ask doctors for examination.**
- **If you drink reagents by mistake, you should immediately ask doctors for help, and drink lots of water to spit out.**
- **If reagents come in contact with your hands or skin, please rinse with water immediately.**
- **The cleaning liquid supporting with the equipment is strongly alkaline, which can not contact with skin and clothing. If it accidentally contacts with your skin or clothes, you should rinse immediately with plenty of water to avoid injury.**
- **The used test tube and other waste materials should be given for proper disposal as medical or infectious waste. If contaminated by blood, it may be infected with pathogens.**

Supply voltage, connection and grounding

- **Make sure this instrument equipped with stable network power and good grounding environment.**

- **The power plug must be inserted into AC 220V power outlet, otherwise, it may cause fire or electric shock.**
- **When installing the equipment, be sure to use the three-core power cable accompanied with the equipment, and it must ensure a good grounding, and must be placed properly so as to be easy to power off. Otherwise, it may cause fire or electric shock.**
- **Don’t damage the insulation sheath of power cord. Don’t pull the power cord strongly or hang heavy objects on it. Otherwise, it may cause short circuit or open circuit, resulting in electrical shock or fire.**
- **When connecting with peripheral devices, you must cut off the power at first. Otherwise, it may cause electric shock or malfunction.**

It is provided in Pharmaceutical Affairs Law to prohibit the modification of medical devices.

Contents

Chapter 1 Brief Introduction

1.1 Product Introduction

1.1.1 Product Name: Automatic Coagulation Analyzer

1.1.2 Type: ALTHEA

1.1.3 Features

1) ALTHEA is a fully automatic Coagulation analyzer for specific clinical in hemostasis, which can be widely applied in fields of the clinical diagnosis of bleeding and thrombotic diseases, and the monitoring and effect observation of thrombolysis and anticoagulantion therapy.
2) Including three measuring methods of clotting, chromogenic and immunologic.
3) It has functions of automatic dilution, automatic calibration and automatic screening analysis, hereinto, calibration curves can be stored.
4) Fibrinogen (FIB) Determination: derived methods and clauss method.
5) A large capacity of history data can be stored: 10000 coagulation response curves are stored, and 100000 testing results can be searched.
6) It can support the output of a variety of integrated reports and connect with many brands of external printers.
7) System maintenance interface, which can be used for engineers to make periodic calibration of the locations of mechanical parts.
8) Function of auxiliary management: built-in department database, doctor database and system log database.

1.2 Composition and structure of the equipment

This analyzer has a series of fully automated analysis functions, such as sample processing by dispensing of samples and reagents, calculation, display and print of results and so on. It is mainly composed of the sampling system, constant temperature system, measurement system, cleaning system and computer system.

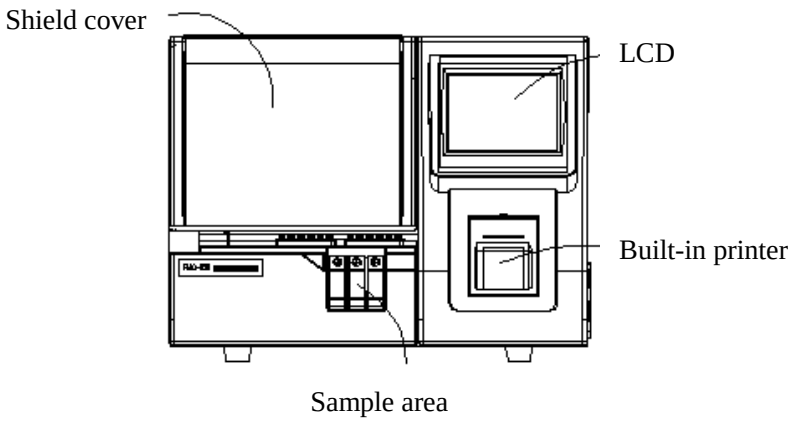


Fig. 1-1 Front View

1.2.1 Sampling System

It can complete the automatic sampling of samples and reagents. Sampling probe has the following three functions:

1) The liquid level detection function, by which the equipment will give tips and make the appropriate treatment with the lack of reagents or samples.
2) The reagent preheating function, by which it can warm up reagent in 3-5 seconds.
3) Anti-collision function

1.2.2 Constant Temperature System

It includes the reagent refrigeration and preheating, incubation of reaction solution and its constant temperature control during the testing.

1) Reagent refrigeration: to ensure the temperature of all the reagent positions among 13℃~15℃.
2) Reagent preheating: to achieve the 37 ℃ constant temperature control for the needle tube of sample probe, and to warm up the reagent quickly within 5 seconds.
3) Incubation Function: There are eight incubation holes in the detection zone with 37℃ constant temperature control.
4) Constant temperature control of testing positions: There are seven testing positions in the detection zone with 37℃ constant temperature control.

1.2.3 Measurement System

The measurement system lies in the right front of working table, including three measuring methods of clotting, chromogenic and immunologic.

1) Coagulometric (Turbimetric) Measurements: there are four testing positions including 9, 10, 11, and 12 as shown in the following figure, taking the semiconductor light-emitting diode of red light (LED) as the illuminator.
2) Chromogenic Measurement: there is one testing position with the test wavelength of 405nm, marked as 13 in the following figure.
3) Immunological Measurement: there is two testing positions with the test wavelength of 575nm, including 14 and 15 as shown in the following figure.
4) There are 8 incubation positions, marked as 1-8 in the following figure.
5) Disposable cup position is marked as 16 in the following figure.

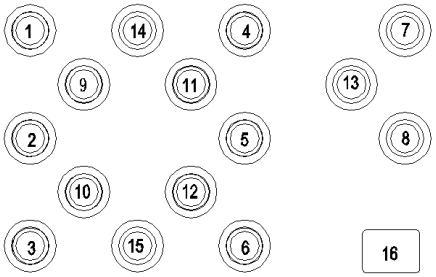


Fig. 1-2 Top view of optical testing postions

1.2.4 Cleaning System

Clean the inside and outside of sampling probe

1) Cleaning pool: It left hole is used for cleaning the inside of sampling probe, and its right hole is used for cleaning the outside of sampling probe.
2) Cleaning bottle: it is used for holding distilled or deionized water.
3) Waste bottle: it is used for holding waste liquid.

1.2.5 Sample Area

1) The number of sample positions
   There are 3 sample racks, each of which has 9 sample positions, and so there are a total of 27 sample positions.
2) Specifications of Sample Tube
   It supports the standard test tube, the original blood collection tube and 1.5ml sample cup;
   The original blood collection tube has the outer diameter among 10mm～16mm, and has the height of no more than 100mm.

1.2.6 Reagent Position

1) Special reagent holder with a basket device;
2) The number of reagent positions: there are a total of 23 reagent positions, hereinto, the first 3 positions are generally defined as cleaning position and diluents position
3) Temperature Accuracy: All have the cold storage function among 13℃～150C.
4) Temperature will get stable within 30 minutes;
5) Size of reagent bottle
   Reagent bottle of 1mL～10mL, suitable for the reagent bottle with outer diameter of Φ14mm～Φ36mm;
   The height of reagent bottle should not be more than 80mm, otherwise, it may cause the firing pin.
   There are all kinds of adapters to ensure using the vial reagent bottles in order to reduce the dead fluid volume as far as possible.

1.2.7 Computer System

Control the running and operation of the equipment.

1.3 Scope of Application

The analyzer applies to test the time and activity of blood coagulation factor, anticoagulation proteins, fibrinolytic system and circulating anticoagulant in the clinical hemagglutination test with optical turbidimetry.

1.4 Test Items

Test items should at least include the determination of prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (FIB) and thrombin time (TT). And test items are shown in Table 1-1.

Table 1-1

Name	Test Item	Methodology	Default Unit
prothrombin time	PT	Coagulation	s
activated partial thromboplastin time	APTT	Coagulation	S(second)
fibrinogen	FIB	Coagulation	mg/dL
thrombin time	TT	Coagulation	S(second)
Protein C	PCco	Coagulation	%
LA1 screening	LA1	Coagulation	S(second)
LA2 screening	LA2	Coagulation	S(second)
factor analysis	II, V, VII, VIII, IX, X, XI, XII	Coagulation	%
antithrombin III	AT3	Chromogenic	%
α2- antiplasmin	α2-AP	Chromogenic	%
plasminogen	Plg	Chromogenic	%
Protein C (for Chromogenic)	PCch	Chromogenic	%
heparin	Hep	Chromogenic	IU/mL
D-Dimer	D-Dimer	Immunologic	ug/mL
fibrinogen degradation	FDP	Immunologic	ug/L

1.5 Technical Data

Table 1-2

Mains input：	a.c.100V/220V，50Hz or 60Hz
Input power：	400VA
Operational environment：	10℃~30℃，relative humidity ≤70％
Storage environment：	-20℃～55℃， relative humidity≤85％。
Test speed：	60 tests/hour. (PT item)
Test position：	Sample rack with 27 test tube positions
Reagent position：	23 cold storage positions of reagents

Chapter 2 Installation and Calibration of Equipment

2.1 Unpacking

2.1.1 Steps of Unpacking

Open the packing of equipment and remove the material for transport. Save the packing box and other packing materials for the future when you need the re-packaging.

1) Packing box should be erect, and its arrow is facing up.
2) Open each side plate of the box by tools, remove the accessories, and check whether they are complete according to the list; if missing, please contact the Linear's after-sales service or vender immediately. Check the contents in the box, which should include the following:
   - ALTHEA host
   - User Manual
   - Packing List
   - Dealer Warranty Certificate
   - Product Acceptance Certificate
3) Remove the top cushion cotton, and then carry the equipment carefully from the bottom of both sides with at least two staff, placed on the operation platform.

Note: For packing accessories, take the packing list as standard. If you find the parts have defects or accessories are not in accordance with packing list, please contact your dealer.

2.1.2 Conveying Means

- Make sure that the arms of analyzer after being used are in Reset state, in particular, the sampling needle should be in the highest position before moving.
- Under the short distance and stable condition, small handcart and other vehicles can be used for transport.
- During the whole moving process, you should pay attention to protect the display on the front panel and the sampling needle from outside force, and not to touch other objects from damage.
- During the whole moving process, you must keep this equipment upright, not tilted and placed on its side.
- During the moving process, you should avoid vibration as possible as you can. After that, the inspection and testing must be given before using it.

Note: Please keep the packing box for the future long-distacne transport. The analyzer must be placed on the horizontal operating table, and can't be placed on the inclined plane.

2.2 Envrionment for Installation and Use

ALTHEA automatic Coagulation analyzer must be installed by professionals. To ensure the equipment can work properly, it should be placed on the workplace meeting the following requirements:

- No direct sunlight;
- No a lot of dust;
- No strong electromagnetic radiation;
- Well-ventilated;
- Avoid humidity and high temperature;
- Avoid severe vibration and shock.

Note：（1）This equipment can work under the environment temperature 15～30℃and the relative humidity less than 70%. Other medical devices mustn't be used near this equipment. You should avoid using this equipment in the too high or low temperature environment, otherwise, it will cause inaccurate results or the damage to the equipment.

（2）After the installation, you should avoid moving it frequently, if necessary, you should move it by the stable cart, and keep the tilt angel less than 15°during moving it.

（3）As it belongs to precision instrument controlled by the computer, it needs to be configured with more than 500W UPS (uninterruptible backup power supply). If the voltage in the laboratory changes beyond 10%, it is recommended to install an external regulator with more than 1000W.

（4）It must be installed and moved by authorized professionals.

2.3 Power Requirement

- a.c.100V / 220V
- 50Hz or 60Hz
- 400VA

Warning：（1）AC power supply must be grounded well (ground voltage ＜5V）.

（2）AC power supply must be stable against sharing power with the high-power electrical appliances. It is better to configure with constant voltage power supply.

（3）If you have found smoke, rare smell or abnormal noise from the equipment, please turn off the power immediately, and contact your dealer.

（4）Unplug the power cord by grasping the plug itself, not the power cord.

2.4 Connect the pipeline.

The equipment should be measured and maintained with cleaning fluid. To ensure the accuracy of test results, please use the pipeline supported with the equipment. For connecting the pipeline, you may follow these steps:

1) Take out the catheters of cleaning fluid and waste fluid from the accessory bag.
2) On the back side plate of the equipment, follow the color of pipe fittings and the marks on the label to connect the pipelines of cleaning bottle and waste bottle.
3) Connect the warning sensor of liquid level for leaning bottle and waste bottle.

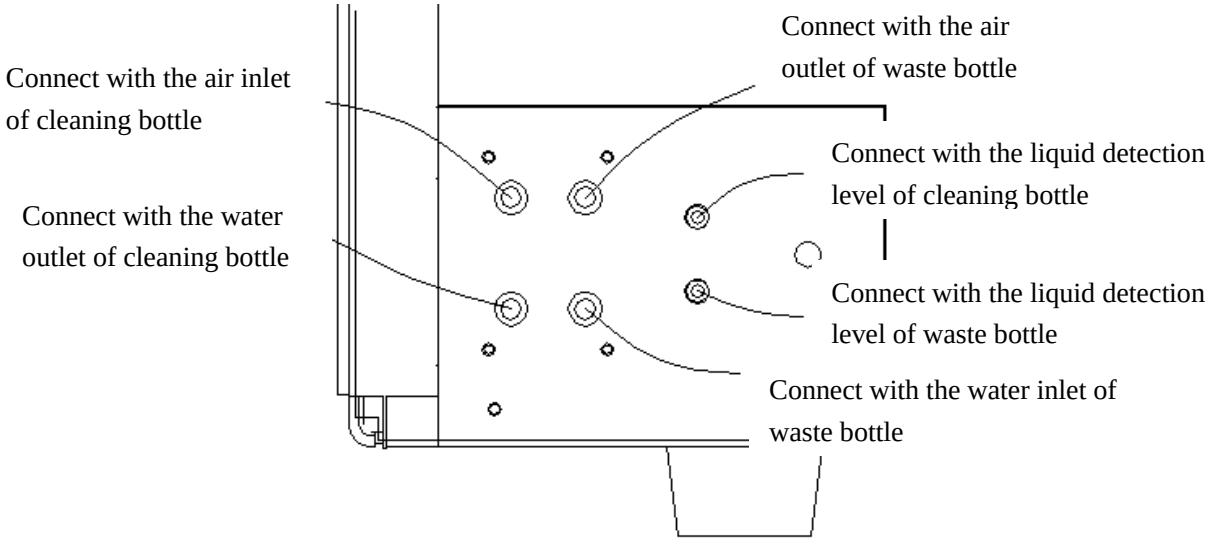


Fig 2-1 Pipeline Connection Diagram

Note：（1）All the pipelines and power cord must be connected in accordance with the marks on the label.

（2）If the waste bottle is tipped for date analysis, waste liquid may counter-flow into vacuum pump, resulting in the damage of parts. Therefore, please make sure that the waste bottle is upright correctly.

（3）Don't pull or cut off the pipelines of cleaning bottle randomly in order to prevent water spray due to the pressure in the bottle. If necessary, you need to unscrew the bottle cap to release the pressure.

2.5 Install the keyboard and mouse

1) Remove the keyboard and mouse carefully from the packing box.
2) Insert the keyboard plug carefully into the interface marked as "Keyboard" on the right side plate of the equipment.
3) Insert the mouse plug carefully into the interface marked as "Mouse" on the right side plate of the equipment.

2.6 Connect an external printer.

1) Connect one end of printer cable into the printer's USB port.
2) Connect the other end of printer cable into the equipment's USB port.
3) Connect the printer with AC power supply by the printer's power cord.
4) Power on the printer to start.

2.7 Calibration of Equipment

The equipment can be calibrated with the standards and quality control. Calibration test does not need to be done every day, but it should be made at least once for the item needing the calibration. Calibration results can be used until the new re-calibration data is saved. However, because the changes of system environment may have some impact on the test, it is recommended for daily calibration test to ensure the accuracy of the test results.

Note：

1) Don't step on the external waste bottle and cleaning bottle.

2) Don't open the back cover, side cover or panel when the current is switched on.

Chapter 3 Startup

3.1 Cautions before starting

Before each starting, the operator should ensure the system is ready according to the following matters:

1) Before starting, check whether the cleaning fluid can meet this test, and whether the waste bottle has been full.
2) Check whether there is adequate paper in the internal or external printer, and whether its installation is in place.
3) The instruction manual must be placed near at hand.
4) Operate and maintain computer according to its instructions.

3.2 Login

After turning on the host and starting the system, the Login window will appear:

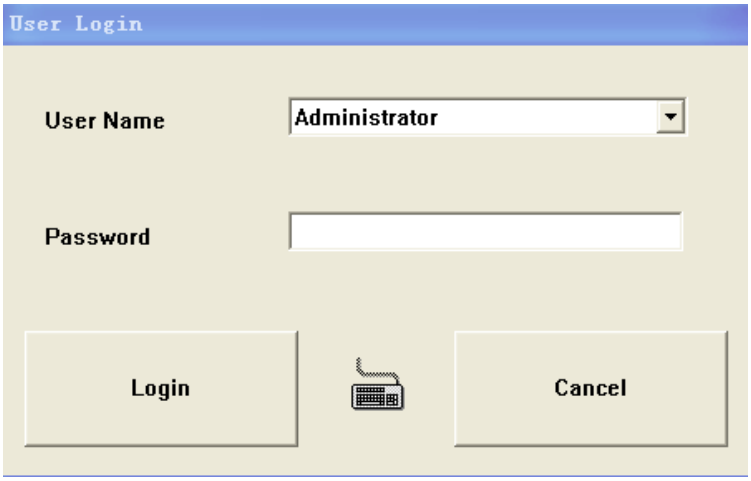


Fig 3-1 Log in

After using the default user “Administrator” and inputting the initial password “888888” (you can change the password in the system settings after logging in), you can perform the test operation. If you don’t use the keyboard, please click the keyboard icon to pop up the soft keyboard for enter the password.

3.3 Main Interface

After logging in successfully, enter into the main interface window.

Fig 3-2 Main Interface

The main interface is the portal for all user functions of ALTHEA analyzer, in which users can click the icon for the specific operation.

Click the “Linear” icon in the middle of the window, and you can see the copyright and version information of the system.Press the Exit key to return to the main menu.

3.4 Functional Module

All functional modules are displayed at the bottom of the main screen, and the function of each part is introduced briefly as follows:

1) Item test: it includes the settings of reagent position, sample information editing, item testing and STAT testing. (See Chapter Ⅵ for details).
2) Quality Control Settings: it includes the settings of quality control material, quality control diagram and the query and print data of quality control. (See Chapter Ⅶ for details).
3) Standard Settings: it includes the settings of standard substance, automatic calibration test, manually entering the calibration data, the query and print of calibration curves and data. (See Chapter Ⅷ for details).
4) Item settings: it includes the information settings of inspection item. (See Chapter Ⅵ for details).
5) History query: it includes the query and print of history sorted by item or by patient. (See Chapter Ⅸ for details).
6) System settings: it includes hospital information, reagent information, worksheet settings, combination settings, log query, system settings and data upload. (See Chapter Ⅴ for details).

Chapter 4 Item Settings

Press the Item Setting key in the main menu to select items:

Fig 4-1 Item Setting

The first 30 items of ALTHEA analyzer belong to the built-in fixed test ones. Presses the Next key to display the next 30 customized items, and then select an item to enter into the Item Setting window:

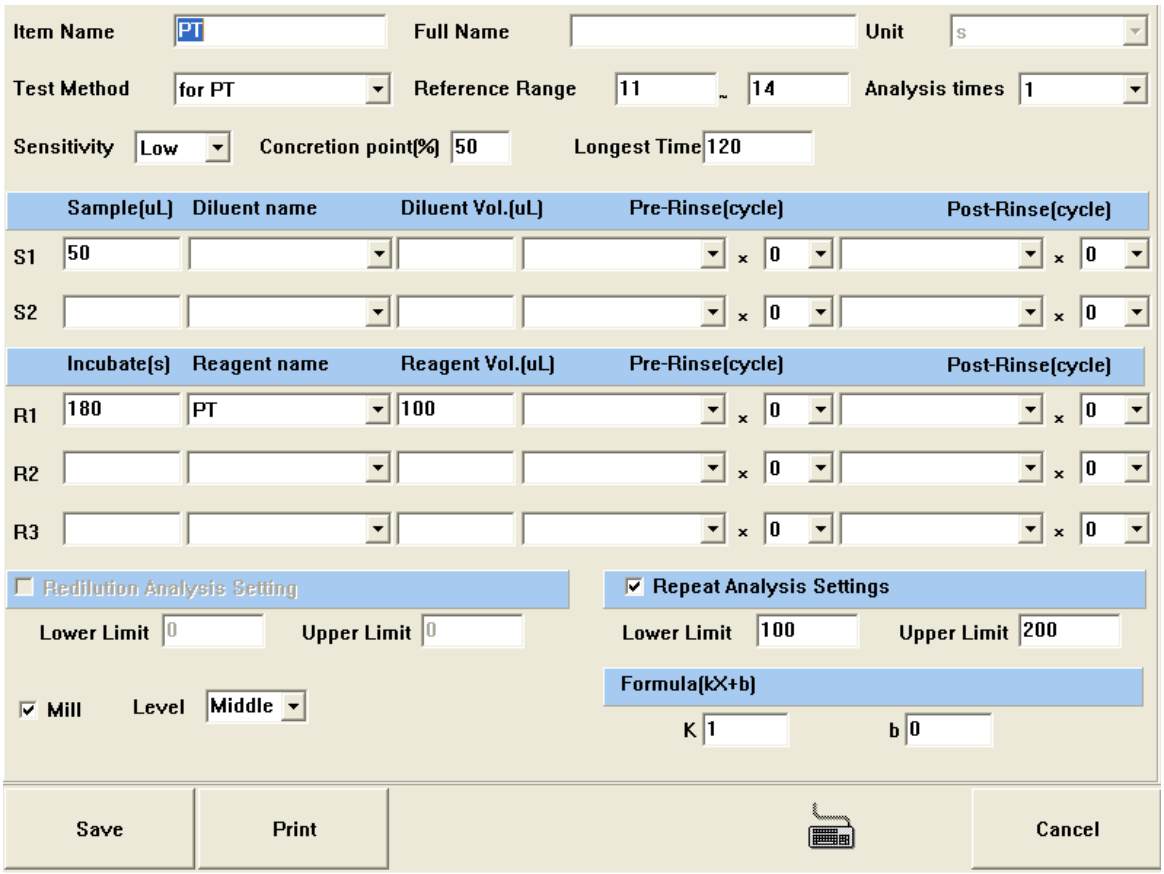


Fig 4-2 Item Setting window

4.1 Item Parameters Settings

In the Item Settings, you can set the item testing parameters, and the following parameters should be set:

- Item Name

  English name of the item, up to 15 characters.
- Chinese Name

  Chinese name of the item, up to 30 characters.
- Unit

  Select the unit, and see the hospital information for unit information in Section 5.4.
- Sensitivity

  Set the sensitivity of the detector, which is sorted into low, medium and high.
- Test Method:

  The system consists of 3 test methods, which are Coagulometric Tests, Chromogenic Tests, and Immunological Tests. For each cure item, it will be subdivided into 25 kinds of specific algorithms. For different testing items, you can select the corresponding test method, for example, taking *for PT* as PT test method, and *for FIB* as FIB test method..
- Reference Range

  Reference range of test results. For the fixed quantity and percentage kinds of items, you can take the normal range of the corresponding results as their reference range, and for other items, you can take the normal range of testing time (unit: second).
- Repeat analysis

Set the Repeat Analysis. When setting two or more times of analysis, the system will automatically calculate the average as the test result, and the frequency of repeating analysis can be set up to 10 times.

- Stop/Start time

  a) Set up a stopping point of blood coagulation for the coagulation method. Set the stopping point among 2%~80%, which can be changed with an increment of 1%.

  b) Set up a starting time for chromogenic assay and immunoassays. Set the starting time among 1s~600s, which can be changed with an increment of 1s.

- The longest time/stopping time

  a) Set up the longest coagulation for the coagulation method, which can be set among 90s~600s.

  b) Set up a stopping time for chromogenic assay and immunoassays, which can be set among 1s~600s.

- S1 sample size(ul)

  Set the volume of absorbed sample, which can be set among 4ul~120ul and be changed with an increment of 1ul. If diluents are not used, it can be set as 20ul or more.

- Name of diluents

  Select the diluents. And set the reagent parameter. See Section 5.1 for details.

- Diluents Volume

  Set the volume of absorbed diluents. If diluents are used only when the standard curve is established, please set the name of diluents and enter 0ul.

Note: Make sure that the total volume of the absorbed diluents and sample is controlled among 20ul~130ul.

- Washing before and after absorbing (sample)

  Set the washing cycle with the maximum of 9 times before and after absorbing samples, and if not washing, please select the “0”.

- S2 sample volume (ul)（At the second step of dilution）

  Set the amount of absorbed sample at the second step of dilution among 4ul~120ul, which can be changed with an increment of 1ul.

- Name of diluents (At the second step of dilution）

  Set the diluents used at the second step of dilution. And set the reagent parameters. See Section 5.1 for details.

- Diluents Volume

  The amount of diluents used at the second step of dilution. It can be set among 0ul~200ul, and be changed with an increment of 1ul.

Note: Make sure that the total amount of diluents and sample is controlled among 20ul~130ul.

- Washing before and after absorbing (At the second step of dilution)

Set the washing cycle with the maximum of 9 times before and after absorbing samples, and if not washing, please select the “0”.

- Incubation time of reagent 1

  Set the time interval with the minimum of 30s between the starting time of heating sample and the time of adding reagent 1, which can be changed with an increment of 30s.However, if the washing is set immediately after absorbing the sample, each washing cycle will be increased with another 30 seconds. And also, if the washing is set before the reagent 1, each washing cycle will be increased with another 30 seconds.
- Name of reagent 1(R1)

  Select the name of reagent. And set the reagent parameters. See Section 5.1 for details.
- Absorption amount of reagent 1(R1)

  Set the absorption amount of reagent 1(R1) among 4ul~200ul, which can be changed with an increment of 1ul.
- Washing before and after absorbing (R1)

  Set the washing cycle with the maximum of 9 times before and after absorbing the reagent 1, and if not washing, please select the “0”.
- Incubation time of reagent 2

  Set the time interval with the minimum of 30s between the times of adding reagent 1 and 2, which can be changed with an increment of 30s. However, if the washing is set immediately after absorbing the sample, each washing cycle will be increased with another 30 seconds. And also, if the washing is set before the reagent 1, each washing cycle will be increased with another 30 seconds.
- Name of reagent 2(R2)

  Select the name of reagent. And set the reagent parameters. See Section 5.1 for details.
- Absorption amount of reagent 2(R2)

  Set the absorption amount of reagent 2(R2) among 4ul~200ul, which can be changed with an increment of 1ul.
- Washing before and after absorbing (R2)

  Set the washing cycle with the maximum of 9 times before and after absorbing the reagent 2, and if not washing, please select the “0”.
- Incubation time of reagent 3

  Set the time interval with the minimum of 30s between the times of adding reagent 2 and 3, which can be changed with an increment of 30s. However, if the washing is set immediately after absorbing the sample, each washing cycle will be increased with another 30 seconds. And also, if the washing is set before the reagent 1, each washing cycle will be increased with another 30 seconds.
- Name of reagent 3(R3)

  Select the name of reagent. And set the reagent parameters. See Section 5.1 for details.
- Absorption amount of reagent 3(R3)

  Set the absorption amount of reagent 3(R3) among 4ul~200ul, which can be changed with an increment of 1ul.
- Washing before and after absorbing (R3)

  Set the washing cycle with the maximum of 9 times before and after absorbing the reagent 3, and if not washing, please select the “0”.

Note: Make sure that the total amount of all the solutions in the cuvette is not less than 150ul, and not more than 400ul.

- Re-dilution analysis settings

  The sample is re-analyzed after the specified multiple of dilution. Set the upper and lower limits of result and the dilution factor; and if the test result is beyond its range, the sample should be tested again after the specified multiple of dilution. Select it by ticking, and the system will start this function.

- Re-testing analysis settings

  The sample needs to be analyzed again. Set the upper and lower limits of result; and if the test result is beyond its range, the sample should be tested again. Select it by ticking, and the system will start this function.

- Modified formula

  Modify the measured results. Modified formula: Y=KX+B; X as measured result, Y as modified result. If the modification is not needed, you can set K=1 and B=0.

Press the Save key to save the parameter information of the current item.

Press the Print key to print the parameter information of the current item.

Press the Exit key to exit from the current interface and return to the main interface.

Table Reference settings of plasma/reagent volume of common items

No.	Item	Name of Sample/Reagent	Volume	Total volume of reaction solution
1	PT	plasma	50	150
		PT reagent	100	
2	APTT	plasma	50	150
		APTT reagent	50	
		$CaCl_2$	50	
3	FIB	plasma	10	150
		diluents	90	
		FIB reagent	50	
4	TT	plasma	100	150
		TT reagent	50	
5	II, V, YII, X	plasma	5	200
		buffer solution	45	
		Factor Deficient Plasma	50	
		PT reagent	100	
6	VII, IX, XI, XII	plasma	5 or 10	200
		buffer solution	45 or 40	
		Factor Deficient Plasma	50	
		APTT reagent	50	
		CaCl2	50	
7	AT3	plasma	10	251

		buffer solution	83	
		thrombin reagent	125	
		substrate	33	
8	D- dimer	plasma	30	155
		buffer solution	5	
		D-D R1	60	
		D-D R2	60	

4.2 Item Test Methods

4.2.1 Coagulation Test (Percentage Test Method)

Take the percentage as a means of testing clotting time.

The level of scattered light is 0% when the reagent has been just added but the coagulation reaction has not been started, and it will become 100% after the coagulation reaction has stopped. Based on the coagulation curve, the clotting time can be obtained that is the required time when the scattered level reaches the predetermined testing percentage. (In the following figure, the coagulation testing point is set as 50%, and users can adjust the percentage of coagulation point for each time according to the practical situation. The smaller the percentage value is, the shorter the time of test result will be.)

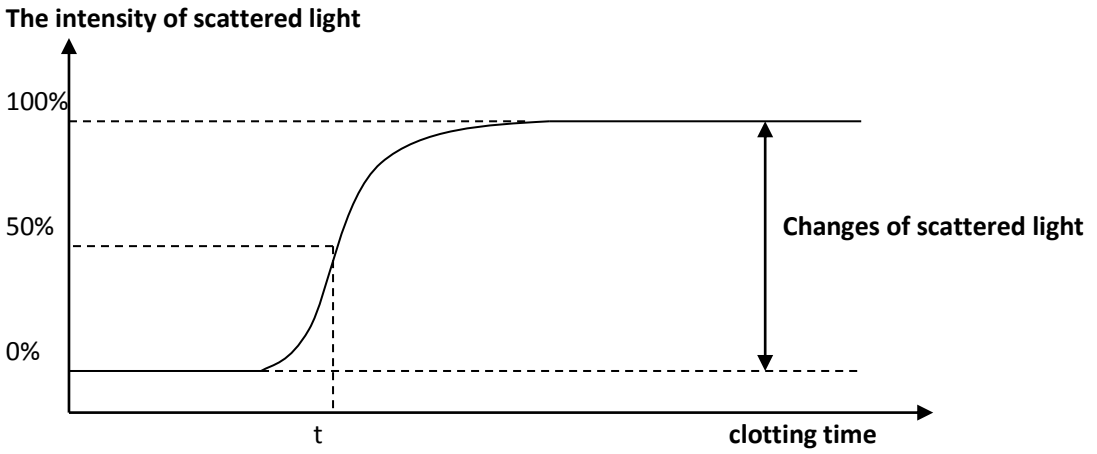


Fig 4-1 Reaction Curve

4.2.2 Chromogenic Tests

Chromogenic tests use the colorimetric principle of measuring absorbance of light (405nm) by the solution in a cuvette. The amount of light that reaches the photo detector is converted into an electrical signal that is proportional to enzyme activity.

4.2.3 Immunological Assay

After the plasma is preheated for some time, add the stabilizing reagent and the antibody sensitive reagent. The solution is exposed to light 575nm. The change in light intensity caused by the antigen antibody reaction is detected as the change in transmitted light.

Chapter 5 System Settings

In the main menu, press the System Settings key to enter the system settings:

Fig. 5-1 System Settings

5.1 Reagent Parameters

In the System Settings screen, press the Reagent Parameters key to enter the reagent parameter settings.

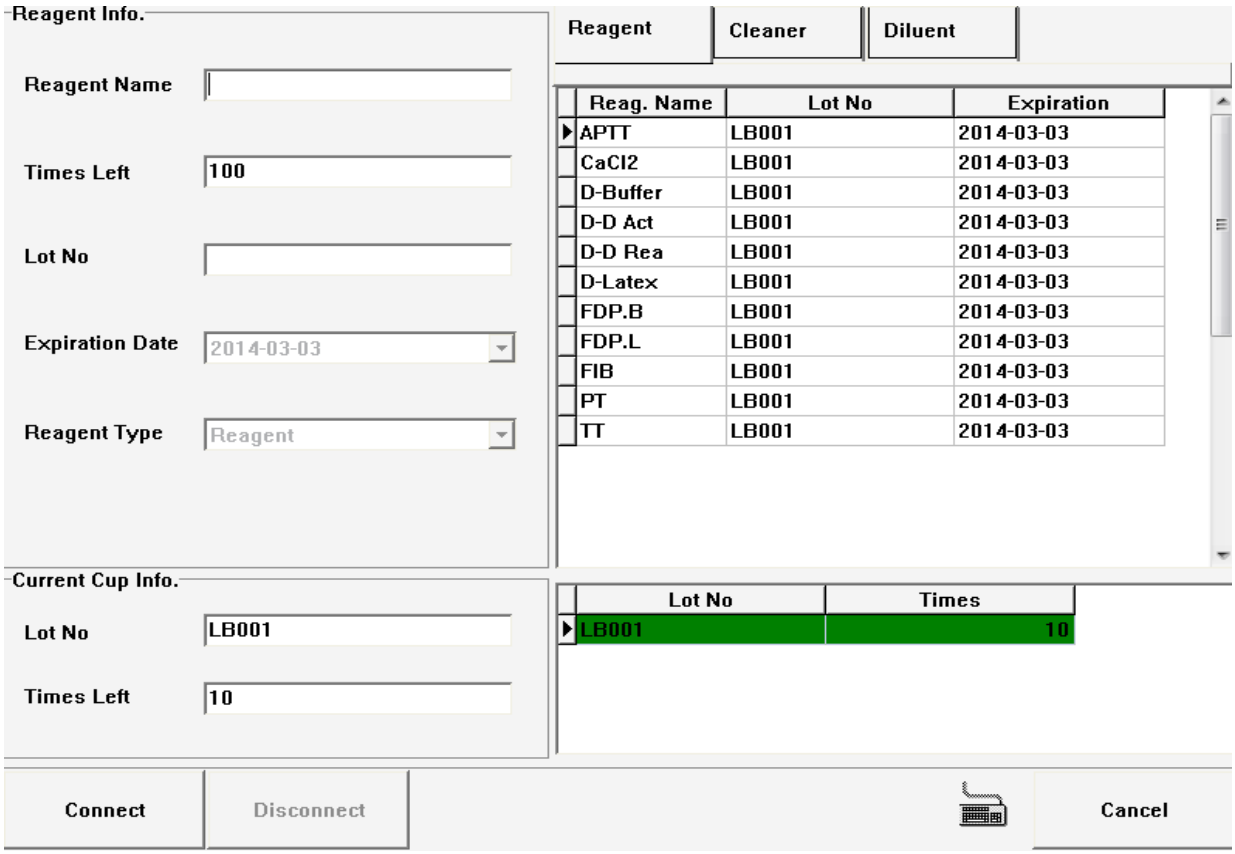


Fig 5-2 Reagent Parameter Settings

Reagent Information, you can get the reagent parameter information from the IC Card which contain reagent information:

- Name of Reagent
  English name of the reagent, up to 8 characters.
- Times Left
  The times left of the reagent..
- Lot No
  Lot no of the reagent, up to 15 characters
- Expiration Date
  Expiration date of the reagent
- Reagent Type
  There are three types in the system, including reagent, cleaning fluid and diluents.

Press the Connect button to connect the IC Card Reader which can get some information from the IC Card.

Press the Disconnect button to disconnect the IC Card Reader.

Press the Cancel button to exit from the current interface

Current Cup Information, display the current cup information, Lot no and Times Left. you can get the reagent parameter information from the IC Card which contain reagent information

5.2 Worksheet Settings

In the Worksheet, you can set up a test group (up to 10 items) for the working list. Three worksheets are provided by the system, and each worksheet can be set with the independent test group and the information of reagent position.

5.2.1 Set the test group.

In the System Settings interface, press the Worksheet Settings key to enter the settings of test group in the worksheet:

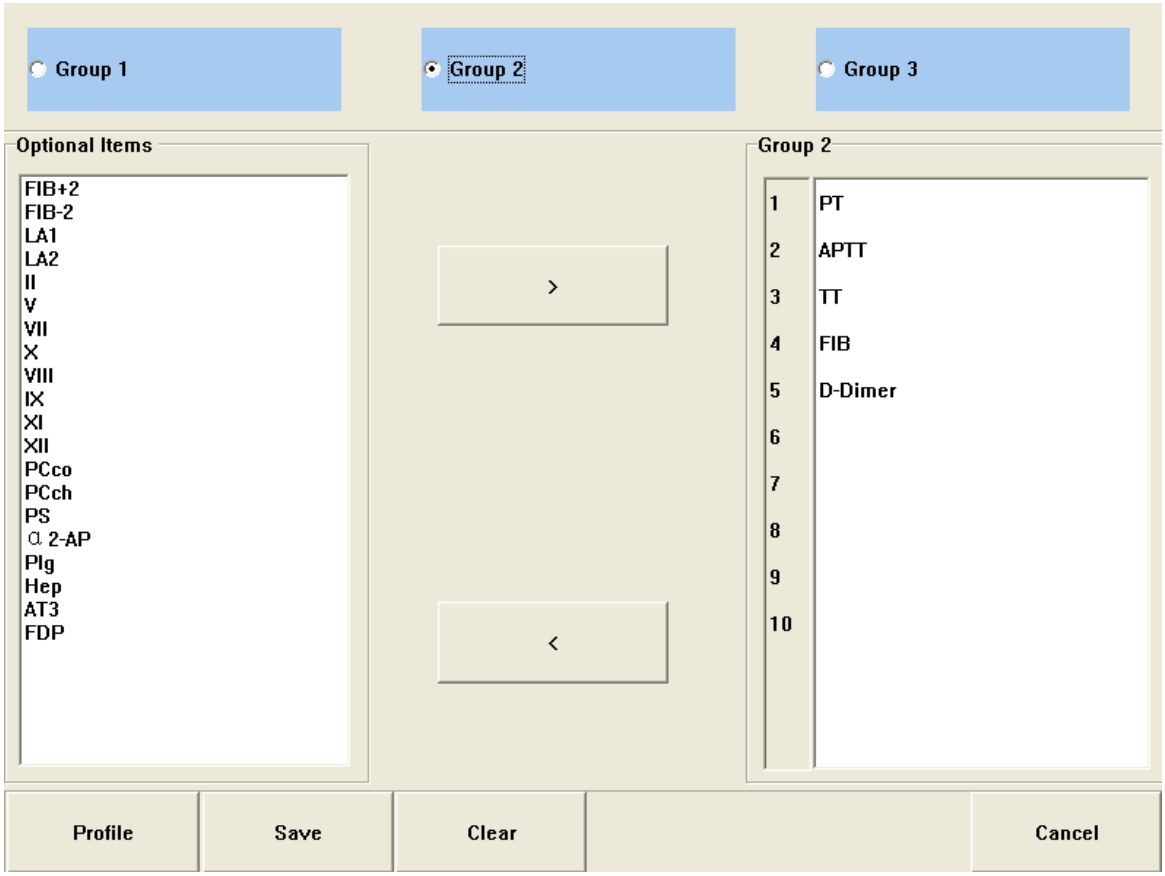


Fig 5-3 Worksheet Settings

Concrete Operation:

1) Select the test group item from the **Available Options** list, and press the < key to add the selected item to the worksheet, if it has been in the worksheet, the Add operation will be not performed; Press the > key to delete the selected item in the worksheet list.
2) Press the Save key to save the information in the current worksheet; and press the Clear key to delete all the items in the worksheet.
3) Press the Exit key to exit from the current interface, and return to the System Settings interface.

5.2.2 Item Group Settings

Press the Group key to enter the Group Settings interface.

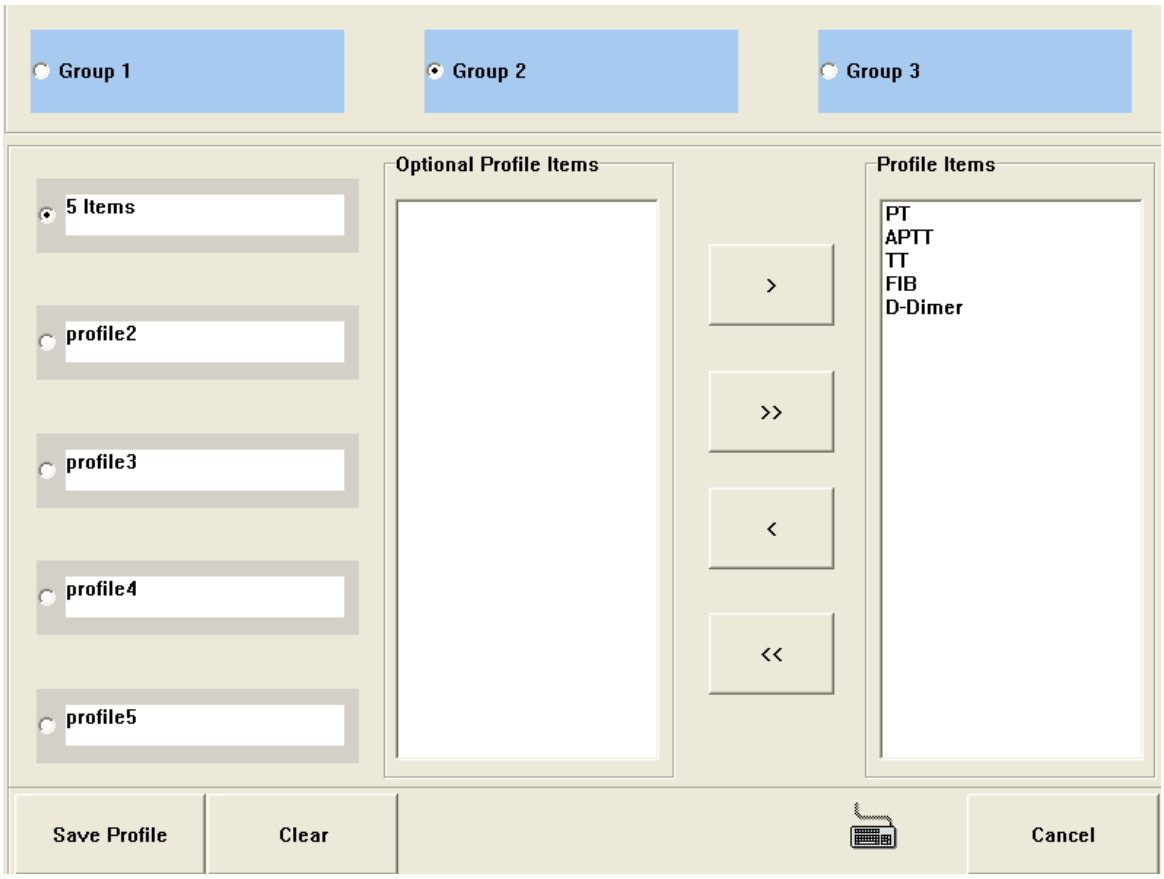


Fig 5-4 Item Group

For the Worksheet Group settings, there are five item groups provided for each group of worksheets; and the item group will be used to select the test items in batch for setting the sample rack in the sample test (See Section 6.2 for the settings of sample rack).

Concrete Operation:

1) Select the worksheet.
2) Select the group.
3) Click the group name, and the input symbol will appear, and then you can modify the group name.
4) Select the items from the **Available Group Options** list, and press the < key to add the selected items to the **Selected Group Options** list; and press the << key to add all the items in the **Available Group Options** list to the **Selected Group Options** list.
5) Select the item from the **Selected Group Options** list, and press the > key to delete the selected item from the **Selected Group Options** list; and press the >> key to clear the **Available Group Options** list.
6) Press the Save Group key to save the group settings in the current worksheet; and press the Clear Group key to clear the group settings in the current worksheet.
7) Press the Return to return to the Worksheet Settings interface.

Note: If you modify the available item in the worksheet that the group belongs to, it will clear the group settings.

5.3 AutoFilter Analysis

In the System Settings interface, press the AutoFilter Analysis key to enter the AutoFilter Analysis settings:

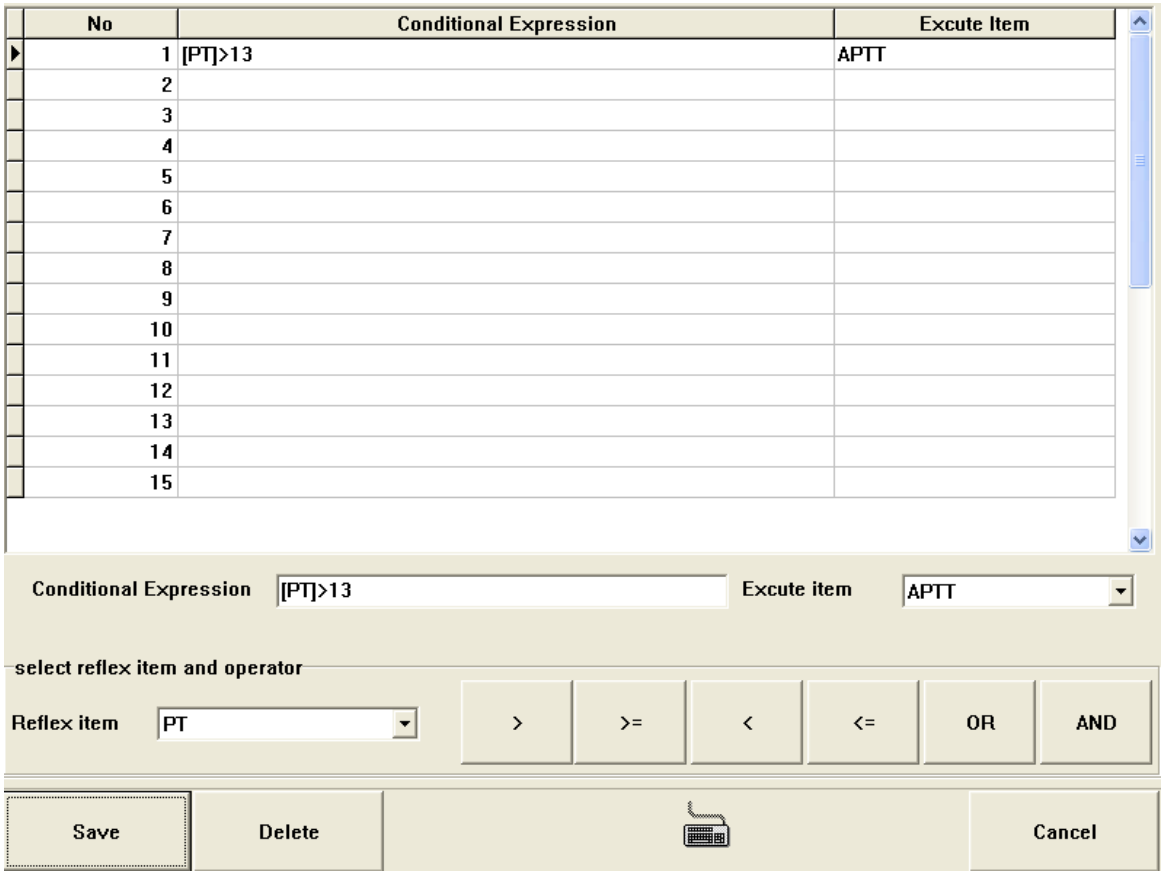


Fig 5-5 AutoFilter Analysis

In the AutoFilter Analysis, if the customized AutoFilter conditions are met, the system will automatically execute the specified item. Take execute item APTT for example, if the AutoFilter [PT] <0.93, the result: when the testing result of PT < 0.93, the system will automatically execute the APTT item.

Concrete Operation:

1) Press the Filter Item key to select the item in the drop-down box. And in the input box of AutoFilter condition, it will show [XXX], hereinto, XXX is the selected item.
2) Press the Operational Character key, and the corresponding operational characters will appear in the input box of AutoFilter condition, such as >,>=, <, <=, OR, AND etc.
3) Repeat the steps 1)-2) to edit the filter formulas which allow only two expressions.
4) Press the Filter Item key to select the item that will be executed automatically in the Execute Item drop-down box.
5) Press the Save key to save the current settings; and press the Delete key to delete the selected record in the list of AutoFilter condition.

Note: Enable the function of AutoFilter Analysis, which will be introduced in Section 5.6.3. This function is unavailable by default.

5.4 Hospital Information

In the System Settings interface, press the Hospital Information key to enter the Hospital Information settings.

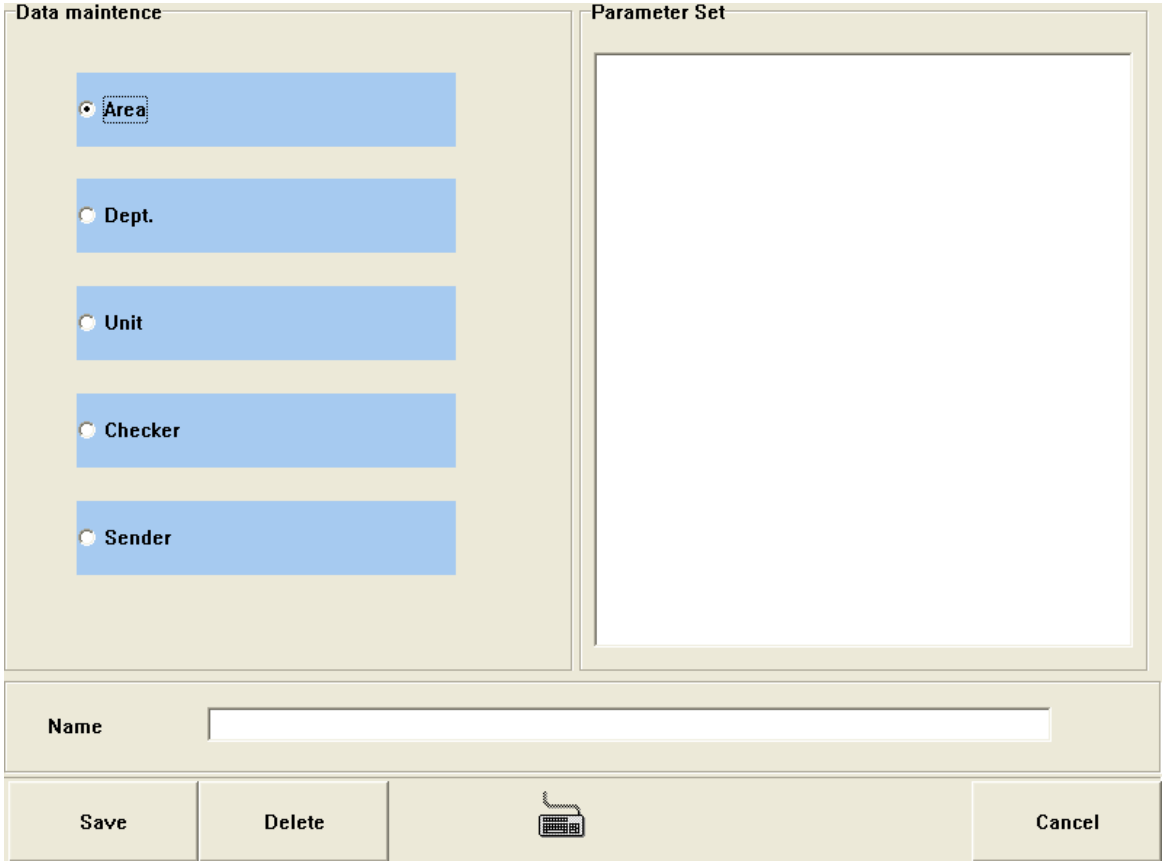


Fig 5-6 Hospital Information Settings

Hospital Information includes disease area, department, unit, verifier and deliverer (up to 100 records for each item). When editing the patient information, you can read the disease area, department, unit, verifier and deliverer directly from the list, avoiding the re-input.

Concrete Operation:

1) Select the “Disease Area”, and the existing parameter information in the **Available Parameters** list will be shown on the right side
2) Type the parameter name in the **Name** input box.
3) Press the Save key to save the current settings.
4) Press the Delete key to select the type of information, and delete the selected record in the **Available Parameters** list.
5) Repeat the steps 2)-4) to edit the hospital information about the department, unit, verifier and deliverer
6) Press the Exit key to exit from the current interface and return to the System Settings interface.

5.5 System Settings

In the System Settings interface, press the System Settings key to enter the System Settings.

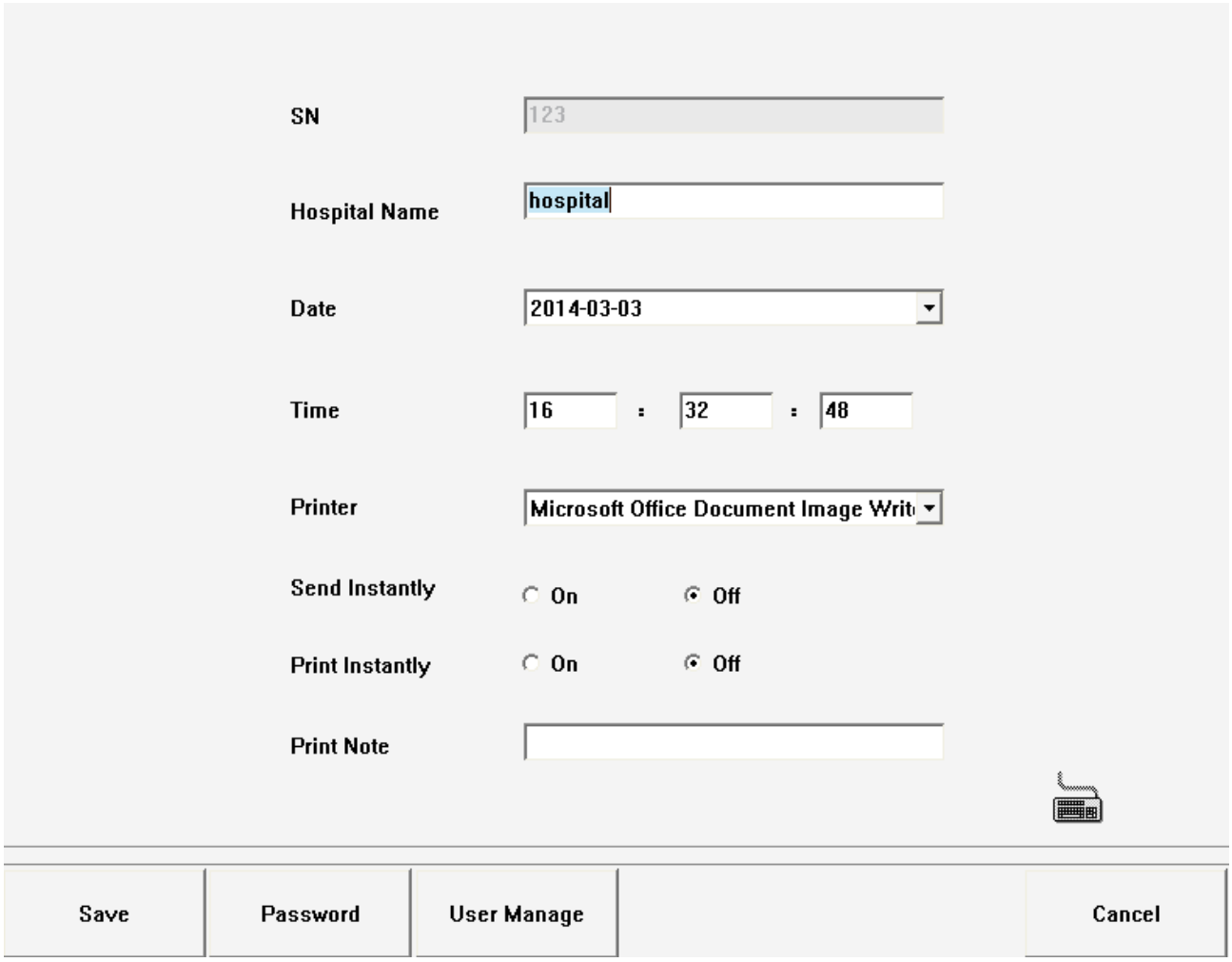


Fig5-7 System Settings

- Hospital name: it can be input by users, up to 30 characters.
- Date and time: Please set it according to the actual standard time. IF you enter the illegal date or time, it will be invalid.
- Printer option: It should be supported by ALTHEA analyzer, which can be selected according the actual configuration by users.
- Touch screen: Calibrate the touch screen.

Press the Save key to save the current settings.

Press the Touch Screen key to calibrate the touch screen.

Press the Password key to modify the password.

Note: If the printer option is inconsistent with the actual configuration, it can't print the output results correctly.

5.6 Optional Function

In the System Settings interface, press the Optional Function key to enter the settings list of system parameters.

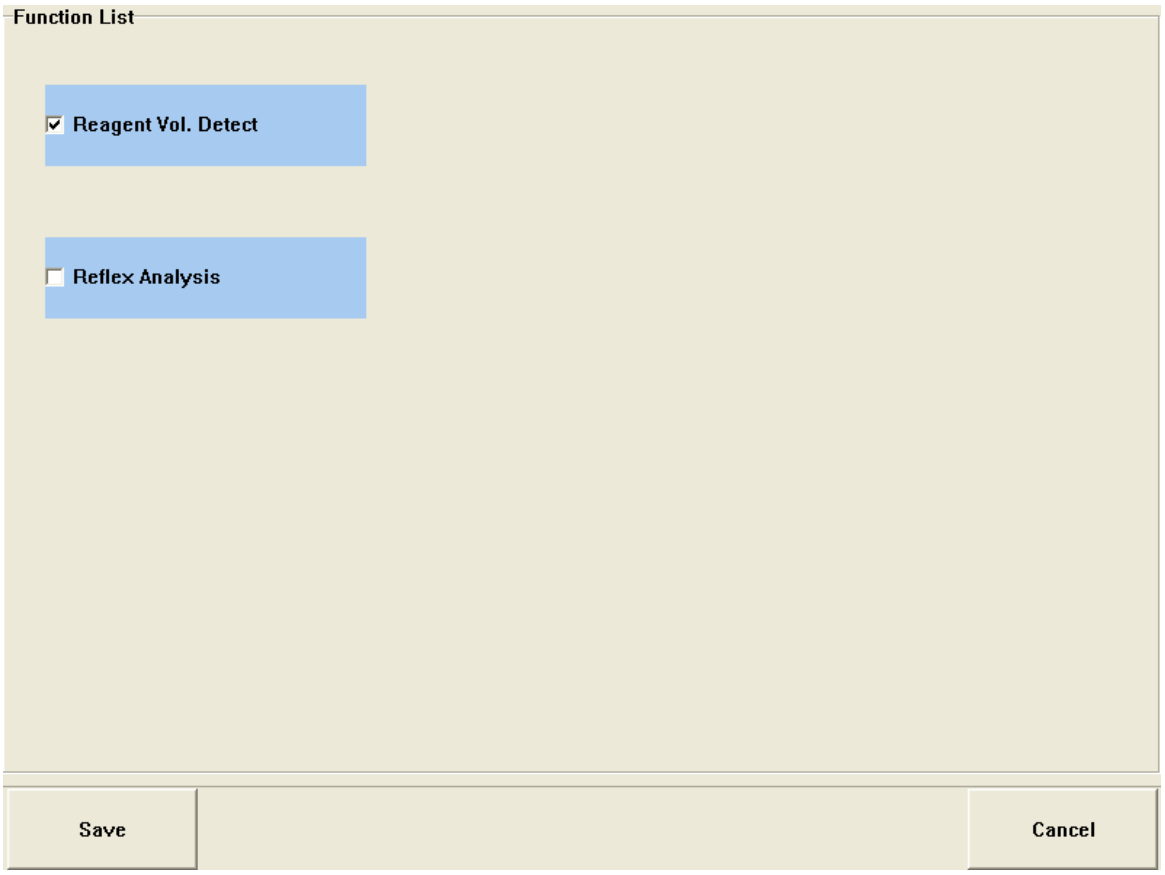


Fig 5-8 Functional Function

The system offers two optional functions of Reagent Volume Monitoring and AutoFilter Analysis.

5.6.1 Reagent Volume Monitoring

It will give real-time monitoring of reagent volume during the test, and when the reagent remains less, the system will alarm. Select it by ticking to start.

5.6.2 AutoFilter Analysis

When the customized AutoFilter condition is met, the system will automatically execute the specified item. Select it by ticking to start; and cancel the tick to stop.

Note: The optional functions are unavailable by default.

5.7 Log Query

In the System Settings interface, press the Log Query key to enter the Log Query.

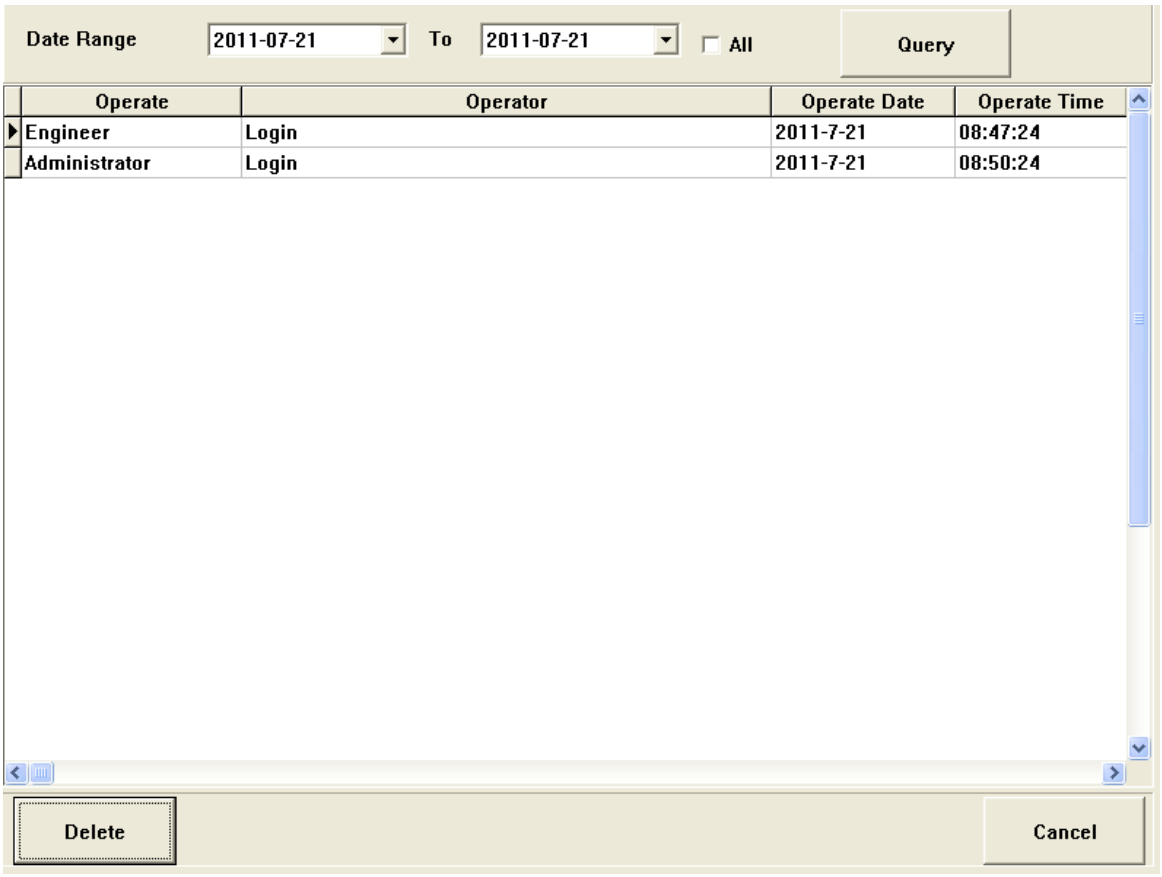


Fig 5-9 Log Query

Each record of system log includes the operator, operation, operation date, operation time and remark. The operation recorded by ALTHEA analyzer contains startup, shutdown, errors and warnings. These records will be automatically generated by the equipment during the operation. There are up to 1000 pieces of records in the database of system log, and all the intraday logs will be displayed by default.

Concrete Operation:

1) Set the query date range.
2) Press the Query key to set the query date range and query the system log.
3) Select the record to be deleted in the System Log list, and press the Delete key to delete; and select the “Select All” by ticking to delete all records.
4) Press the Exit key to exit from the current interface and return to the System Settings interface.

5.8 Data Upload

In the System Settings interface, press the Data Upload key to enter the Data Upload.

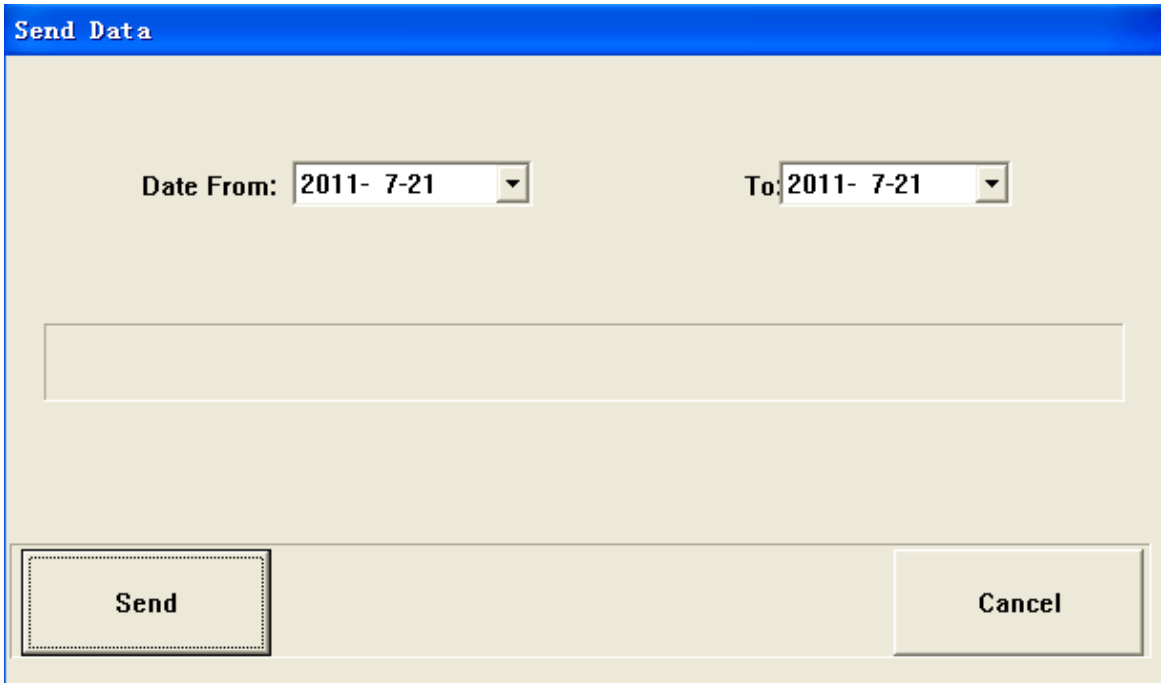


Fig 5-10 Data Upload

Data upload is to upload the test data of ALTHEA analyzer to the laboratory information system for further processing.

Concrete Operation:

1) Set the query date range.
2) Press the Upload key to upload the eligible test data.
3) Press the Exit key to exit from the current interface and return to the System Settings interface.

Chapter 6 Test

Press the Test key in the main menu to enter the sample test.

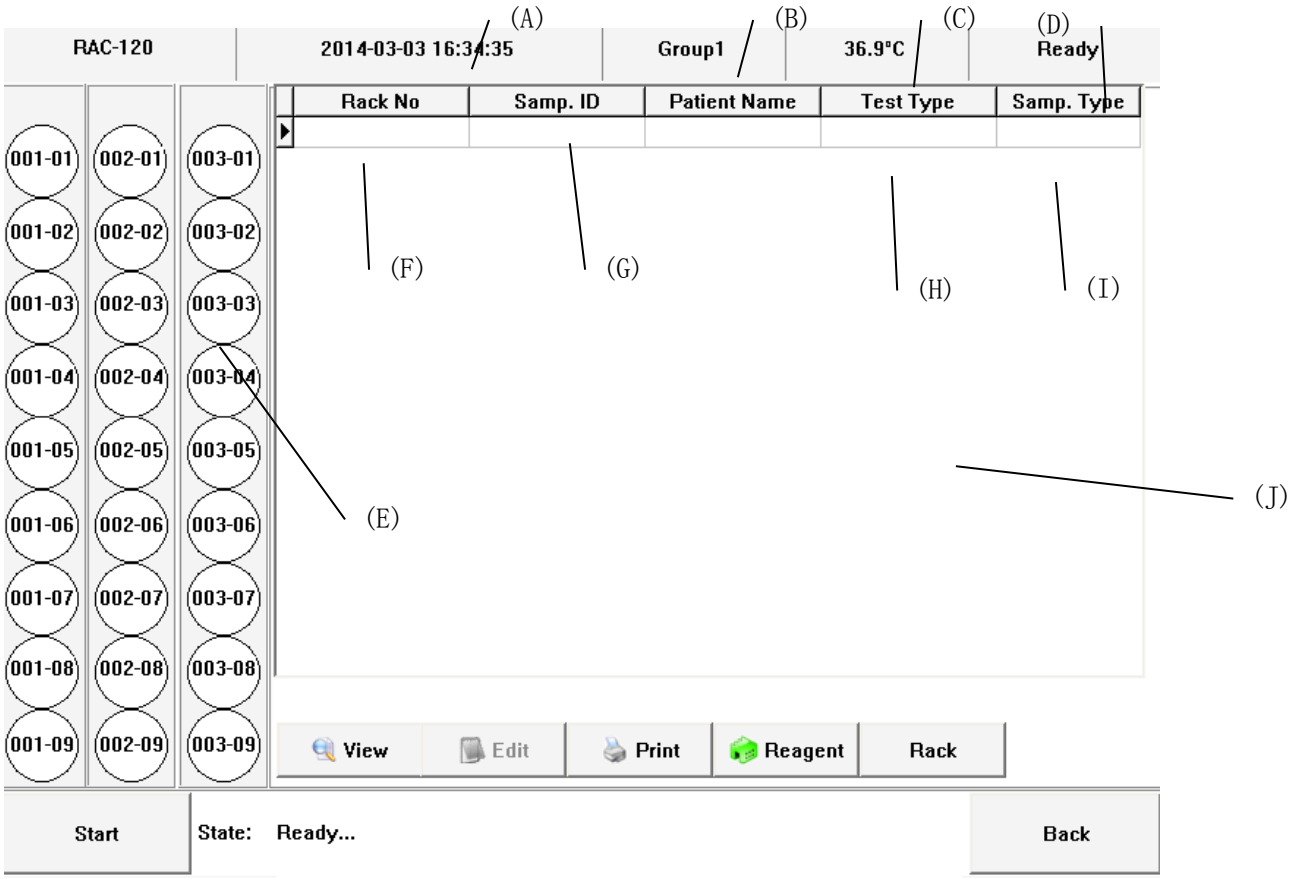


Fig 6-1 Sample Test

(A) Date and time: it displays the test date and time of the current system.

(B) Worksheet: it displays the name of the worksheet at work.

(C) Temperature: it displays the temperature at the test position. Click the Temperature to open the system temperature monitoring window; and click it again to close this window.

(D) System test status: It displays the current system test status, including: Ready, routine test and STAT test.

(E) Sample rack: there are three separate sample racks, on each of which 9 samples can be placed. Sample racks have the serial number of S1-S2-S3.

(F) Number of sample rack: it means the holder number of the current sample, and the daily holder number is unique. For example, 002-01 means the first sample on the second sample rack.

(G) Sample No. ID: it means the ID of the current sample No. with up to 20 characters.

(H) The state of sample: it shows the state of the current sample, including the routine test and STAT test.

(I) Sample type: it shows the sample type, including the patient sample and quality control material.

(J) Information list of sample rack: it shows the hole information of the current sample rack.

6.1 Reagent Position

6.1.1 Settings of Reagent Position

In the Test screen, press the Reagent Position key to enter the settings of reagent position.

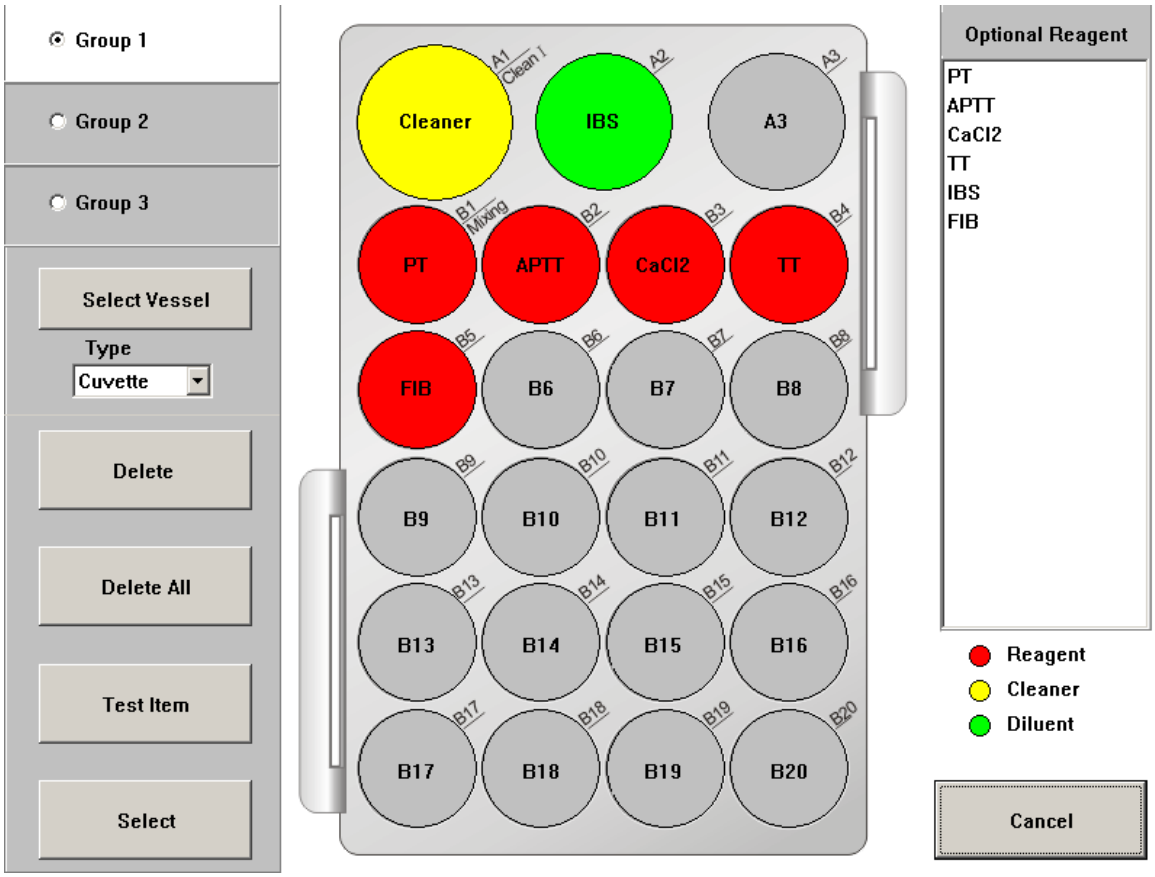


Fig 6-2 Settings of Reagent Position

In the Settings of Reagent Position, it can set the position of the reagent required in the test item of each worksheet.

Concrete Operation:

1) Select the **Worksheet 1**, and then all the reagents required in the test item of this worksheet will be displayed in the **Optional Reagents** list on the right side of the screen.
2) Select the reagent in the **Optional Reagents** list, and click the position to be placed, at this time, the key will be marked with different colors according to the type of reagent.
3) Press the Single Clear key, and click the reagent position that needs being cleared, at this time, the key becomes gray, indicating that this operation is successful; and press the All Clear key to clear all the current reagent position.
4) Press the Test Item key, and then the test items in this worksheet will be displayed in the **Test Item** list on the right side of the screen. Meanwhile, switch the key into the Optional Reagent and click it, and then all the reagents required in the test item of this worksheet will be displayed in the **Optional Reagent** list on the right side of the screen.
5) Select the **Worksheet 2/Worksheet 3**, and then repeat the steps 1)-4).
6) If the micro-measuring cup is used, it needs to select the type as micro-measuring cup after selecting the reagent position, and then click the Select Container.

6.1.2 Select the worksheet.

Select the current worksheet to make the item test for the testing group of this worksheet (up to 10 test items).

Concrete Operation:

1) Select the current worksheet. Select the worksheet, and then press the Select key.

6.2 Sample Rack

Sample Rack is used to set the testing information of patient sample, such as sample type, test items, container type, and so on.

6.2.1 Information of Sample Rack

In the Test interface, press the Sample Rack key to enter the settings of sample rack.

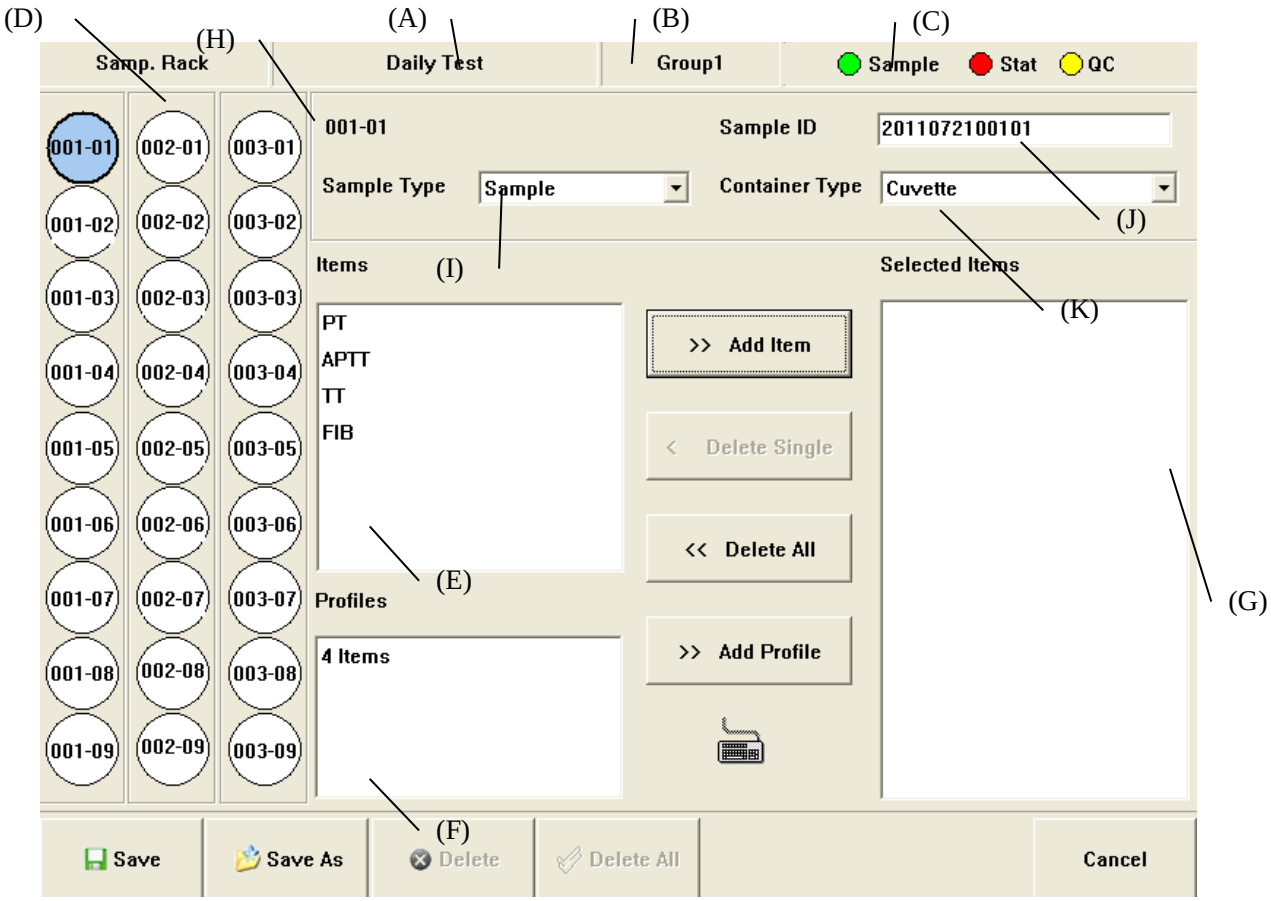


Fig 6-3 Settings of Sample Rack

(A) Status of system test: it shows the status of the current system test (routine test or STAT test).

(B) Worksheet: it shows the name of the worksheet at work.

(C) Mark of sample type: it displays the following information: patient sample (green), STAT sample (red) and quality control material (yellow).

(D) Sample rack: there are three separate sample racks, on each of which 9 samples can be placed. Sample racks have the serial number of S1-S2-S3.

(E) Item List: It contains all the test items in the current selected worksheet (See Section 4.2 for the worksheet settings; and see Section 5.1 for selecting the worksheet and specifying the reagent position).

(F) Combined List: It contains all the combined test items in the current worksheet (See Section 4.2 for setting the combined item of worksheet); a combined item may contain up to 10 test items. It can avoid repeating the operations, and effectively improve the speed of setting the sample rack.

(G) Selected item list: Select the item list that needs to be tested for this sample.

(H) Number of Sample Rack: it shows the holder number of the current sample, and the daily holder number is unique, for example, 002-05 means the fifth sample in the second sample rack.

(I) Sample type: It shows the type of sample, including the patient sample and quality control material.

(J) Sample No. ID: the current sample No. ID, up to 20 characters that can be edited.

(K)Type of sample storage container

6.2.2 Settings of Sample Rack

Concrete Operation:

1) In the **Sample Rack**, click the selected hole of sample rack, the sample rack No. of which will be displayed on the upper right side of the interface, and the sample No. will be automatically generated (The generating rule of sample No.: Year + Month + Day + Holder No., e.g. 2008122500203 means December 25, 2008, and the third hole of the second sample rack).
2) Click the **Sample Type** drop-down box, and select the type of this sample hole.
3) Users can manually modify the sample number, however, if the edited sample number has existed, it can't succeed modifying.
4) In the **Item List**, select the item that needs to be added. Press the >> Add Item key, and the added item will be displayed in the Selected Item List on the right side. (See Section 5.2 for setting the worksheet; and see Section 6.1 for selecting the worksheet and specifying the reagent position).
5) In the **Combined List**, select the group that needs to be added. Press the >> Add Group key, and all the test item of this group will be displayed in the **Selected Item List** on the right side. (See Section 5.2 for setting the group item of worksheet)
6) In the **Selected Item List**, select the item to be deleted, and press the <Delete Single key to delete the selected item.
7) Press the <<Delete All key to clear the selected item list.
8) Press the Save key to save the current parameter settings.
9) Repeat the steps 1)-8) to set the information of other sample hole.
10) Select the hole of sample rack, and then press the Delete key to delete the parameter information of this hole.
11) Press the Exit key to exit from the current interface and return to the Test interface. In the Test interface, it will display the hole information of all the current sample racks that have been set successfully.

6.3 Sample Test

6.3.1 Preparation

Prepare for the test:

1) Select the worksheet, and set the reagent position correctly.
2) Edit the information of sample rack.
3) Check whether the reagent storage position is consistent with the settings of worksheet.
4) Ensure sufficient amount of reagent.
5) Check whether the information of the sample rack is consistent with the parameter settings of sample rack.
6) Make sure the cuvettes are adequate for testing.
7) Check whether the waste bottle is full. If it is full, please clear it.
8) Check whether the cleaning bottle is empty. If it is empty, please fill up.

6.3.2 Collection and Requirement of Specimen

1) Collection of Specimen

Draw off venous blood, and put the mixture of venous blood and anticoagulant agent with the ratio of 9:1 into the anticoagulant vacuum tube filled with The content of sodium citrate is 3.8% or 3.2% and then gently invert it for 10 times to make full blending without a clot and bubble, and make a mark on the tube.

2) Disposal of failed specimens

For failed specimens such as coagulation, a clot, severe hemolysis, severe jaundice, lipemia, blood volume not meeting the requirements, no mark, the sample that has been collected for more than 2 hours and not been stored according to the relevant requirements and so on, they should be disposed according to the processing flow constituted by the hospital.

3) Specimen Storage

The test should be finished within 4 hours after collecting the specimen. It can be stored within 8 hours under 2～8℃, and plasma after the separation can be sealed for 2 weeks below -20℃. And the sample after being analyzed can't be stored.

4) Prepare for the test

After the sampling, the plasma should be separated as soon as possible (within 60 minutes), and then the specimen should be centrifuged with 3000r/min for 10-15 minutes to make the plasma layering.

6.3.3 Explanation for Testing Process

Explanation for Testing Process:

1) Sample Rack consists of three separate sample frames (S1-S2-S3). The sample test will be made by taking a separate sample frame as unit, that is to say, making a test following the order of S1-S2-S3 (9 samples).
2) When making a test for S1 sample frame, it is in the "locked" state, and the other two sample frames is in the "open" state. ("Locked" state indicates that the sample frame has gone into the test state, and users are not allowed to make additional sample or STAT sample for this frame; "Open" state indicates that users are allowed to make additional sample or STAT.)
3) Operate for the sample frame in the "Open" state.

- Modify the sample information: modify the edited information of sample hole.
- Additional sample: edit the sample hole not having been set.
- Additional STAT: STAT sample can be tested first. If the sample holes have been set, the sample for routine test will be replaced by STAT sample; If the sample holes haven't been set, please edit the sample hole not having been set.

6.3.4 Testing Operation Flow

Testing Operation Flow:

1) In the Test interface, press the Start key to start a test and enter the starting position of the cuvette.

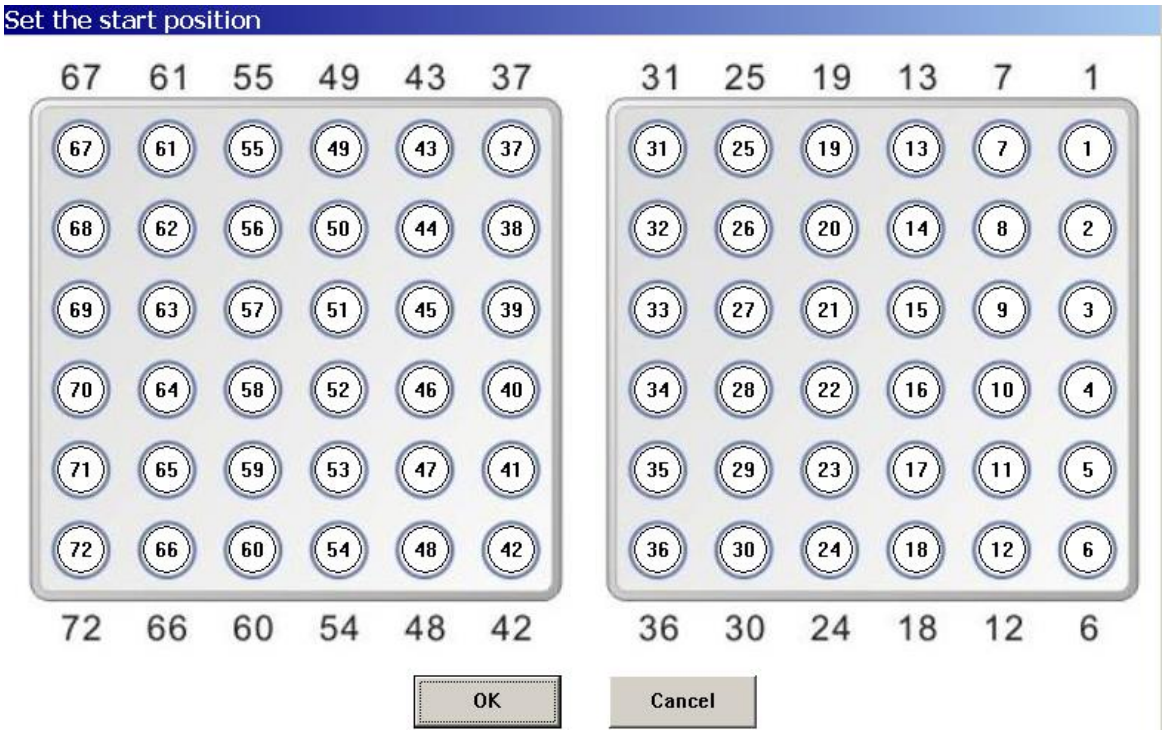


Fig 6-4 Select the starting position of cuvettes

2) After selecting the starting position of cuvettes, it will prompt: "Please confirm the cuvettes /reagent/sample tubes have been placed correctly!". After the confirmation, start the sample test normally.
3) the system will take the cuvettes to start the test. Press the Confirm key to exit from the current interface, the Test interface will appear, and the S1 sample frame is in the "Locked" state (getting dark gray):

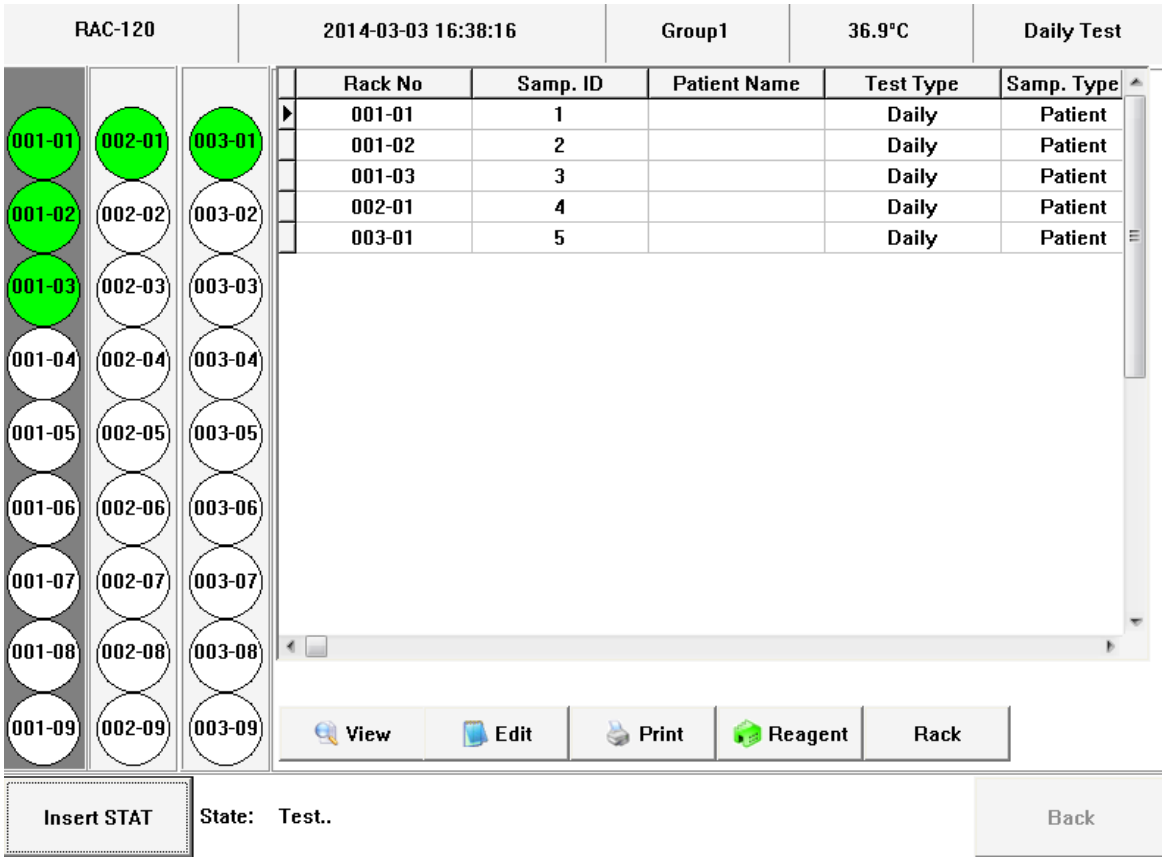


Fig 6-5 Test State

In the Test interface, press the Routine Test key on the upper right, and the following interface will appear:

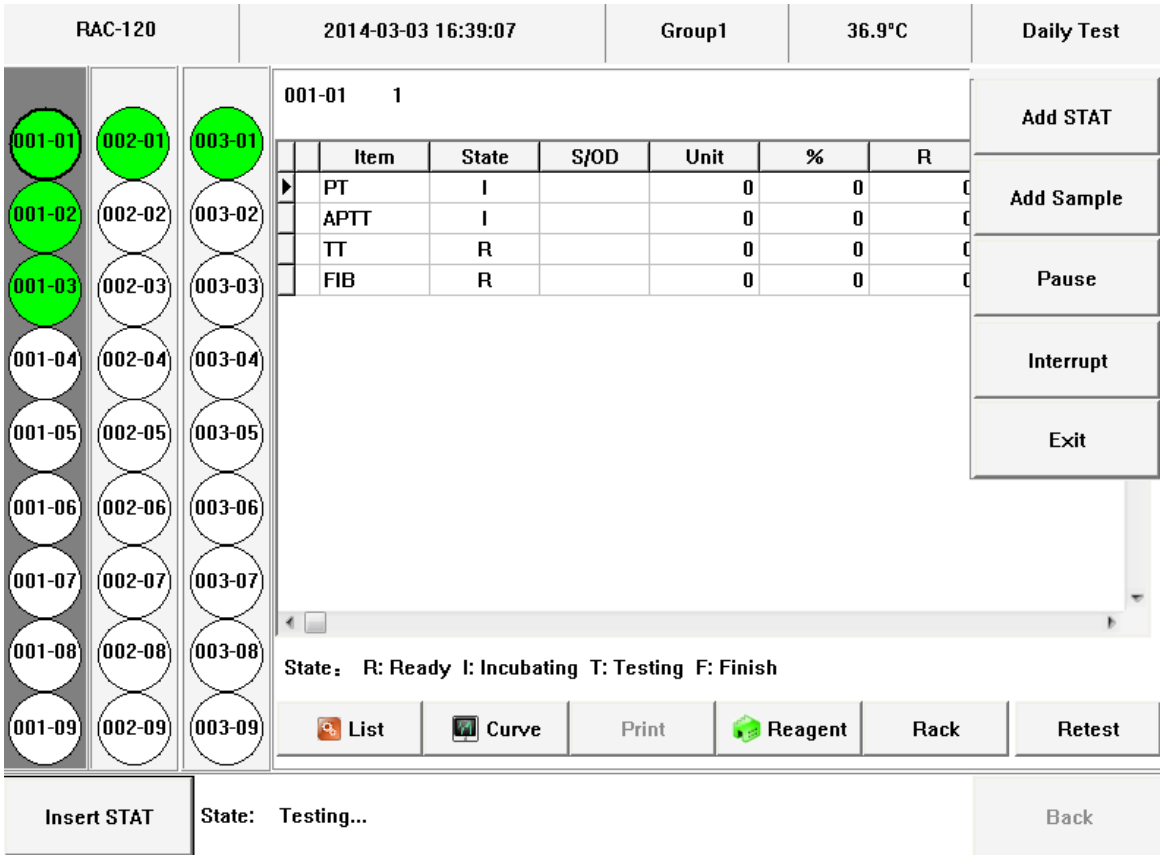


Fig 6-6 Testing Process Control

4) Press the Additional Sample or Additional STAT key to enter the settings of sample rack (See Section 6.2 for details):

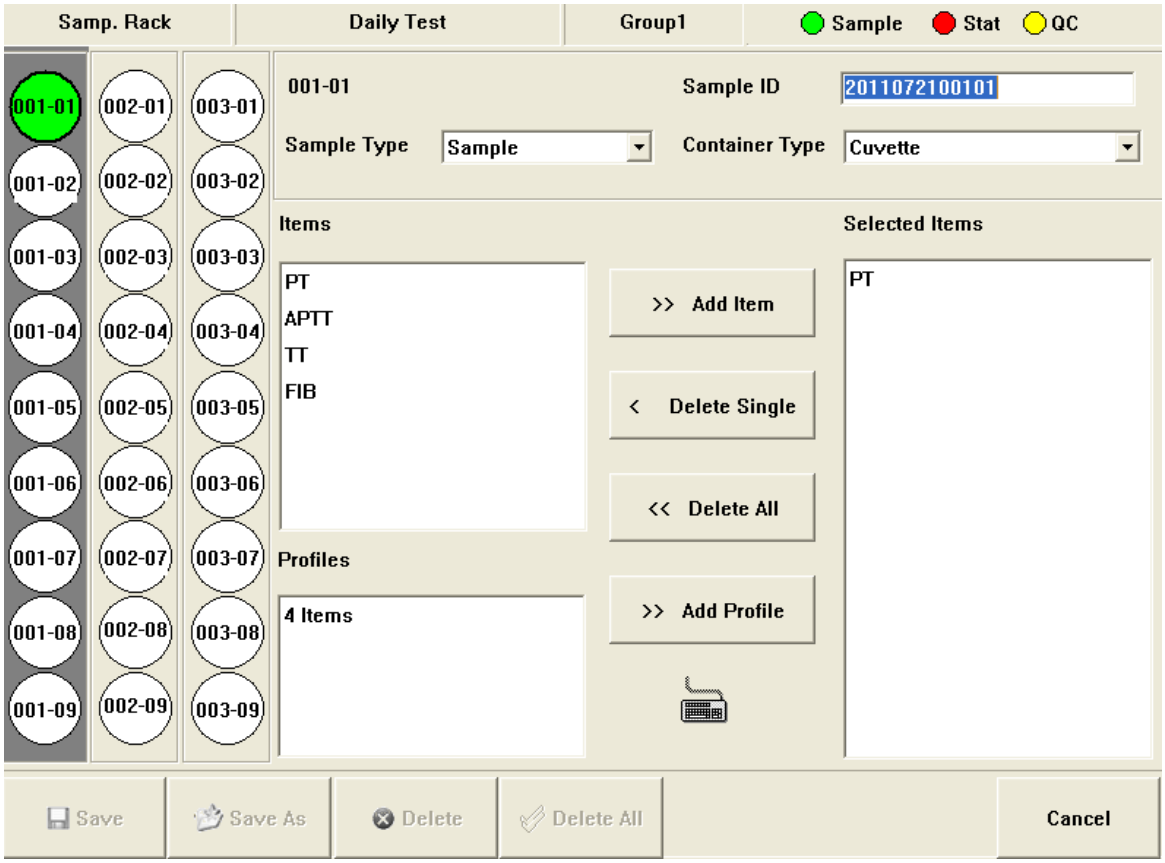


Fig 6-7 Sample Settings During the Test

Note: When the sample frame is in the "Locked" state, it gets dark gray; and in the "Open" state, it can only be saved.

5) Press the Test Pause key to suspend the current test. After pausing, all the tests will stop after finishing the current action cycle, and the mechanical arm will reset, prompting the end of test. After the test stopping, only after throwing the cuvettes manually could the next test start.

6) View the information of sample hole. Select the sample record from the information list of sample rack in the Test interface, and press the View button (or click the sample hole on the sample rack) to pop up the sample hole list:

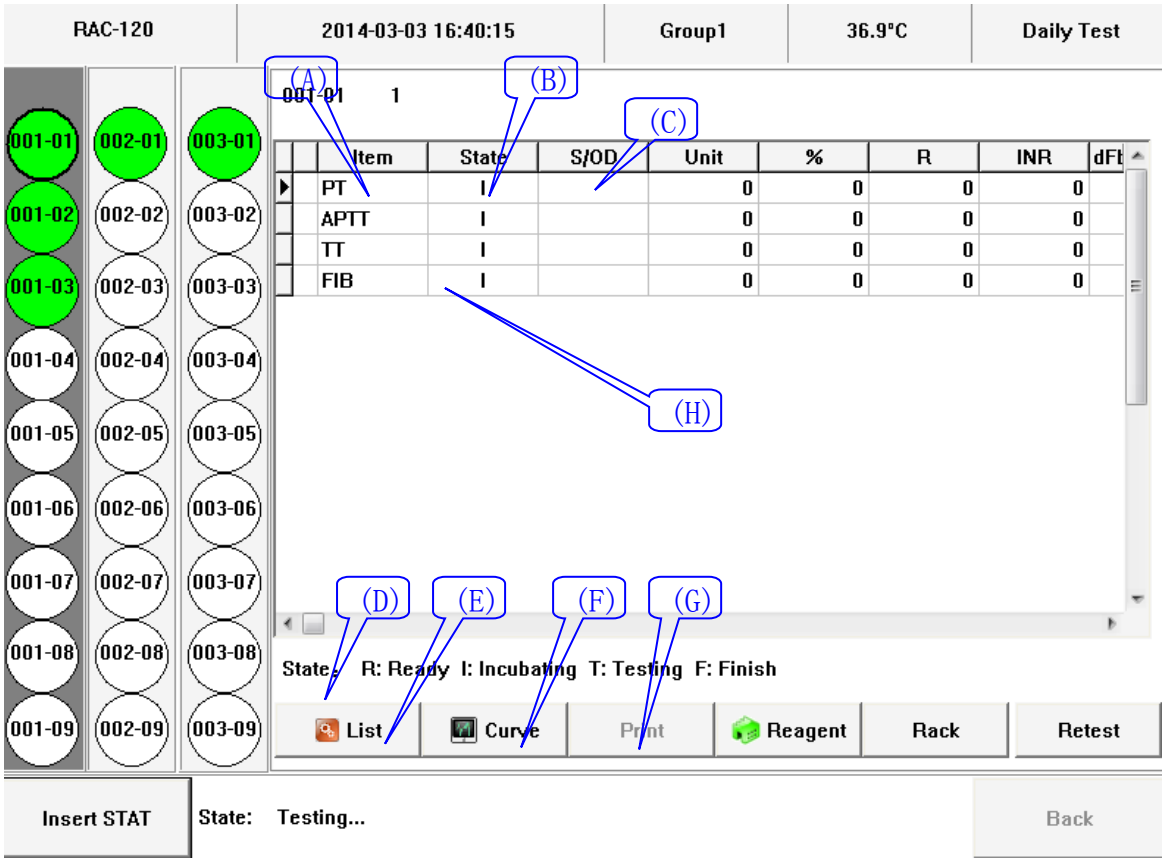


Fig 6-8 Test State

(A) Test Item: it shows the test item in this sample hole.

(B) Test State: it shows the test state of test item, including R-ready to test, I-incubation, T-in the test and F-finish the test.

(C) S/OD： It shows the result of item test, time or OD value;

%、R、INR、DFbg： It can automatically calculate the result on the base of actual measurement.

(D) Tip of test state: it shows the prompting message of test state for test item.

(E) Return: Return to the “sample rack information list”.

(F) Curve of test item: View the curve of test item.

(G) Print: Print the test results of sample hole.

(H) Sample hole information list: It shows the hole information of the current sample rack.

7) Edit the basic information of patient. From the information list of sample rack in the Test interface, press the Detail key to enter the basic information of patient.

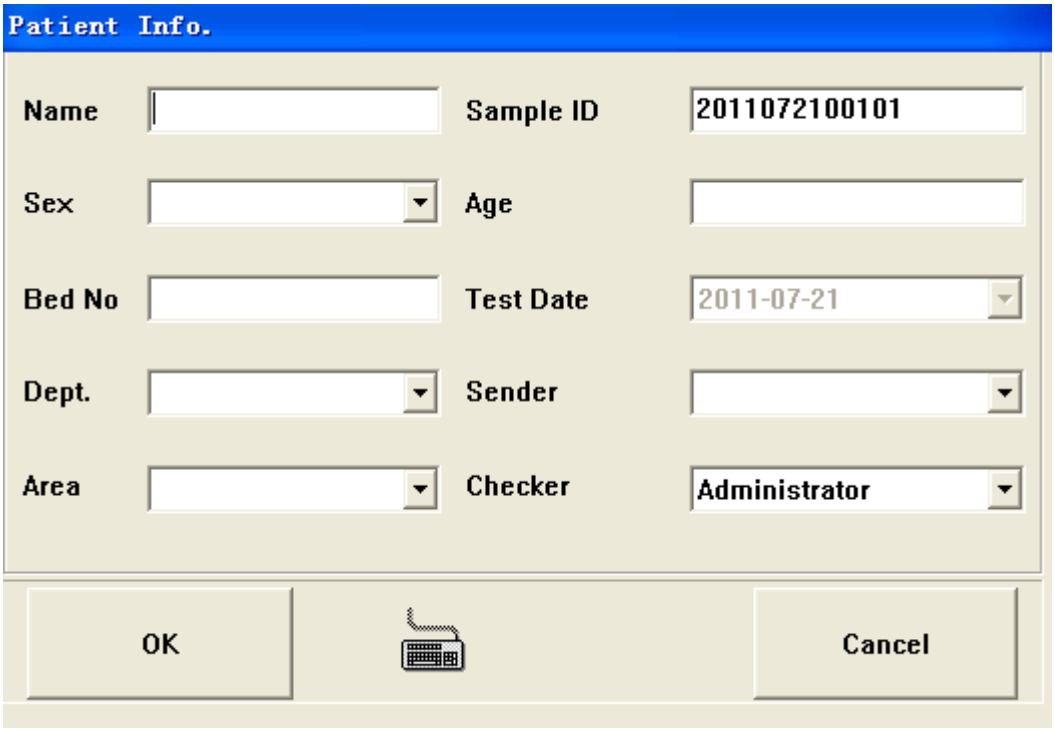


Fig 6-9 Edit the basic information of patient.

8) After finishing a test, you can retest the test item of any sample hole. And press the Sample Rack key to enter the Sample Rack interface, and then select the item to be re-tested:

Select the sample hole, and press the Retest key to enter the selected item for retesting:

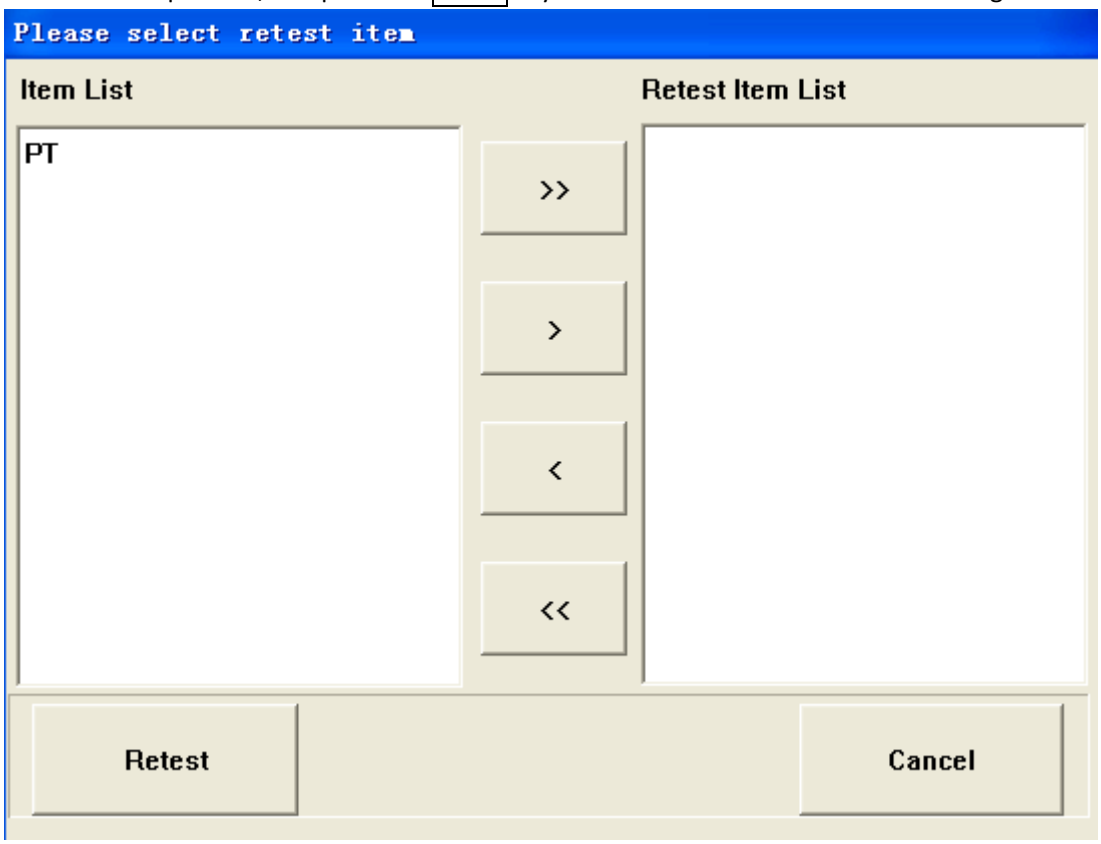


Fig 6-10 Select the item to be retested

Select the item to be retested, and press the Retest key to exit from the current interface and return to the Test interface, and then press the Start key to start testing.

Note: The used reagents, quality control materials and standard materials should be within the period of validity.

Chapter 7 Quality Control

ALTHEA provides 12 quality control documents.

In the Main Menu, press the Quality Control key to select the quality control item:

Fig 7-1 Quality Control Item

Select the item to enter the selection window of quality control document

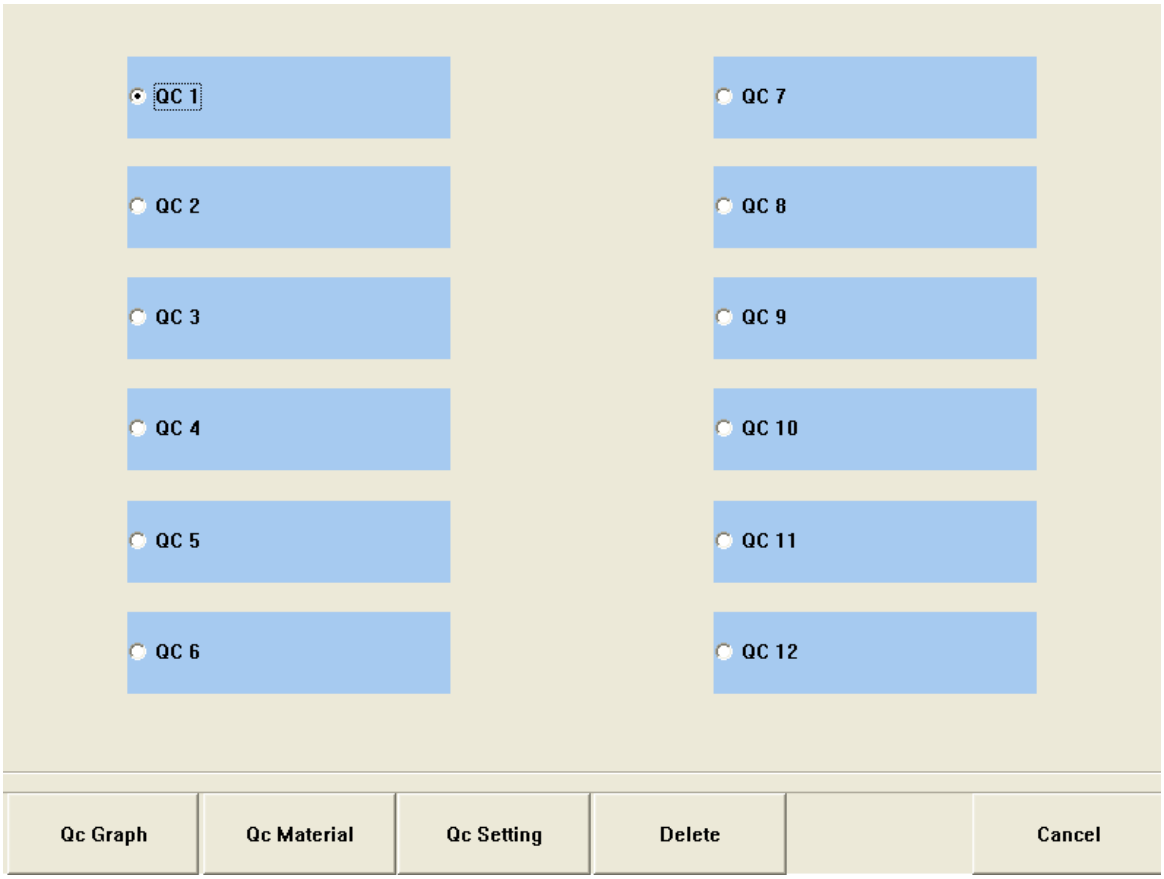


Fig 7-2 Selection Window of Quality Control Document

7.1 Settings of Quality Control Materials

Select the quality control document, and press the Quality Control Materials to enter the settings of quality control materials:

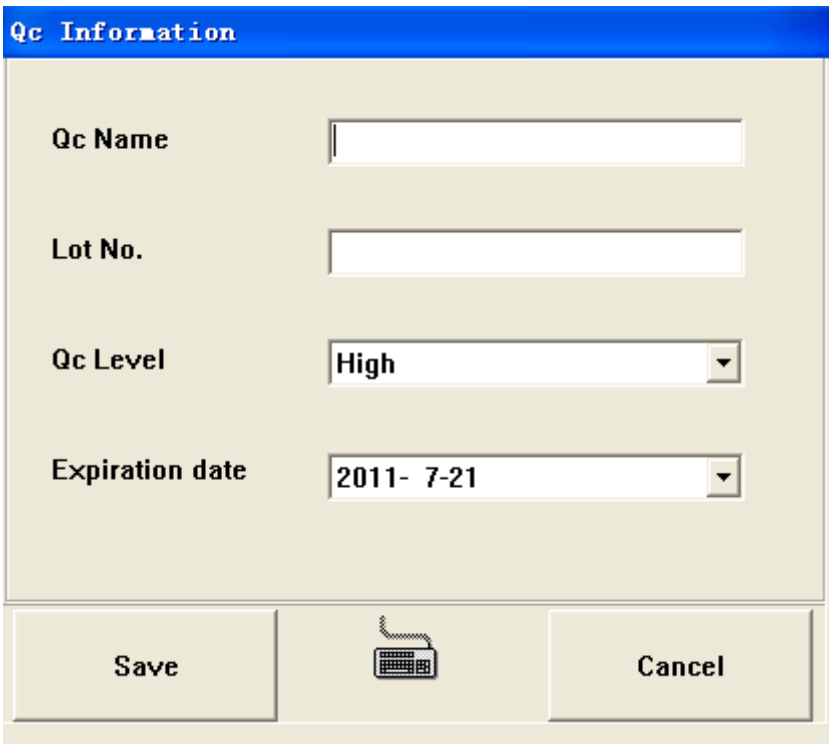


Fig 7-3 Settings of Quality Control Materials

Parameters of quality control material include:

- Name of Quality Control: name of quality control
- Batch number: the batch number of quality control
- Level of quality control: The level of quality control materials is divided into Low, Middle and High values.
- Effective Date: It means the effective use date of quality control materials. When the current system date is beyond the effective date, this quality control material won't appear in the test list of optional quality control.

Press the Save key to save the parameters of quality control.

Press the Exit key to exit from the current interface, and return to the Selection Window of Quality Control Document.

7.2 Quality Control Diagram

Select the Quality Control Document, and press the Quality Control Diagram key to enter Quality Control Diagram:

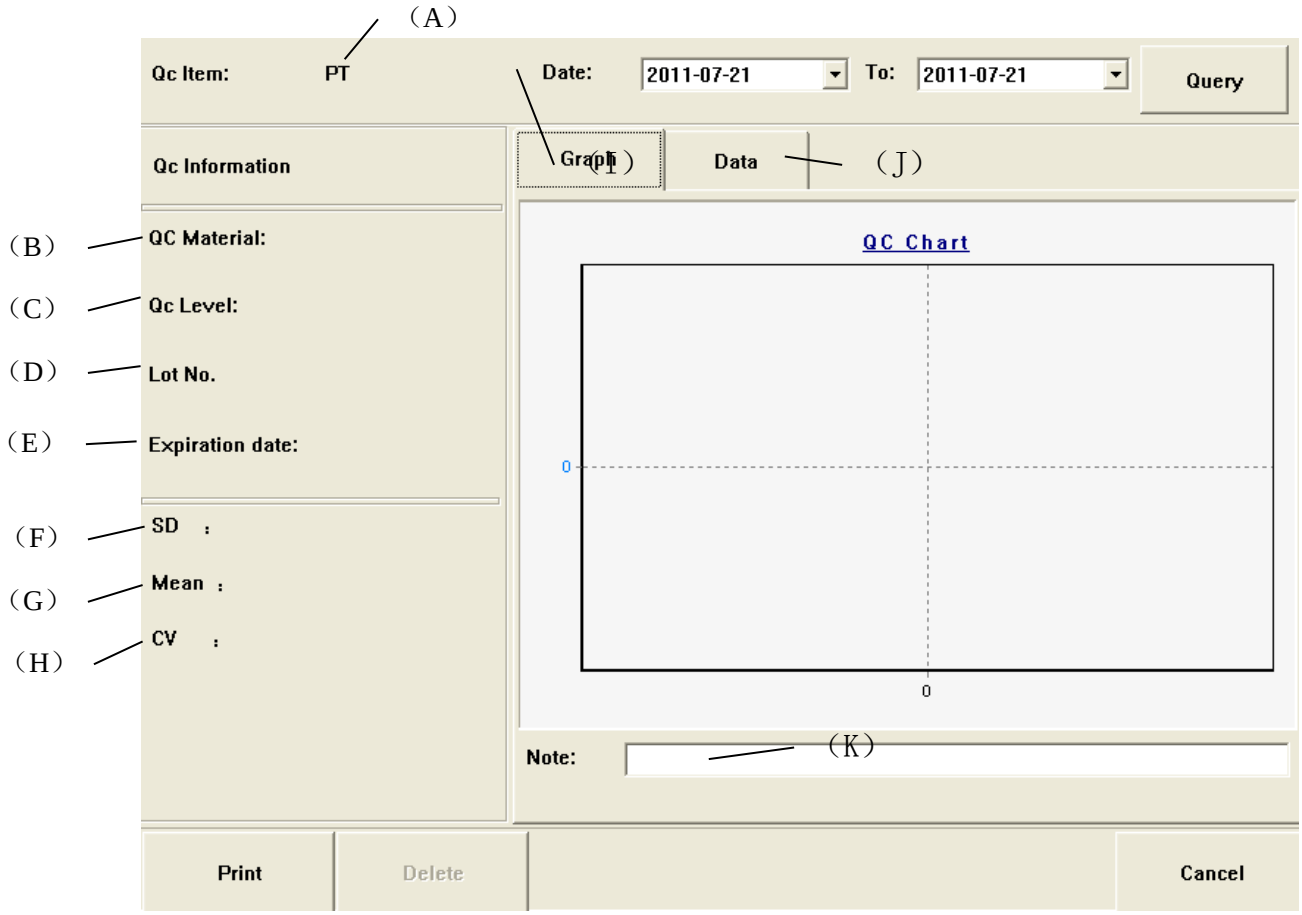


Fig 7-4 Quality Control Diagram

(A) Quality Control Item: It shows the quality control item.

(B) Quality Control Material: Name of quality control material.

(C) Level of quality control: The level of quality control materials is divided into Low, Middle and High values.

(D) Batch number: the batch number of quality control

(E) Effective Date: It means the effective use date of quality control materials.

(F) SD: Standard Deviation

(G) Mean: Mean

(H) CV: CV value

(I) Quality Control Diagram: View the quality control curve.

(J) Quality Control Data: View the quality control data.

(K) Prompt: it shows whether the quality control is in control.

7.2.1 Parameters of Quality Control Item

Select the Quality Control Item, and press the Quality Control Settings key to enter the Parameter Settings of Quality Control interface:

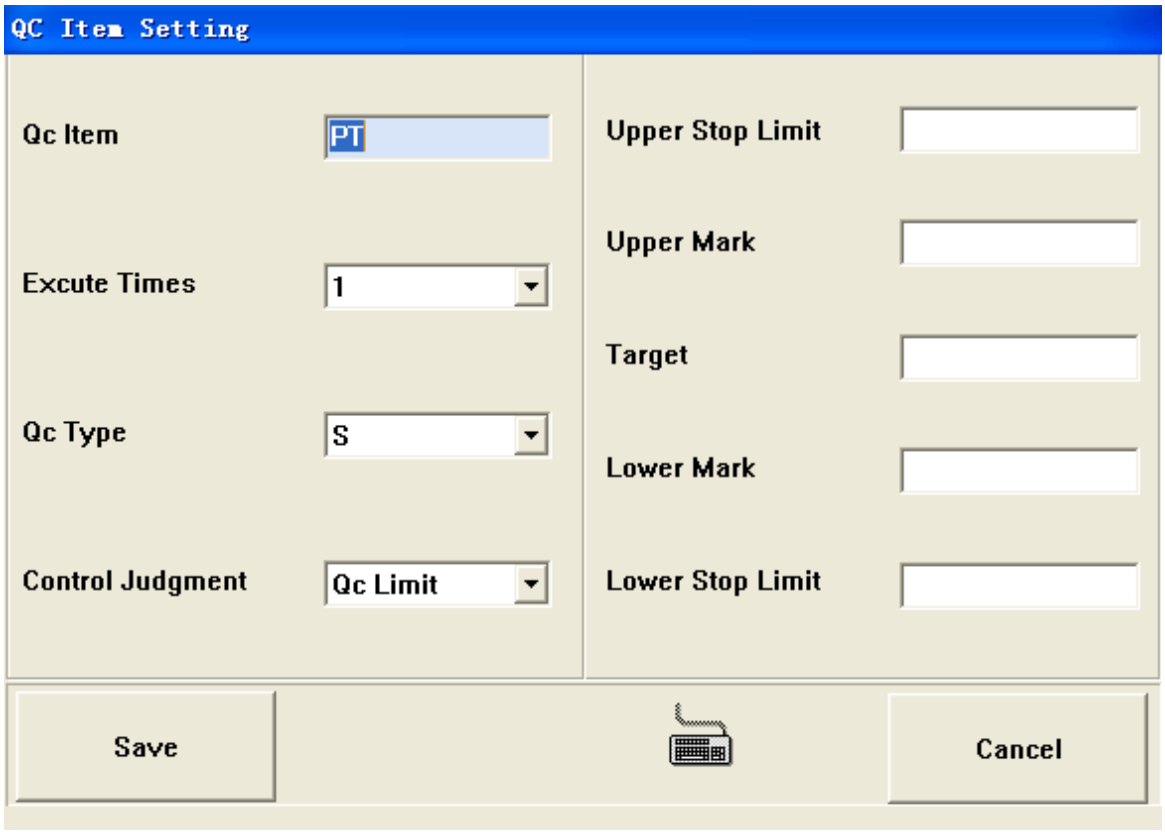


Fig 7-5 Quality Control Settings

Quality control item includes the following parameters:

- Quality Control Item: It shows the quality control item.
- Execution Frequency: It means the times of repeating the quality control test.
- Type of Quality Control: The type of quality control is divided into %, R, INR and dFIB.
- In-control Judgment: Judge whether the quality control is in control, which is divided into control limit and multi-rule quality control.

Press the Save key to save the parameter information of quality control.

Press the Exit key to exit from the current interface, and return to the Quality Control Diagram interface.

7.2.2 Judgment Rule of Quality Control

Judge whether quality control is under control, which is divided into control limit and multi-rule quality control.

1) For the QC control limits, it needs to set parameters. During the testing of quality control, if it is beyond the setting range, the alarm will be given.
   - Upper Stop Limit: QC data is beyond the upper limit.
   - Upper Mark: QC data is beyond this value.
   - Target value: Mean value of quality control
   - Lower Mark: QC data is beyond this value.
   - Lower Stop Limit: QC data is beyond the lower limit.
2) For the multi-rule quality control, the following parameters need to be set:
   - Target value: Mean value of quality control
   - Standard Deviation: QC standard deviation
   - Exceed ±2SD for one time: If the QC data exceeds ±2SD for one time, the system will warn that quality control is beyond the control range.
   - Exceed ±3SD for one time: If the QC data exceeds ±3SD for one time, the system will warn that quality control is beyond the control range.
   - Exceed ±2SD continuously for two times: If the QC data exceeds ±2SD continuously for two times, the system will warn that quality control is beyond the control range.
   - Exceed ±2SD continuously for four times: If the QC data exceeds ±2SD continuously for four times, the system will warn that quality control is beyond the control range.
   - Exceed ±2SD for two times in the same batch: If the QC data exceeds ±2SD continuously for four times in the same batch, the system will warn that quality control is beyond the control range.
   - Beyond or Below the mean value continuously for 10 times: If the QC data is beyond or below the mean value continuously for 10 times, the system will warn that quality control is beyond the control range.

Chapter 8 Calibration

In the Main Menu, press the Calibration key to select the calibration item:

Fig 8-1 Calibration Item

Select the item to enter the Calibration Curve interface:

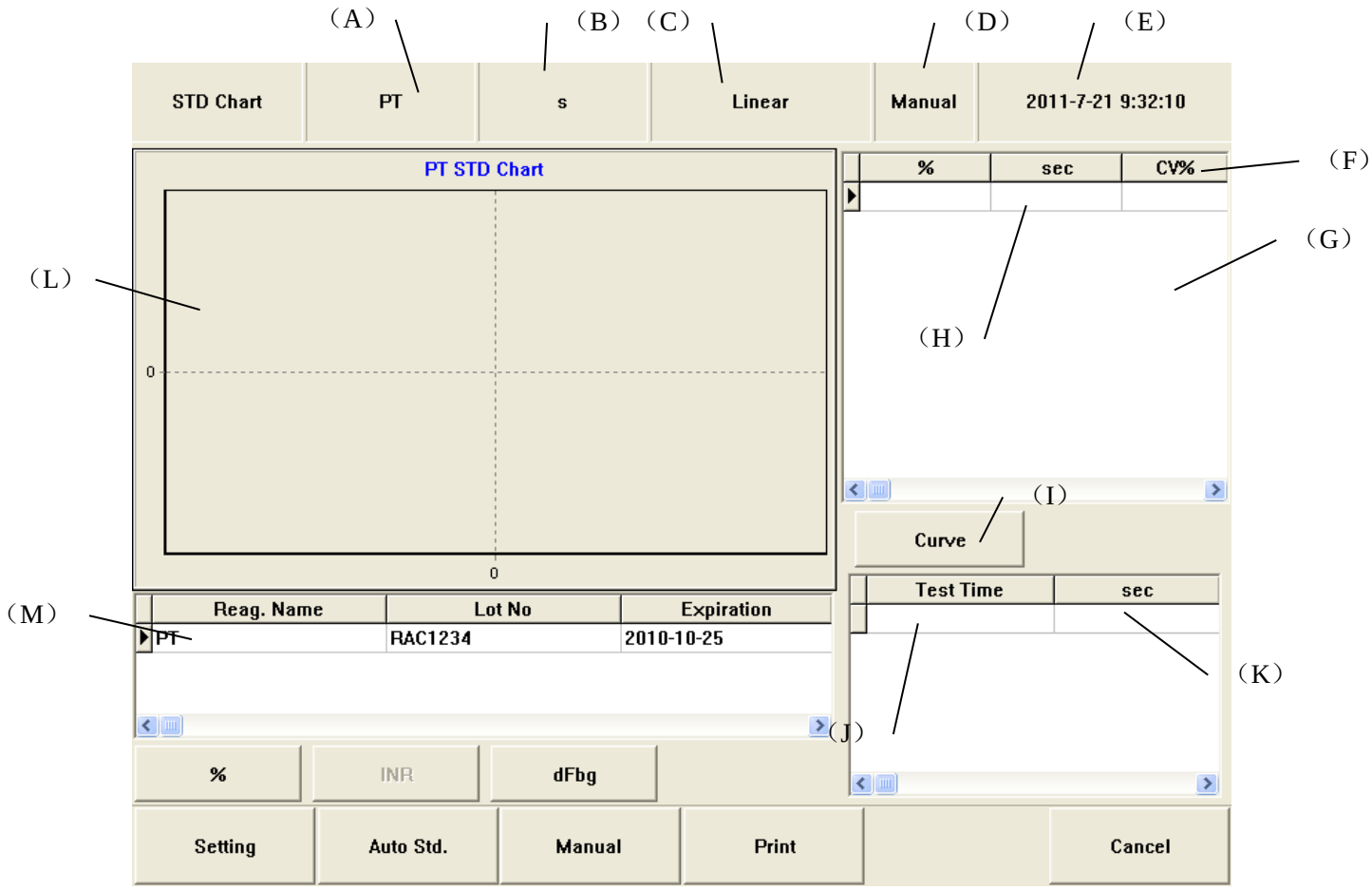


Fig 8-2 Calibration Curve Interface

(A) Calibration Item: It shows the name of calibration item.

(B) Type of calculation parameters: The calibration type is divided into % (concentration), R, INR and dFIB.

(C) Methods of Calibration: There are four methods of calibration, including Broken Line Regression, Linear Regression, Double Logarithmic Linear Regression and Double Logarithmic Broken-line Regression.

(D) Calibration Mode: Manual (manual dilution calibration); Automatic (Automatic dilution calibration).

(E) Date and time of calibration

(F) CV%: When repeating the calibration, the system will automatically calculate CV%.

(G) List of calibration results: There are up to 6 calibration data results with different gradients.

(H) Calibration Result: There are up to 6 calibration measured results with different gradients.

(I) Reaction curve: It shows the reaction curve of each measured data.

(J) Calibration time: It shows the testing time of calibration data.

(K) Data list of repeating calibration: It contains the data needing to repeat calibration.

(L) Calibration curve: The calibration curve consist of up to 6 data values with different gradients.

(M) Reagent Information: It contains all the reagent parameters required in the calibration item. (Include reagent name, batch number and effective period).

8.1 Settings of Calibration Parameters

In the Calibration Curve interface, press the Calibration Settings key to enter the settings of calibration parameters:

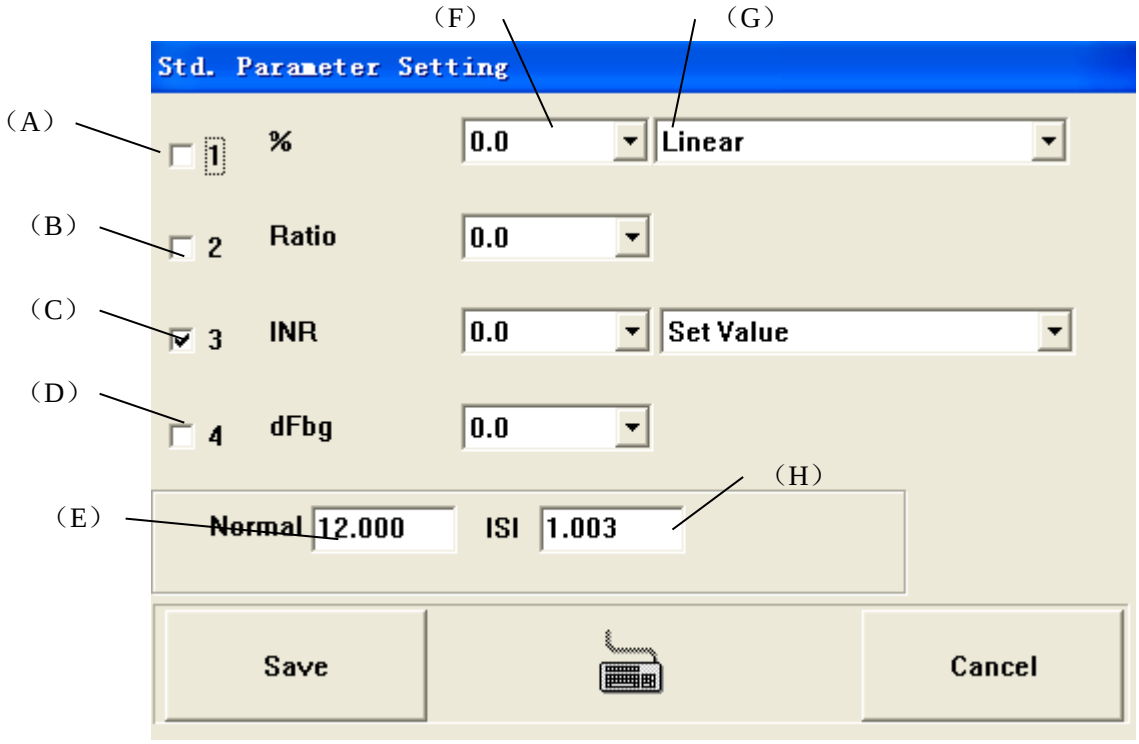


Fig 8-3 Settings of Calibration Parameters

(A) Calculation Item 1: % Percentage Activity

(B) Calculation Item 2: Ratio (PT ratio)

$$\text{PT ratio} = \frac{t}{PT\ average\ value}$$

t= Actual clotting time of PT sample

PT average value= PT average value of normal patients in the laboratory

(C) Calculation Item 3: INR international standard value

$$\text{INR} = (\text{PT ratio})^{ISI}$$

ISI= International sensitivity index determined by the manufacturers of thromboplastin reagent

(D) Calculation Item 4: dFIB(PT derivative FIB)

(E) Normal value: PT normal value (that is the normal PT value of patients in the laboratory).

(F) Decimal point.

(G) Methods of Calibration: There are five methods of calibration including Broken Line Regression, Linear Regression, Double Logarithmic Linear Regression and Double Logarithmic Broken-line Regression.

(H) ISI: International sensitivity index determined by the manufacturers of thromboplastin reagent

Press the Save key to save the calibration parameters.

Press the Exit key to exit from the current interface, and return to the Calibration Curve interface.

8.2 Manual Input

In the Calibration Curve interface, press the Manual Input key to enter the manual input of calibration data:

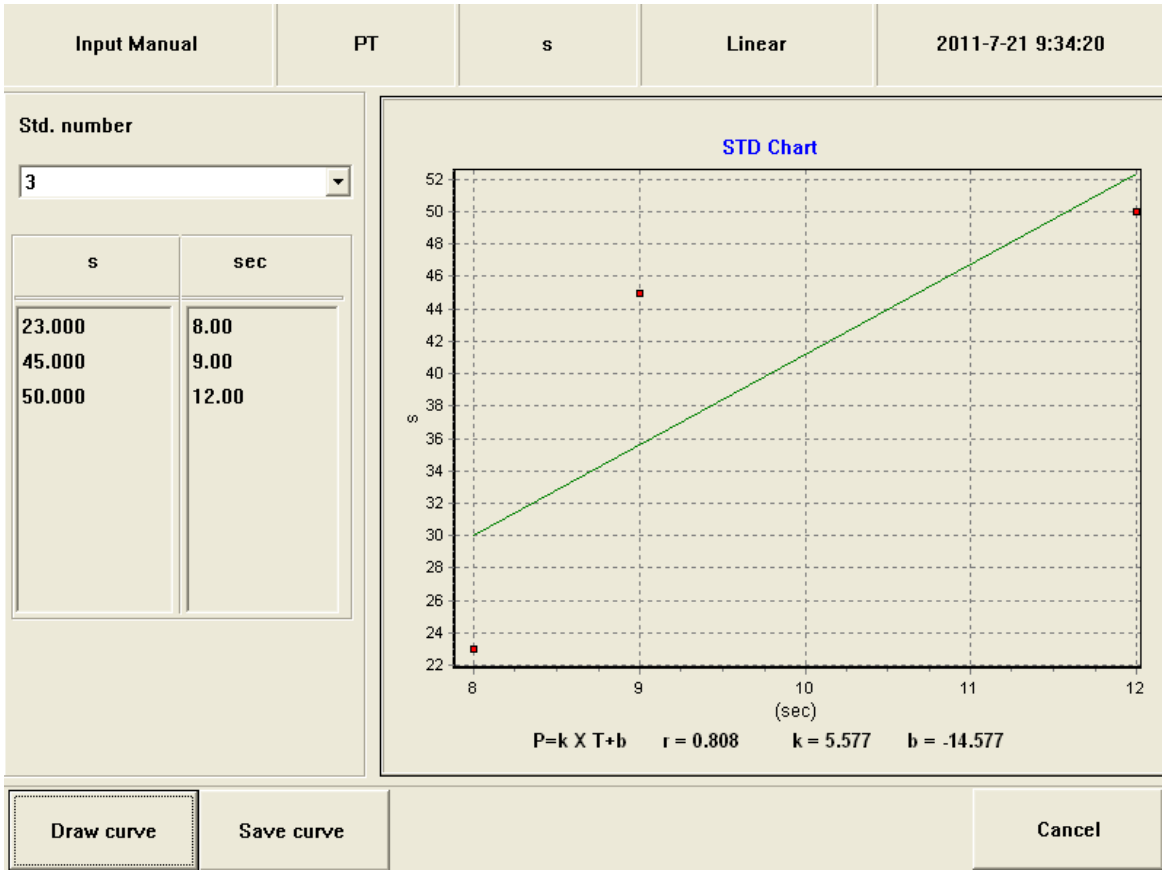


Fig 8-4 Manual Input of Calibration Data

Concrete Operation:

1) In the Calibration Number drop-down box, select the calibration number (up to 6 calibration values)
2) Click the list, and pop up the Digital Input window:

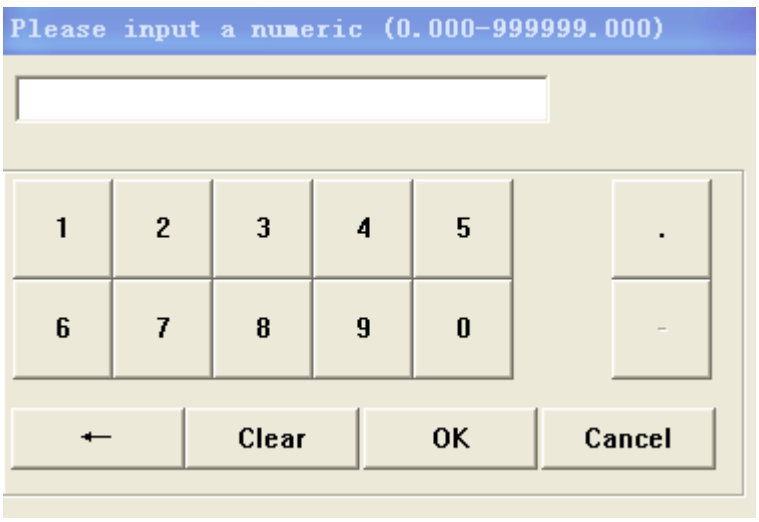


Fig 8-5 Data Input

3) Input the number, and press the ← key to move the cursor one place to the left; press the Clear key to clear the input box; and press the Cancel key to exit from the current interface and return to the Manual Input interface.
4) Press the Confirm key to save and exit from the current interface, and return to the Manual Input interface.
5) Repeat the steps 2)-4), and input the complete calibration data.
6) Press the Draw Curve key to display the calibration curve according to the manually input calibration data.
7) Press the Save Curve key to take the current drawn curve as the latest calibration curve.
8) Press the Exit key to exit from the current interface and return to the Calibration Curve interface.

8.3 Calibration Analysis

In the Calibration Curve interface, press the Calibration Analysis key to enter the Calibration Analysis:

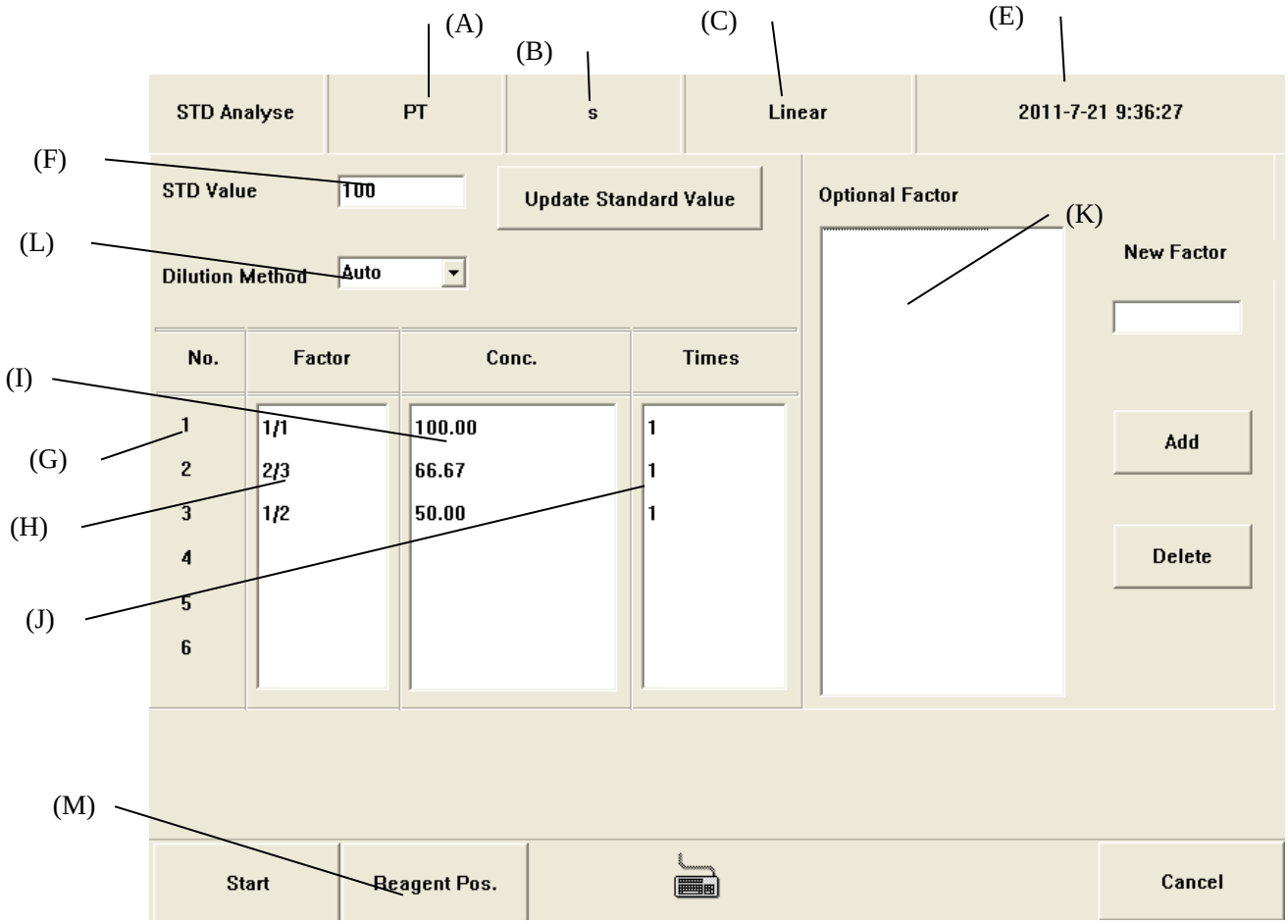


Fig 8-6 Calibration Analysis

(A) Calibration Item: Calibration Analysis Item
(B) Type of calculation parameters: The calibration type is divided into % (concentration), R, INR and dFIB.

(C) Methods of Calibration: There are five methods of calibration including Broken Line Regression, Linear Regression, Double Logarithmic Linear Regression and Double Logarithmic Broken-line Regression.

(E) Date and time of calibration

(F) Concentration of standard material: see the instructions of reagent.

(G) Gradient No.: Related to the number of calibration.

(H) List of dilution factor for each gradient: the dilution factor of concentration.

(I) Concentration List for each gradient: The system will automatically calculate the concentration according to the concentration of standard material and its corresponding dilution factor.

(J) Analysis Number List: the number of repeating the calibration analysis.

(K) Dilution Factor List: The system offers a variety of dilution factors.

(L) Automatic Dilution and Manual Dilution

(M) Reagent position: Select the worksheet group, and set the reagent position.

8.3.1 Prepare for calibration

Prepare for calibration:

1) Select the worksheet, and set the reagent position required in the calibration item correctly.
2) Check whether the reagent storage position is consistent with the settings of worksheet.
3) Ensure sufficient amount of reagent.
4) Make sure the cuvettes are adequate for testing.
5) Check whether the waste bottle is full. If it is full, please clear it.
6) Check whether the cleaning bottle is empty. If it is empty, please fill up.
7) Automatic Dilution Calibration: The calibration plasma is placed in the first sample hole on the sample frame S1;

   Manual Dilution Calibration: The prepared calibration plasma will be separately placed from the first hole to the sixth one on the sample frame S1.

8.3.2 Automatic Dilution Calibration

Concrete Operation:

1) In the **Concentration of Standard Material** input box, input the concentration of standard material.
2) In the **Dilution Factor List** on the right side, click continuously to select the dilution factor (Advanced user can increase and delete the dilution factor).
3) Based on the selected dilution factor, the system can automatically get the dilution factor for each gradient which will be displayed in the **List of dilution factor for each gradient**.
4) Based on the relation between concentration of standard material and its responding dilution factor, the system will automatically calculate the concentration which will be displayed in the **Concentration List for Each Gradient.**
5) Click the **Analysis Number List**, and pop up the Digital Input window to input data, and press the Confirm key to save and exit from the current interface.
6) Repeat the step 5) to input the complete analysis number.
7) The calibration plasma is placed in the first sample hole on the sample frame S1;
8) Press the Start key to start testing.
9) After finishing the test, it will automatically display its calibration curve. Calibration result requires monotone, otherwise, it will prompt “Automatic calibration data is illegal”.

10) Press the Exit key to exit from the current interface, and return to the Calibration Curve interface.

8.3.3 Manual Dilution Calibration

Concrete Operation:

1) Select the Manual Dilution.
2) Select the number of standard materials.
3) In the **Concentration of Standard Material** input box, input the concentration of standard material.
4) Click the **Analysis Number List**, and pop up the Digital Input window to input data, and press the Confirm key to save and exit from the current interface.
5) Repeat the step 5) to input the complete analysis number.
6) The prepared calibration plasma with up to 6 groups of different gradients will be separately placed from the first hole to the sixth one on the sample frame S1.
7) Press the Start key to start testing.
8) After finishing the test, it will automatically display its calibration curve.
9) Press the Exit key to exit from the current interface, and return to the Calibration Curve interface.

8.4 Print the calibration data.

In the Calibration Curve interface, press the Print key to print the calibration data.

Chapter 9 Historical Data

For the historical data, there are two query modes of Query by Item and Query by Patient.

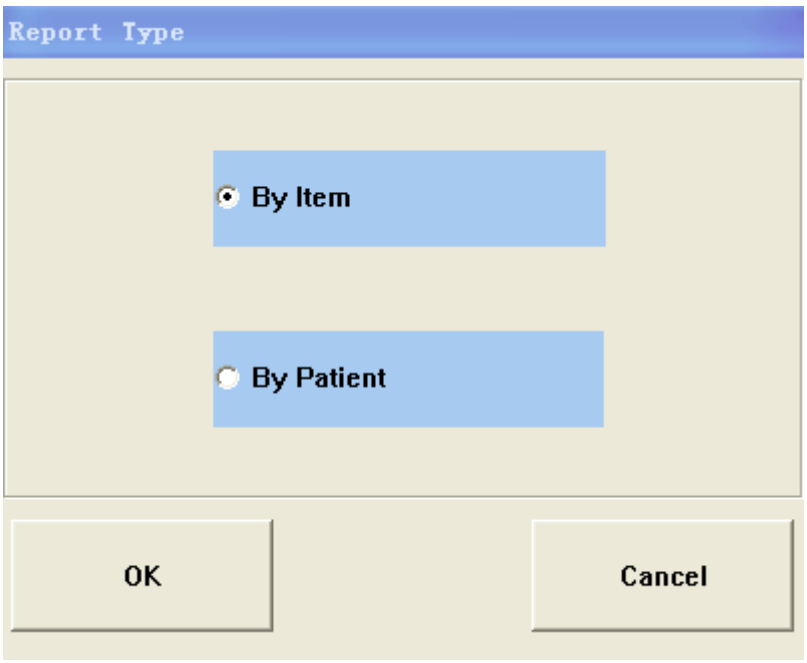


Fig 9-1 Query Mode

9.1 Query by Item

Press the “By Item”, and press the Query key to enter the list of item query results ：

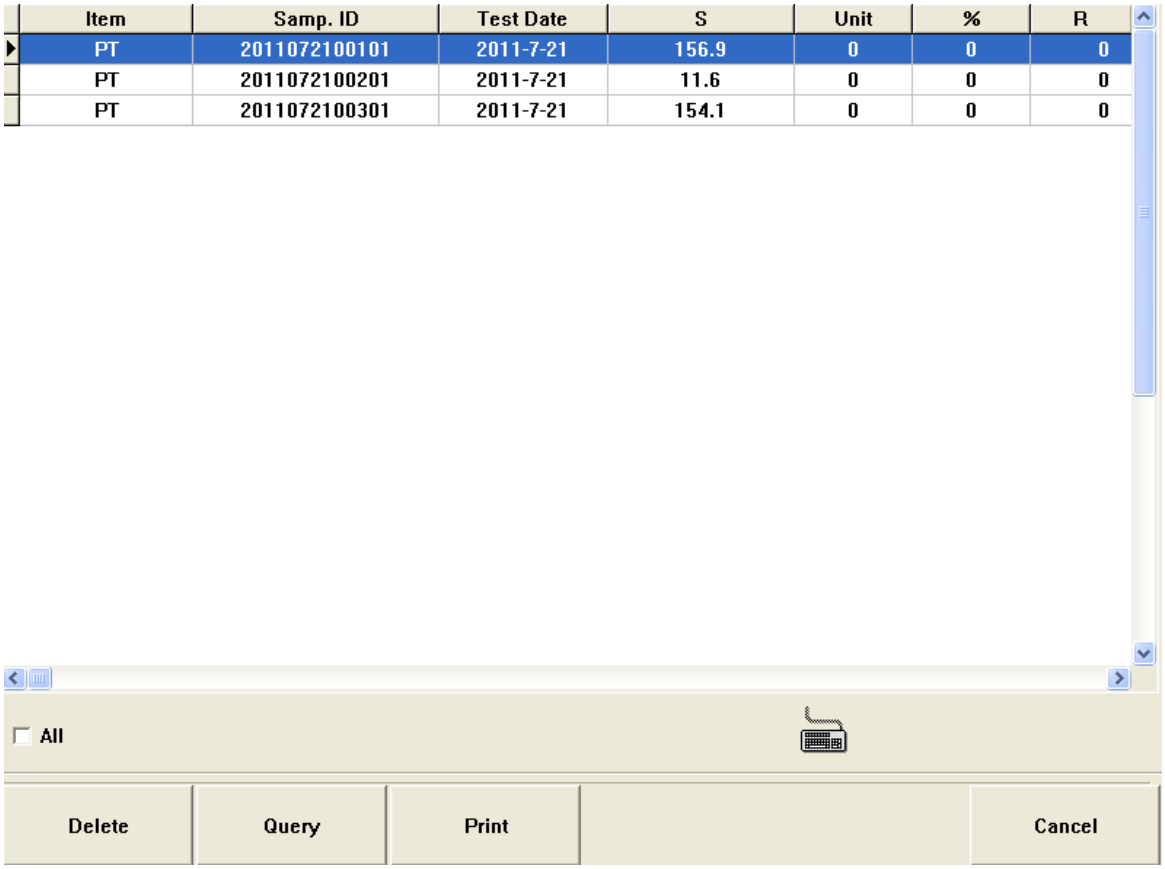


Fig 9-2 Query by Item

There are up to 1000 pieces of patient information stored in the historical patient information database.

9.1.1 Item Information Query

In the Item Query Result interface, press the Query key to enter the Query by Item:

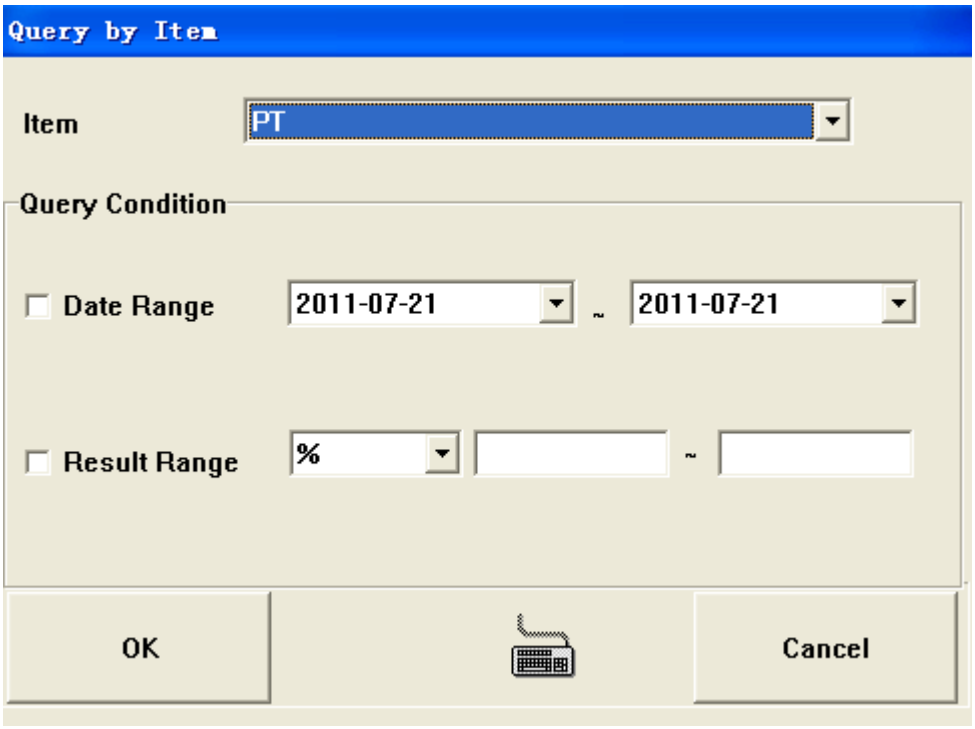


Fig 9-3 Item Information Query

1) Select the query item in the **Test Item** drop-down box.

2) Set the query condition. Select the "Date Range" by ticking to set the query range; Select the "Result Range" by ticking, and select the result type and set the result range in the Result Type drop-down box.

3) Press the Query key to query and exit from the current interface; press the Cancel key to exit from the current interface.

9.1.2 Delete the item test result

In the Item Query Result interface, there are the following delete operations:

- Delete one record: In the query results, click the selected record, and press the Delete key to print the selected record.
- Delete multiple records: In the query results, press the ctrl key and click to select the multiple records at the same time, and then press the Delete key.
- Delete all records: Select the "All" by ticking, and then press the Delete key.

9.1.3 Print the item information

In the Item Query Result interface, there are the following print operations:

- Print one record: In the query results, click the selected record, and press the Print key to print the selected record.
- Print multiple records: In the query results, press the ctrl key and click to select the multiple records at the same time, and then press the Print key.

- Delete all records: Select the “All” by ticking, and then press the Print key.

9.2 Query by Patient

Select the “By Patient”, and press the Query key to enter the patient information list:

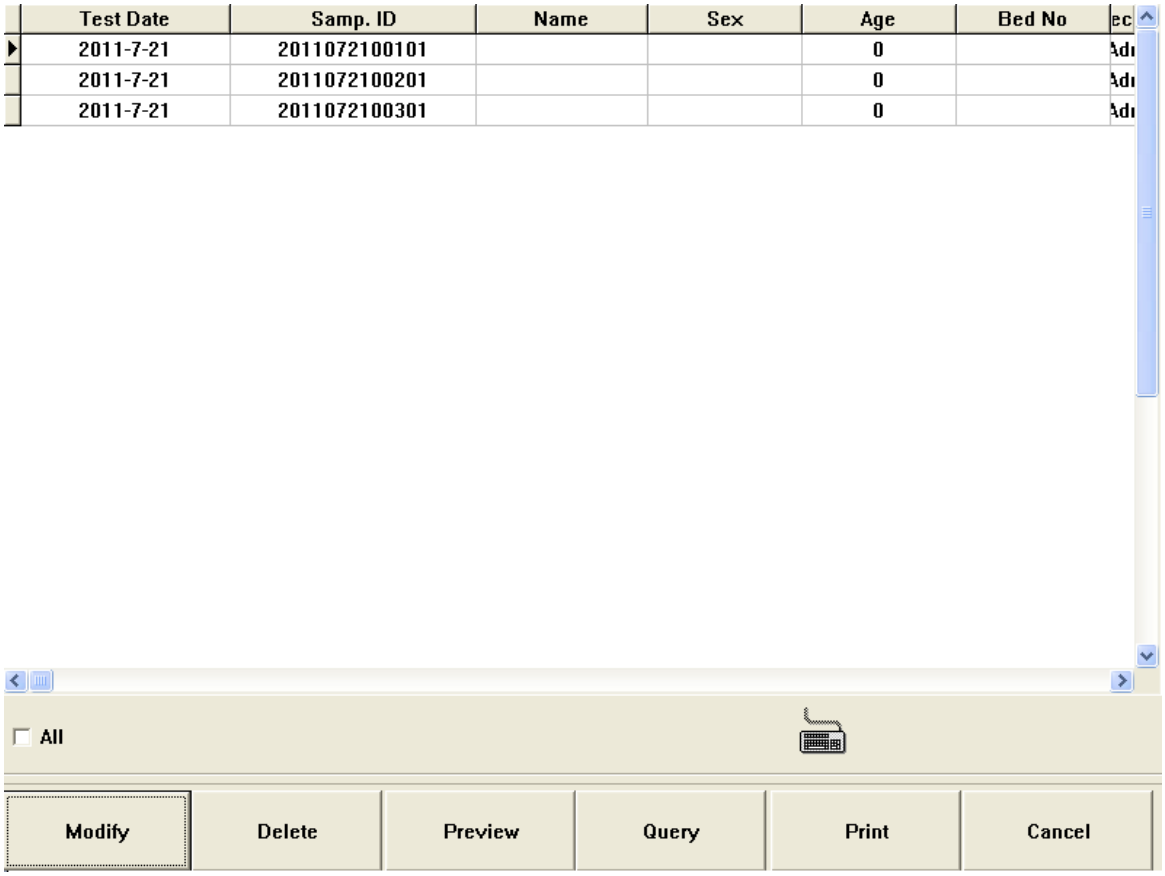


Fig 9-4 Patient Information List

9.2.1 Patient Information Query

In the Patient Information interface, press the Query key to enter the Patient Information Query:

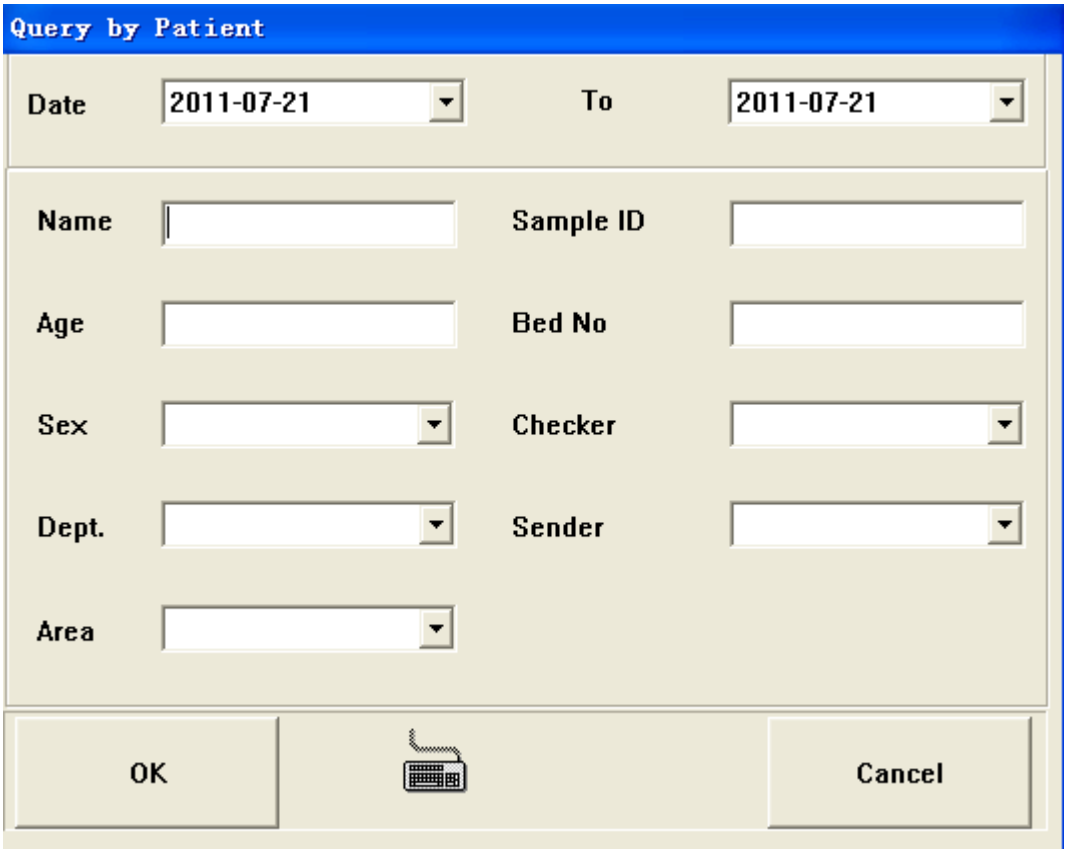


Fig 9-5 Patient Query

Concrete Operation:

1) Set the query range.
2) Set the query condition, which can be a combination of various query conditions including name, age, gender, department, disease area, sample number, bed number, verifier and deliverer.
3) Press the Query key to query and exit from the current interface; press the Cancel key to exit from the current interface.

9.2.2 Modify the patient information

In the Patient Information Results interface, press the Modify key to edit the basic information of patient :

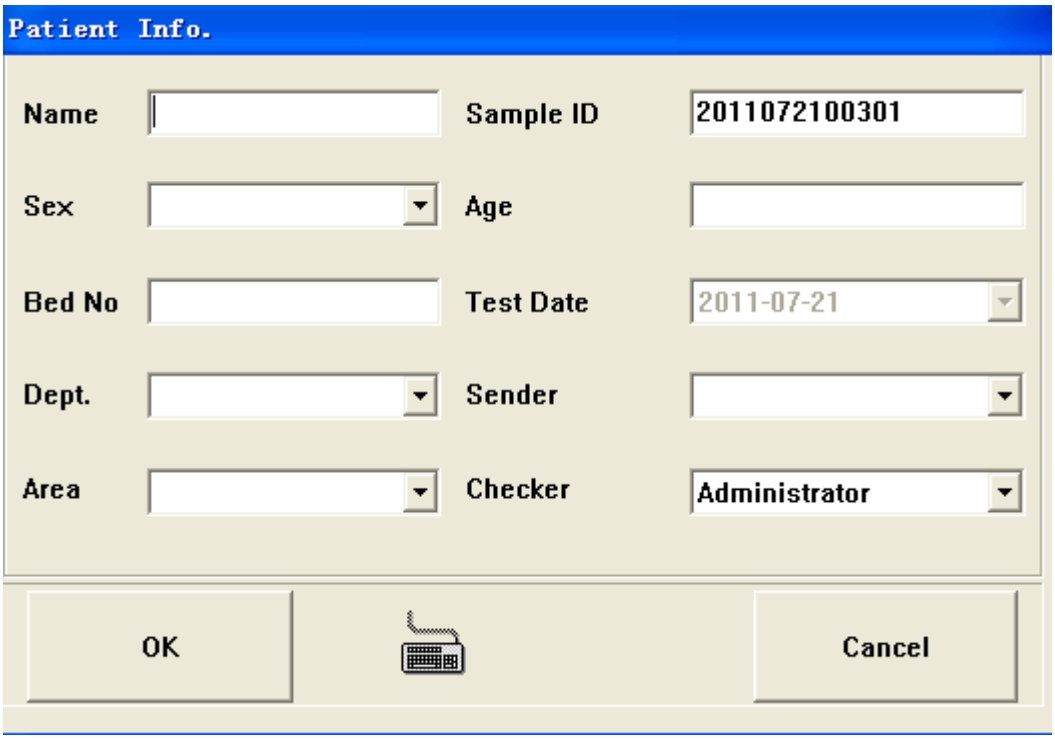


Fig 9-6 Patient Information Input

You can select the gender, department, disease area, deliverer and verifier in the drop-down list from the information management database, and see Section 4.4 for the operation of the database. After finishing the patient information input, press the Confirm to save, and press the Cancel to give up the changes.

9.2.3 Preview the results of patient

After selecting a patient, press the Preview key to enter the preview window, and then his testing results of all the items will be displayed in the list：

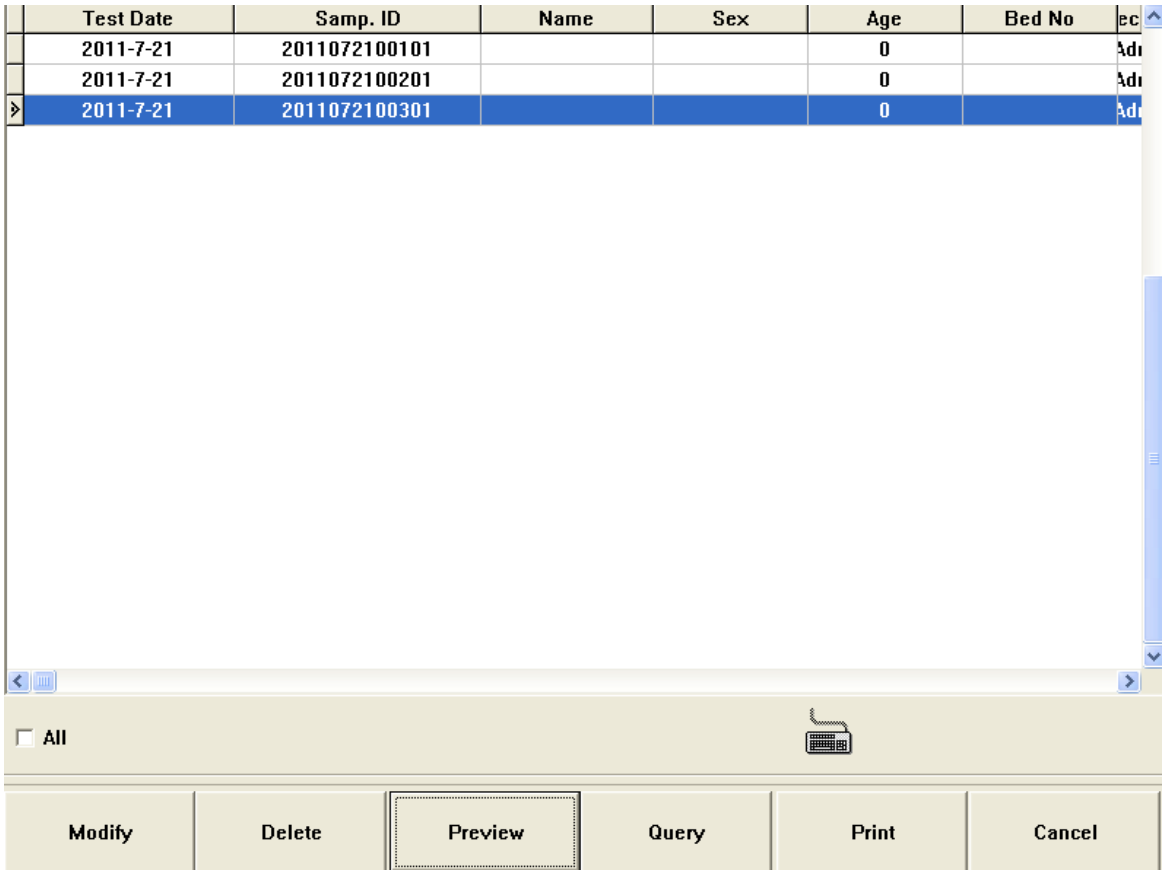


Fig 9-7 Preview the Results

In the Patient Information Results interface, click any column to sort all patient records in the list, and click for the first into descending order, and click again into ascending order. There will be the corresponding mark "▼" or "▲" after the name of the current sort column. If there are a large number of patients, it may take longer time of sorting (tens of seconds).

9.2.4 Delete the patient record

In the Patient Information Result interface, there are the following delete operations:

- Delete one record: In the query results, click the selected record, and press the Delete key to delete the selected record.
- Delete multiple records: In the query results, press the ctrl key and click to select the multiple records at the same time, and then press the Delete key.
- Delete all records: Select the “All” by ticking, and then press the Delete key.

9.2.5 Print the patient record

In the Patient Information Result interface, there are the following print operations:

- Print one record: In the query results, click the selected record, and press the Print key to print the selected record.
- Print multiple records: In the query results, press the ctrl key and click to select the multiple records at the same time, and then press the Print key.
- Print all records: Select the “All” by ticking, and then press the Print key

Chapter 10 Shutdown System

After finishing the test, please shut down the equipment normally. In the Main Menu, press the Shutdown key, and then the Exit interface will be displayed.

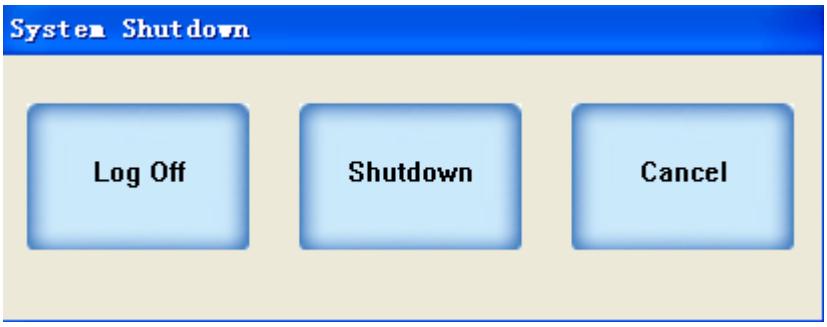


Fig 10-1 Shutdown System

Click the Logout key to switch to the Login screen.

Click the Shutdown key and the system will automatically back up data, and then shut down the whole system. After shutting down the computer control system, please power off.

Click the Cancel to cancel this operation and return to the main interface.

Note: Back up the historical data and other test data into CD or other media regularly.

Chapter 11 Instrument Maintenance

Note：（1）When maintaining the instrument, such as cleaning the dusty of fans, disinfection, cleaning the machinery rail and the sampling/reagent needles, please turn off the power.

（2）For the pollution warnings of degrading the plastics such as waste barrel, cuvettes, reagent bottle and so on, it should be disposed according to the country's laws and regulations.

11.1 Schedule Maintenance

Users should periodically clean and maintain the sampling needle and mechanical rail.

1) Daily Maintenance
   - The used cuvettes should be discarded.
   - Disposal of waste fluid
   - Wipe away the residual liquid on the reagent holder.
   - Clean the sample/reagent needle.
2) Weekly Maintenance
   - Pipe cleaning
   - Equipment cleaning
3) Monthly Maintenance
   - LED calibration
   - Clean the powder or debris on the test hole and incubation hole.
4) Quarterly Maintenance (three to six months)
   - To maintain the machinery rail, clean the stain/dust, and then spray/coat with special grease.
   - Clean the interior of lotion bottle, and clean the filter on the outlet pipe of lotion bottle for one time.
   - Calibrate the mechanical position.

11.2 Maintenance Guide

11.2.1 Clean the sampling needle

1) Clean the sampling needle following the whole cleaning steps after the daily use;
2) If you need to continue working with it, it should be cleaned once every 24 hours.
3) If there is still obvious dirt on the surface of needle after the cleaning is completed, please turn off the power, and then scrub the sampling needle by the gauze or other materials soaked with alcohol from top to bottom, paying attention to the scrubbing strength to prevent it from bending or breaking.

Warning：

（1）Because the tip of sampling needle is sharp, please be careful of cleaning to prevent being scratched.

（2）When cleaning needles, please wear the rubber gloves and others for the protection.

（3）After the operation is completed, please wash your hands with disinfectant, otherwise, it is easy to be infected by bacteria.

（4）Medical waste and infectious waste should be completely removed.

11.2.2 Disposal of waste cuvettes

The cuvette for this equipment is once only. After finishing the testing for each item, the cuvette will be automatically discarded in special collection box.

Collection box is located on the right side of the equipment, and it is recommended to throw away the cuvettes in the collection box at least once every day, preventing that the cuvettes in the collection box are too much to work normally.

11.2.3 Disposal of waste fluid

When waste bottle is full or after the equipment is used every day, you need to discard the waste fluid.

1) Turn the lid of waste bottle counterclockwise, and then pick it up from the bottle.
2) Pour the waste fluid in the waste bottle into the special collection position.
3) Put the lid on waste bottle, and screw it clockwise tightly.

Warning：

（1）Waste materials or liquids should be properly treated as medical or infectious waste. If contaminated by blood, it may be infected with pathogens.

（2）Please wear rubber gloves to deal with waste liquid. After that, please wash your hands with disinfectant.

Note：（1）If the waste liquid is beyond the warning level during the testing process, the instrument will automatically send alarm, and terminate the subsequent item test, and prompt the user to handle the waste liquid in the waste bottle.

（2）Ensure that the waste bottle is upright, otherwise, it will damage the parts of liquid road or bring the risk of biological infection.

11.2.4 Clean the water drop on the reagent position

After the daily test or powering on continuously for 24 hours, make routine cleaning.

1) Open the shield cover ;
2) Wear gloves to wipe off the water drop on the table of reagent position and cleaning position with paper towel or gauze cloth;
3) There may be condensation water drop on the inside of each reagent hole, and you can wear gloves to wipe off with paper towel or gauze cloth.
4) Cover the shield cover .

11.2.5 Replace the built-in paper

Built-in printer is at the lower right of the equipment.

1) Open the printer cover.
2) Remove the rubber bar, paying attention to its temperature to prevent scalding.

3) Replace the new paper.
4) Hold down the paper, and then load the rubber bar.
5) Replace the printer cover.

11.2.6 Supplement the cuvettes or replace the holder of cuvettes.

During the test, if there are insufficient cuvettes, the equipment will automatically stop the follow-up testing, and prompt needing to replace new cuvette.

1) After the testing stops, open the shield cover .
2) Remove the holder of cuvette.
3) Put the new cuvettes into the holder, and after the supplement, replace the holder into the equipment.

Warning： Only after the test stopping can the cuvettes be supplemented or the holder of cuvette be replaced in accordance with the prompt of operating system. Prohibit supplementing the cuvettes or replacing the holder of cuvette during the arm movement and other testing processes, otherwise, the injury will be caused by the movement of arm.

11.2.7 Supplyment the cleaning fluid

1) After the test stopping, unscrew the lid of cleaning bottle counterclockwise;
2) Put the new cleaning solution into the bottle.
3) Screw the lip clockwise.

11.2.8 Replace the fuse

The fuses are placed next to the power switch on the left side of the instrument, and there are two fuses for each instrument.

1) Turn off the power switch;
2) Unscrew the clip of fuse counterclockwise by the slot type screwdriver.
3) Replace new fuse. **Fuse Specification: T5.0AL 250V**
4) Insert the clip of fuse into the hole of fuse.
5) Tighten it clockwise.

Warning: The above specifications of fuse must be used.

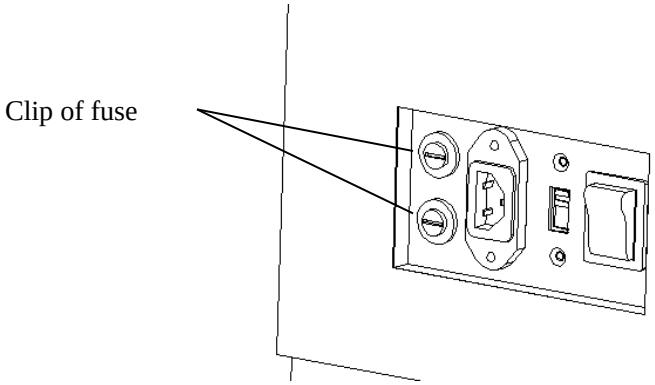


Fig 11-1 Diagram of Replacing Fuse

Chapter 12 System Failure and Treatment

In this chapter, it describes the common faults and treatments of the instrument. If you can't still remove the faults following the explanations in this chapter or need more and detailed information, please contact the Customer Service Department of Linear.

	Fault	Solution
1)	Analyzer can't start.	Check whether the plug is loosened. Check the fuse. Check the voltage.
2)	The illuminator at the test area doesn't light up.	Check the power supply before replacing the illuminator. If the computer and instrument can start normally, you need to replace the illuminator.
3)	The program can't be downloaded.	Restart after the shutdown for 10 seconds.
4)	Printer can't start.	Check whether the plug is loosen. Check the ON/OFF button. Check the fuse.
5)	Printer can't print.	Check whether the connection is normal.
6)	There is no liquid in the cleaning pool.	Check whether the cleaning bottle is sealed well. Check whether the pressure pump works normally. Check the perfusion tube.
7)	Liquid spills in the cleaning pool.	Check whether the waste bottle is sealed well. Check whether the vacuum pump works normally. Check whether air leaks from the pipe.
8)	No reading in the testing bit.	Check whether the illuminator at the test area lights up. Check whether there is signal output from the pre-amplifier board. Check whether the optical parameters are set reasonably.
9)	AD value of the signal is too high with the saturation.	Check whether the optical parameters are set reasonably. Check whether there are objects set at the test area. Check whether the suction probe is blocked.
10)	The repeatability of results is bad.	The contaminated cuvette is used. The volume of reaction liquid is less than 150ul. Check whether the reagent is sufficient. Check whether the sample is sufficient.

		Replace the illuminator. The connection of signal line is bad. Reaction solution has been contaminated. Reagent is out of date or is precipitated. The hole at the test area is contaminated, or there is waste liquid or residue.
11)	Suction volume of sampling needle is not constant.	Check whether the suction probe is blocked. Pipe may be replaced.
12)	Quality control is not within the range of target value.	Check the validity period of quality control solution, and make sure the quality control solution hasn't been contaminated. Check whether the parameters of item settings need to be modified. Re-test with other methods. Check the incubation temperature, and re-test with the new reagent or quality control.
13)	There are vesicles in the probe.	Make sure that the piston is close and has no leakage. Clean the probe with the solution of soil temperature 20 (2 drops/1 liter of distilled water) Replace the 0-ring in the probe. Check the pipe connected with probe.
14)	Samples are contaminated.	Sample probe isn't connected well so as to result in the leakage. Clean it properly or replace the probe. Clean the wash tub. Ensure that there is no residual liquid on the probe. Make sure that the cleaning fluid is new, and hasn't been contaminated. In the Item Settings, adopt the double flushing. Sample tube is dirty, needing to be replaced.
15)	Incubation chamber is not hot.	Check the temperature settings, and adjust it to 37℃.
16)	There is liquid leakage from the analyzer.	Check whether the discharge pipe of waste liquid is inserted into the waste bottle. Overfill from the waste bottle. Wash tub is blocked.

Warning：（1）If the equipment fails, please contact with the agents in order to get technical support!

（2）The equipment can be repaired only by the professionals confirmed by Linear. If you need to replace parts, please contact with Linear or dealers.

Appendix： Name and Content of Poisonous and Harmful Substance or Elements

1. Name and Content of Poisonous and Harmful Substance or Elements

Name of Parts	Poisonous and Harmful Substance or Elements					
	Plumbum （Pb）	Hydrargyrum （Hg）	Cadmium （Cd）	Hexavalent chrome （Cr（VI））	Polybrominated biphenyl （PBB）	Polybrominated Diphenyl Ethers （PBDE）
Built-in circuit board	×	o	o	o	o	o
Shell	×	o	o	×	o	o
Display screen	×	o	o	o	o	o
Photoelectricity parts	×	o	o	o	o	o
Internal electronic wire	o	o	o	o	o	o
Accessories	×	o	o	o	o	o

o： It indicates that the content of the poisonous and harmful substance in all homogeneous materials of this part is below the limit defined in SJ/T11363-2006 standard.

×： It indicates that the content of the poisonous and harmful substance in at least one of homogeneous materials of this part is beyond the limit defined in SJ/T11363-2006 standard.

2． Description of Logo

Lifetime logo of environment protection

Logo meaning: This electronic information product contains some poisonous and harmful materials, and has environmental protection service life of 20 years, during which it is safe to use, and beyond which, it should be put into the recycling system.