# Automated Chemistry Analyzer
# Chemray 120
# User's Manual

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# How to use the Manual

Thank you for using Chemray 120 Automated Chemistry Analyzer. Before operating the instrument, be sure to read the Manual carefully.

To get the best results, you must be aware of our instrument and its performance before clinical diagnosis and testing.

This is the User's Manual for Rayto Chemray 120 Automated Chemistry Analyzer. It describes the installation, daily use and maintenance, etc. of the instrument. After reading the Manual, please keep it properly for future reference.

**The functions may vary depending on the version or configuration of the instrument.**

Please keep all packing materials for future storage, transportation or return to the manufacturer for repair.

If you have any questions, contact your dealer.

**Meaning of Symbols**

***Warning: Indicates when the user ignores this symbol and misuses the instrument, casualties, serious injury or serious property loss may be caused to the user.***

***Caution: Indicates when the user ignores this symbol and misuses the instrument, injury, wrong output results or property loss may be caused to the user.***

**Precautions for Diagnosis**

***Caution: The product is a clinical examination instrument for inspection. Clinical diagnosis based on testing results should be conducted by doctors according to the clinical symptoms of the patients by combining other inspection results.***

# Representation

Rayto reserves the right for the final explanation of the User's Manual.

The illustrations in the Manual give typical examples only and may not be completely consistent with the actual displaying on the product. Take practicality as standard. Never use the illustrations for other purposes.

Without written consent of Rayto, no individual or organization may duplicate, modify or translate the contents of the Manual.

Rayto will be responsible for the safety, reliability and performance of the product only when all the following requirements are met:

- Assembly, re-debugging, expansion, improvement and repair should be conducted by persons recognized by Rayto;
- The product is operated according to the Manual;
- The related electrical equipment complies with the national standards.

# Caution

- The instrument must be used by medical examination professionals or trained doctors, nurses or

laboratory technicians.

## Warning

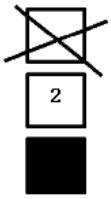
- If no satisfied maintenance/repair plan is achieved, the instrument may fail abnormally and may endanger personal health.
- Ensure to use the instrument in the conditions specified in the Manual. Otherwise, it may cause the instrument's failure to function normally and unreliable measurement results, damage the components of the instrument, and endanger personal safety.

# Major Icons Used in the Instrument

Symbols on the instrument

| | |
|---|---|
|  | This means that the labeled item could lead to personal injury and/or damage to the analyzer.<br>The symbol is labeled beside the power outlet and some external interface. |
| SN | The symbols for “SERIAL NUMBER”, The serial number shall be after or below the symbol, adjacent to it. |
|  | The symbol means the product is in vitro diagnostic medical device. |
|  | The symbol indicates the manufacturer and its address, after which are shown its name and address. |
|  | The symbol indicates biological pollution, marked in the part where the instrument contacts the clinical reagent. The symbol appears in black side and yellow background. |
|  | The operator should follow the instructions under the symbol, otherwise, may result in personal injury. |

Symbols on the sales packaging

| | |
|---|---|
|  | The symbol means that the environment of instruments must be dampproof in the course of transport, and instrument must be kept in a dry environment. |
|  | This means that instrument should handle with care in the course of transportation, so as not to damage it. |
|  | The symbol means the instrument packaged should not be upended at any time |
|  | The symbol means that the level piled up can't exceed 2 layers, as not to damage instrument. |
|  | The symbol indicates temperature range of the analyzers during storage and transportation. |

# Warning and Safety Instruction

For in vitro diagnosis only. Carefully read the following warning before use and strictly follow it.

**Warning: Read the following precautions carefully before using the instrument.**

- **In case of peculiar smell, smog or noise during use, immediately turn off the power and remove the plug from the socket, and immediately apply for inspection with the dealer or our agent. If you continue to use the instrument in that case, fire, electric shock or casualties may be caused.**
- **Prevent blood, reagent or metal pieces, such as staple, etc., from entering the instrument. Otherwise short circuit or fire may be caused. In case of abnormality, immediately turn off the power and unplug the plug from the socket, and immediately apply for inspection with the dealer or our agent.**
- **Do not touch the electronic circuit in the instrument. Particularly, touch with wet hand may cause electric shock.**
- **Wear rubber gloves and use the specified tools, parts and components when maintaining and inspecting the instrument. When the operation is ended, wash hands with disinfectant. Otherwise the skin in contact with blood may be infected or scalded or get an electric shock.**
- **Be very careful when treating samples. Be sure to wear rubber gloves, otherwise infection may be caused. In case the sample enters the eye or wound, immediately rinse with plenty of clear water and receive examination by a doctor.**

**Use and Disposal of Reagent**

- **Prevent the reagent from being contact with skin and clothing during operation.**
- **In case the reagent enters the eye, immediately rinse with plenty of clear water and receive examination by a doctor.**
- **If you swallow the reagent, immediately consult a doctor and drink water generously to spit the reagent.**
- **If your hand or skin is stained with the reagent, immediately rinse with clear water.**
- **The cleaning solution supplied with the instrument is highly alkaline, and should not be in contact with skin or clothing. In case your skin or clothing is stained with it, immediately rinse with plenty of water to prevent injury.**
- **Used test tubes and other consumables for the instrument should be disposed properly as medical waste or infectious waste. If contaminated by blood, etc., they may be infected by pathogen.**

**Voltage, Connection and Grounding of Power Supply**

- **Ensure the power supply and grounding environment of the instrument are good and steady.**
- **Never insert the power plug into a socket other than 220V AC socket. Otherwise fire or electric shock may be caused.**

- **Be sure to use the three-core cable supplied with the instrument in installation, ensure good grounding, and put the instrument in a place for easy power off operation. Otherwise fire or electric shock may be caused.**
- **Never damage the insulating covering of the cable. Do not jerk the cable or hang heavy objects with the cable. Otherwise short circuit or open circuit may be caused, thus causes electric shock or fire.**
- **Be sure to turn off the power before connecting peripheral equipment. Otherwise electric shock or failure may be caused.**

**In accordance with the Pharmaceutical Affairs Law, modification of medical instruments is prohibited.**

# Table of Contents

# Chapter 1 Introduction

## 1.1 Introduction

### 1.1.1 Product Name Automated Chemistry Analyzer

### 1.1.2 Model Chemray 120

### 1.1.3 Features

Chemray 120 is an analysis instrument for clinical biochemical tests developed by using photoelectric, automation and computer technologies. The instrument adopts transmission turbidimetry and calculates concentrations of samples according to the Beer-Lambert's Law.

## 1.2 Composition and Structure of the Instrument

### 1.2.1 Structure Diagram

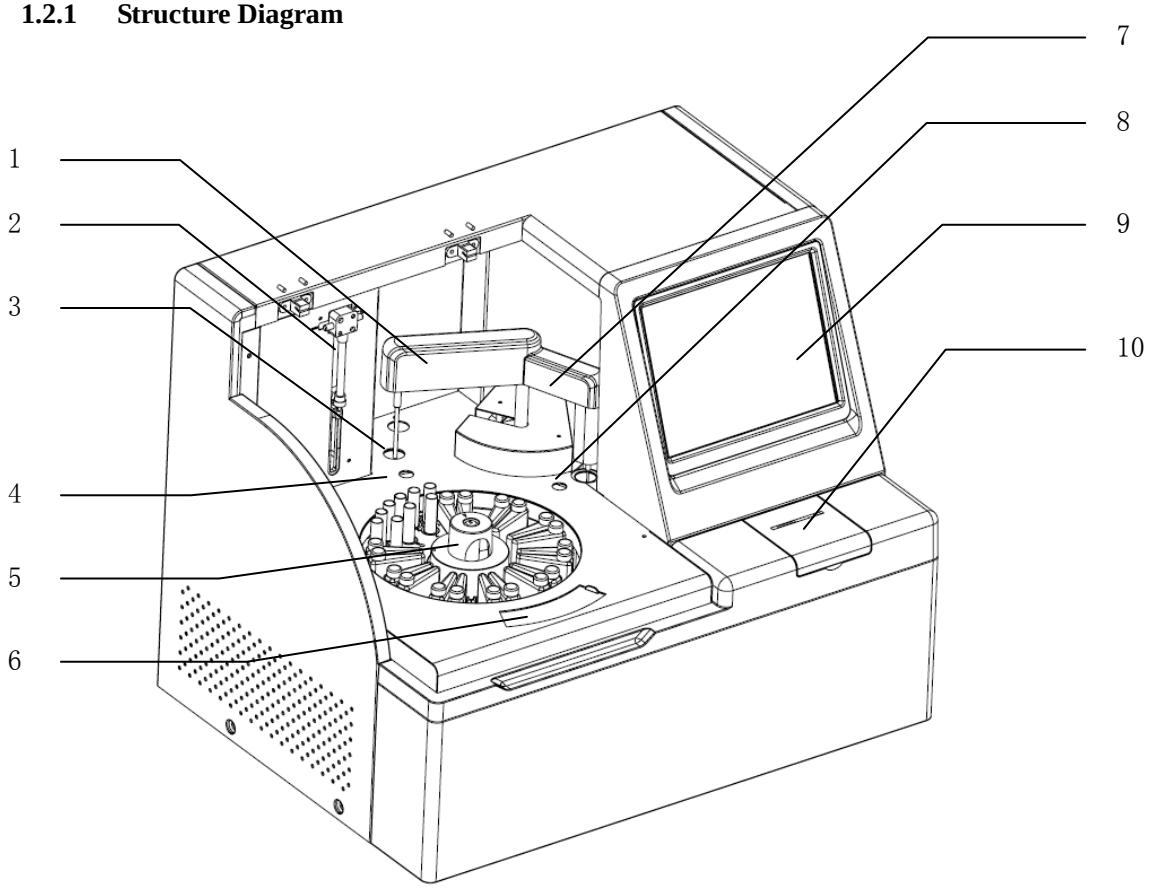



Figure 1-1 Structure Diagram of Chemray 120

1 — Sampling probe
2 — Syringe
3 — Probe cleaning position
4 — Sampling position
5 — Reagent/ sample/ reaction tray
6 — Assay cup pick-and-place opening
7 — Rabble
8 — Rabble cleaning position
9 — Display
10 — Internal printer

### 1.2.2 Right Side Diagram

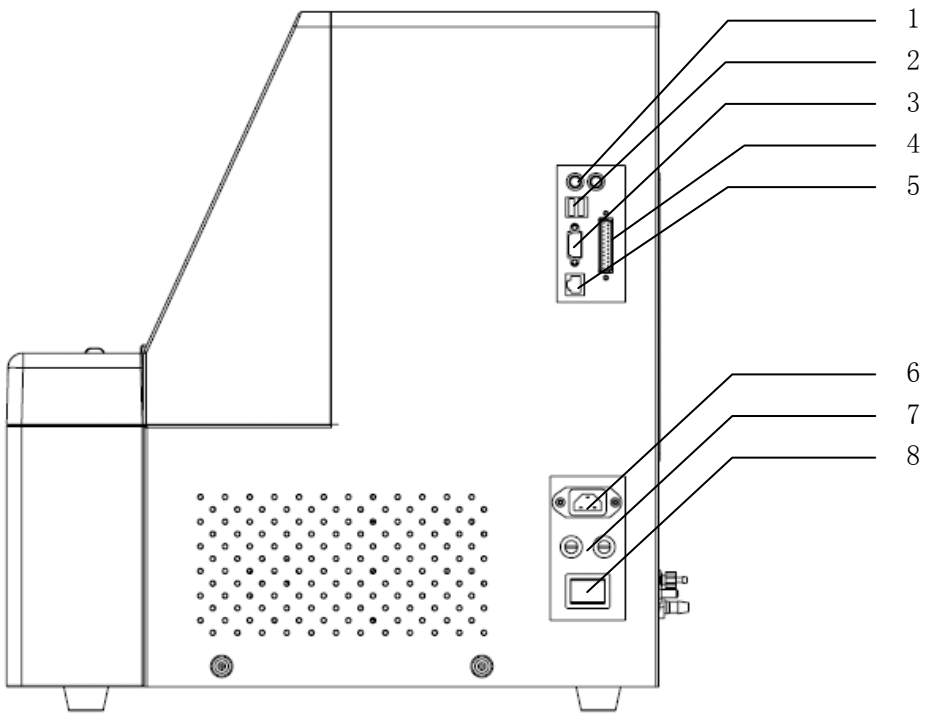



Figure 1-2 Diagram of Interfaces on the Right Side Panel of Chemray 120

| | | |
|---|---|---|
| 1 — Keyboard/mouse interfaces | 2 — USB interface | 3 — Serial interface |
| 4 — Parallel interface | 5 — Network interface | 6 — Power input interface |
| 7 — Fuse | 8 — Power switch | |

### 1.2.3 Rear Side Diagram

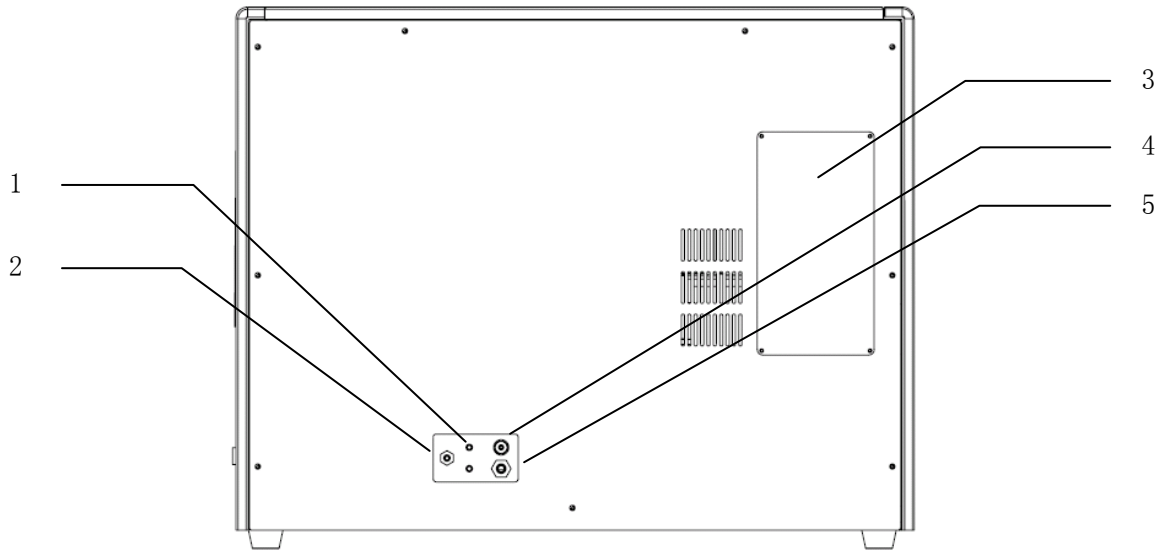



Figure 1-3 Diagram of Interfaces on the Rear Side of Chemray 120

1 — Cleaning solution/ waste liquid sensor interface

2 — Ground pole

3 — Bulb replacement opening

4 — Cleaning solution interface

5 — Waste liquid interface

## 1.3 Performance

Steady testing results, easy operation, and fast testing.

## 1.4 Scope

For clinical regular biochemical measurement and other absorption spectrophotometry measurement.

## 1.5 Technical Parameters

| | |
|---|---|
| **Test Methods:** | End-point method, two-point method, rate method, etc. |
| **Computational Methods:** | Factor method, single point calibration, multi-point calibration, linear regression, nonlinear regression, etc. |
| **Spectral Modes:** | 8 opticalfilters (340, 405, 450, 510, 546, 578, 630 and 670 nm) |
| **Reagent Positions:** | 26 positions |
| **Sample Positions:** | 9 positions |
| **Light Source:** | 12 V/20 W long life halogen lamp |

| | |
|---|---|
| **Stray Light:** | Absorbance ≥2.3A |
| **Display:** | LCD |
| **Printing:** | Internal printer, external printer (optional) |
| **Working Condition:** | 20℃～30 ℃; RH40%～85%, no condensation, Atmospheric Pressure 86kPa～106kPa |
| **Storage Condition:** | 0℃～50 ℃; RH≤93%, indoor environment without corrosive gas and with good ventilation. |
| **Working Power:** | a.c.100V/240V, 50Hz/60Hz |
| **Input Power:** | 350W |
| **Fuse:** | T5.0AL 250V, Φ5×20 |
| **Dimensions:** | 640mm (L) ×480mm (W) ×510mm (H) |
| **Weight:** | 45kg |

# Chapter 2 Installation and Correction

## 2.1 Unpacking

### 2.1.1 Steps of Unpacking

Unpack the instrument and remove the materials for transport. Keep the packing case and packing materials properly for future repacking.

1) Put the wooden case cover on the level ground horizontally. Use the screwdriver and pliers to open the metal latch around the wooden case. Be careful in operation and prevent the sheet metal from cutting hand.
2) Take out the accessories and check the objects against the accessories list. If any object is missed, immediately inform Rayto's after service department or retailer. Check the contents in the packing case and check that the following are included: (refer to the packing list)
   - One mainframe
   - Factory Inspection Certificate
   - Chemray 120 User's Manual
   - Packing List and Quality Analysis Certificate
   - Big and small reagent bottles
   - Assay cup
   - Micro sample cup

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***Caution: The accessories packed should be consistent with the packing list. If any component is missed or inconsistent with the packing list, please contact the retailer.***

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### 2.1.2 Handling Method

The structure of the whole machine is composed of the rack, and the sheet metal parts and plastic parts on the surface. Two persons are required to handle the machine. The two persons stand on each side of the machine respectively, put hands on the sides of the bottom racks, lift up the machine horizontally, and put it on the level desk.

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***Caution: Keep the packing case for packing before long distance transport. The instrument must be put on a level operation desk, rather than angular surface.***

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## 2.2 Installation and Use Environment

The product must be installed by professionals. In order to ensure the instrument works normally, put it in a workplace meeting the following requirements:

- No direct sunshine;
- No large amounts of dust;
- No strong electromagnetic radiation;
- Easy power off operation;

- A level, solid desk that is big enough;
- With good ventilation;
- Avoid moist and high temperature;
- Avoid violent vibration and impact.

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***Caution (1) The normal working environment for the instrument is temperature of 20℃～30 ℃ and HR40%～80%.***

***(2) After installation, try to avoid frequent movement. To move the instrument, use a steady cart. The angle of inclination should not be greater than 15 ° when it is moved.***

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

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## 2.3 Requirement of Power Supply

The power supply must be a.c.110V-220V, 50Hz-60Hz, with good grounding. If the voltage change of the lab is ＞±10%, it is suggested to install an external voltage stabilizer of above 1500 W. The machine is a precision instrument automatically controlled by computer, therefore it must be equipped with UPS (Uninterrupted Power Supply) of above 1500 W.

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**Warning: (1) The AC power supply must be grounded properly.**

**(2) Check that the input voltage complies with the requirement of the instrument. The AC power supply must be stable. Sharing a power supply with high power electrical appliances is prohibited. It is better to be equipped with a regulated power supply.**

**(3) Before connecting the cable, check that the switch of the instrument is off.**

**(4) In case of smog, peculiar smell or abnormal noise, immediately turn off the power and contact the retailer.**

**(5) To unplug the cable, grasp the plug, rather than the wire.**

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## 2.4 Installation

- Put the machine on the level desk
- Connect the machine and AC power supply with the cable
- Connect the cleaning solution bottle and waste liquid bottle to the machine according to the marking on the rear panel
- Add a proper amount of purified water to the cleaning solution bottle
- Put the waste liquid bottle on the ground, so that the waste discharge system can work normally
- Turn on the power switch of the machine and start the control software
- To switch off the machine, turn off the applications and then turn off the power switch

## 2.5 Correction

Standard substances can be used to correct the instrument. The instrument needs not to be corrected for each test. However, for items requiring calibration, regular calibration tests are needed. The changes in the system environment may impact the tests to a certain extent, so a calibration test is suggested each time the machine is switched on to ensure the accuracy of test results.

After each calibration, QC substance must be used to verify the accuracy of the machine.

For the calibration and QC test methods, refer to “Daily Tests”.

# Chapter 3 Start

## 3.1 Precautions before Starting the Machine

Before you start the machine each time, pay attention to the following to ensure the system is ready:

1) Check the status of the instrument. Check that the mainframe has no obvious physical damage; there is no dust or liquid accumulated on the surface of the workbench; the pipes, printer, etc. are properly connected;
2) The power supply is properly connected, with good grounding;
3) Check whether the paper for the internal or external printer is adequate and whether it is installed in place;
4) Adequate deionized water and cleaning solution have been added to the specified positions on the reagent tray;
5) The waste liquid barrel has been emptied, and the cleaning solution is adequate;
6) Operate and maintain the instrument according to the instructions, and keep the User's Manual in a handy place.

## 3.2 Logging on to the System

When the machine is started, the Chemray 120 software will run automatically, and the system will enter the user login screen, as shown in the figure:

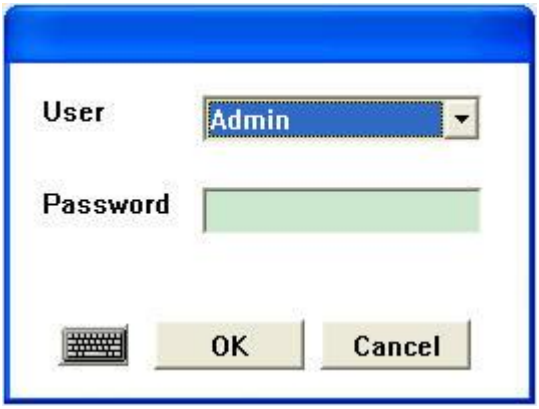


Figure 3-1 Login

Select a user name and input the password, and press the Login key to login, or press the Cancel key to turn off the system automatically.

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***Caution: The user name of the system administrator is "Admin", and the initial password is "888888". You can change the password freely. Please keep the changed password in mind! If you press the Cancel key on the login screen, the system will be turned off automatically.***

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After login, the system will conduct self-check and initialization automatically, as shown in the figure:

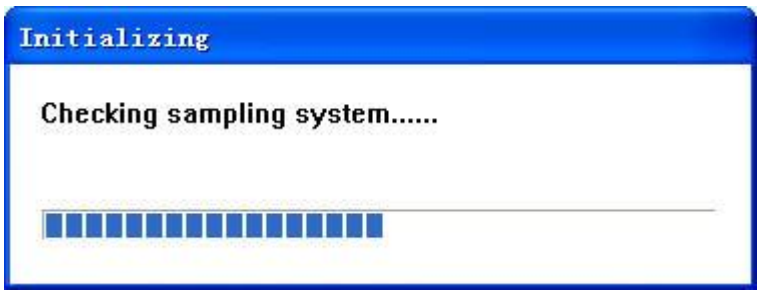


Figure 3-2 Initialization

Self-check and initialization include the following contents:

- Connecting frond end: Test whether the communication between the control software and middle computer software is normal.
- Units shaking hands: Test whether the status of the various units is normal.
- Sending parameters: Read system parameters from the middle computer.
- System reset: Conduct whole machine reset and hydraulic circuit perfusion to prepare for testing.
- Replacing cuvettes: Replace 1 - 9-fold of cuvettes in turn. Each time a fold is replaced, press the OK key. To skip the replacement, click the Stop key quickly and select Yes from the pop-up box.

## 3.3 Main Screen

After cuvette replacement, the system will enter the main screen. Here, “Waiting for stable light source” is displayed on the top of the screen. The test can be commenced only when the light source becomes stable and “Ready” is displayed on the upper part of the screen, as shown in the figure:

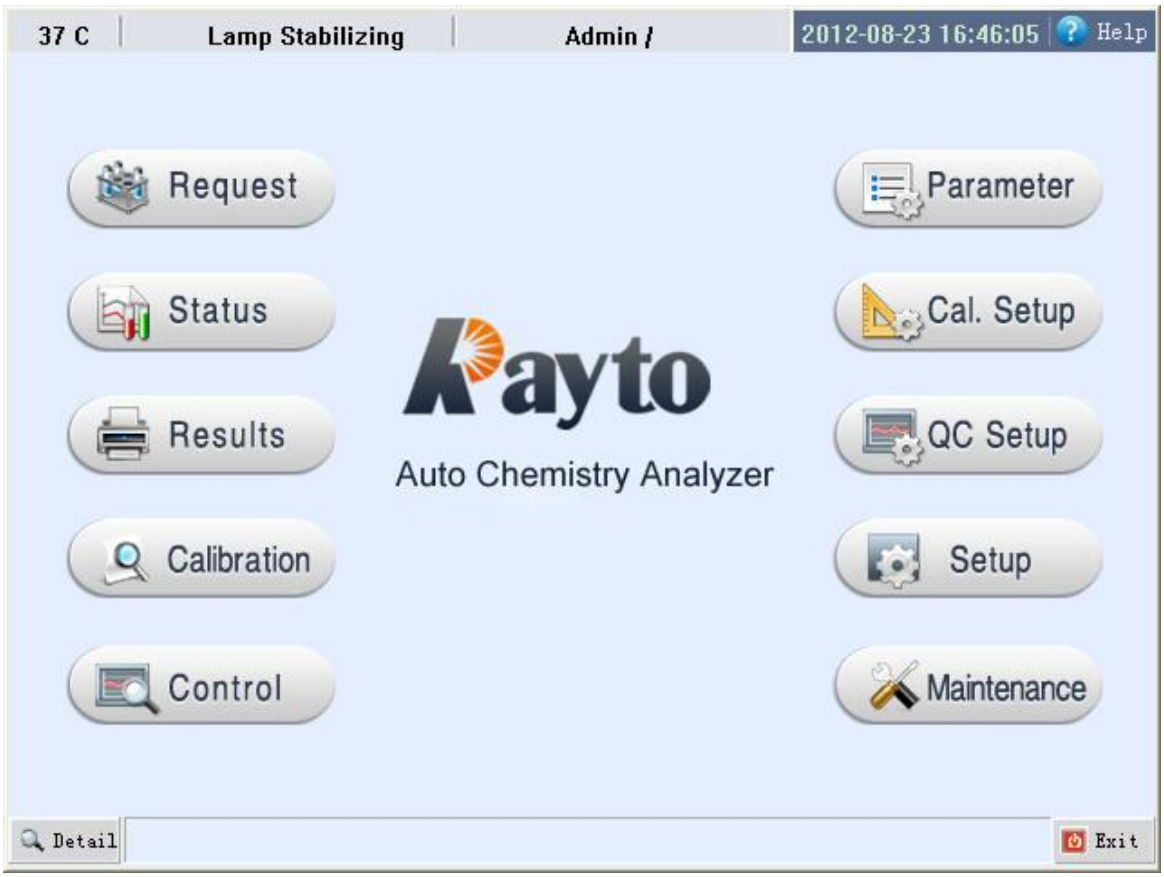


Figure 3-3 Main Menu

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***Caution: Each time the power is switched on, it takes 30 minutes for the light source to become stable. If the test is commenced before the light source becomes stable, the accuracy of the results may be affected.***

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## 3.4 Function Modules

The main screen contains 10 function modules:

1) Sample Entry: Used to apply for test samples, including regular samples, emergency treatment samples, QC substances, and standard substances;
2) Test Status: Used to view the test status and test results;
3) Print Report: Used to inquire, edit and print sample information, sample test results, and historical reagent blank test records;
4) Standard Inquiry: Used to inquire standard curves and calibration test results;
5) QC Inquiry: Used to inquire QC test results, including QC data, QC charts and QC results statistics;
6) Item Setup: Used to set the test control parameters of biochemical items and edit non-biochemical items for external data entry;
7) Standard Setup: Used to set parameters of standard substances for application for standard substance tests in the Sample Entry module;
8) QC Setup: Used to set parameters of QC substances for application for QC substance tests in the

Sample Entry module and for statistics of QC results in the QC Inquiry module;

9) System Setup: Including system control parameter setup, reagent setup, section setup, user management, etc.
10) Maintenance: Used for daily maintenance of the system, including data maintenance, log maintenance, and simple function debugging.

# Chapter 4 Item Setup

## 4.1 Item Parameter Setup

**Function Brief: To set the control and calculation parameters of biochemical items and non-biochemical items.**

### 4.1.1 Biochemical Items

Press “Item Setup” on the main screen to enter the Item Setup page, as shown in the figure:

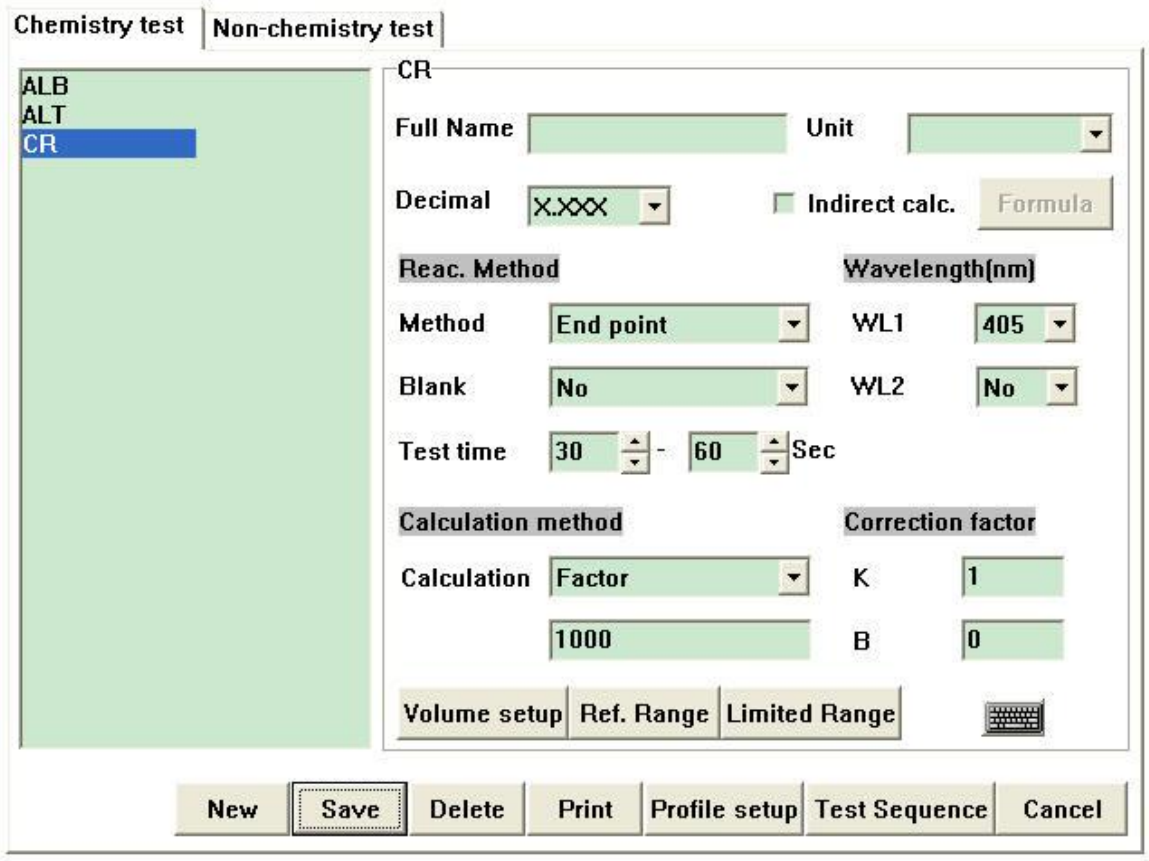


Figure 4-1 Item Setup

**Add Item**

Press the new key and input the name of the item to be added. Input the various parameters of the item to be added in turn and press the Save key.

**Modify Item**

Select the item to be modified from the list, and the corresponding parameters will appear on the right. Move the cursor to the information to be modified in turn and press the Save key.

**Delete Item**

Select the item to be deleted from the list and press the Delete key.

**Print Item Parameters**

Select the item to be printed from the list and press the Print key.

**Item Parameters Description**

1) **Full Name:** Input the full name or description information of the item.
2) **Unit:** Input or select the unit of the test results of the item.
3) **Decimal Point:** Select the number of digits after the decimal point of the item results on the general report to be printed, with a maximum of 3 digits after the decimal point.
4) **Indirect Calculation:** If the results of the item can be obtained through the calculation of other items, select Indirect Calculation and press the Calculation Formula button to enter the screen as shown in the figure:

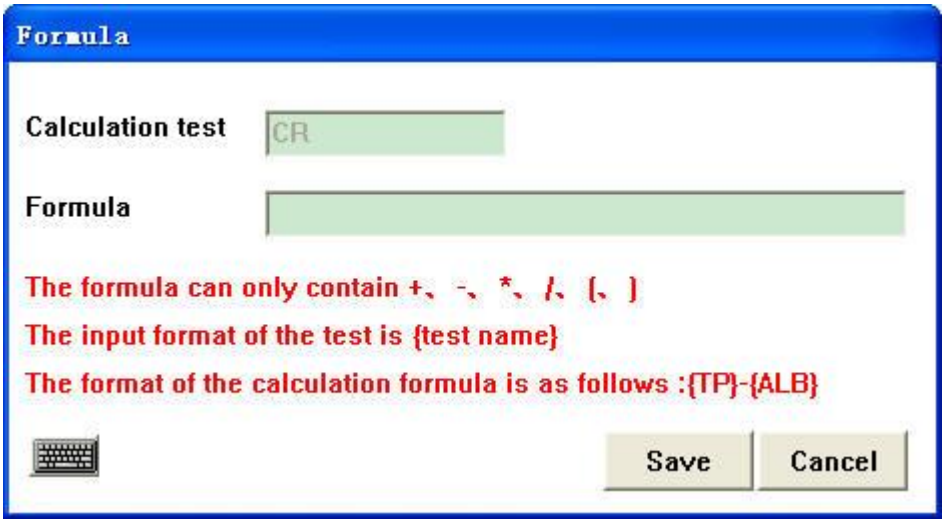


Figure 4-2 Indirect Calculation Setup

Input a calculation formula in the Calculation Formula input box. If GLB can be calculated through the difference between TP and ALB, input {TP}-{ALB} in the calculation formula for the GLB item.

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***Caution: A calculation formula is composed of +, -, *, /, (, ), digits and {Item Name} only. Otherwise the formula is regarded as invalid.***

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5) **Wavelength:** Wavelength set according to the instructions of the reagent. If the single wavelength test is adopted, set wavelength 1 only and select None for wavelength 2. However, in order to eliminate external interference, it is suggested to use the dual-wavelength test.
6) **Test Method:** Select End-Point Method, Two-Point Method, or Rate Method.
7) **Blank Test:** Select None, Reagent Blank, Sample Blank, or Pre-sample Blank.
   - None: The blank value needs not to be reduced;
   - Reagent Blank: The reagent and sample volumes for normal tests are used, and the sample is substituted with distilled water or saline;
   - Sample Blank: The reagent and sample volumes for normal tests are used, and the reagent is substituted with distilled water;
   - Pre-sample Blank: The blank value after the reagent 1 and sample are mixed should be

reduced.

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***Caution: With the end-point method, the absorbance value of the reagent blank test is reduced; with the two-point method and rate method, the variation per minute of the reagent blank test is reduced.***

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***Caution: Pre-sample Blank can be selected only when the dual reagent end-point method is used to test items.***

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**8) Measurement Time:** To set the start time ane end time of measurement respectively. For single reagent items, the range of measurement time is 30-600 seconds; for dual reagent items, 30-300 seconds.

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***Caution: With the end-point method, usually only one measurement point is specified; if more than one measurement point is specified, the average of the points is taken as the calculation value. With the two-point method, the measurement time should not be less than 30 seconds. With the rate method, in order to ensure the accuracy of the test results, it is suggested that the measurement time be greater than 90 seconds. For the two-point method and rate method, set measurement time as long as possible.***

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**9) Calculation Method:** Select the corresponding calculation method according to the actual needs. When the Factor Method is selected, you can input factor values manually.

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***Caution: The signs of the factors of items tested with the rate method reflect the change directions of the curve. If it is downward reaction, the factor is negative, otherwise the factor is positive.***

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**10) Correction Factor:** Linear correction factor of system test results: Result = Measurement *K+B. In general, no correction is needed: K=1, B=0. However, for items tested with the factor method, the factor can be used to correct the error of the instrument.

**11) Dosage Setup**

- Setup of Sample Volume for Initial Test: Input the sample volume. The range is 3-45μL, accurate to 0.1μL. If the sample of the item needs to be prediluted before the test, select the Predilute option and input the sample volume and diluent volume in the boxes below in turn (the volume ranges of the sample to be prediluted and diluent are 2-100μL and 20-450μL respectively), as shown in the figure:

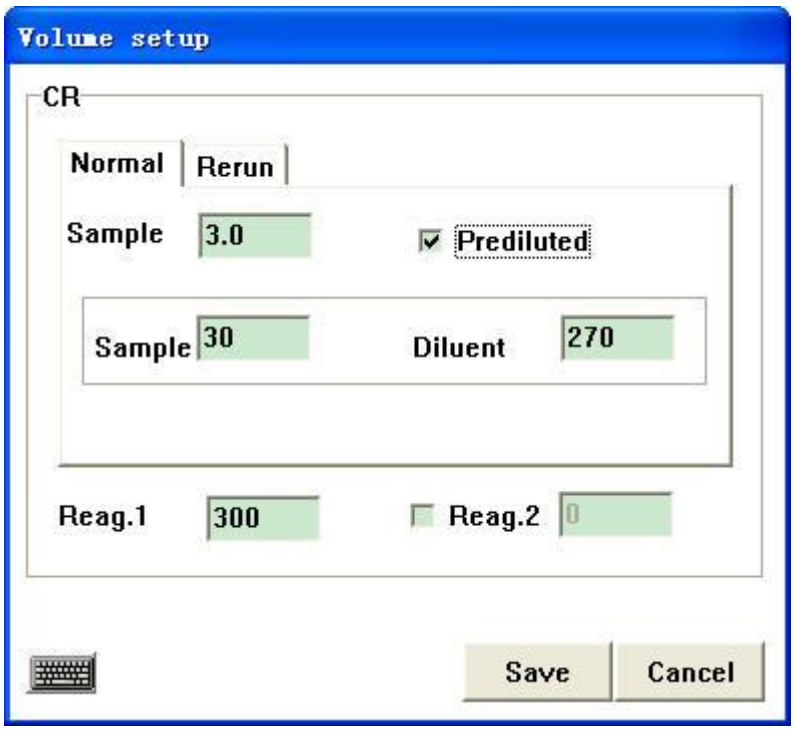


Figure 4-3 Sample Volume for Initial Test

- Setup of Sample Volume for Retest: When the test results exceed the linear range, retest may be conducted. In the retest, the specified sample volume is resucked up according to the test results on the high or low side. Input the sample volumes for retest for results on the high side and for results on the low side in turn. If the sample of the item needs to be prediluted before the retest for results on the high side, select the Predilute option and input the volumes of sample to be prediluted and diluent in the boxes below, as shown in the figure:

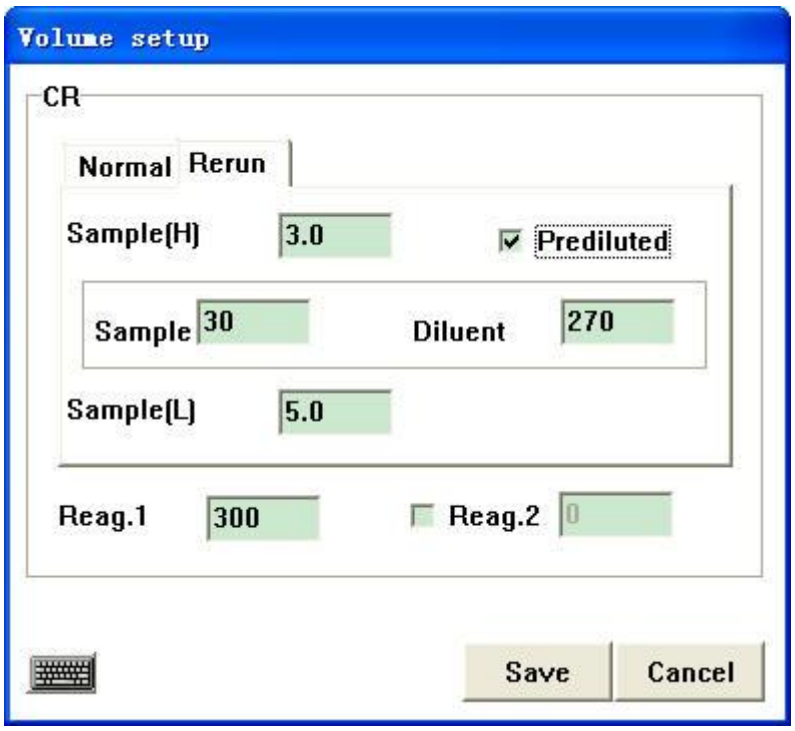


Figure 4-4 Sample Volume for Retest

- Reagent Volume: The accuracy of reagent volume is 1 μL. Input the volume of reagent 1. If the dual reagent test is adopted, also select Reagent 2 and input the volume of reagent 2.

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***Caution: If the dilution ratio is specified for the samples of a patient, the samples of the patient are prediluted before test according to the dilution ratio set. Otherwise the dilution ratio specified in the item setup parameters is used.***

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***Caution: Only when the test results exceed the linear range of the instrument and automatic retest or manual retest is conducted, will the dosage set in Retest be used. Otherwise, the dosage set in Initial Test is used.***

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**12) Reference Range**

Specify the division criterion of the reference range and the corresponding values of reference range according to the instructions of the reagent, as shown in the figure:

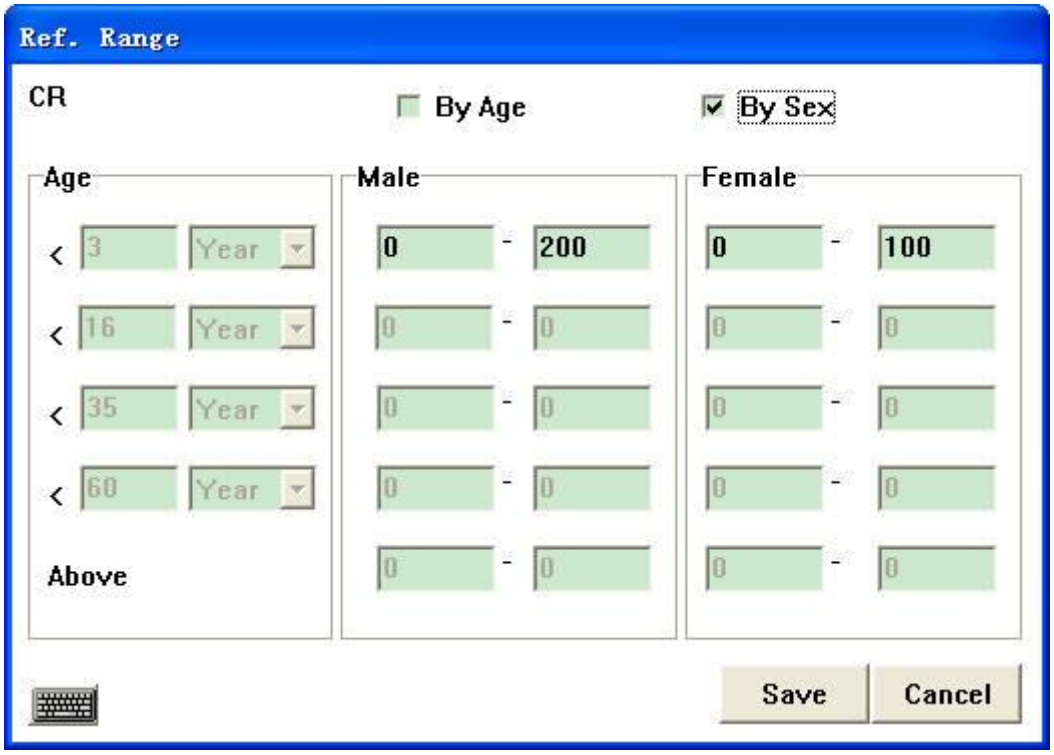



Figure 4-5 Reference Range

**13) Limitative Range**

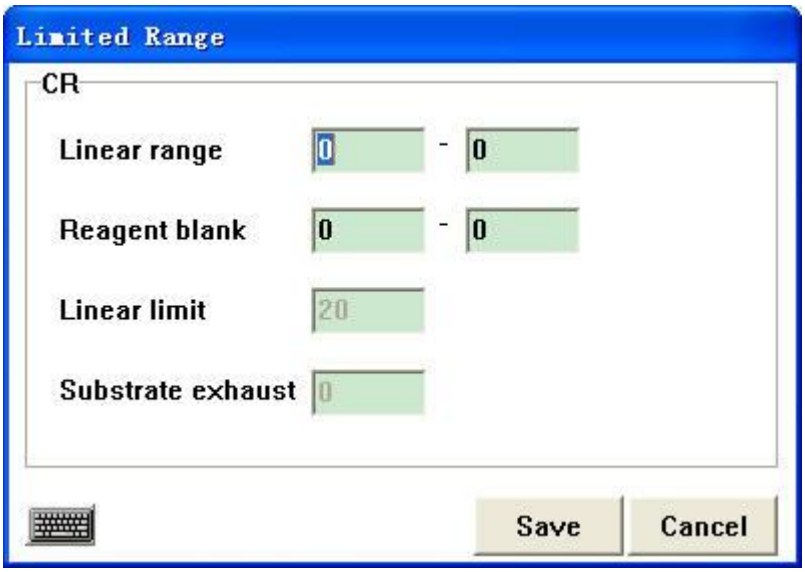



Figure 4-6 Limitative Range

- **Linear Range:** Test range of the instrument or reagent. When the test results exceed the range, the results are unreliable, and retest after dilution or retest after concentration is needed.
- **Reagent Blank:** The valid range of reagent blank. When the reagent blank exceeds the range, the system will treat the reagent as failure. The unit is 1/10000 absorbance.
- **Linearity Limit:** Effective for the rate method only. The system calculates the linearity in the test period automatically. When the linearity reflecting the curve exceeds the set

range, the results will have the corresponding sign. The setup range of linearity limit is 0-300. The setting 0 indicates no judgment. The default is 20. The calculation formula of linearity limit is:

- ◆ Number of test points > 9
  - Linearity = (Change rate of the first 6 points - Change rate of the last 6 points)/ Change rate of all points
- ◆ 4≤ Number of test points ≤8
  - Linearity = (Change rate of the first 3 points - Change rate of the last 3 points)/ Change rate of all points

- **Substrate Exhaust Limit:** Effective for the two-point method and rate method only. Some high concentration (active) samples exhaust the substrate, which makes the reaction no longer a kinetic method reaction. In order to correctly reflect the determination results, the substrate exhaust limit (a certain absorbance) needs to be set which should be exactly the critical point between linear zone and nonlinear zone (kinetic method) or 1 level reaction zone and multi-level reaction zone (fixed time method) in the reaction curve, the minimum (the reaction curve bends downward) or maximum (the reaction curve bends upward) absorbance value before the substrate is exhausted within the reaction time. The substrate exhaust limit of an item is closely related to the reagent kit used. The unit is 1/10000 absorbance. The setting 0 indicates no judgment.

**Test Sequence Setup**

Press the Test Sequence key to enter the screen as shown in the figure:


Figure 4-7 Test Sequence Setup

The function is used to set the test priority of items. Select the item for which the test sequence needs to be set, use the Up and Down keys or mouse to adjust it to the proper position, and press the Save key after adjusting all items.

To restore the default test sequence, press the Restore key and save the setting.

---

***Caution: The default test sequence is in alphabetical order of item names.***

---

**Combination Setup**

Press the Combination Setup key to enter the screen as shown in the figure:

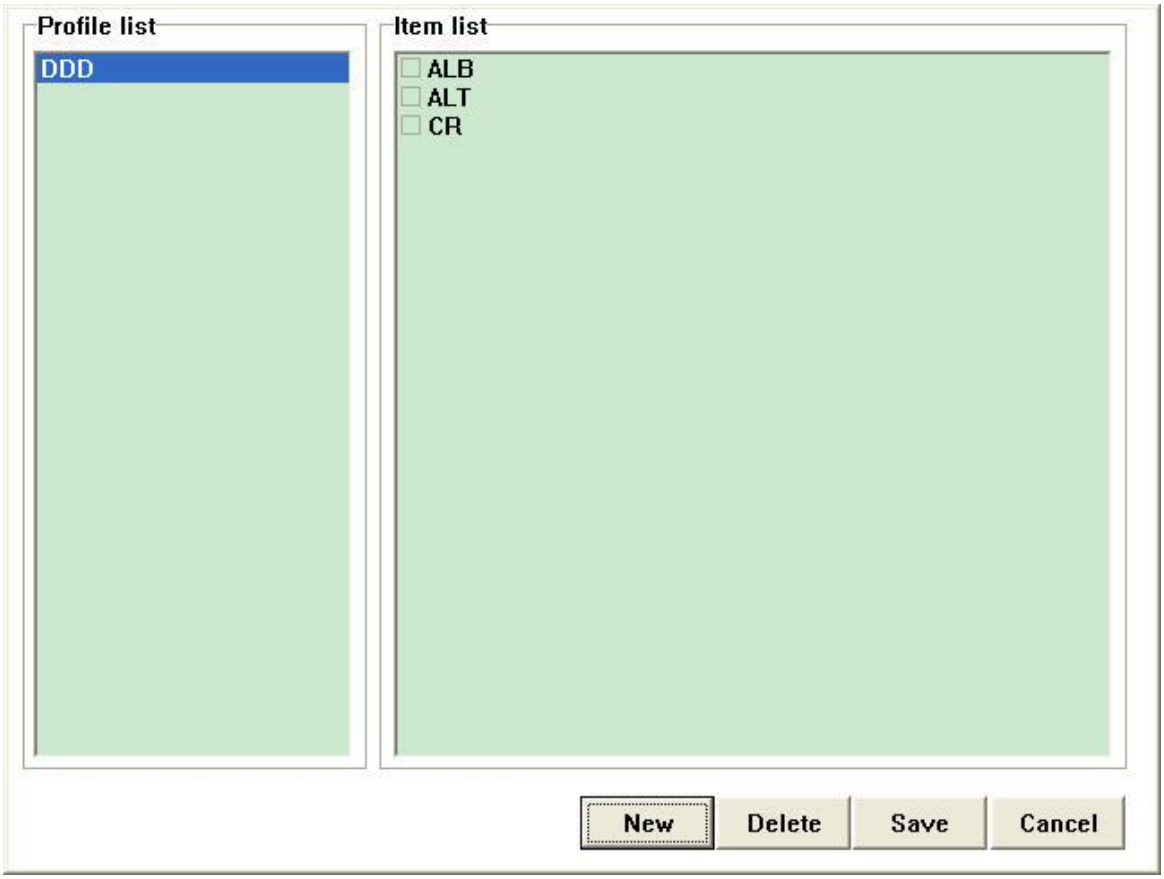



Figure 4-8 Combination Setup

**Add Combination**

Press the Add Combination key, input the name of the new combination, and press the OK key. Select the items to be included in the combination and press the Save key.

**Modify Combination**

Select the combination to be modified from the combination list, modify the items included in the combination, and press the Save key.

**Delete Combination**

Select the combination to be deleted from the combination list and press the Delete Combination key.

**4.1.2 Non-biochemical Items**

To input the results of non-biochemical items tested by other equipment to the system, set the parameters of the non-biochemical items to be input. Select the Non-biochemical Items page as shown in the figure:

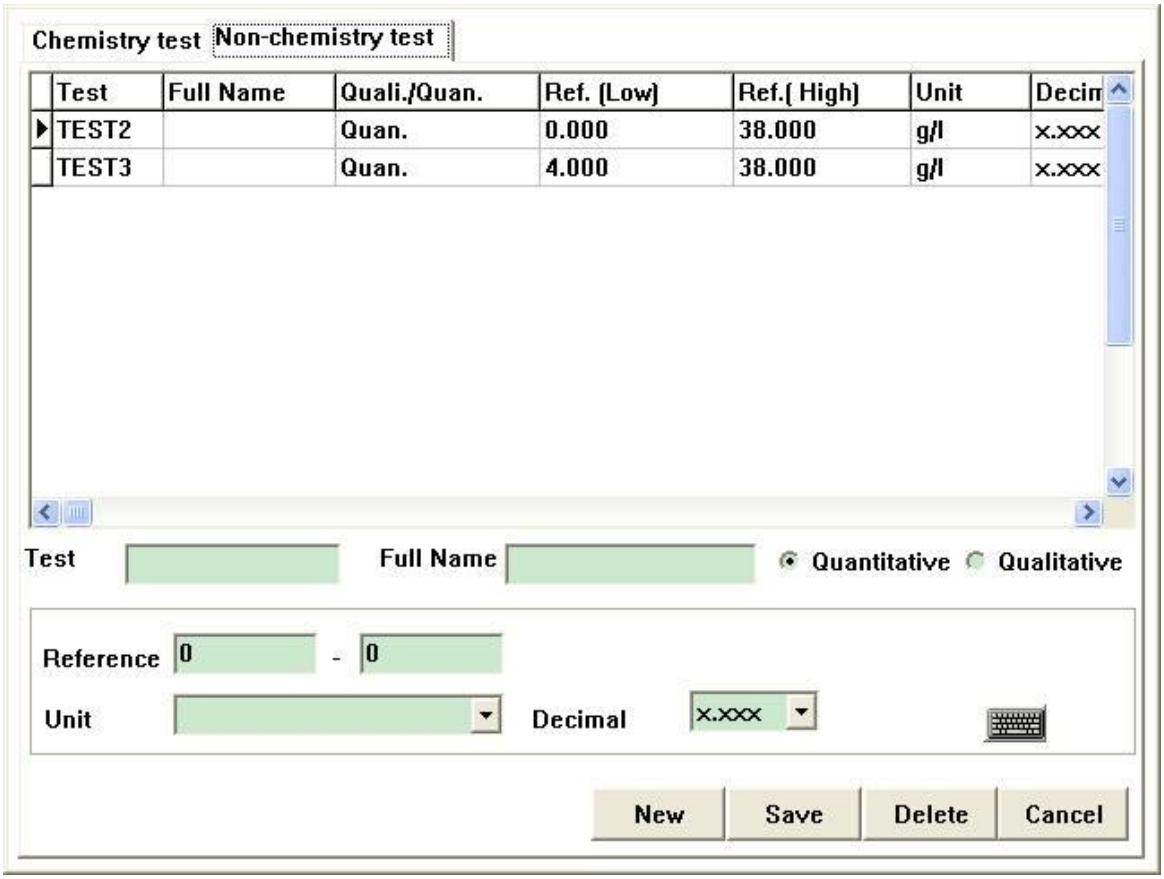



Figure 4-9 Non-biochemical Items Setup

**Add Non-biochemical Item**

Press the Add key, input the item name, full name, qualitative or quantitative and reference value of the non-biochemical item added in turn, and press the Save key.

**Modify Non-biochemical Item**

Select the non-biochemical item to be modified from the list, modify the full name, qualitative or quantitative and reference value, and press the Save key.

**Delete Non-biochemical Item**

Select the non-biochemical item to be deleted from the list and press the Delete key.

## 4.2 Item Test Methods

According to the requirements of the reagent instructions, set the test parameters of the item in the Biochemical Setup module, and specify the reagent position in the System Setup – Reagent Setup module. If the item needs calibration, make standard setup according to the parameters indicated on the standard substance of the item. Refer to "8.1 Standard Setup".

Enter the Sample Application module, and apply for test samples and required standard substances. Enter the Test Status module and press the Start button to start the test. During the test, you can press the Pause or Stop key at any time.

The test results will be saved to the worksheet and historical records automatically. You can view

the test results and reaction curves at any time.

The test methods include: end-point method, two-point method, and rate method. For details, see the appendix.

The calculation methods include: factor method, single point calibration, multi-point straight line calibration, multi-point fold line calibration, double logarithmic curve calibration, parabola calibration, exponential curve calibration, and Logistic-Log 4P. For details, see the appendix.

# Chapter 5 System Setup

On the main screen, click System Setup to enter the screen as shown in the figure:


Figure 5-1 System Setup

## 5.1 System Parameters

**Functions Brief: Including automatic retest switch, automatic transmission switch, and reaction tray temperature setup.**

From the System Setup menu, select System Parameters to enter the screen as shown in the figure:

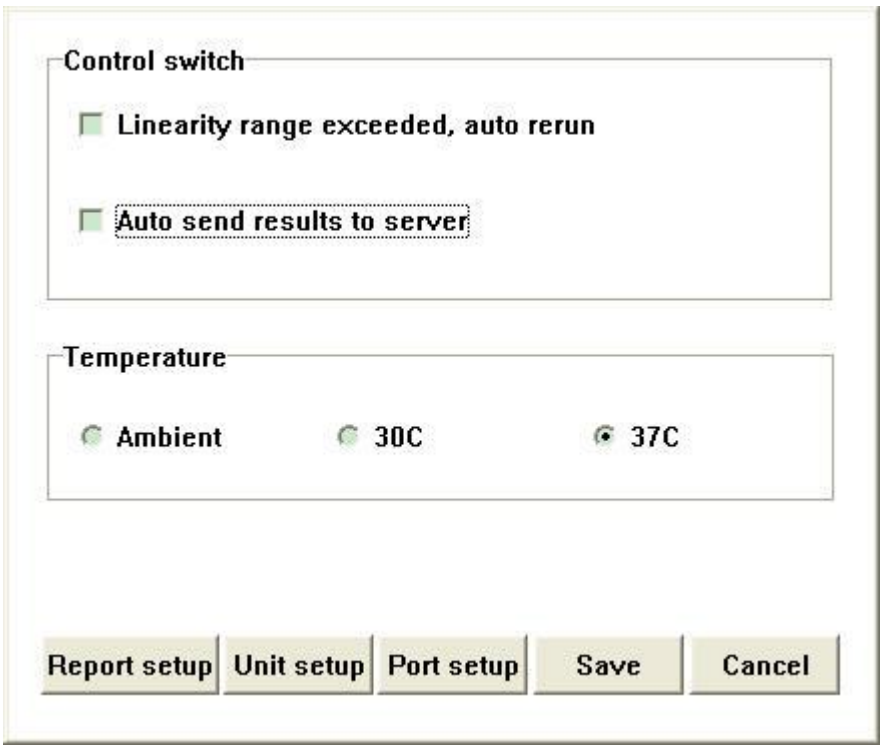



Figure 5-2 System Parameters Setup

**Control Switch Setup**

- If option 1 is selected and the test results exceed the linear range, when the initial test is finished, retest will be conducted automatically.
- If option 2 is selected, the test results will be sent to the server specified by the system on real time basis. (The supporting receiving software needs to be installed on the server.)

**Reaction Tray Temperature**

Set the target temperature of the reaction tray according to the requirements of the reagent instructions.

## 5.2 Report Setup

**Function Brief: To set the title, annotation and printing format of a general report.**

From the system parameter screen, select Report Setup to enter the screen as shown in the figure:

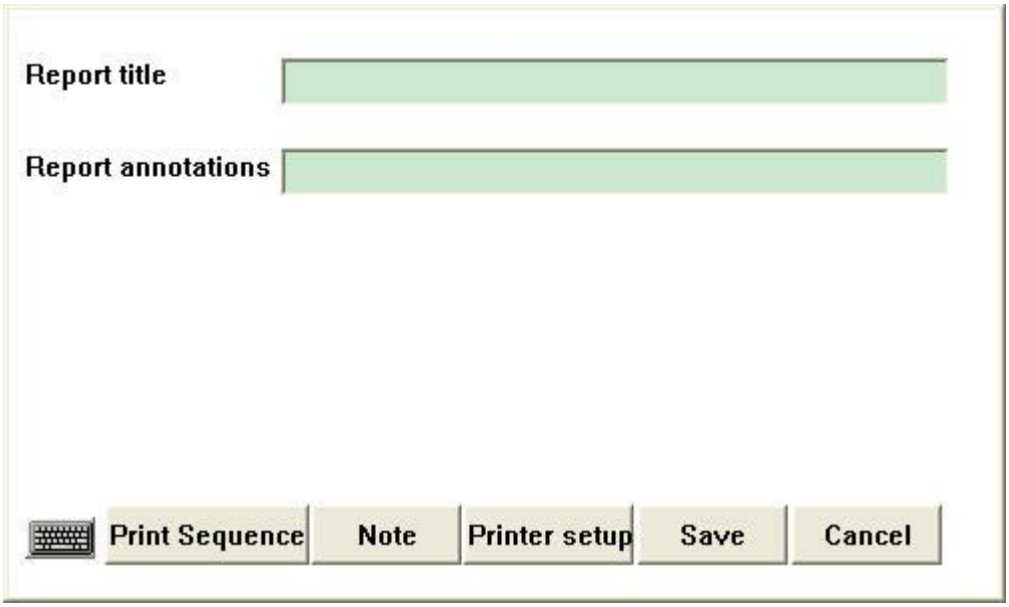



Figure 5-3 Printing Setup

**Report Title:** Set the title of the patient report, such as "Inspection Report of ××××Hospital".

**Report Annotation:** Set the remark of the patient report, such as "Note: The inspection results are for the sample only."

**Printer:** Specify the type of printer to be used. Select Internal Printer or External Printer.

**Printing Sequence:** Set the printing sequence of the items in the general report.

**Remarks:** Set the remarks that may be needed in the general report.

**Printer Setup:** When External Printer is selected, the printer needs to be set up. Specify the printer name, paper attribute, etc., as shown in the figure:

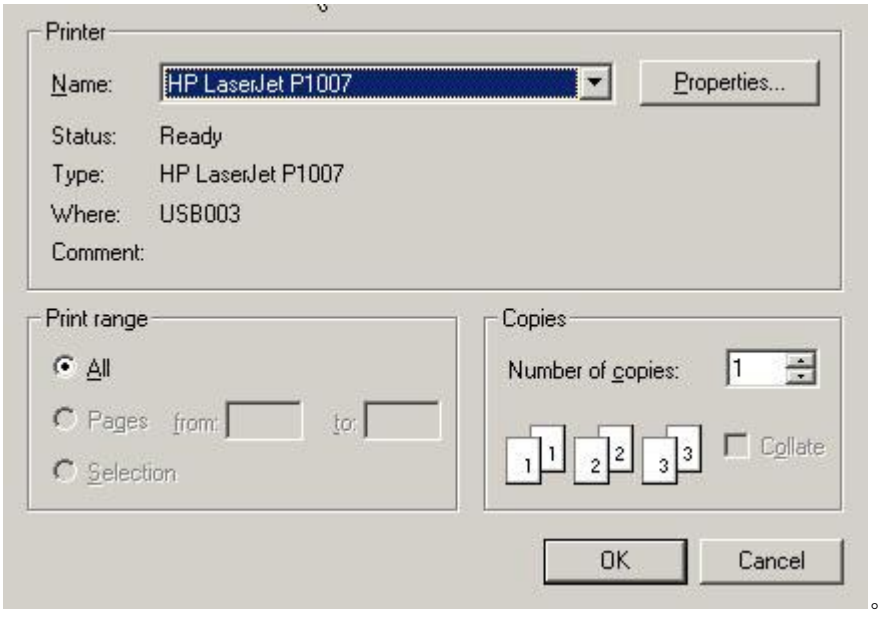



Figure 5-4 Printer Setup

## 5.3 Unit Setup

**Function Brief: To set the unit of results of test items.**

Select Unit Setup on the System Parameters screen to enter the screen as shown in the figure:

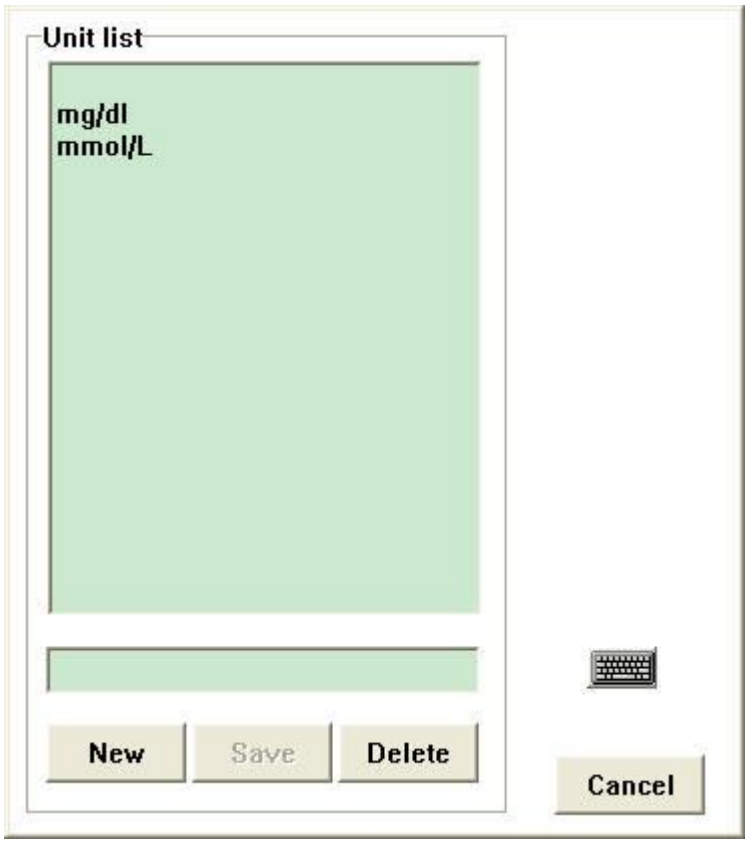



Figure 5-5 Unit Setup

**Unit List:** Displays all units defined by the user;

**Add Unit:** Press the Add key, input the unit in the input box, and press the Save key;

**Delete Unit:** Select the unit to be deleted from the list and press the Delete key.

## 5.4 Port Setup

**Function Brief: To set the IP address and port number of the data receiving server.**

Select Port Setup on the System Parameters screen to enter the screen as shown in the figure. Set the IP address and port number of the server on which the data receiving software is installed. If automatic and manual data transmission is not needed, the port needs not to be set.

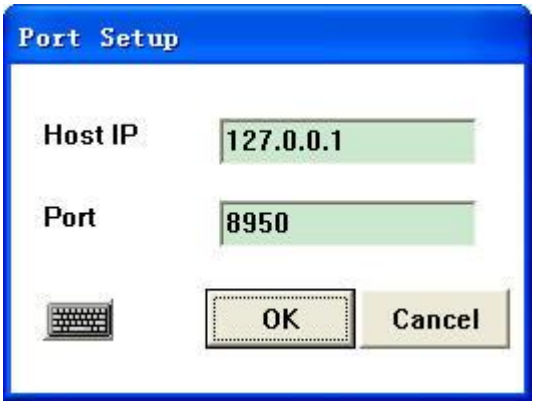


Figure 5-6 Port Setup

## 5.5 Reagent Setup

**Function Brief: To specify reagent positions and other reagent information for test items.**

Select Reagent Setup on the System Setup menu to enter the screen as shown in the figure:

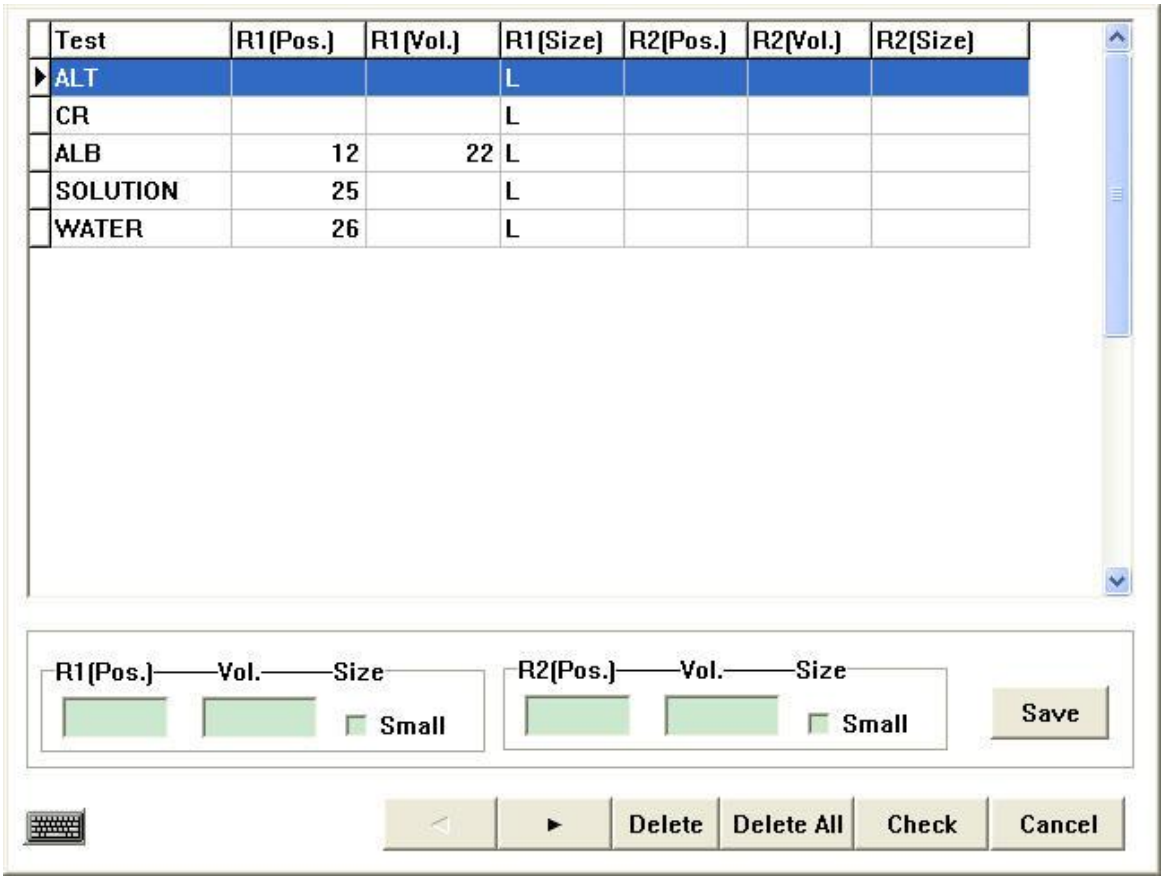



Figure 5-7 Reagent Setup

**Modify Reagent Information**

Select an item, set the positions and remaining volumes of reagent 1 and reagent 2 respectively and the model of the reagent bottle, and press the Save key.

---

***Caution: The last two reagent positions are for diluent and deionized water respectively. Never put other reagents in them.***

---

**Delete Reagent Information**

Select an item and press the Delete key to delete the reagent information of the item. Press the Delete All key to delete all defined reagent information.

**Reagent Test**

Press the Reagent Test key, and the system will detect the remaining volume of the reagent for which the position has been specifid.

***Caution: Before reagent test, specify the reagent positions corresponding to the various items. Otherwise reagent test is impossible.***

## 5.6 Section Setup

**Function Brief: To set the sections and doctors involved in patient information entry.**

Select Section Setup from the System Setup menu to enter the screen as shown in the figure:

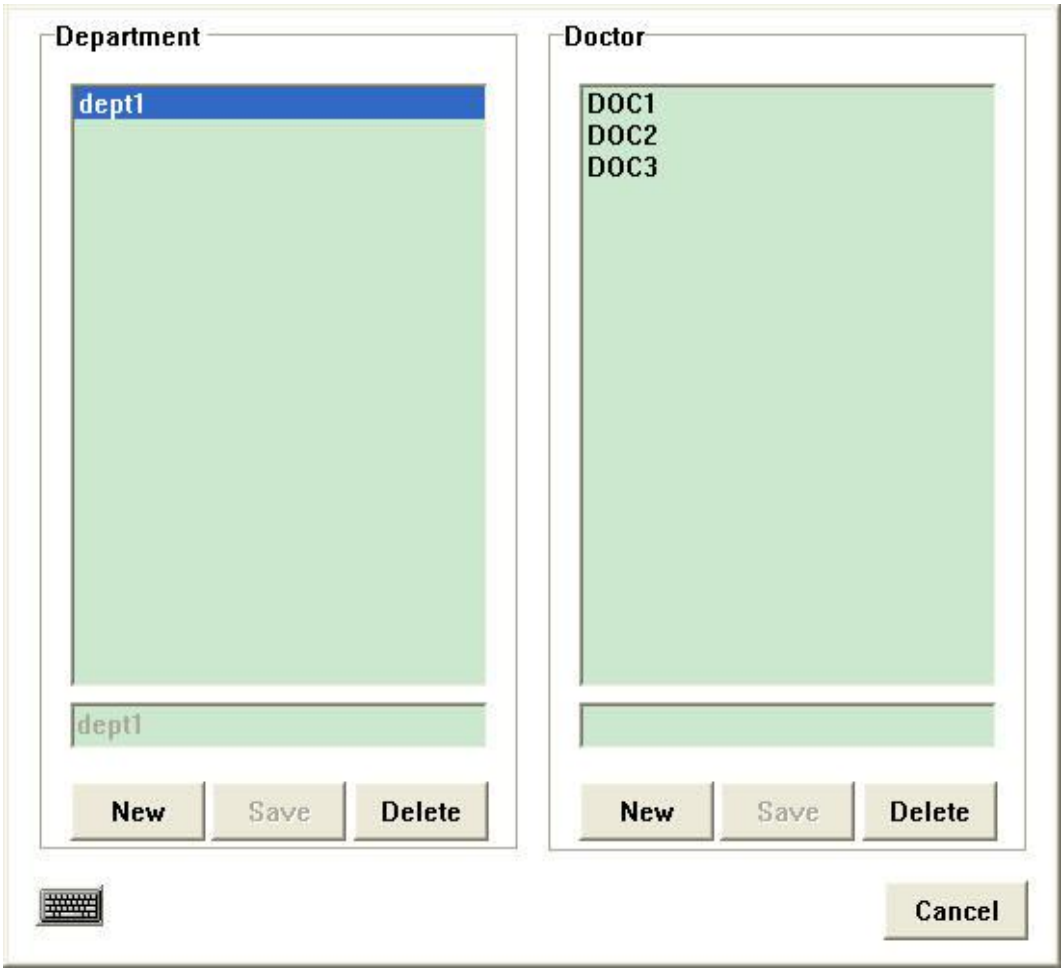



Figure 5-8 Section Setup

**Add Section**

Below the section list, press the Add key to input the section name and press the Save key.

**Delete Section**

Select the section to be deleted from the section list and press the Delete key.

**Add Doctor**

Select a section, and all doctors in the section will be displayed in the doctor list. Below the doctor list, press the Add key, input the doctor name, and press the Save key.

**Delete Doctor**

Select a section, and all doctors in the section will be displayed in the doctor list. Select the doctor to be deleted from the doctor list and press the Delete key.

## 5.7 User Management

**Function Brief: To set the privilege and password of a user.**

Select User Management from the System Setup menu to enter the screen as shown in the figure:

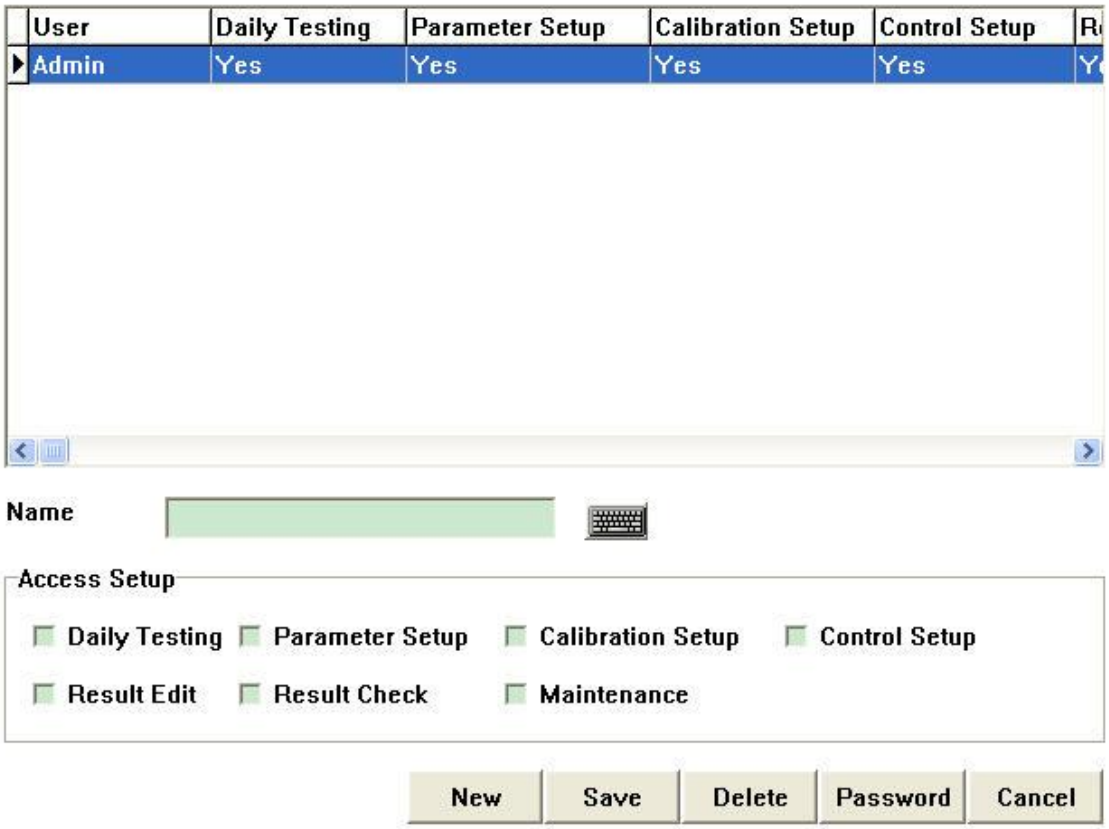



Figure 5-9 User Management

**Add User**

Press the Add key, input the user name in the User Name input box, select and set the privilege, and press the Save key.

**Modify User Privilege**

Select a user from the list, reselect and set the privilege, and press the Save key.

**Delete User**

Select a user from the list and press the Delete key.

---

***Caution: Only the administrator "Admin" can add, delete and modify user privilege.***

---

**Modify Password**

Select a user from the list and press the Modify Password key. The screen as shown in the figure will appear:


Figure 5-10 Modify Password

Input the password and new password, input the new password again for confirmation, and press the Modify Password key.

# Chapter 6 Test

## 6.1 Sample Entry

**Function Brief: To set test application.**

Click Sample Entry on the main menu to enter the Sample Application screen as shown in the figure:

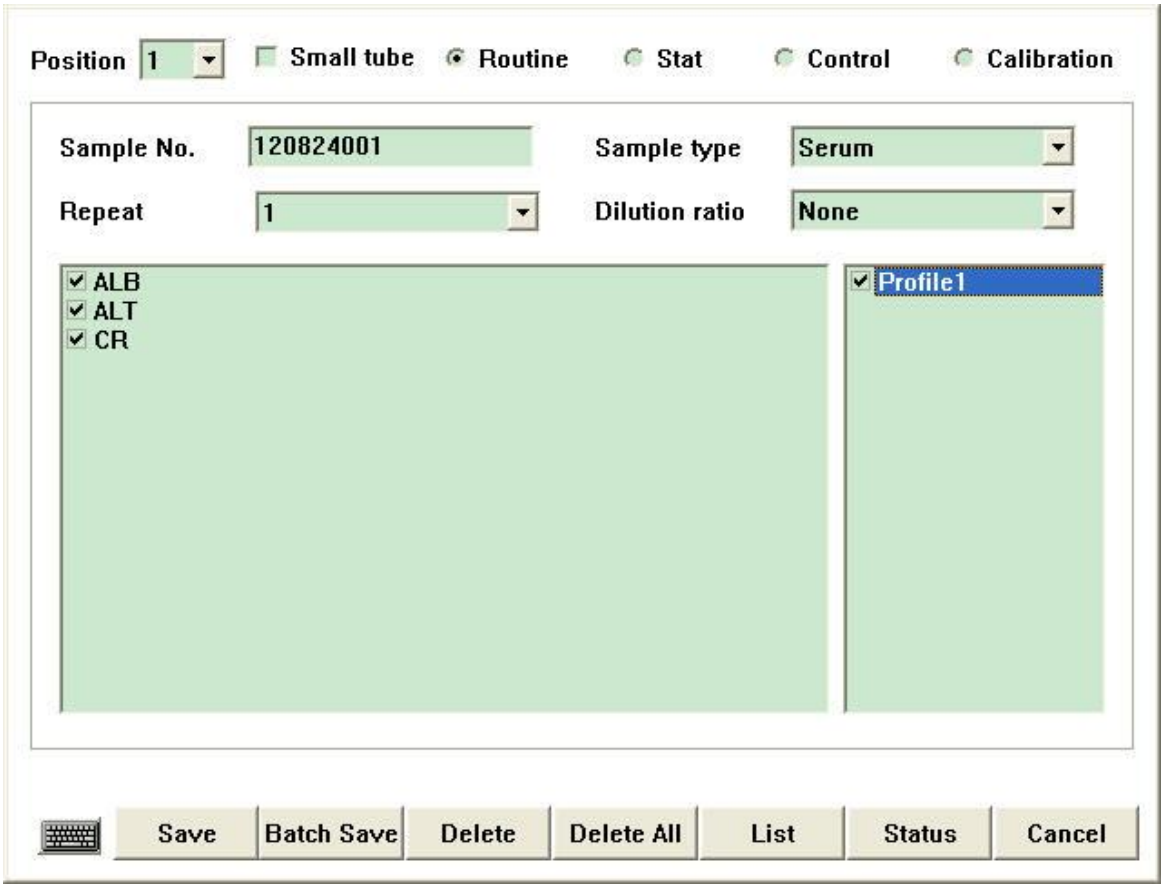



Figure 6-1 Sample Entry

### 6.1.1 Sample Application

- **Edit a Sample**

  Step 1: Select Sample Position. If micro sample cup is adopted, select Micro Cup;

  Step 2: Select the sample type Regular or Emergency Treatment;

  Step 3: Input the sample number and specify the sample type;

  Step 4: Select the repeat count and dilution ratio; (default repeat count: 1; default dilution ratio: Not Dilute)

  Step 5: Select test items and test combinations;

  Step 6: Press the Save key;

  Step 7: Finish a sample application.

- **Edit Multiple Samples**

  Step 1: Input the start sample number and specify the sample type;

  Step 2: Select the repeat count and dilution ratio; (default repeat count: 1; default dilution ratio:

Not Dilute)

Step 3: Select test items and test combinations;

Step 4: Press the Batch Save key, and the screen as shown in the figure will appear:

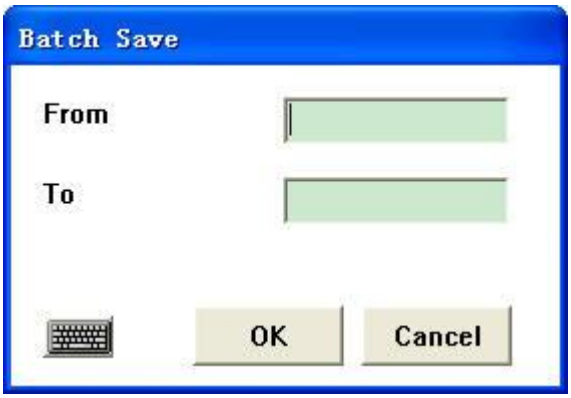



Figure 6-2 Batch Save

Step 5: Input the start sample position and end sample position, and press the OK key.

Step 6: Finish the batch sample application.

---

***Caution:***

- ***The system generates sample numbers automatically according to the rule of "Date" + "Serial Number", such as 090903001.***
- ***In batch sample application, the system starts from the sample number input and sequentially increases the sample numbers generated automatically. For example, when ***018 is input, the sample numbers of the batch application are ***018, ***019, ***020 and so on.***
- ***When the application is finished, you can make manual modification.***
- ***If the micro sample cup is used, select Micro Cup. Only when the sample cup type is set correctly, can the system treat sample exception accurately.***
- ***If the worksheet has samples not applied for on the current day, the software will prompt you to delete them.***

---

---

***Caution: The number of sample positions and reagent positions can be configured freely as needed. The default configuration is 9 sample positions + 26 reagent positions. The combination rule is when 2 reagent positions are reduced, 3 sample positions will be increased.***

---

### 6.1.2 QC Substance Application

The QC Substance Application screen is as shown in the figure:

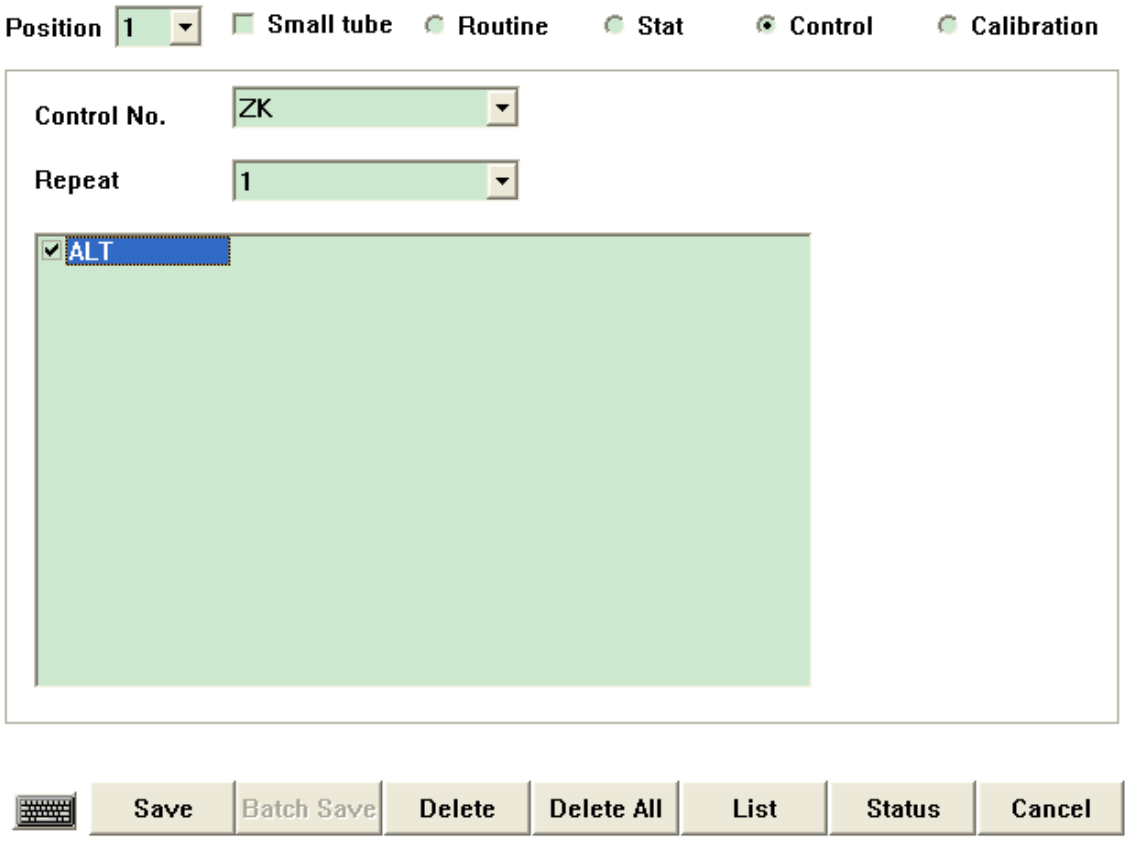



Figure 6-3 QC Substance Application

Step 1: Select Sample Position. If micro sample cup is adopted, select Micro Cup;

Step 2: Select the sample type QC;

Step 3: Select the QC substance number, and the QC items included in the QC substance will be displayed in the list below;

Step 4: Select the repeat count;

Step 5: Select the QC items from the list;

Step 6: Press the Save key;

Step 7: Finish the QC substance application.

### 6.1.3 Standard Substance Application

The Standard Substance Application screen is as shown in the figure:

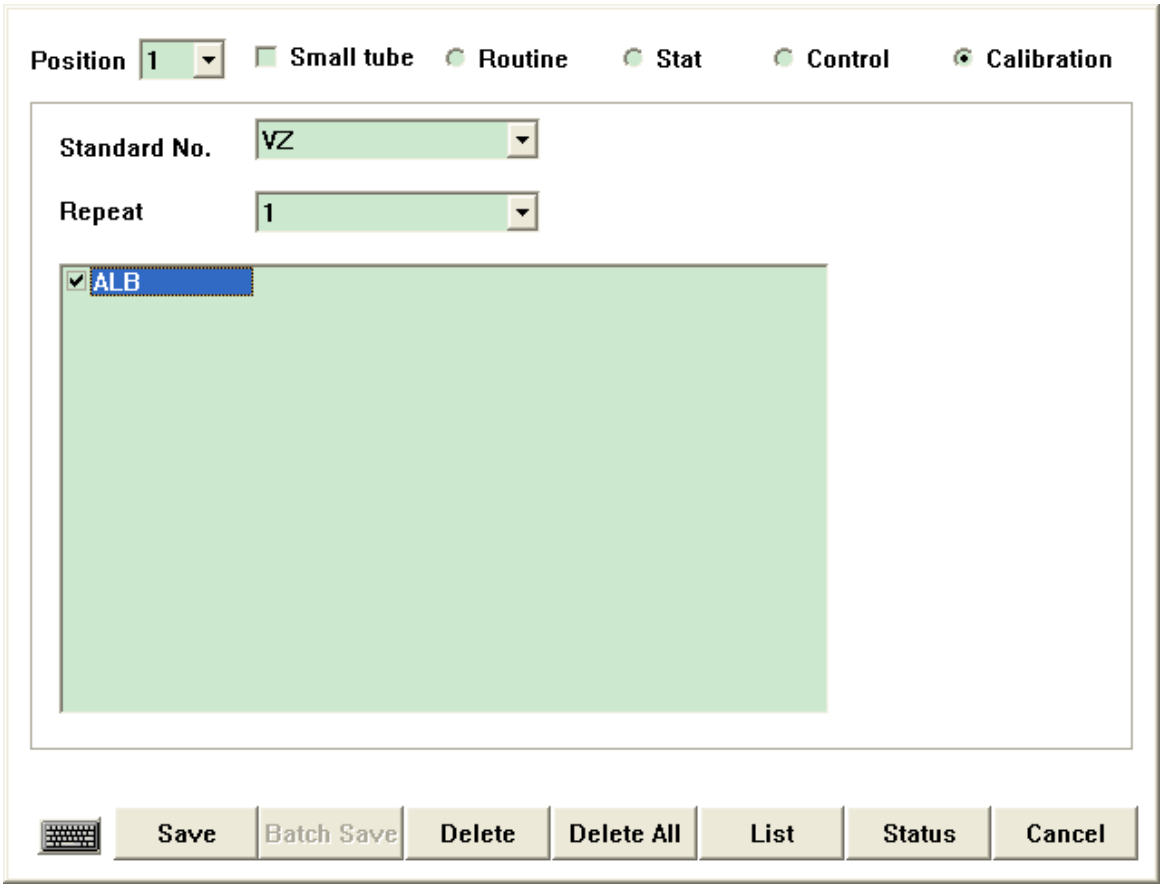



Figure 6-4 Standard Substance Application

Step 1: Select Sample Position. If micro sample cup is adopted, select Micro Cup;

Step2: Select the sample type Standard;

Step 3: Select the standard substance number, and the calibration items included in the standard substance will be displayed in the list below;

Step 4: Select the repeat count;

Step 5: Select the calibration items from the list;

Step 6: Press the Save key;

Step 7: Finish the standard substance application.

**List**

Click the List key to enter the screen as shown in the figure:

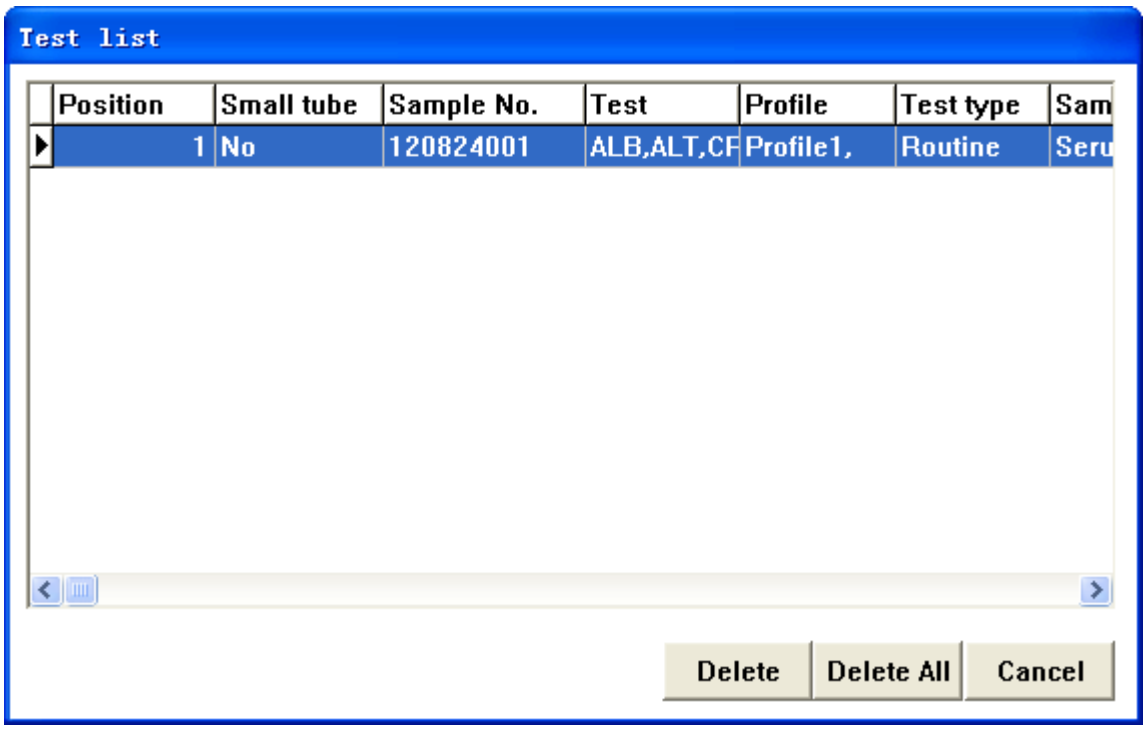



Figure 6-5 List

The list displays all sample tests, QC tests and calibration tests applied for in the worksheet. The list is used to check and confirm the test contents applied for in the worksheet.

***Caution: When all sample applications are finished, click List for verification and confirmation to avoid mistake or omission!***

**Delete Sample**

Select a sample from the list and press the Delete key to delete the selected application; press the Delete All key to delete all applied samples.

## 6.2 Sample Test

**Function Brief: To start the applied test and view the test status and results.**

On the main screen or Sample Entry screen, press the Test Status key to enter the screen as shown in the figure:

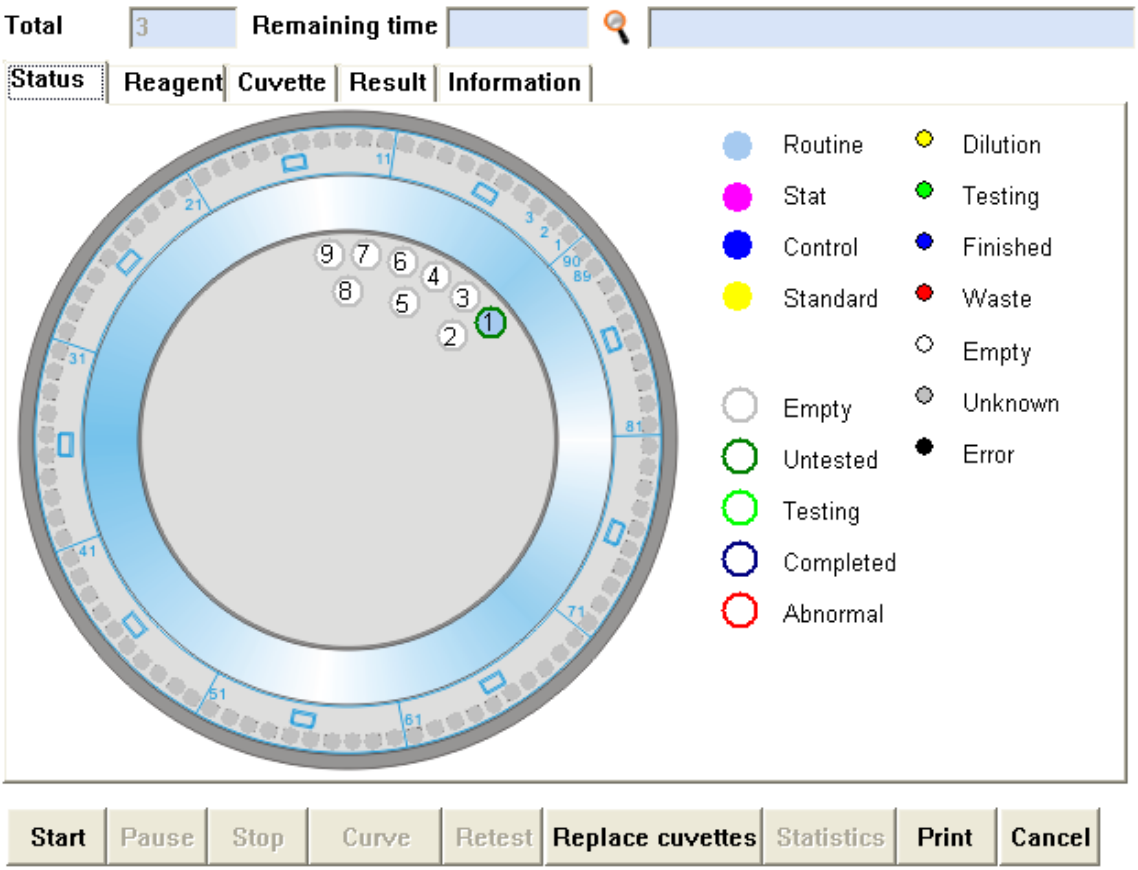



Figure 6-6 Test Status

Press the Start key, and the prompt box as shown in the figure will appear:

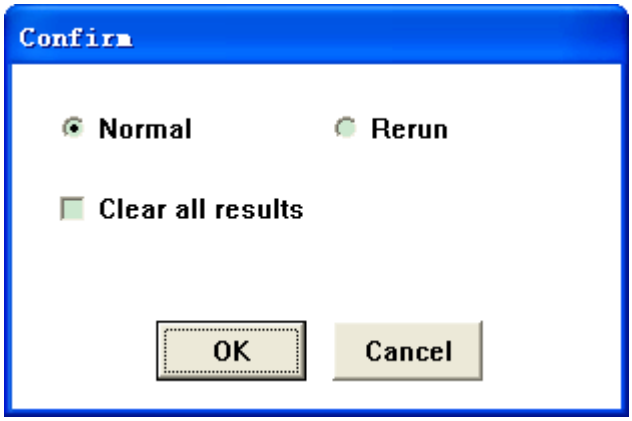



Figure 6-7 Worksheet Confirmation

**Initial Test**

To conduct initial test for the tests not finished or retests in the current worksheet.

**Retest**

To conduct retest for the results exceeding the linear range of the finished tests in the current worksheet.

**Clear Test Results**

To clear the results of the finished tests in the current worksheet and restart all tests.

Before confirming the start of the test, confirm the above information. To modify the information, press the Cancel key. Or press the OK key, and the Test Sequencing screen will appear, as shown in the figure:

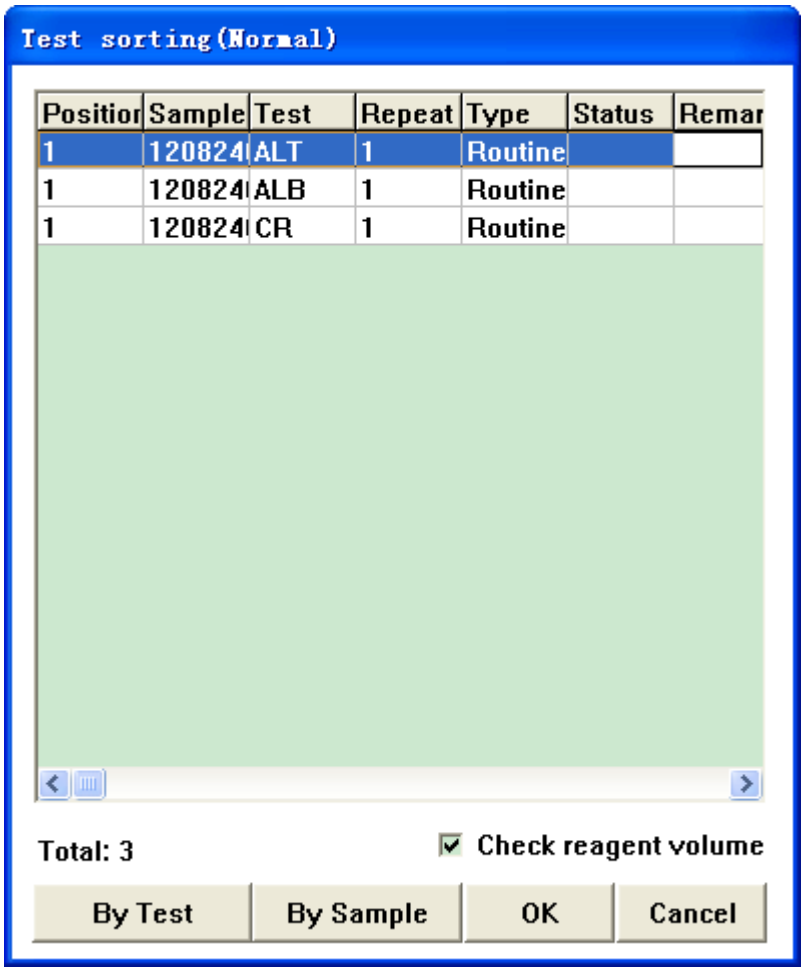



Figure 6-8 Test Sequencing

The system sorts the tests according to the test sequence specified in Test Sequence Setup (see "4.1 Item Setup") by default. If you want to readjust the sequence, you can press the "Sort by Item" key or "Sort by Sample" key or use the mouse to drag the items in the list. After adjusting the test sequence, press the OK key to start the test; or press the Cancel key to give up the test.

***Caution: The Status column in the list indicates whether the test has been finished. If the test has been finished, Finish is displayed; otherwise nothing is displayed.***

If a test is to be conducted for the first time after the machine is started or the cuvette is replaced, before adding the sample, the system will detect cuvette blank automatically. When the detection is finished, the following cases may occur:

Case 1: All cuvette blanks are valid, and the system starts the test;

Case 2: Some cuvette blanks are invalid, and the system prompts you whether to replace the cuvettes, as shown in the figure:

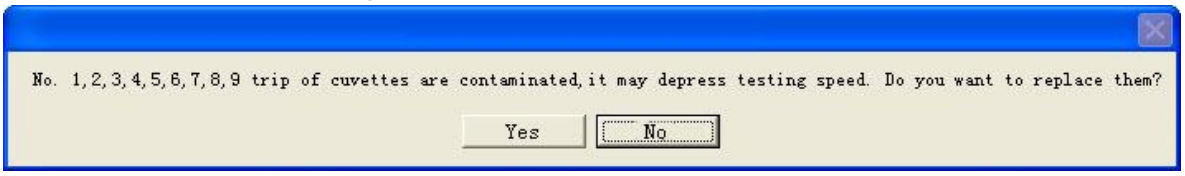



Figure 6-9 Prompt of Cuvette Replacement

Select Yes to cancel the test. Then you may replace the cuvette;
Select No to continue the test and skip the cuvettes that can't be used automatically;

Case 3: When the energy of the cuvette blank is too low (all 340nm cuvette blanks are less than 30,000), the system will give the following prompt message automatically:


Figure 6-10 Prompt of Energy of Cuvette Blank being Too Low

Here you should conduct troubleshooting according to the prompt. If the gain setup has no abnormity and clean cuvettes have been put, and the problem is caused by the aging of the light source, please contact the after service department to replace the light source.

## 6.3 Test Status

**Function Brief: To view the test results and status of the current worksheet.**

Select the Test Status page on the Test Status screen, and the real time status of each assay cup, sample cut and reagent bottle is displayed with the chart:

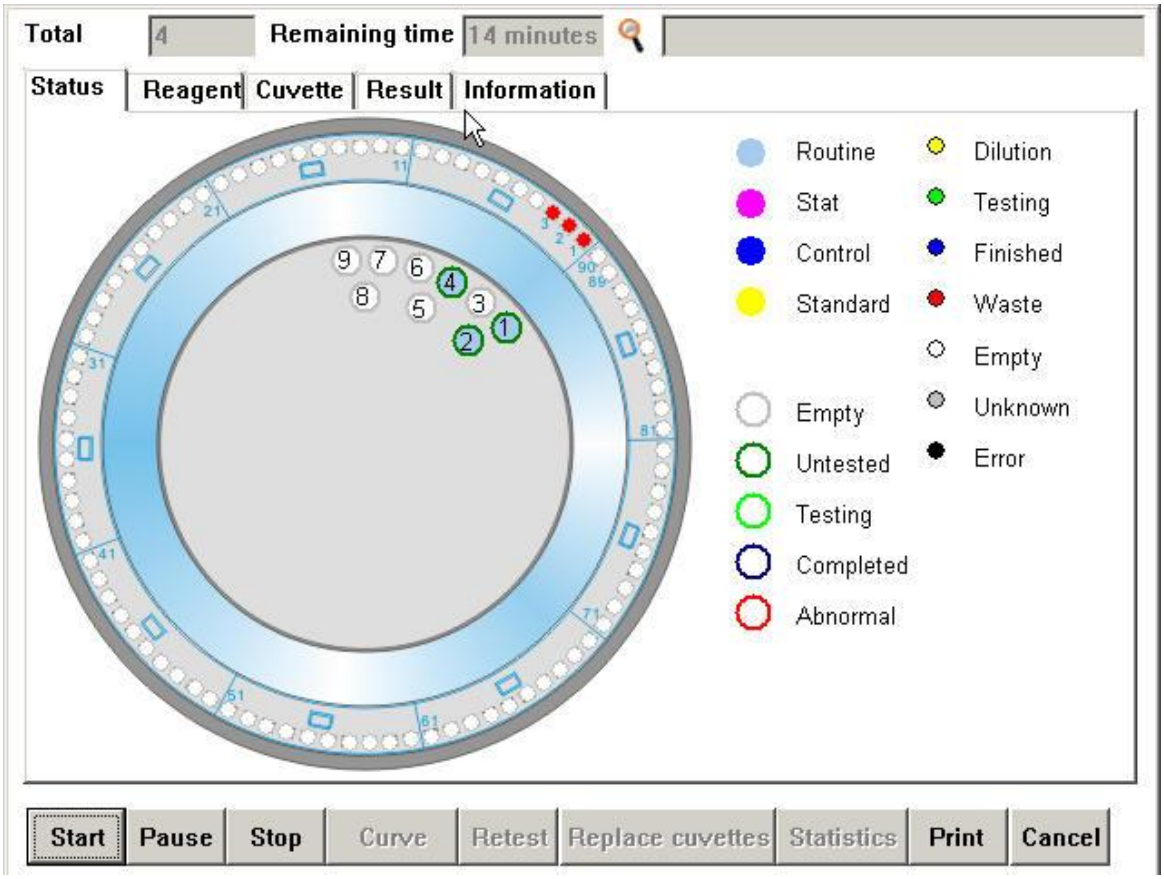



Figure 6-11 Test Status – Test Status

Select the Reagent page on the Test Status screen and view the use situation of the reagent involved through the list:

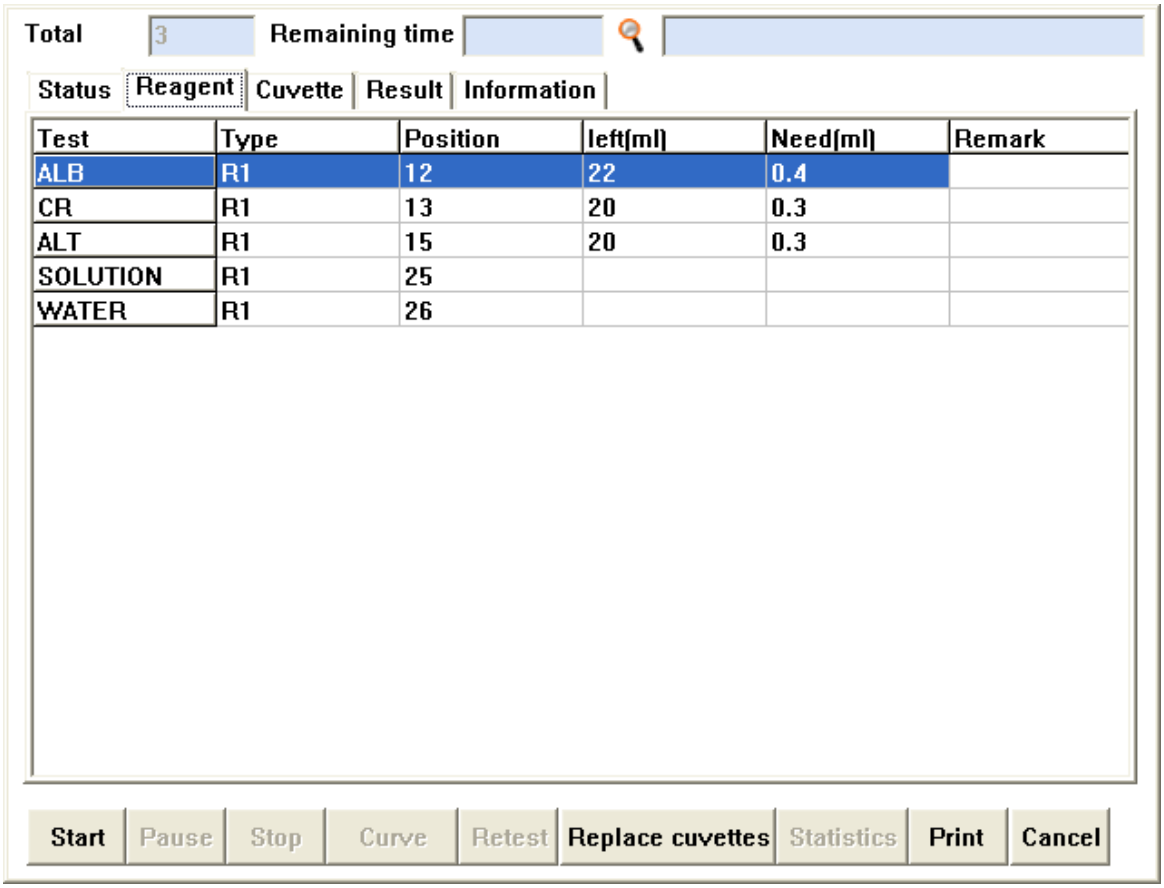



Figure 6-12 Test Status — Reagent

Select the Assay Cup page on the Test Status screen to view the test situation in each assay cup through the list:

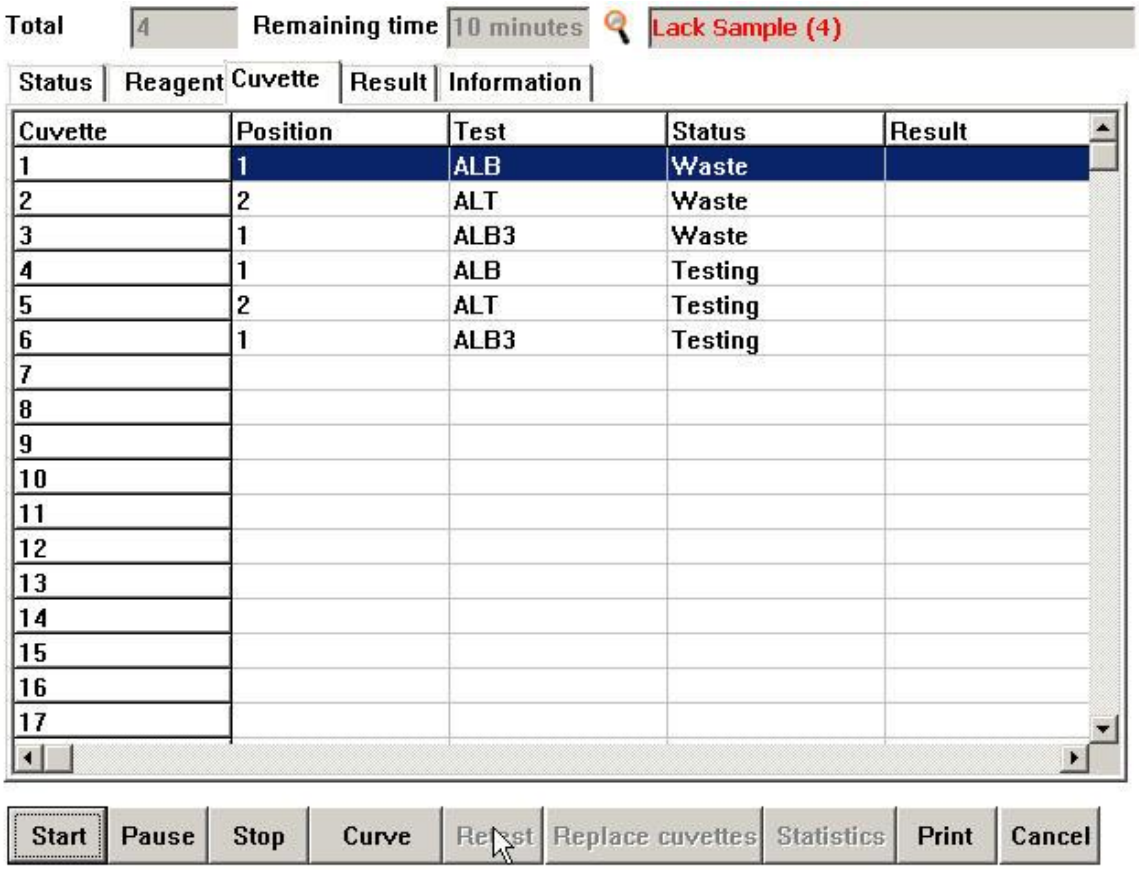



Figure 6-13 Test Status — Assay Cup

Select the specified assay cup from the assay cup information list and press Reaction Curve to view the reaction curve of the test, as shown in the figure:

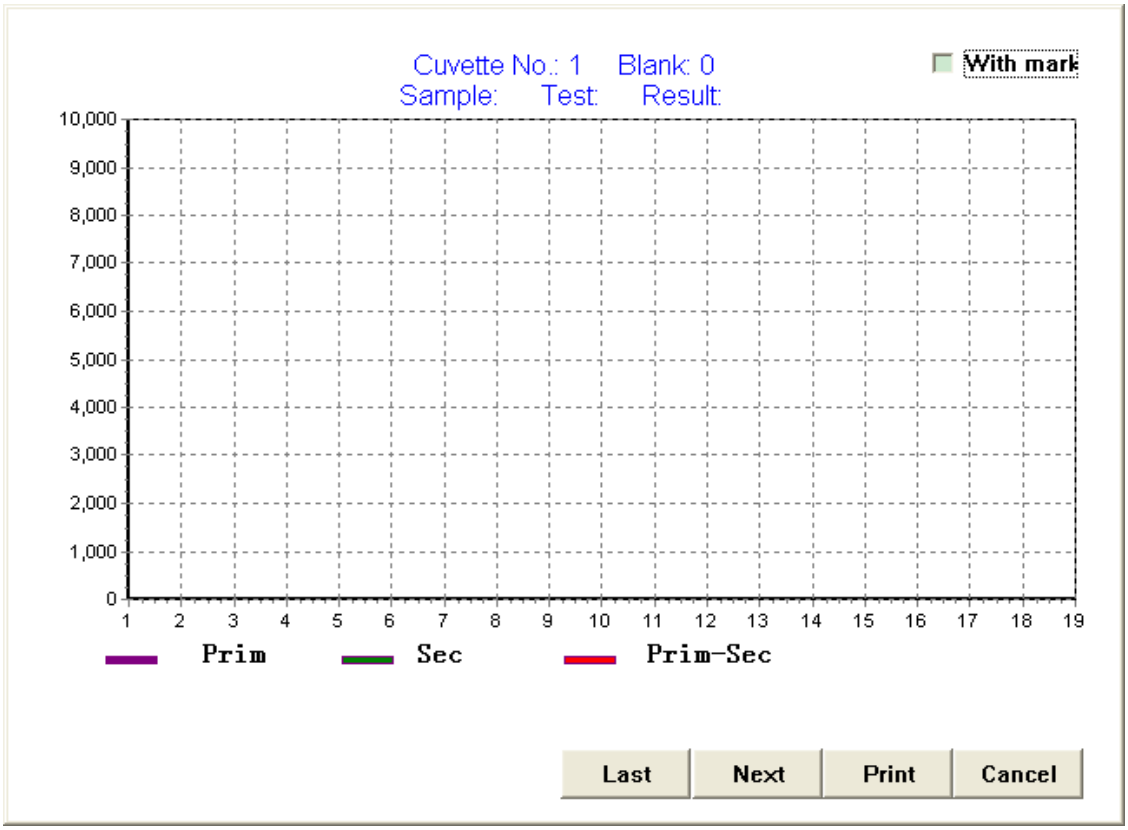


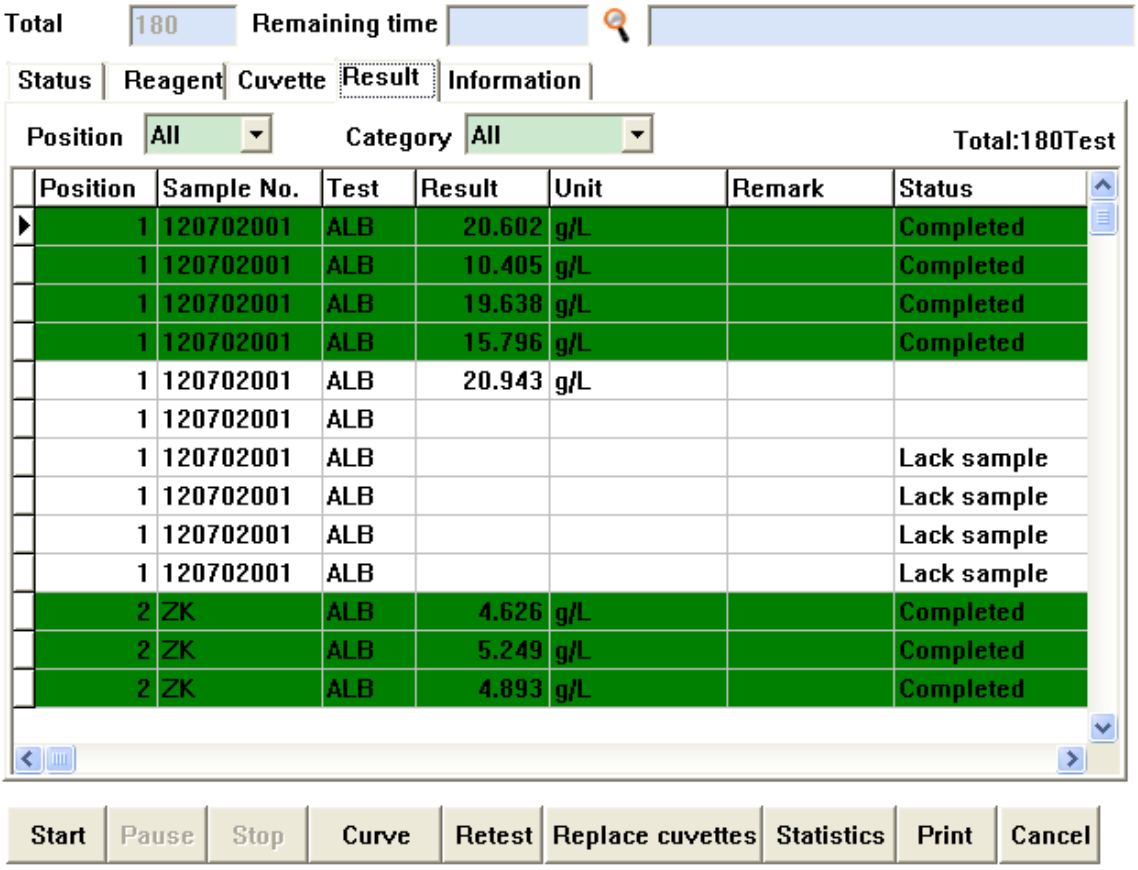
Figure 6-14 Reaction Curve

Press Previous and Next to view the reaction curve of each assay cup position in order;

Press the Print key to print the reaction curve of the current assay cup position;

Press the Return key to exit reaction curve view;

Select the Results page on the Test Status screen to view the test results meeting the specified criteria through the list (in the list, the red background of test records indicate Normal; the green background indicates Finished; and the white background indicates Unfinished).




| Position | Sample No. | Test | Result | Unit | Remark | Status |
|---|---|---|---|---|---|---|
| 1 | 120702001 | ALB | 20.602 | g/L | | Completed |
| 1 | 120702001 | ALB | 10.405 | g/L | | Completed |
| 1 | 120702001 | ALB | 19.638 | g/L | | Completed |
| 1 | 120702001 | ALB | 15.796 | g/L | | Completed |
| 1 | 120702001 | ALB | 20.943 | g/L | | |
| 1 | 120702001 | ALB | | | | |
| 1 | 120702001 | ALB | | | | Lack sample |
| 1 | 120702001 | ALB | | | | Lack sample |
| 1 | 120702001 | ALB | | | | Lack sample |
| 1 | 120702001 | ALB | | | | Lack sample |
| 2 | ZK | ALB | 4.626 | g/L | | Completed |
| 2 | ZK | ALB | 5.249 | g/L | | Completed |
| 2 | ZK | ALB | 4.893 | g/L | | Completed |

Figure 6-15 Test Status — Results

- **Display Type:** Specify the sample position and type, and the system will screen the test records according to the requirement automatically.
- **Reaction Curve:** Select a test from the list and press the Reaction Curve key to view the reaction curve corresponding to the test (the reaction curve can be viewed only when the test is finished, otherwise the system prompts a message “The reaction curve does not exist”)
- **Retest:** Select the results for which retest is needed from the list and press Retest to mark the selected records with “Retest”. If the system is running a test, a test marked with “Retest” will be added automatically; otherwise the system will run retest in the next test.
- **Statistics:** Statistics of items in the results list can be conducted by sample, QC and standard. The statistical results include total, finished, average, standard deviation and coefficient of variation, and can be printed.
- **Print:** Print the results of finished patient sample tests.

**Indication**

The symbols “A<” and “A>” indicate the test results exceed the linear range.

The symbol “**” indicates the results of the retest still exceed the linear range.

**Status**

“Ready” indicates the test is going to begin;

“Test” indicates the test is being conducted;

“Finished” indicates the test has been finished;

“Test Fails” indicates reagent/sample addition failure (i.e. collision) or reagent/sample lack during a test;

“Test Given Up” indicates the item for which the test has not been finished or started is aborted.

**Unit**

**“**SE” indicates substrate exhaust;

**“**OL” indicates the results exceed the linear range;

Select the Results page on the Test Status screen to view the test results meeting the specified criteria through the list.

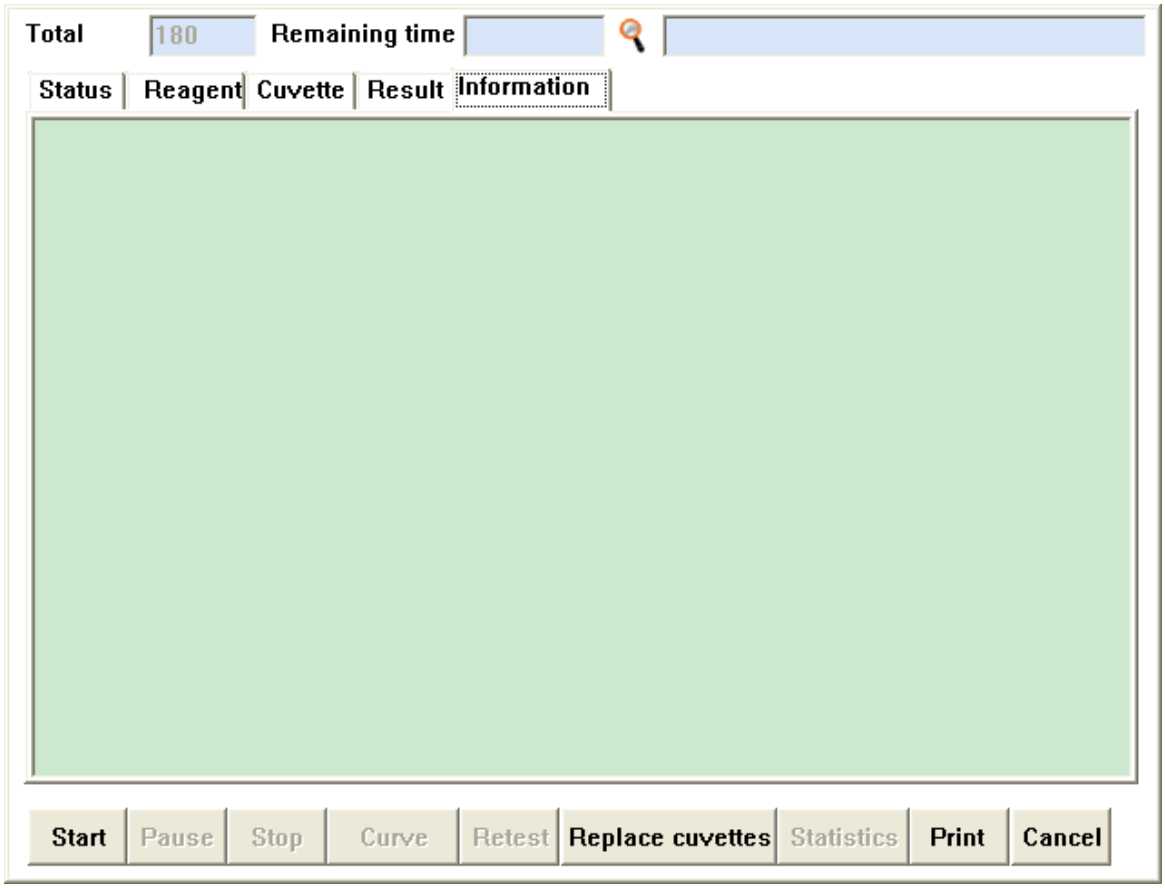



Figure 6-16 Test Status — Message

**Number of Tests**

Prompt of the total number of tests included in the Current Worksheet.

**Remaining Time**

Prompt of the remaining time for finishing the tests in the Current Worksheet.

**Prompt Message**

Displays the prompt messages during the tests in the worksheet, including start time, end time, reagent/sample lack, etc. Press the Clear key to clear the messages from the list.

**Replace Cuvette**

Press Replace Cuvette and replace all cuvettes in turn according to the prompt messages.

## 6.4 Pause and Stop

If you want to pause or stop a test, press the corresponding key. In which, “Pause” means stopping addition of new tests, but the test started will be continued till finished; “Stop” means aborting all tests, including cancelation of tests started.

# Chapter 7 QC

## 7.1 QC Setup

Press the QC Setup key on the main screen to enter the screen as shown in the figure:

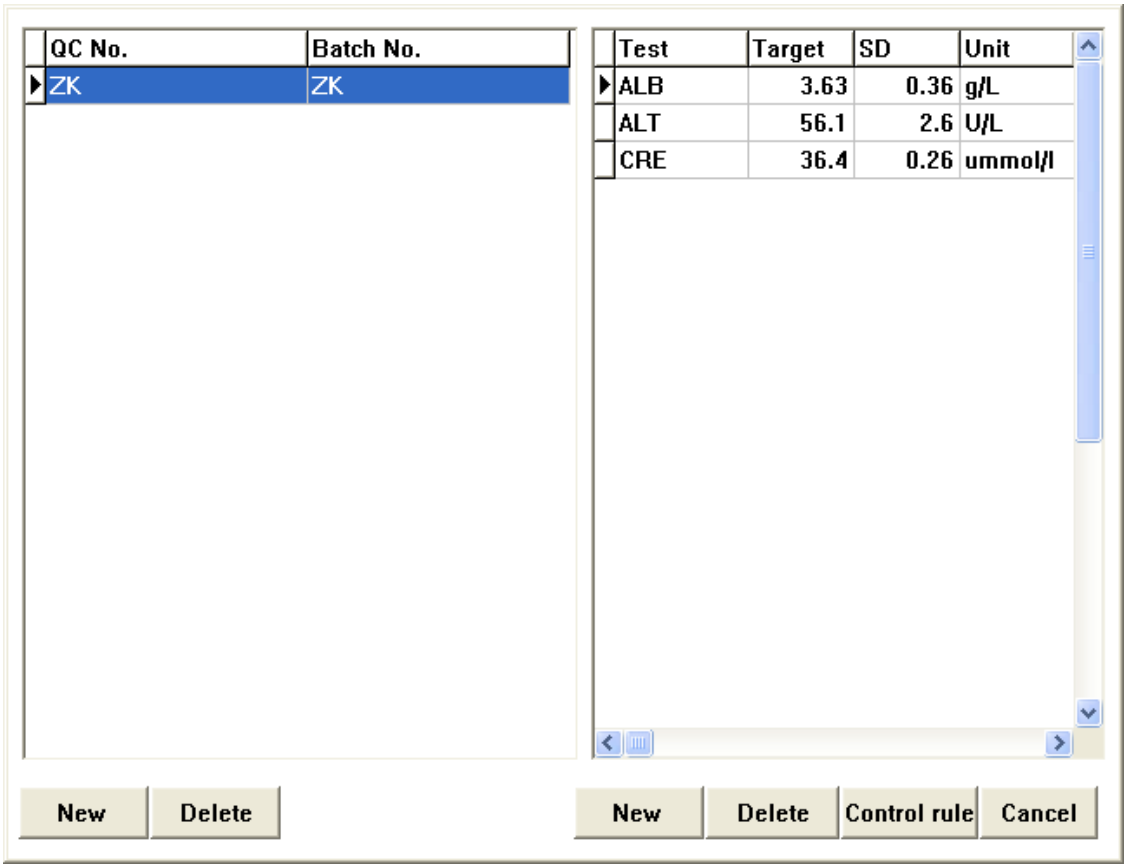



Figure 7-1 QC Setup

**Add QC**

Press the Add QC key, input the number and batch number on the screen that appears, and press OK to save the setting. Add the QC items included for the QC substance in turn.

**Delete QC**

Select the QC substance to be deleted from the QC substance list and press the Delete QC key.

**Add QC Item**

Specify a QC substance and press the Add Item key. Select Add or the QC item to be modified on the screen that appears, input the target value and SD, and press the Save key.

**Delete QC Item**

Select a QC substance from the QC substance list, and the QC items included will be displayed on the left list. Select the QC item to be deleted and press the Delete Item key.

**Set QC Rule**

Select a QC substance from the QC substance list, and the QC items included will be displayed on the left list. Select the time for which you want to set the QC rule and press the QC Rule key to enter the screen as shown in the figure:

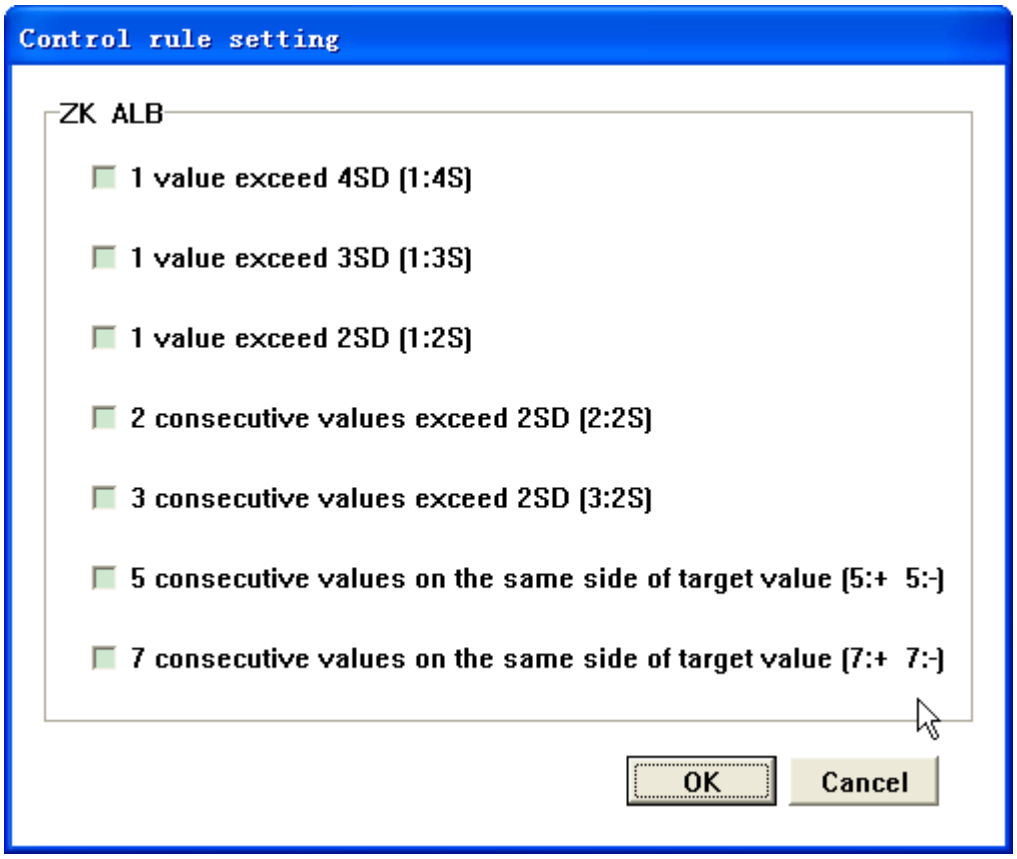



Figure 7-2 QC Rule Setup

Select the QC warning rule for the item from the 7 rules and press the OK key to save the setting.

## 7.2 QC Application

See “6.1.2 QC Substance Application”.

## 7.3 QC Inquiry

**Function Brief: To inquire the test results in the specified time range of the specified QC item.**

Select the QC Inquiry page as shown in the figure:

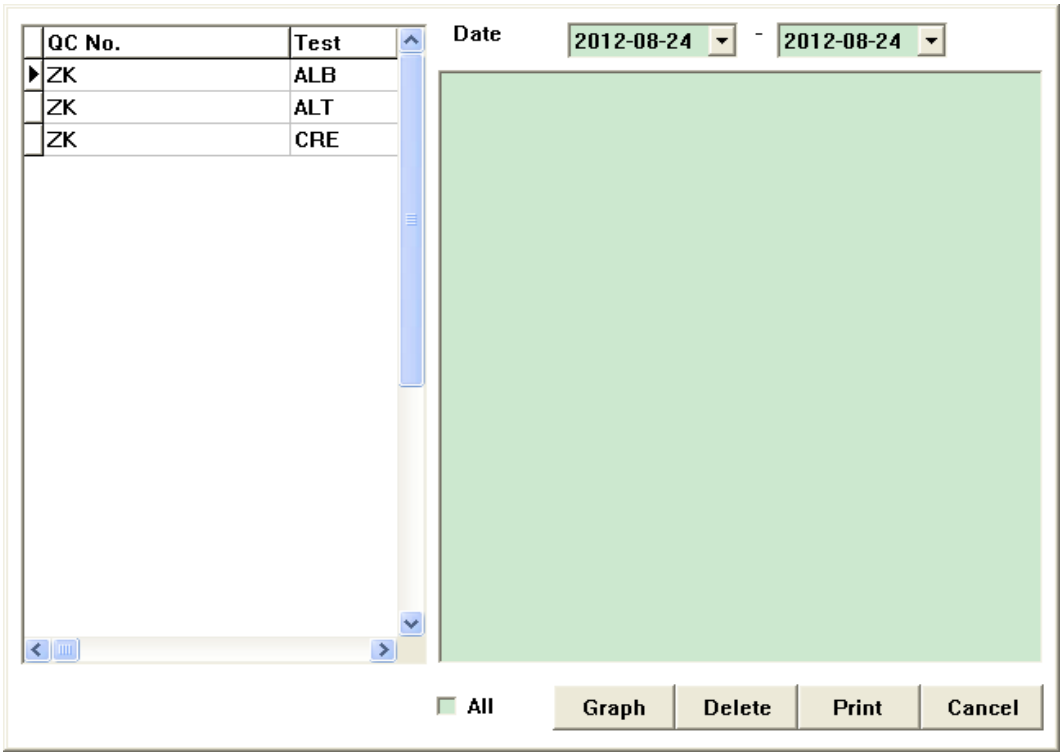



Figure 7-3 QC Inquiry

**View QC Data**

Select the QC item to be viewed from the left list and specify the date range of inquiry, and all test data meeting the criteria will be displayed in the data list on the right.

**View QC Chart**

Select the data points to be drawn from the data list and press QC Chart to display the QC chart:

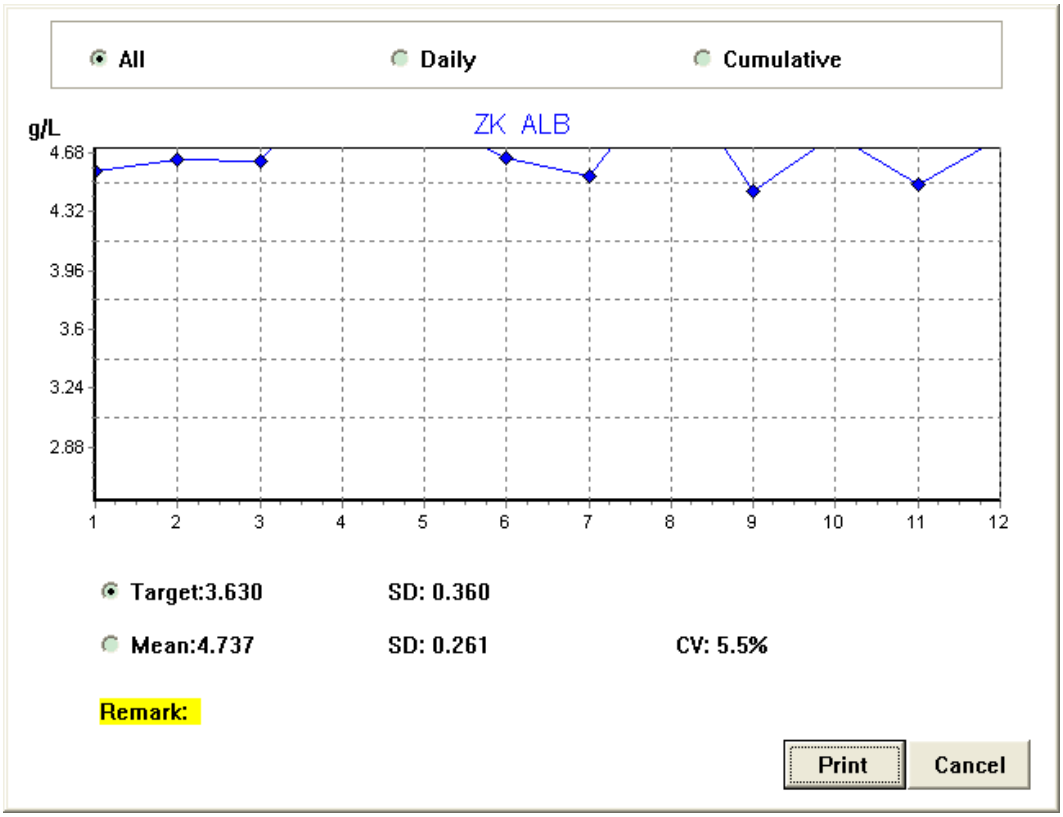



Figure 7-4 QC Chart

The screen displays the target value and SD value of the QC item as well as the statistical results of the selected data: average, SD, and CV. The system can change the QC chart according to the drawing mode specified by you. Press the Print key to print the QC chart displayed on the graphical screen.

- **Real Time QC Chart:** Drawing all data, with each QC datum corresponding to different abscissas on the chart.
- **Daily QC Chart:** Calculating the average of the data in the same day, and drawing the points corresponding to the average of each day only, with the average of each day corresponding to different abscissa.
- **Cumulative Chart:** Drawing all data, with the data in the same day corresponding to the same abscissa.

**Delete QC Data**

Select the QC data to be deleted from the QC data list and press the Delete key.

**Print QC Data**

Select the QC data to be printed from the QC data list and press the Print key.

# Chapter 8 Calibration

## 8.1 Standard Setup

Press the Standard Setup key on the main screen to enter the screen as shown in the figure:

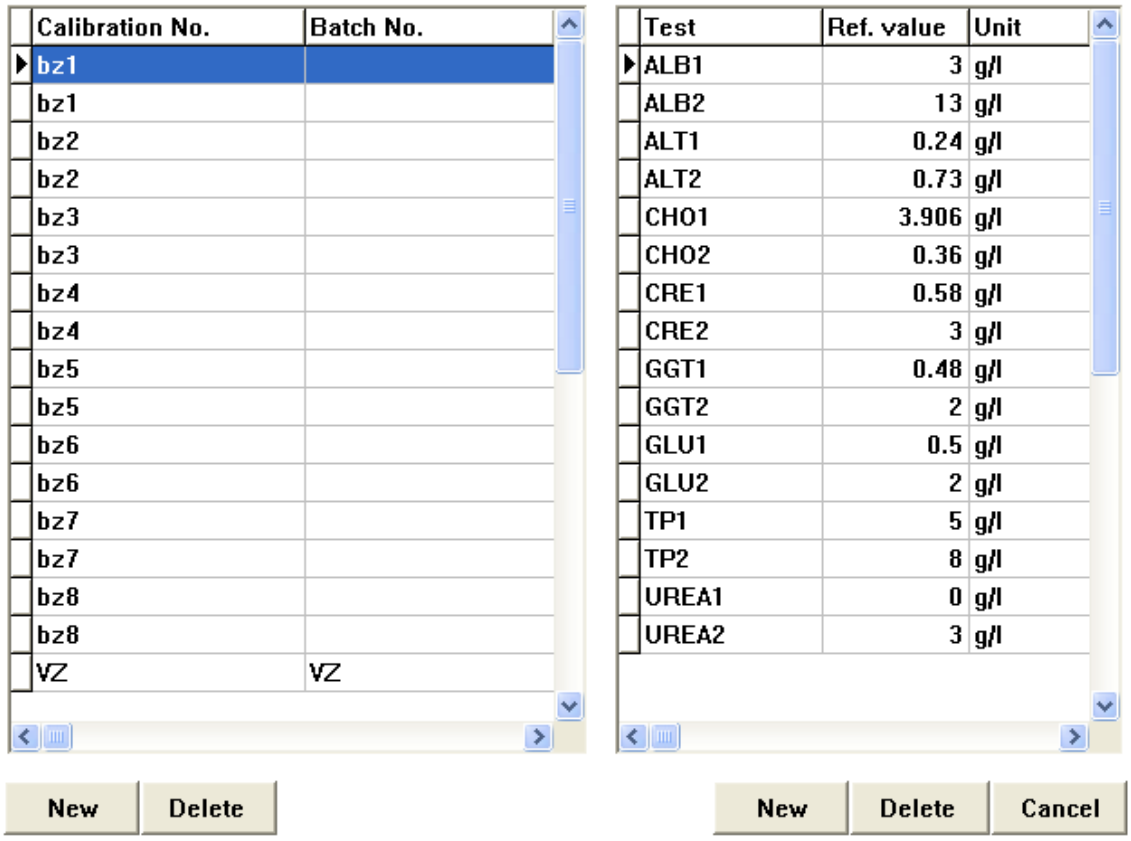



Figure 8-1 Standard Setup

**Add Standard**

Press the Add Standard key, input the number and batch number on the screen that appears, and select OK to save the setting. Add the calibration items included for the standard substance in turn.

**Delete Standard**

Select the standard substance to be deleted from the standard substance list and press the Delete Standard key.

**Add or Modify Calibration Item**

Specify a standard substance and press the Add Item key. Select Add or the calibration item to be modified on the screen that appears, input the reference value, and press the Save key.

**Delete Calibration Item**

Select a standard substance from the standard list, and the calibration items included will be displayed on the left list. Select the calibration item to be deleted and press the Delete Item key.

***Caution: When an existing standard substance is deleted, the calibration results corresponding to the standard substance will also be deleted. When an existing calibration item is modified or deleted, the calibration results corresponding to the calibration item will also be deleted.***

## 8.2 Standard Application

See “6.1.3 Standard Substance Application”.

## 8.3 Standard Inquiry

**Function Brief: To inquire the calibration results of the specified item.**

Select the Standard Inquiry page as shown in the figure:

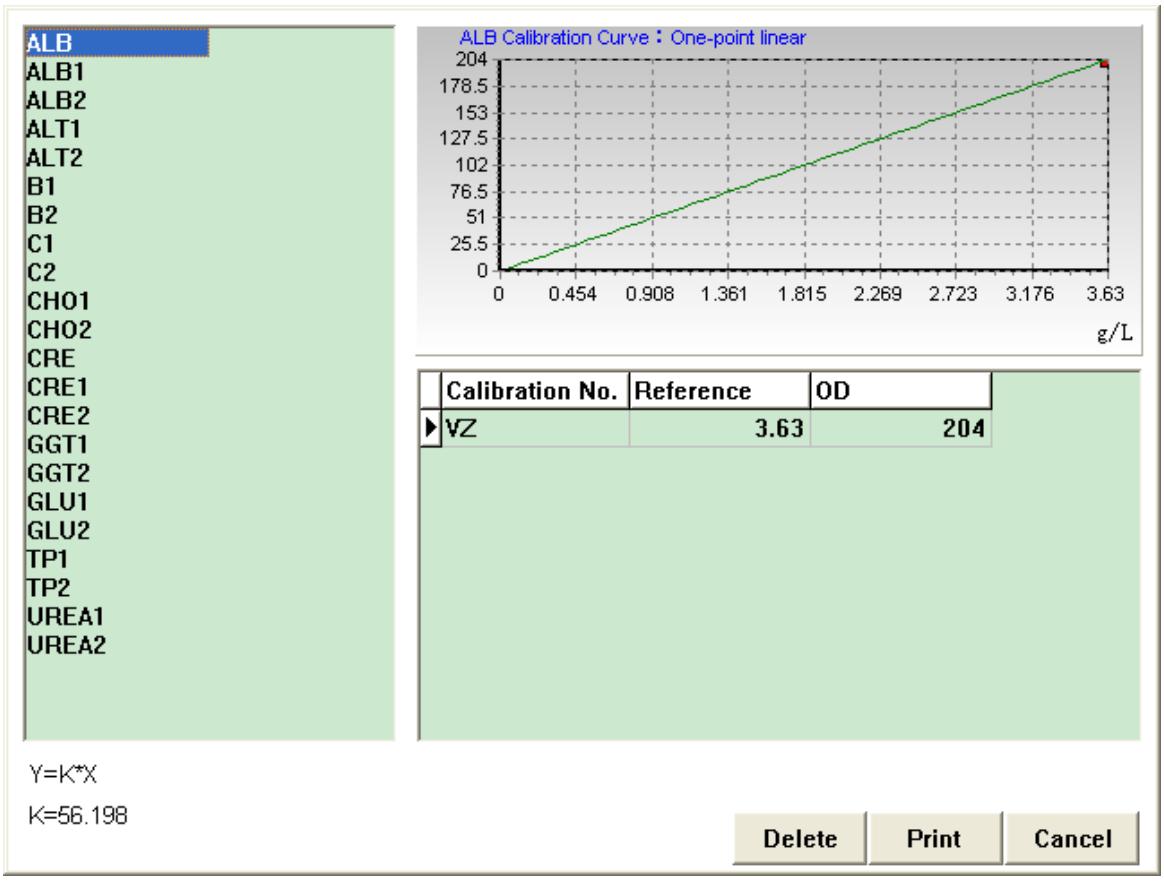



Figure 8-2 Standard Inquiry

**View Calibration Results**

The left list displays all items with calibration test finished. Click an item, and the corresponding calibration data and standard curve will be displayed on the right automatically.

**Delete Calibration Results**

Select the calibration results to be deleted from the calibration data list and press the Delete key.

**Print Calibration Results**

Select the item for which you want to print calibration results from the left list and press the Print key.

# Chapter 9 Report Printing

## 9.1 Patient Records Inquiry

**Function Brief: To inquire patient records meeting the specified criteria. You can edit and view the basic information and test results of the selected patient one by one.**

Click Print Report – Patient Report on the main screen to enter the Patient Records Inquiry page as shown in the figure:

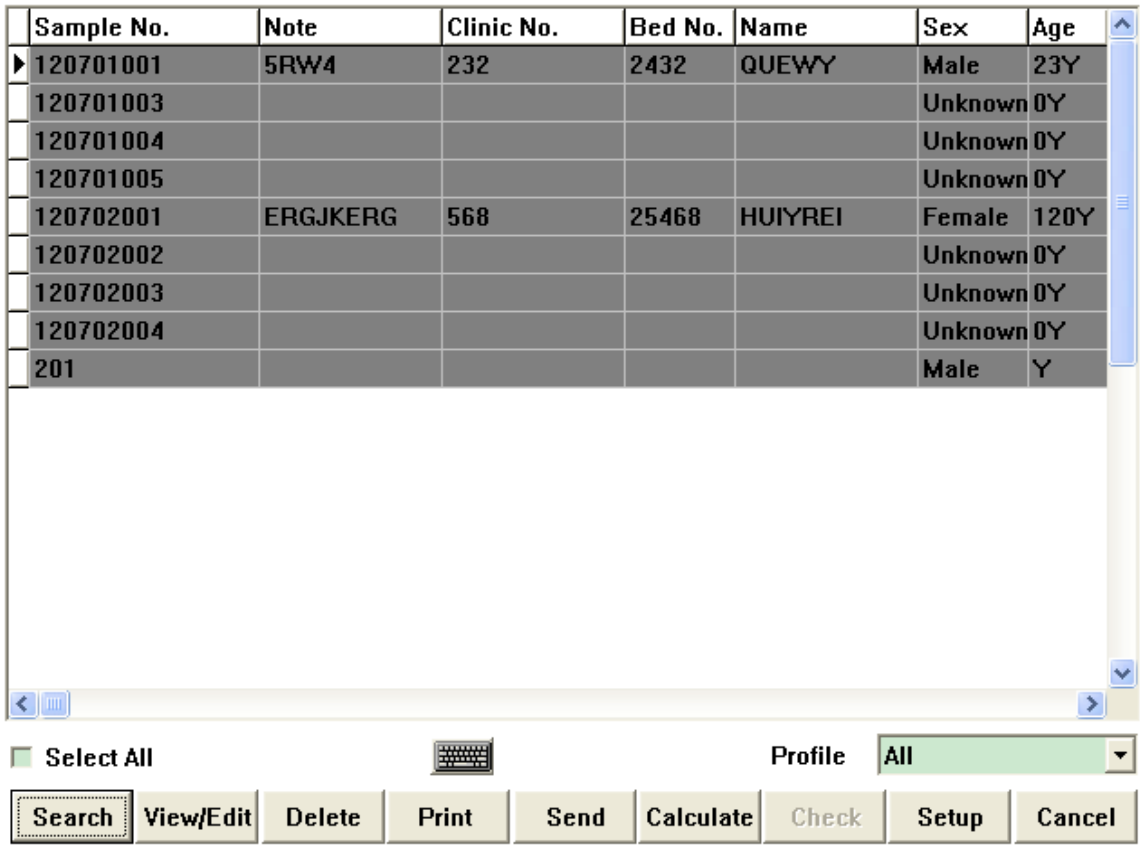



Figure 9-1 Patient Records

### Inquire Patient Records

Press the Inquire key, and the screen as shown in Figure 9-2 will appear:

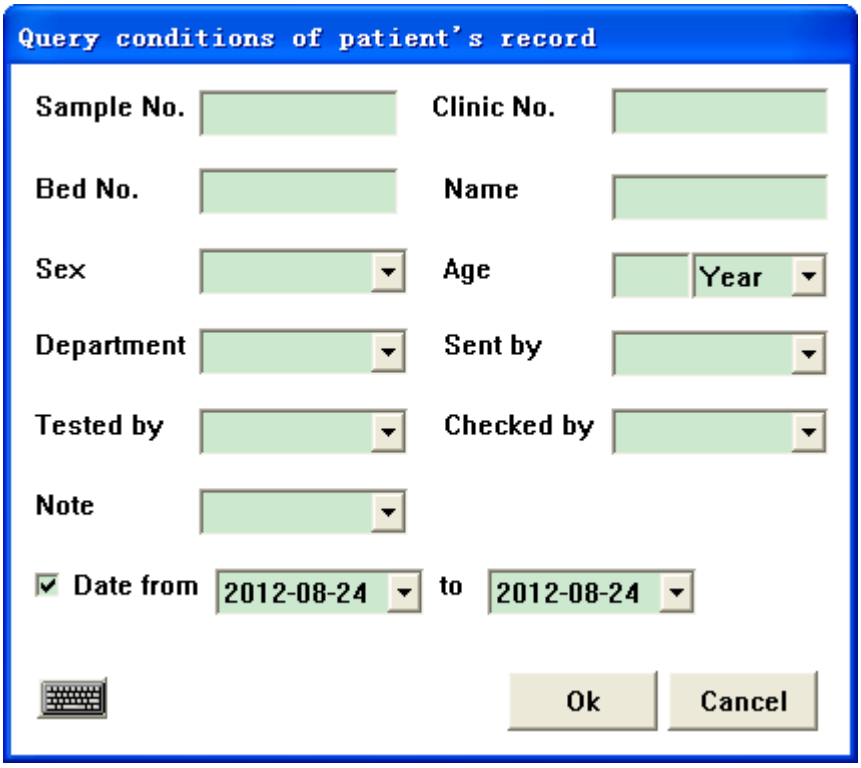



Figure 9-2 Patient Records Inquiry Criteria

Input the inquiry criteria and press the OK key, and the list will display all patient records meeting the criteria.

***Caution:***

- ***The patient results exceeding the reference range are presented with red background;***
- ***After the retest for the patient results, the results of the current and preveious tests are displayed in the Results and History fields respectively.***

**Edit Patient Information**

Select a patient from the list and press the Edit key to enter the screen as shown in the figure:

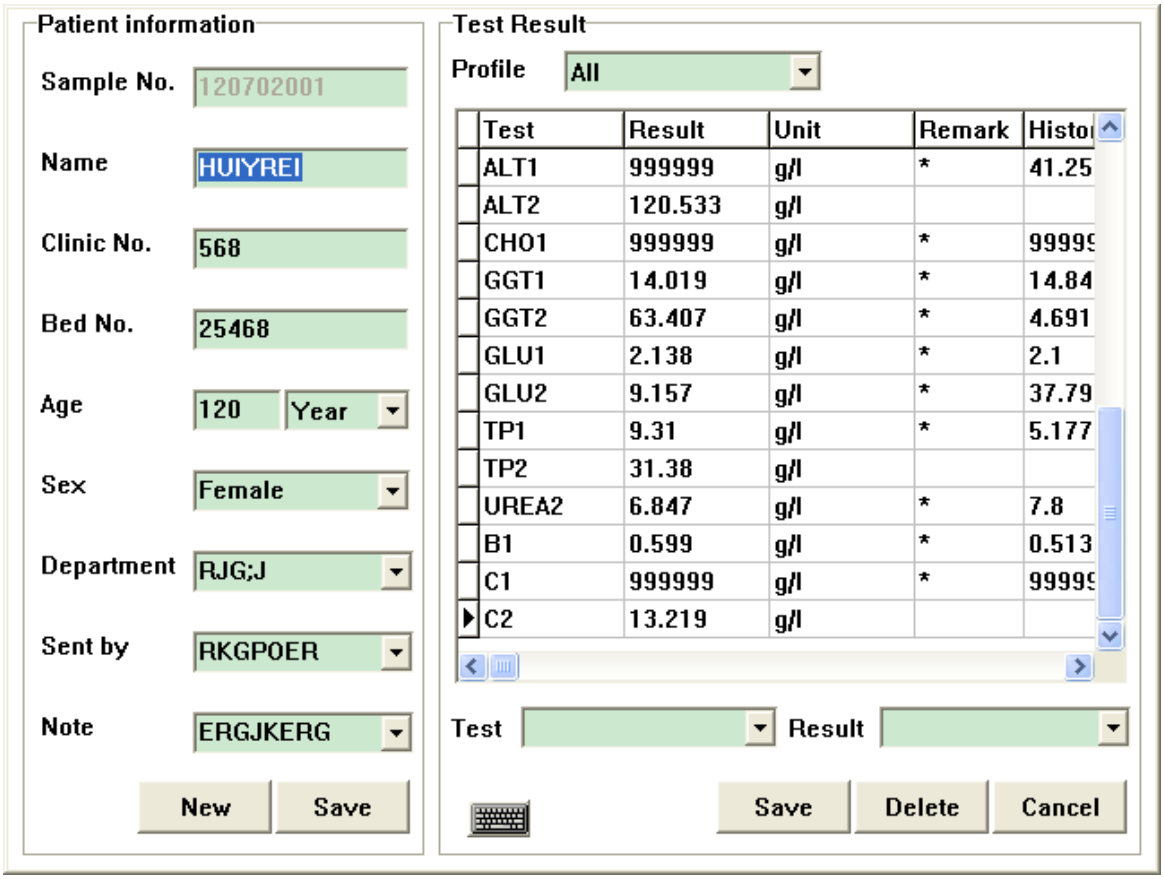



Figure 9-3 Edit Patient

**Add Patient Records**

Press the Add key, input the basic information of the patient in the left list, and press the Save key.

**Edit Basic Information of Patient**

Edit the information in the left list as needed and press the Save key.

**Edit Patient Test Results**

The test results corresponding to the selected patient are displayed on the right list. You can add, modify or delete the test results.

---

***Caution:***

- ***Test results for which the retest has been finsihed or test results manually added or modified are marked with "*" at the end.***
- ***Results on the high or low side are marked with "↑" and "↓" respectively.***
- ***The added patient sample number must not be an existing sample number, otherwise the system will overwrite it automatically.***

---

**Delete Patient Records**

Select the records to be deleted from the patient records list or select “Select All” and press the Delete key. The system will delete the specified patient records and all corresponding test records.

**Setup**

To achieve login or logout of the examiner as well as format selection of external reports.

**Examine Patient Results**

Select the examined patient records from the patient records list or select “Select All” and press the Examine key. The system will finish the examination automatically. Before the examination, the examiner should press the Setup key to login. (The patient records examined and those not examined are on white background and grey background respectively.)

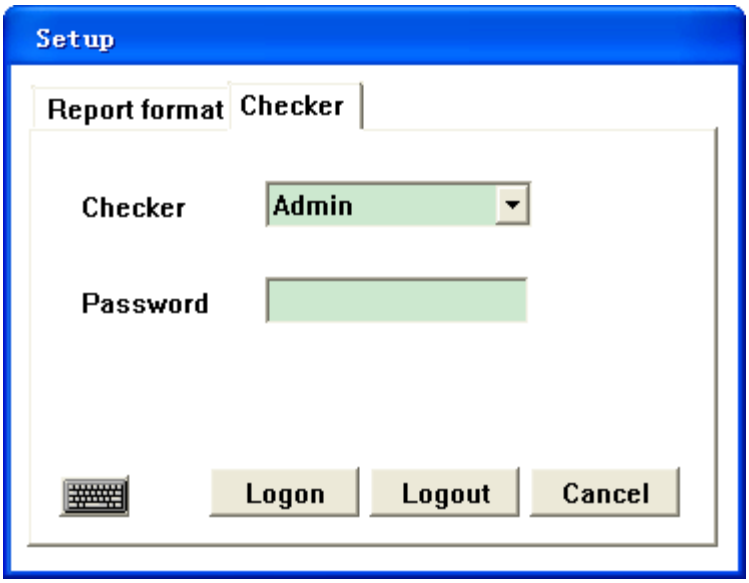



Figure 9-4 Examiner Login and Logout

---

***Caution: Each time the report is examined, the examiner should logout to protect the examination privilege against illegal use by other operators. Operation Step: Enter the Patient Records – Setup screen, select the current examiner and input password, and press Logout.***

---

**Indirect Calculation**

Select the patient records for indirect calculation from the patient records list or select “Select All” and press the Calculation key. The system will calculate the item results of the selected patient automatically according to the system setup parameters.

**Send Patient Test Results**

Select the patient records to be sent from the patient records list or select “Select All” and press

the Send key. The system will send the test results of the selected patient to the specified receiving software.

**Print Patient Report**

Select the patient records for which you want to print the report from the patient records list or select “Select All” and press the Print key. The system will generate the patient report automatically. Before printing the report, you should press the Setup key to set the format of the patient report, as shown in the figure:

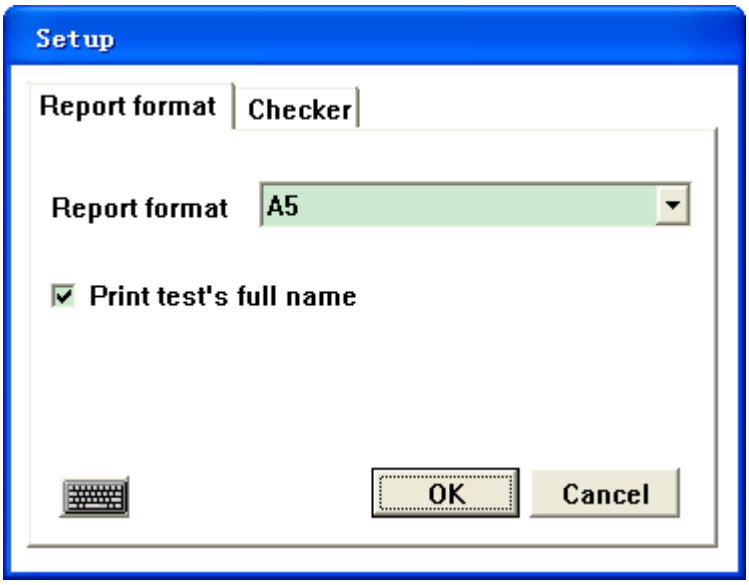



Figure 9-5 Report Setup

**Report Format:** Select the paper format of the report from the dropdown options.

**Print Full Name of Item:** Select whether the full name of the test item will appear on the patient report.

## 9.2 Test Records Inquiry

**Function Brief: To inquire the test records meeting the specified criteria.**

Click Print Report – Historical Records on the main menu to enter the Historical Records Inquiry page as shown in the figure:

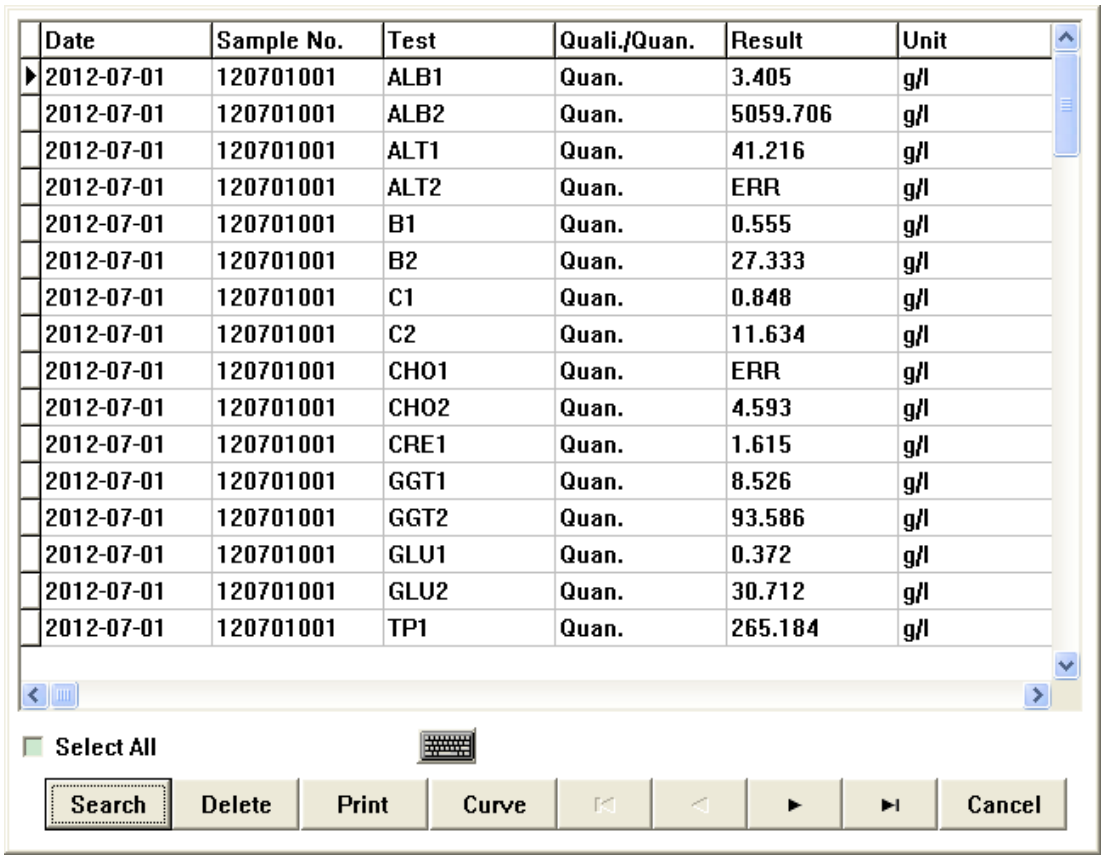



Figure 9-6 Test Records

**Inquire Test Records**

Press the Inquire key, and the screen as shown in the figure will appear:

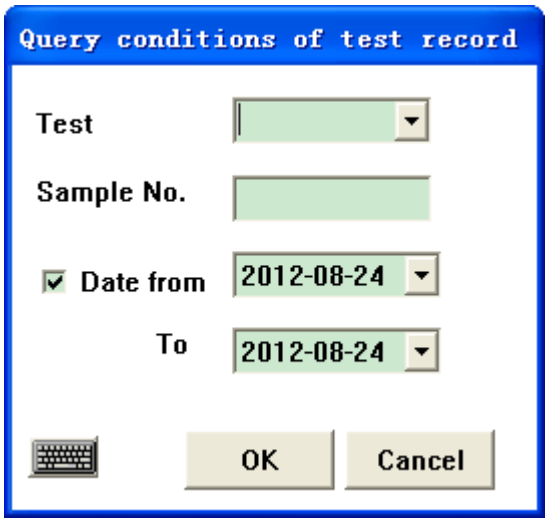



Figure 9-7 Test Records Inquiry Criteria

Input the inquiry criteria and press the OK key. The list will display all test records meeting the criteria.

***Caution: Test results for which the retest has been finsihed or test results manually added or modified are marked with "*" at the end.***

**Delete Test Results**

Select the records to be deleted from the test records list or select “Select All” and press the Delete key.

**Print Test Results**

Select the records to be printed from the test records list or select “Select All” and press the Print key.

**View Reaction Curve**

Click the test records to be viewed and press the Reaction Curve key. The system will display the reaction curve of the test, as shown in the figure:

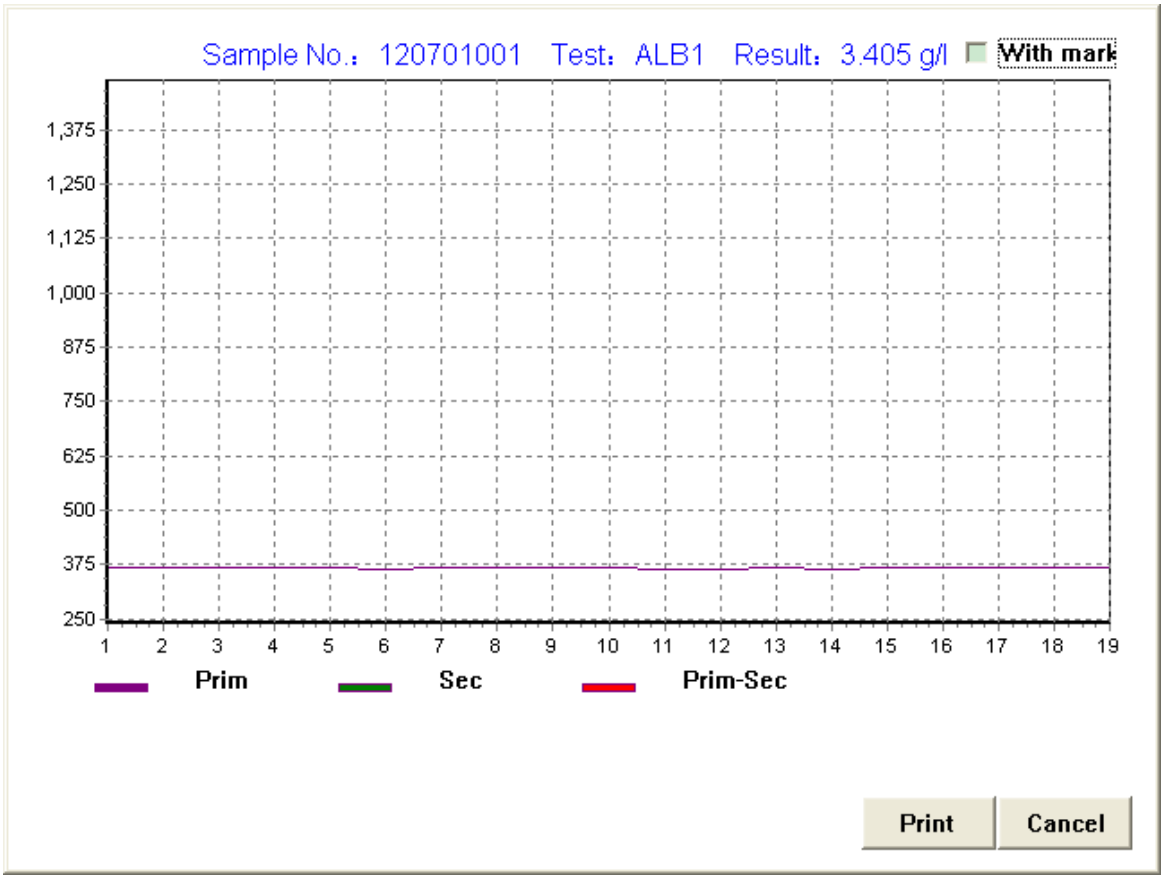



Figure 9-8 Reaction Curve

Press the Print key to print the curve.

## 9.3 Reagent Blank Records Inquiry

**Function Brief: To inquire the historical records of the reagent blank of the specified item.**

Select the Reagent Blank Inquiry page as shown in the figure:

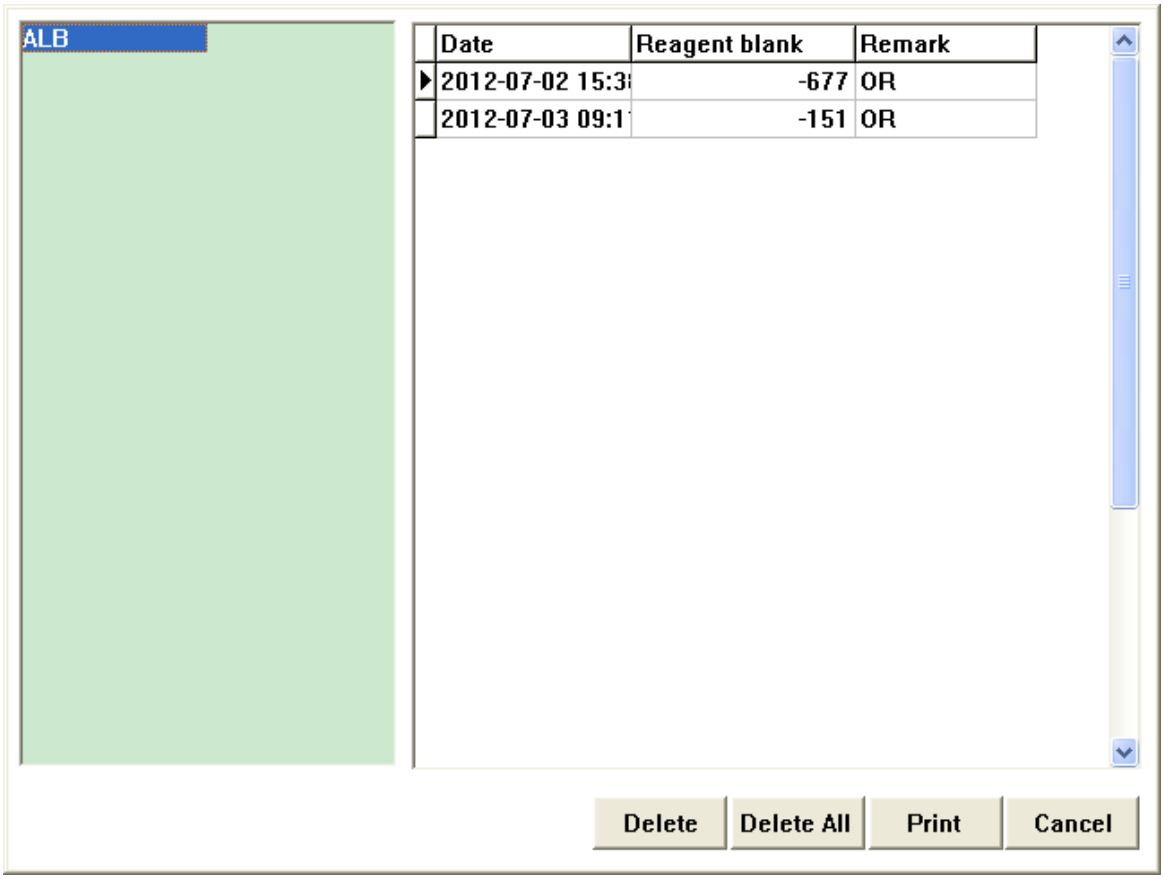



Figure 9-9 Reagent Blank Inquiry

The left list displays all items with the reagent blank test finished. Click the item to be inquired, and the right list will display the historical reagent blank record of the item.

Press the Delete key to delete the selected reagent blank record from the list.

Press the Delete All key to delete all reagent blank records from the list.

Press the Print key to print all reagent blank records in the list.

***Caution: Results exceeding the reagent blank range are marked with "OR".***

# Chapter 10 Turn Off System

Click Switch Off below the main menu to logout or exit the operation, as shown in the figure:

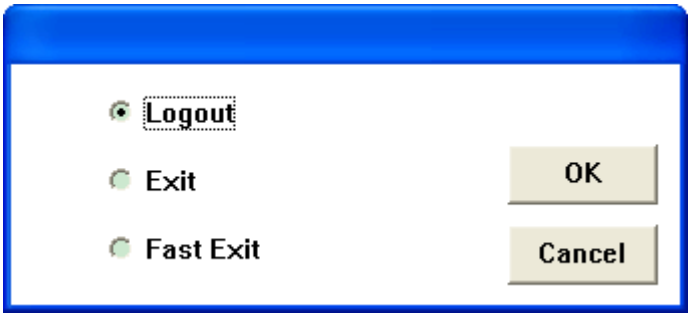



Figure 10-1 Logout and Exit

Select Logout to logout and relongin.

Select Exit, and the system will turn off the software and control system automatically after the necessary cleaning.

Select Quick Exit, and the software and control system will be turned off automatically.

---

***Caution: If the current user is a super user, when Quick Exit is selected, the software will be turned off and Explorer will be turned on, and the control system will not be turned off!***

---

# Chapter 11 Maintenance

## 11.1 Regular Maintenance

**Daily Maintenance**

Wipe the dirt on the workbench with a cloth soaked with neutral cleaning solution;

**Weekly Maintenance**

Gently wipe the sampling probe and rabble with a cloth dipped in alcohol;

Check whether the flows of the washing water in two cleaning pools are normal.

**Monthly Maintenance**

Clean the external cleaning solution tank;

Clean the water supply and drainage system.

---

***Caution: The diaphragm pump and rabble can't be replaced without permission of engineers from Rayto.***

---

## 11.2 Maintenance Instructions

11.2.1 Maintenance Procedures for Running and Normal Modes

Click Maintenance on the main menu of the operation software to enter the Maintenance page.

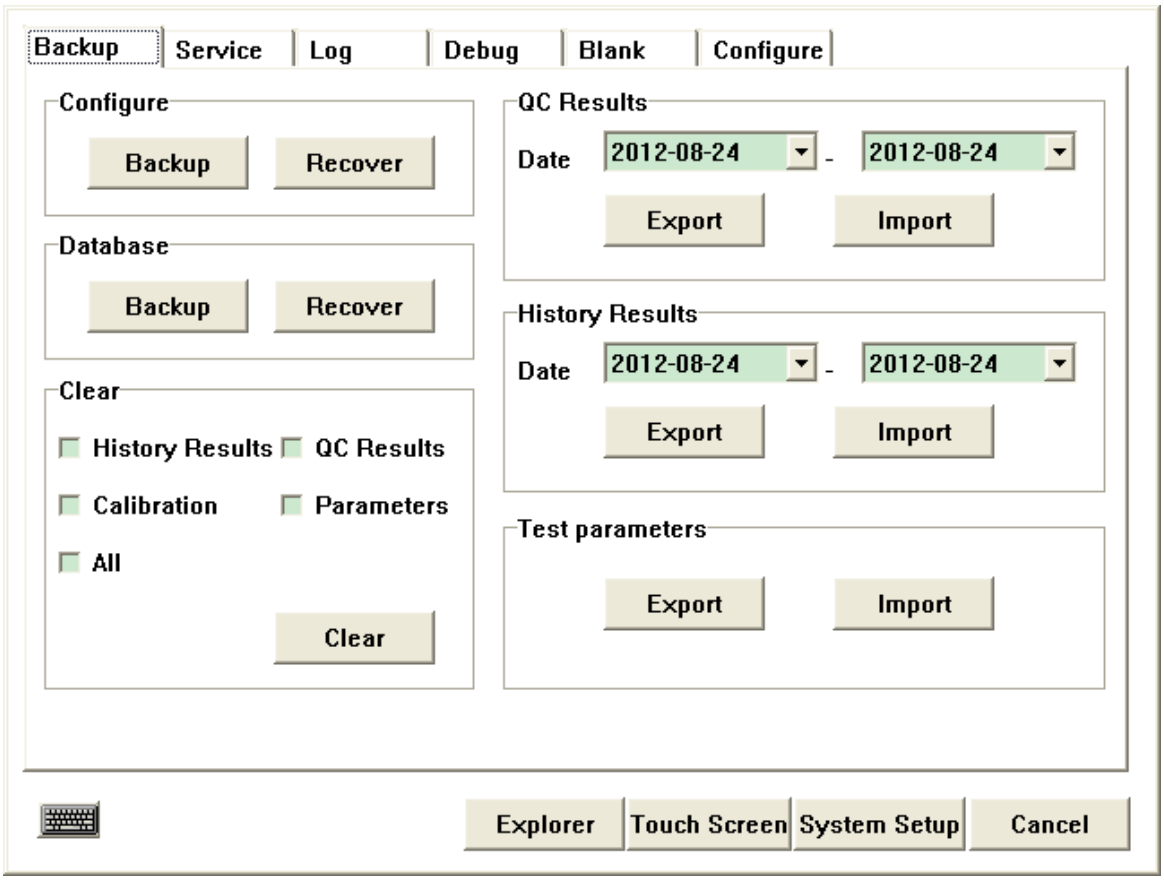



Figure 11-1 Maintenance — Data Maintenance

**Backup and Restoration of Configuration Parameters**

The configuration parameters are the best correction parameters suitable for hardware system obtained during the production of the machine, including positional parameter, motor control parameter, temperature correction parameter, gain parameter, cuvette blank threshold, and optical filter configuration parameter. The functions of the various parameters are as follows:

- The positional parameter is used to correct the mechanical positioning of the system, such as descent altitude of the sampling probe, liquid sucking and spitting positions, photoelectric collection position, etc.
- The motor control parameter is used to control the working mode of each motor.
- The temperature correction parameter is used to correct the accuracy of the reaction tray and preheat temperature control.
- The gain parameter is used to control the signal gain coefficients corresponding to the various wavelengths.
- The cuvette blank threshold is used to set the cuvette blank warning limit. When the cuvette blank exceeds the range set, the cuvette blank will be regarded as invalid and will not be used.
- The optical filter configuration parameter is used to record the wavelengths corresponding to the various filters configured in the system.

In order to prevent the configuration parameters from being damaged or lost, which causes the equipment to fail to function correctly, please make backup of the configuration parameters in the normal mode, so that the configuration parameters can be restored by using the Restore function when necessary.

**Backup and Restoration of Database**

The database is data files used to store setup parameters and historical test results. Make backup of the database regularly, so that the database can be restored in case data are damaged or lost.

**Data Purging**

Used to purge data of specified types in the database. Data types can be selected according to the actual needs. Once purged, data can’t be restored!

- Historical Data: Test results and basic information of patients.
- QC Data: Results of QC tests.
- Calibration Data: Results of calibration tests.
- Setup Parameters: Item setup parameters, standard setup parameters, QC setup parameters, combination setup parameters, calculation item setup parameters, non-biochemical item setup parameters, reagent setup parameters, system setup parameters, and worksheet setup and test data input by users.
- All Data: Including all above data.

**Export and Import of QC Results**

To export all QC results of tests in the specified time range. The data exported will be saved to the specified path. When necessary, the QC results in the specified time range can be imported from the file.

**Export and Import of Historical Data**

To export the patient sample test results in the specified time range. The data exported will be saved to the specified path. When necessary, the patient sample test results in the specified time range can be imported from the file.

**Export and Import of Item Setup Parameters**

To export the current item setup parameters of the system. The data exported will be saved to the specified path. When necessary, the item setup parameters can be imported from the file.

---

***Caution: Only the administrator can restore configuration parameters, restore database, import QC data, import historical data, import item setup parameters, and purge data!***

---

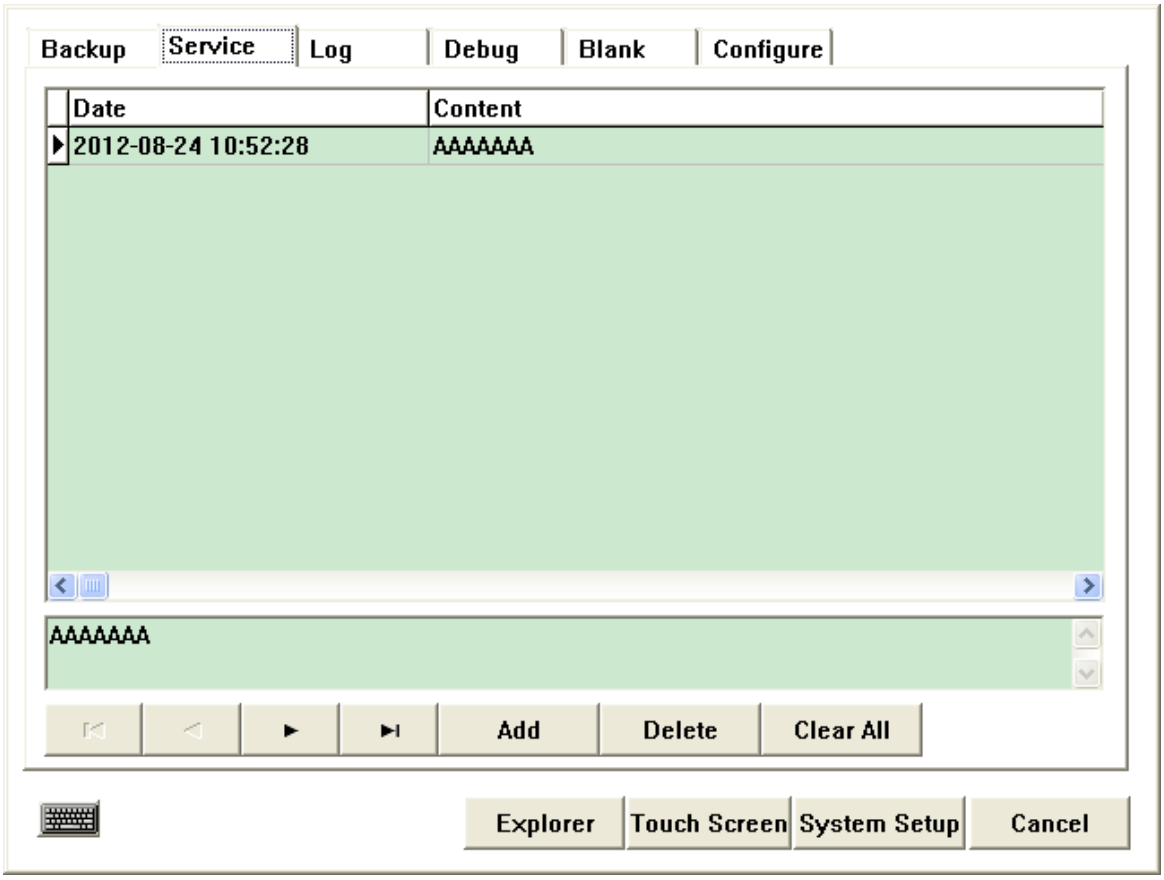



Figure 11-2 Maintenance — Repair Record

**Add Repair Record**

Press the Add key, input the repair records to be added in the window that appears, and save the setting.

**Delete Repair Record**

Select the record to be deleted from the list and press the Delete key. To delete all repair records, directly press the Clear All key.

***Caution: Only the administrator can add and delete repair records!***

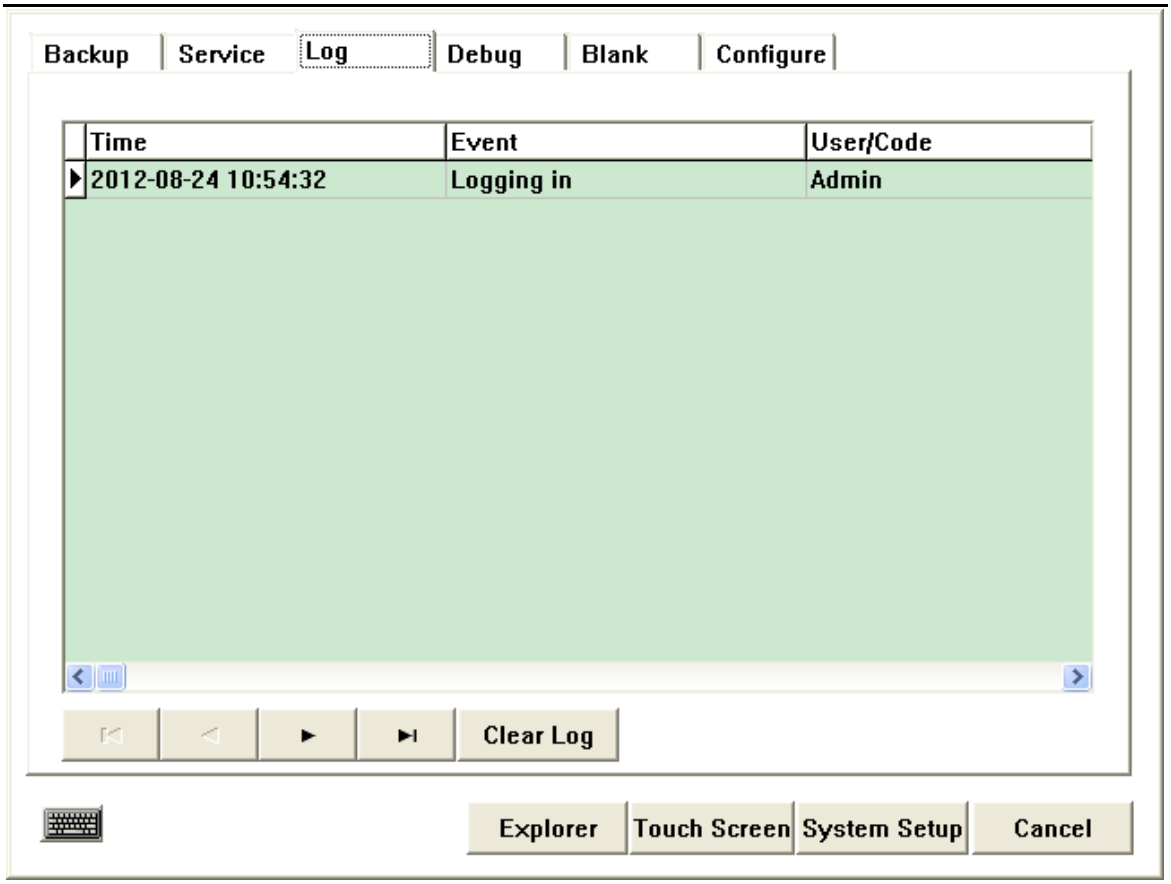



Figure 11-3 Maintenance — Log

The list displays all system log records. To delete all log records, press the Clear Log key.

***Caution: Only the administrator can clear logs!***

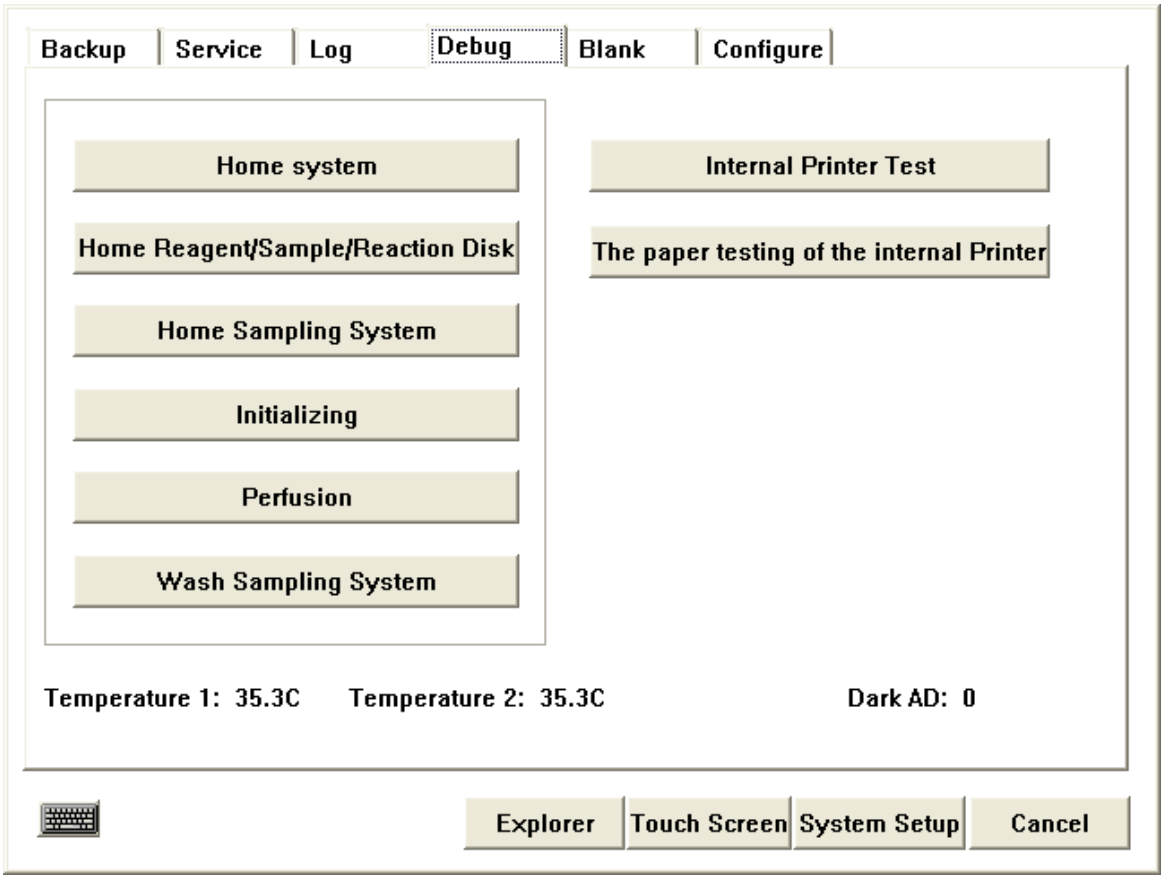



Figure 11-4 Maintenance — Operation

On the “Status Detection” page, you can operate the status detection of various components of units.

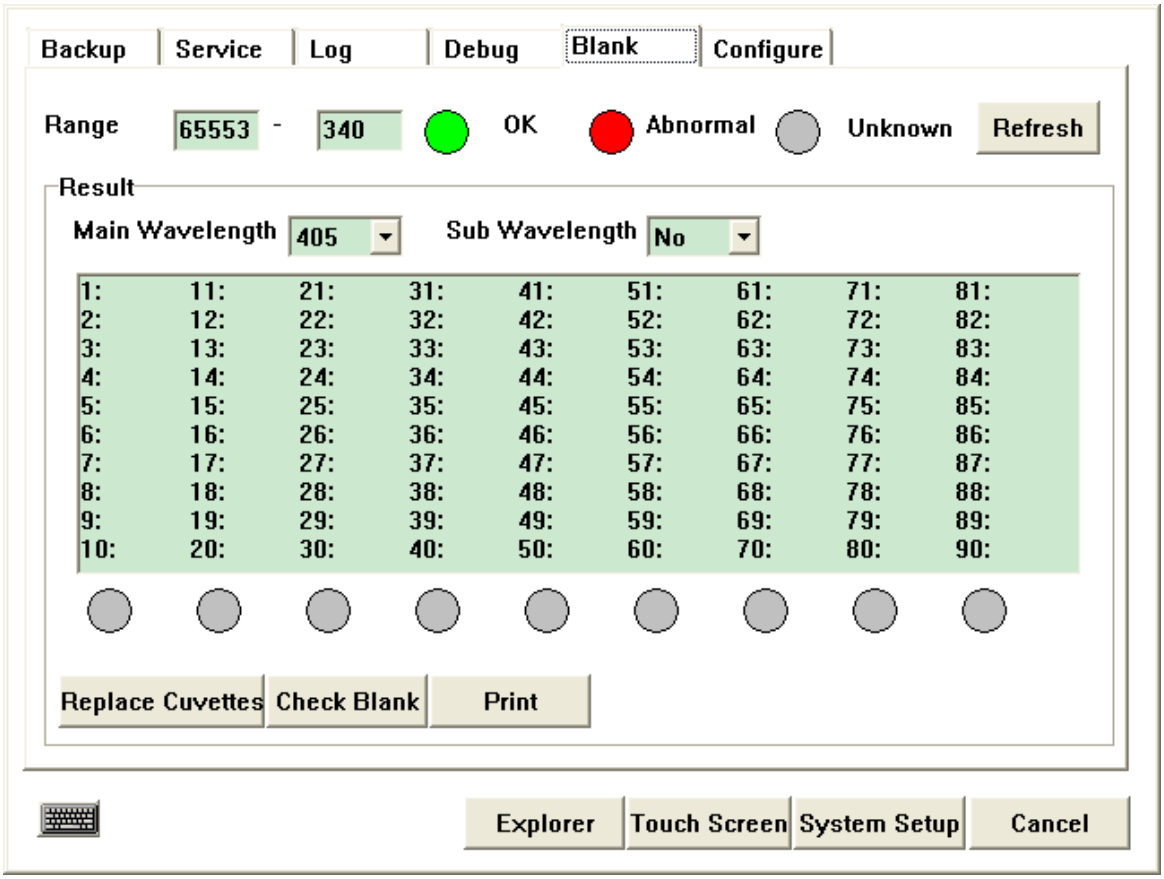



Figure 11-5 Maintenance — Cuvette Blank

**Replace Cuvette**

When Replace Cuvette is pressed, the system will turn the 9-fold of cuvettes to the Manual Replacement window in turn and prompt you for replacement. Press the Stop key to stop the replacement of the remaining cuvettes.

**Cuvette Blank Detection**

When the Cuvette Blank Detection key is pressed, the system will detect the cuvette blanks for various wavelengths of 90 cuvettes automatically and then display the cuvette blank value corresponding to the specified wavelength automatically.

**Blank Screening**

Set the screening range of the cuvette blank corresponding to the specified wavelength and press the Refresh key. The system will judge the validity of each fold of cuvette blank according to the range set and indicate it with a color.

**Print**

Press the Print key to print the cuvette blank values displayed in the list.

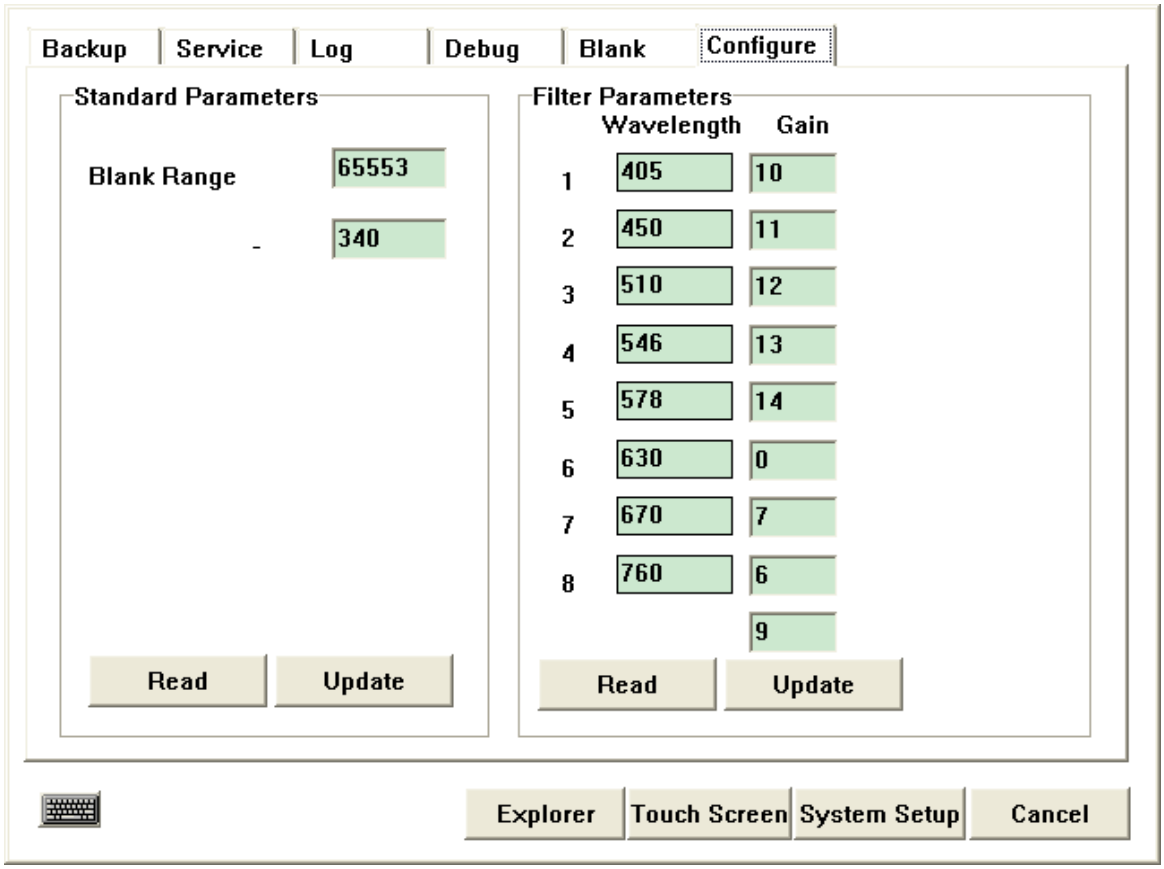



Figure 11-6 Maintenance — Configuration

**Standard Parameters**

The Blank range is the standard for judging if the reaction cuvette can be used. If the blank of the reaction cuvette is within the range, it is judged as valid; otherwise, it is judged as invalid. The system will automatically skip the invalid reaction cuvettes. Press "Read parameters" button to obtain the current blank limit parameters of the system. Enter the blank range, and then press "Update Parameters" button to save.

The amount of sample and reagent positions can be free combination, if you need to increase or reduce the sample positions, please input the sample position amount, for example: 9,12,15,42, then press "Update Parameters" button to save.

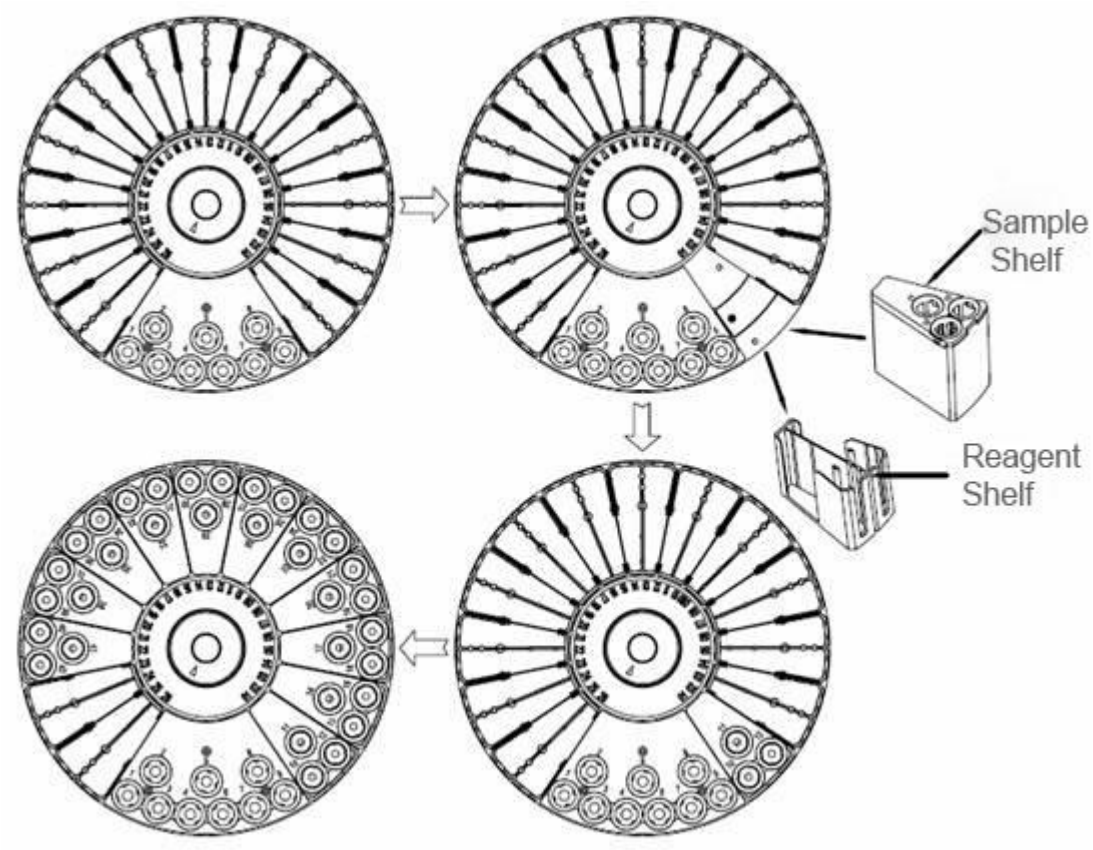
---

***Caution: The blank range must be obtained through actual tests. If the range is unreasonable, the system can't conduct the test normally! When different batches of assay cups are replaced, enter the Cuvette Blank page to conduct the test and view the cuvette blank range of the batch; and then set appropriate restriction parameters according to the test results of various wavelengths.***

---

***Note:*** ***Before changed the sample position amount, please fix the corresponding sample and reagent shelf at the first. The amount of sample and reagent position must be the same as the actual positions; otherwise, it's possible lead to software abnormal. Every time changed the sample position amount, the system will be cleaned all reagent setting automatically, user need to set the reagent again.***

Please according to the number order on the Sample shelf to replace the sample and reagent shelf, please check as following:




**Optical Filter Parameter**

"Wavelength" displays the wavelengths corresponding to the 8 optical filters of the system in turn. The Gain column displays the gain coefficients corresponding to the 8 wavelengths in turn. When the gain coefficient corresponding to a wavelength needs to be adjusted, you may modify it manually or press Automatic Gain Configuration to get the appropriate gain coefficients, and press Update Parameter to save the parameter obtained. (When the cuvette blank energy of a wavelength is on the low side, the corresponding gain coefficient should be increased. Otherwise the gain coefficient should be decreased.)

***Caution: Common users must not modify the parameters on the Configuration page,***

***otherwise the accuracy of system tests may be affected!***

11.2.3 Maintenance and Upkeep for Long-term Out of Use

- Before long-term out of use of the machine, keep the washing bottle empty and run Hydraulic Circuit Perfusion in running maintenance to completely drain the liquid from the hydraulic circuit.
- Take out all test cups in the reaction positions and empty the residual cups on the reagent tray and sample tray. Wipe the surface of the workbench clean with cotton ball.

# Chapter 12 System Failure and Treatment

This chapter describes the common faults and trouble shooting of the instrument. If the trouble can't be cleared after the tips in this chapter have been followed or you need more details, contact Rayto's Customer Service Department.

| Fault | Solution |
|---|---|
| The software can't run normally. | ● Check whether the mainframe of the analyzer has been turned on;<br>● Check whether the control serial port cable is connected to the control computer and analyzer correctly;<br>● Check whether the control computer uses the port specified by the system software. |
| The cuvette blank is invalid. | ● Check whether a clean cuvette is replaced;<br>● Check whether the cuvette is stained;<br>● Check whether the light source energy is normal;<br>● Whether the cuvette blank range is set correctly;<br>● Whether the gain coefficients corresponding to various wavelengths are reasonable. |
| The volume of liquid filled is inaccurate. | ● Check whether the sampling pipeline is properly closed;<br>● Check whether the perfusion of the hydraulic circuit is adequate;<br>● Check whether the liquid volume correction factor is normal;<br>● Check whether the status of the syringe is normal;<br>● Check whether the deionized water has been used up;<br>● Check whether the pipeline is connected correctly. |
| The sampling probe is not positioned correctly. | ● Check whether the sampling probe is straight down;<br>● Whether standard reagent bottles and sample tubes are used. |
| Liquid remains on the surface of the sampling probe. | ● Check whether there is dirt on the outer wall of the sampling probe;<br>● Check whether the sampling probe tube is worn;<br>● Check whether the fountain in the cleaning pool when the sampling probe is being cleaned is appropriate;<br>● Check whether the sampling pipeline is properly closed;<br>● Check whether the perfusion of the hydraulic circuit is adequate;<br>● Check whether the deionized water has been used up. |
| The positioning of the rabble is incorrect. | ● Check whether the rabble is straight down;<br>● Check whether the rabble is loose. |

**Warning: (1) In case of failure of the instrument, contact the agent immediately so as to obtain technical support!**

**(2) Only professionals recognized by Rayto may repair the instrument. To replace accessories, contact the manufacturer or agent.**

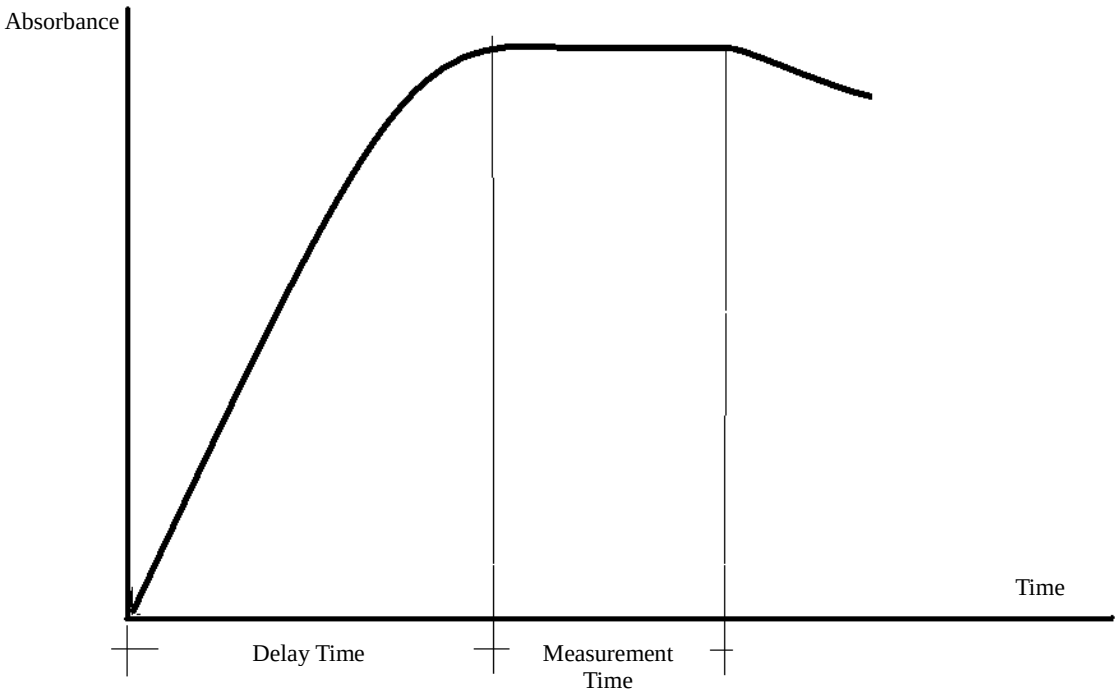
# Chapter 13 Safety Protection Device and Accident Treatment

- Ensure the grounding is normal when using the machine.
- When the machine is conducting tests normally, any operation in the working area of the machine is prohibited so as to prevent moving parts from injuring the operator.
- To replace the bulb, switch off the machine and wait half an hour to prevent heating components from scalding the operator.
- If any accident occurs when the machine is running, such as probe collision, abnormal noise of the rabble or motor or peculiar smell, switch off the power immediately. Contact the customer service staff for treatment.
- In case of fire, use powder fire extinguisher to put out the fire.

# Appendix A: Test Methods

## A.1 End-Point Method

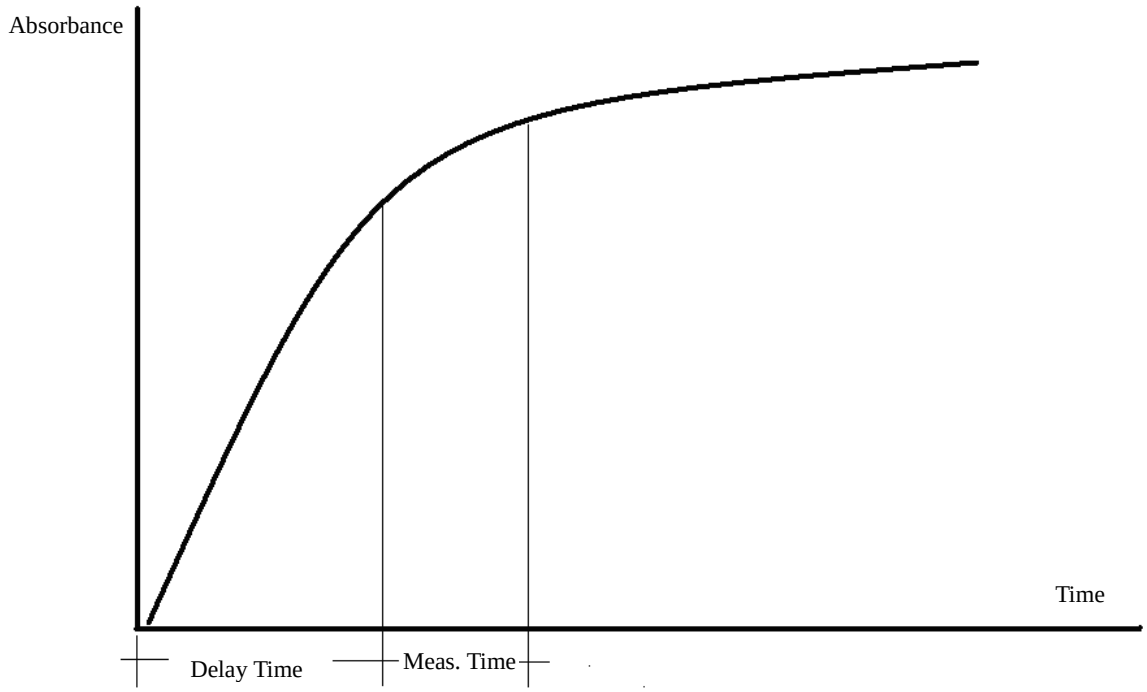
When the tested substance is fully converted to a product after a certain time in the reaction, the absorbance of the reaction liquid will not be increased (or decreased) any longer, and the end point is reached; the concentration of the tested substance is obtained according to the end point absorbance – this is the End-Point Method.




End-Point Method

## A.2 Two-Point Method

Two-Point Method: In a certain reaction time, the reaction rate is in proportion to the concentrations of reactants. As the reactants are being consumed continuously, the reaction rate is reduced continuously, which is reflected by the increasing (or decreasing) absorbance and the reducing rate. Measurement must be conducted in the certain time period. In the time period, the increase or decrease of the absorbance is in proportion to the concentration of the measuring object.

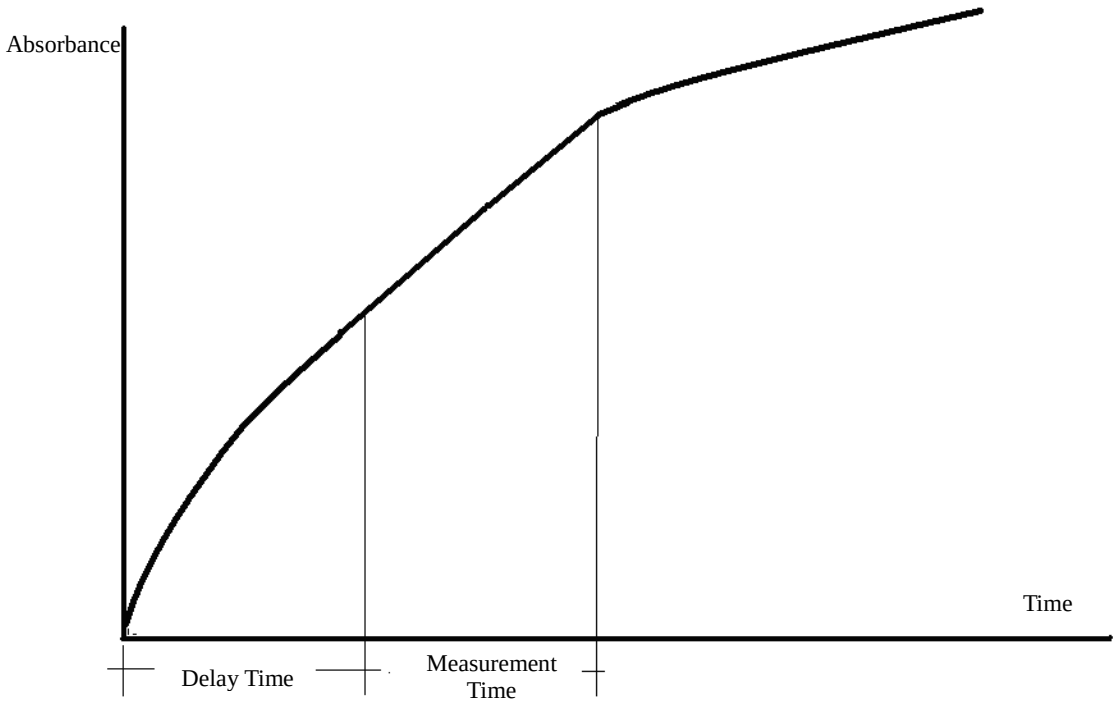



Two-Point Method

## A.3 Rate Method

Rate Method: The reaction rate is in proportion to the zero power of the concentration of the measuring object, that is, unrelated to the concentration of the measuring object. Therefore, throughout the reaction, the reactants can generate a product at a constant rate, thus the absorbance of the measuring solution is evenly decreased or increased under a wavelength, with the rate of decrease or increase (ΔA/min) in proportion to the activity or concentration of the measuring object. The rate method, i.e. the so-called kinetic method, also called continuous monitoring method, is mainly used to determine the enzymatic activity.

In fact, the concentration of the substrate is impossible to be high enough. As the reaction proceeds, when the substrate is consumed to a certain extent, the reaction rate is no longer in proportion to the enzymatic activity. Therefore, the Rate Method aims at a certain time period.




Rate Method

# Appendix B: Names and Contents of Toxic/Hazardous Substances or Elements

**1. Names and Contents of Toxic/Hazardous Substances or Elements**

| Component | Toxic/Hazardous Substance or Elements | | | | | |
|---|---|---|---|---|---|---|
| | Lead (Pb) | Mercury (Hg) | Cadmium (Cd) | Hexavalent Chromium (Cr (VI)) | Polybrominated Biphenyls (PBB) | Polybrominated Diphenyl Ethers (PBDE) |
| Built-in circuit board | × | ○ | ○ | ○ | ○ | ○ |
| Shell | × | ○ | ○ | × | ○ | ○ |
| Display | × | ○ | ○ | ○ | ○ | ○ |
| Photoelectric components | × | ○ | ○ | ○ | ○ | ○ |
| Internal electronic wire | ○ | ○ | ○ | ○ | ○ | ○ |
| Accessories | × | ○ | ○ | ○ | ○ | ○ |

○: Indicates the content of the toxic/hazardous substance in all homogeneous materials of the component is below the limit specified in the SJ/T11363-2006 standard.
×: Indicates the content of the toxic/hazardous substance in at least one homogeneous material of the component exceeds the limit specified in the SJ/T11363-2006 standard.

**2. Description of Mark**

Environmental protection use period mark


Meaning of the mark: The electronic information product contains certain toxic/hazardous substances, with the environmental protection use period of 20 years. You can use it within this period. When this period expires, the product should enter the recycling system.