

Operation Manual

MaxLYZER Smart

Semi Auto Chemistry Analyzer



Manufacturer

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PREFACE

Thank you for purchasing semi-auto chemistry analyzer.

This manual introduces safety and the correct use of machine, read it carefully before use.

For this operator's manual, the issued date is 2022.06 (Version: V10).

■ Precautions in using this manual

- Before using the analyzer, please read this manual thoroughly and understand it for relevant operation instructions.
- Without permission, can't copy and duplicate any manual chapters.
- Please keep this manual properly for convenient use.





■ Whom and What this manual is for

This manual is written for clinical laboratory professionals, explain how to operate this analyzer

- Intended User
People who received professional training will available to read this manual to learn more information about analyzer. It is necessary to read it carefully before using analyzer.
- Purpose
Help user to understand the performance of analyzer well and operate it well.




■ Safety symbol marks used in this manual

Ensure to understand well of below signs, it is important to you!

When you see...	Then...
 Warning	This sign is warning you that a wrong operation will cause serious injury.
 Caution	This sign is warning you that machine system was damaged or in an unreliable situation.
 Note  Biohazard	<p>This sign warning you some important information that requires your Note.</p> <p>This sign warning you that will cause a potentially biohazardous condition.</p>

■ **Labels used on the System**

The labels attached to the panels of the system use symbols to clarify the meaning of the text. The list below shows the symbols that are used on the analyzer.

Symbol	Meaning
	Serial number
	Biohazard Warning: risk of potentially biohazardous infection
	ON (main power)
○	OFF (main power)
	The device is in full compliance with the council directive concerning in vitro diagnostic medical devices IVDR/746

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1. PRECAUTIONS ON USE AND INSTALLATION ENVIRONMENTS

1.1. Safety Cautions

For safety and effective use, please obey the following conditions.

■ **Prevention of Breakage and Flammability**



Warning

- Analyzer must be installed in right place and good conditions refer to the manual.
 - Analyzer has to be installed in an unsuitable environment, please contact technical support first.
 - Remove any screws on the rear panel of machine is forbidden.
 - Any liquid come into inside of machine, please contact technical support.
-

■ **Preventing infection**



Biohazard

- Inappropriately handling test solution, waste solution may lead to biohazardous infection. Do not touch the test solution, waste solution with your hands. Wear gloves and lab coat, and goggles if necessary.
 - In case your skin contacts the test solution or waste solution, follow standard laboratory safety procedure and consult a doctor.
-

■ **Preventing Personal Injury Caused by Lamp house**



Warning

- Light sent by the lamp house may hurt your eyes. Do not stare into the lamp when the system is in operation.
 - If you want to replace the lamp house, first switch off the MAIN POWER and then wait at least 15 minutes for the lamp to cool down before touching it. Do not touch the lamp before it cools down, or you may get burned.
-

■ Precautions on use

For getting best test results, please obey the following conditions.



Note

- Please don't shaking or touch machine when it is working; otherwise will influence test result.
 - Quality control is necessary to use for checking machine in good work condition or not.
 - Daily maintenance is very important. Unstable test results and short service life most cause of carelessness.
 - Process calibrator, controls and reagent please refer to their instruction.
 - Any wet or chemical materials away from touch screen.
 - Volume of sample and reagent, corrected value of wavelength and incubation time must accord with the instruction of reagent kits, calibrator kits or control kits.
 - Any doubts of operation, please read this manual first.
-

1.2. Installations Environments



Caution

Make sure the instrument is installed in a place meeting the following requirements. Otherwise, it will not perform as promised.

1.2.1. Installation Environment Conditions

- The instrument is for indoor use only.
 - The bearing platform should be level (gradient less than 1/200).
 - The bearing platform should be free of shaking.
 - The installation site should be well ventilated.
-



Caution

The instrument radiates heat while operating. A well ventilated environment helps keep the room temperature stable. Use ventilation equipment if necessary.

- The installation site should be free of dust as much as possible.
- The installation site should not be in direct sun.
- The site should not be near a heat or draft source.
- The installation site should be free of corrosive gas and flammable gas.
- The site should not be disturbed by large noise or power supply.
- The instrument should not be placed near brush-type motors and electrical contacts that are frequently turned on and off.
- Do not use such devices as mobile phones or radio transmitters near the instrument. Electromagnetic waves generated by those devices may interfere with operation of the instrument.
- The altitude height of the installation site should be lower than 2000 meters.

1.2.2. Temperature And Humidity Conditions

- Ambient temperature: 15°C~35°C, with fluctuation less than $\pm 2^{\circ}\text{C}/\text{H}$.
 - Relative humidity: 35%RH - 80%RH, without condensation.
-



Caution

Operating the instrument in an environment other than the specified may lead to unreliable test results.

If the temperature or relative humidity does not meet the above-mentioned requirements, be sure to use air-conditioning equipment.

1.2.3. Power Requirements

- Power supply: AC 100-240V, 50/60Hz.
- Three-wire power cord, which should be grounded properly.
- The distance between the power socket and the system should be less than 2.5 meters.

2. SYSTEM DESCRIPTION

2.1. Outline Of Functions

The instrument is semi-auto chemistry and coagulation analyzer for in vitro diagnostic use in clinical laboratories and designed for in vitro quantitative determination of clinical chemistries in serum, plasma, urine or cerebrospinal fluid samples.



Caution

Some samples may not be analyzed on the instrument based on parameters the reagents claim capable of testing. Consult the reagent manufacturer or distributor for details

2.2. Outline Of Screen Operations

2.2.1. Main Screen

Turn on machine you will see the main screen.

This screen allows you to enter different function dialog box by click 8 main icons.

Table1 Outline of each main icon functions

Main button	Function
Test	Do sample, QC test, reagent blank and standard test
View Result	View test results after analysis, or history samples information. Query QC results, Standard results. Clear and backup the data.
Reagent Setup	Setup the assay parameters that for analysis.
QC Setup	Setup the QC parameters that for analysis.
System Setup	Setup printer, data and language, Combo box configuration. Define sleep time and do touch screen calibration.
Maintenance	Do flow cell washing, pump calibration, optical calibration.
About	Display the version information about instrument and software.
Power management	Shut down the program or run sleep mode of instrument.

2.2.2. Screen Elements

- **Edit box**



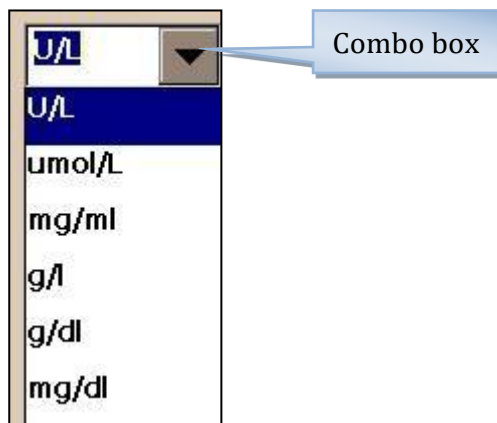
You can enter characters in the edit box from touch screen or USB keyboard. USB keypad reserve for habits of user.


- **Button**



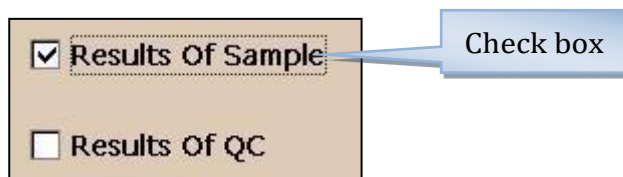
Click a button and you can access the function it indexes.

- **Combo box**



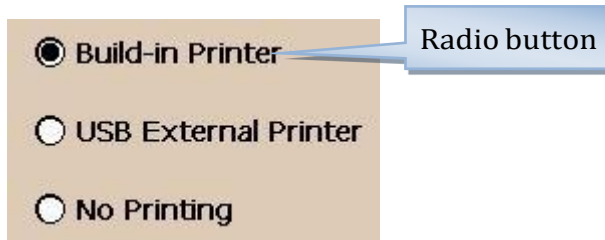
Click  and a list will be displayed, as the figure above shows. Click the desired item to select it.

- **Check box**



Click a check box to select the option it represents and click it again to deselect it. Note that for a given group of check boxes, you can choose more than one of them at one time.

- **Radio button**



A screenshot of a software interface showing three radio button options. The first option, "Build-in Printer", is selected, indicated by a filled black circle. A blue callout box with the text "Radio button" points to this selected option. The other two options, "USB External Printer" and "No Printing", are unselected, indicated by empty white circles. The entire selection area is highlighted with a light brown background.

Build-in Printer

USB External Printer

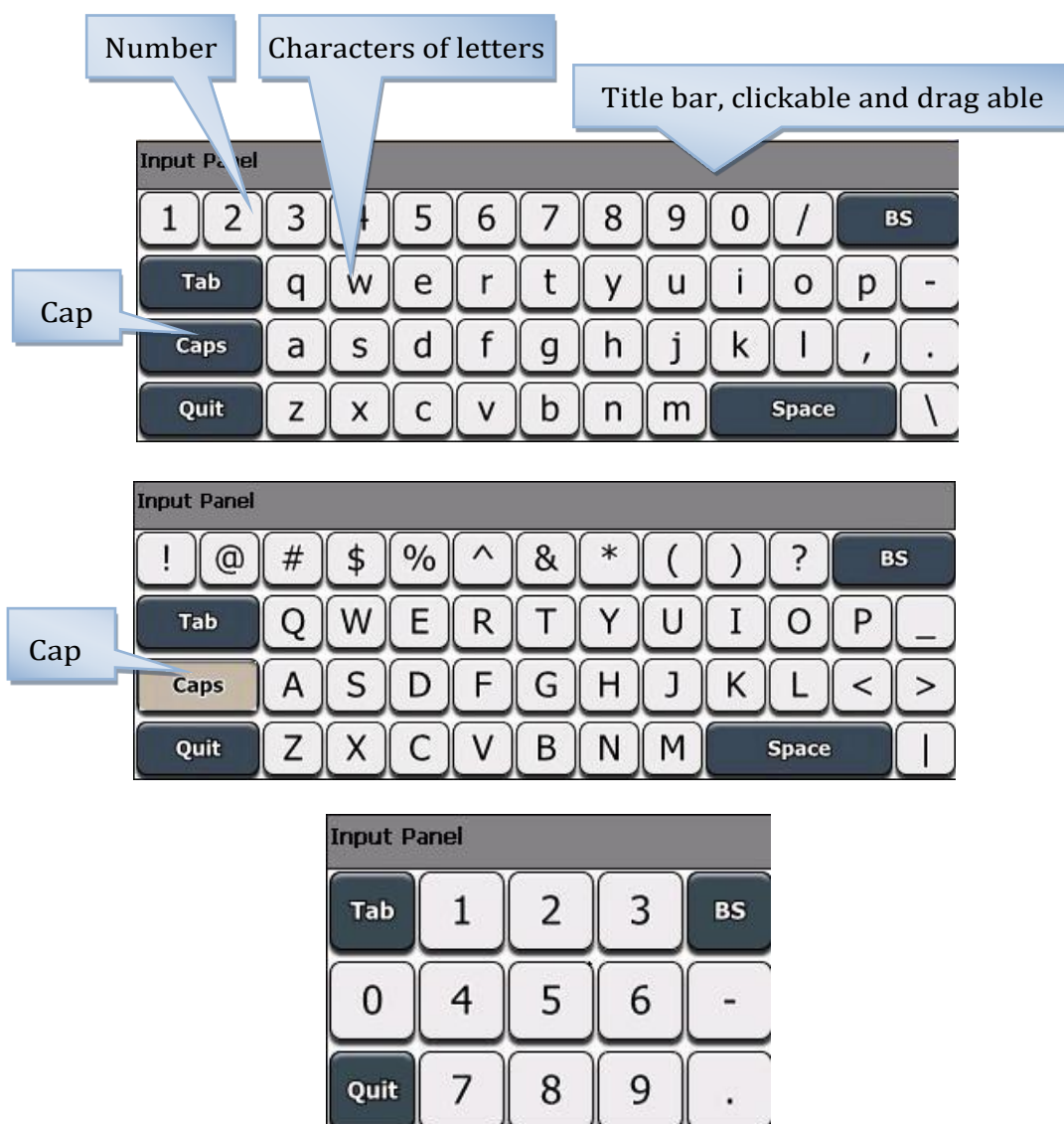
No Printing

Click a radio button to select the option it represents.

Note that for a given group of radio buttons, you can only select one of them.

2.3. Input Panel Functions

The input panel can popup automatically when you input characters, numbers in each dialog of software, as the figure below shows.



- Click Tab button to go to next edit box.
- Click Quit button to close the input panel.

2.4. External USB Mouse And USB Keyboard

USB mouse and USB keypad will reserve for people who get used to use traditional computer.

Connect USB mouse or USB keypad cable to instrument USB port, then it can work.

USB Keyboard



USB mouse



Note

Do not use the right button of USB mouse, it has no function.

2.5. External USB Printer

Build-in thermal printer and external printer will available to print all kinds test report.

USB Printer



- USB printer configuration requirements:
 - Support PCL 3 GUI print language.
- Recommended printer model as below

Printer model

HP LaserJet P1108

HP LaserJet 2035

HP LaserJet M1213nf MFP

HP LaserJet M1136

HP LaserJet P1106

- External USB printer setup process:
 1. Connect printer cable to instrument USB port.
 2. Please go to “System Setup”→select “USB External Printer” radio button.



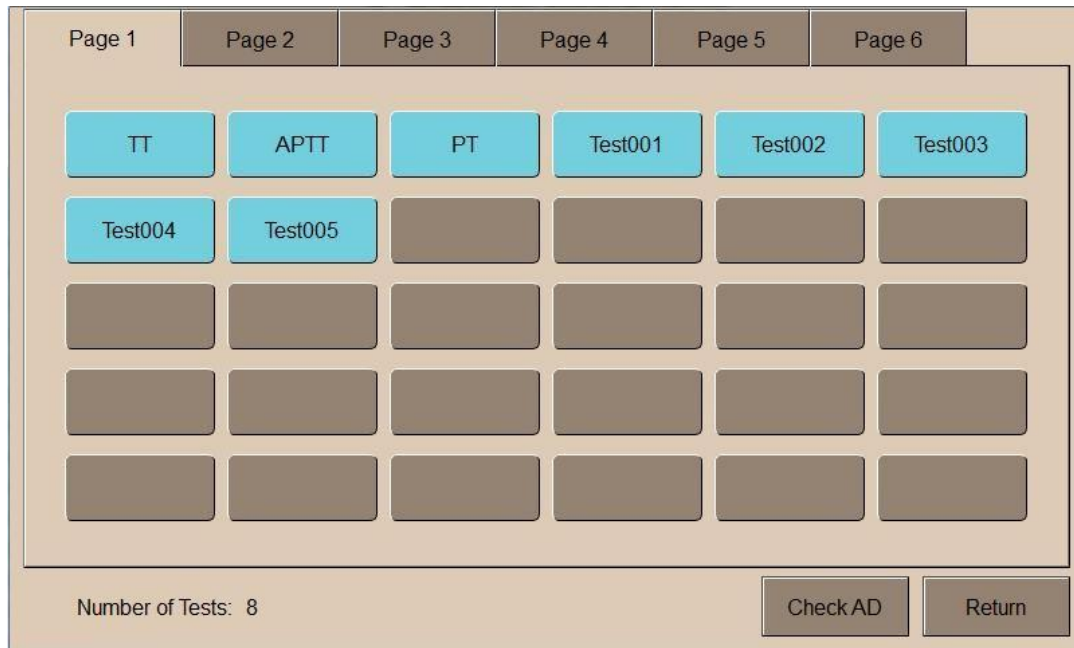
Note

The external USB printer have to support PCL 3 GUL print language, otherwise, it cannot work. If any question, please contact printer manufacture or technical support.

3. SOFTWARE INTRODUCTION

3.1. Test

Click "Test" icon on main screen, the following screen will be displayed:



This screen allows you to choose an assay ready for testing or do AD check.

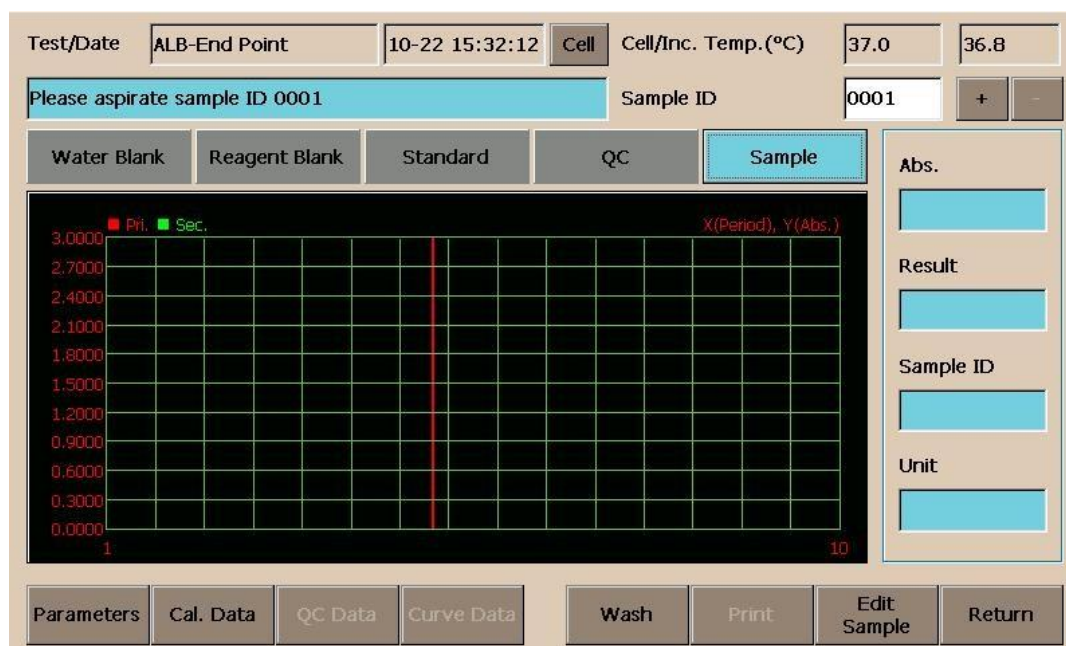
- **Page1-6:** Choose a page then click a test key, machine go to test the selected assay.
- **Number Of Tests:** Display the total number of tests
- **Check AD button:** Click this button to do AD check
- **Return button:** Click this button to return to main screen



Note

System has 6 pages default, include 180 test keys. If the total number of tests was more then 180, the page will be increased automatically.

3.1.1. Clinical Chemistry Assay Test

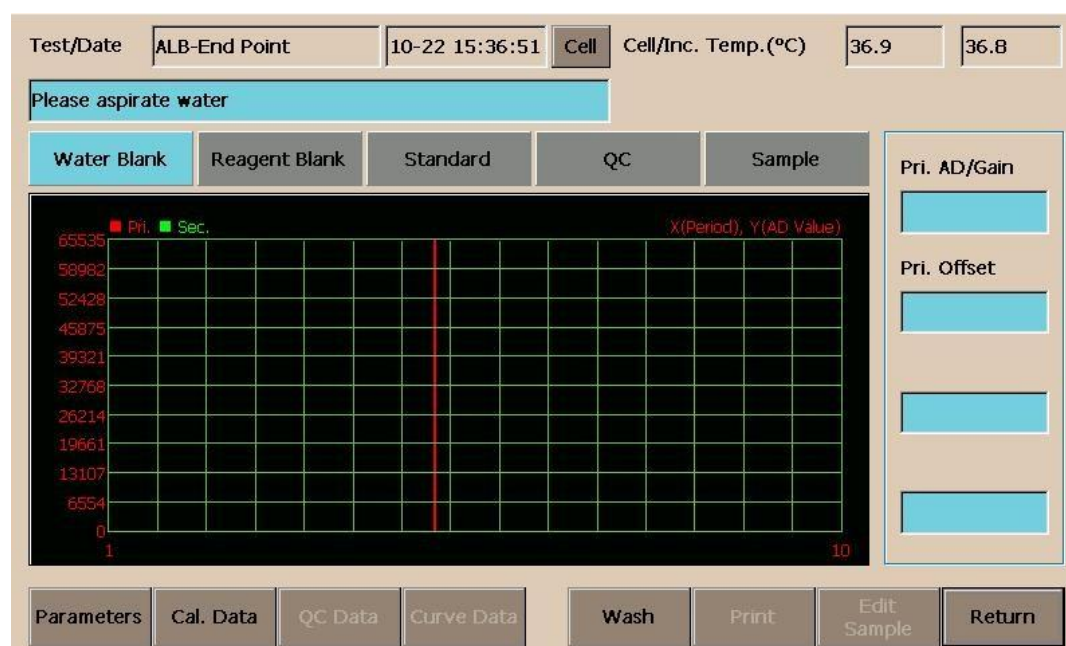


This is test screen, it allows you to do water blank, reagent blank, standard, QC and sample test, display real time reaction curve, temperature and date.

- **Test/Date:** Display the test name and real time date.
- **cell:** Display the colorimetric mode, flow cell mode or cuvette mode.
- **Cell./Inc. Temp.:** Display the real time temperature of flow cell and incubator side.
- **Reaction curve:** machine read one absorbance per second during incubation time and testing time, the absorbance of incubation time shows on the left side of the red line, absorbance of testing time shows on the right side of the red line. the horizontal axis is time, vertical axis is absorbance.
- **Water Blank:** Click this button to start Water Blank testing.
- **Reagent Blank:** Click this button to start Reagent Blank testing.
- **Standard:** Click this button to start Standard solution testing.
- **QC:** Click this button to start QC testing.
- **Sample:** Click this button to start Sample testing.
- **Parameters button:** Click this button to popup Parameters dialog. In this dialog, you can view Reagent settings of current test.
- **Cal. Data button:** Click this button to popup Calibration data dialog. In this dialog, you can view the detail calibration information, reagent blank absorbance, standard absorbance and K value.
- **QC Data button:** Click this button to popup QC data dialog. In this dialog, you can view the detail QC information, target value and SD value.

- **Curve Data button:** Click this button to popup curve data dialog. In this dialog, you can view the detail value(point and absorbance) of current reaction curve.
- **Wash button:** Click this button to wash the flow cell and tube by water.
- **Print button:** Click this button to print current test result.
- **Return button:** Click this button to return to main screen.

3.1.1.1. Water Blank Test



This screen allows you to test AD and Offset value of distilled water, this value will be the zero point of absorbance and be saved.

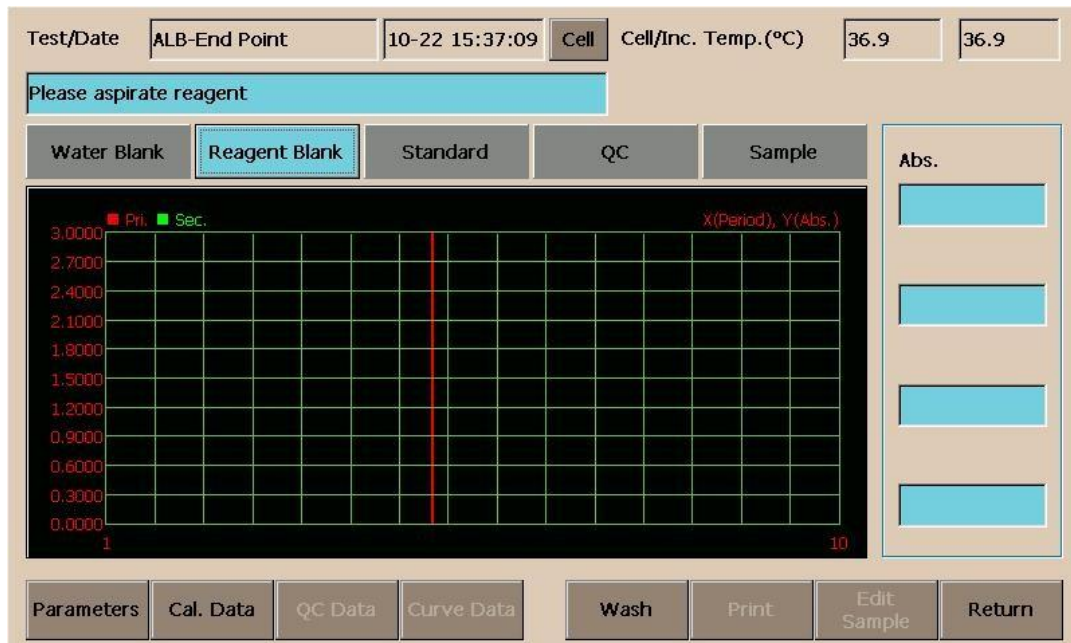
- **Please aspirate water:** Insert aspirate tube into distill water, then press aspirate button to aspirate distilled water, machine start testing AD and Offset value.
- **Pri. AD/Gain:** Display the primary filter AD and Gain value after testing.
- **Pri. Offset:** Display the Primary filter Offset value after testing.



Caution

The normal range of AD value is 35000-59000, Offset value is 0-4000. If out of this range, System will popup warning message when click Reagent, Calibrate, QC and Sample button.

3.1.1.2. Reagent Blank Test



This screen allows you to test reagent blank absorbance which will be deducted when machine calculate results and be saved.

- **Please aspirate reagent:** Insert aspirate tube into reagent, then press aspirate button to aspirate reagent, machine start testing reagent blank absorbance.
- **Abs.:** Display reagent blank absorbance after testing.



Caution

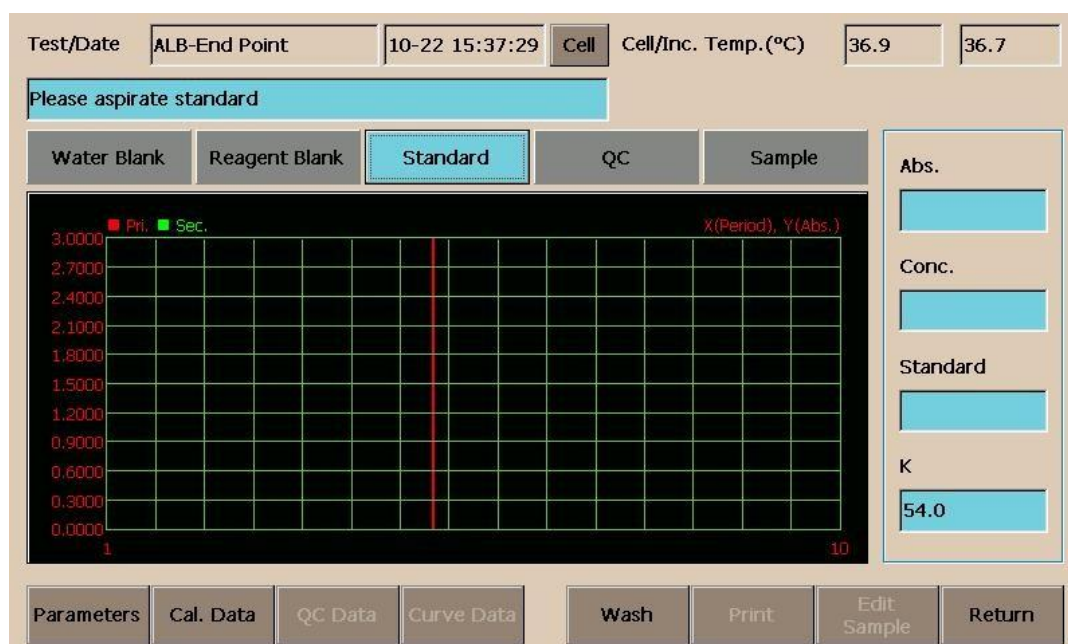
Use new lot number of reagent, it is better to re-check reagent blank. Used reagent blank value will cause test result unreliable.



Note

If on “Reagent setup” dialog box, the “Blank Type(S0)” was water. The reagent blank button is disable.

3.1.1.3. Standard Test



This screen allows you to test standard solution absorbance. If multi-standard calibration, test each standard solution from low concentration to high.

- **Please aspirate standard:** Insert aspirate tube into standard solution, then press aspirate button to aspirate standard, machine start testing standard absorbance.
- **Abs.:** Display standard solution absorbance after testing.
- **Concentration:** Display standard solution concentration after testing.
- **Standard:** Display standard number after testing.
- **K:** Display the K value saved before testing, new K value after testing.



Caution

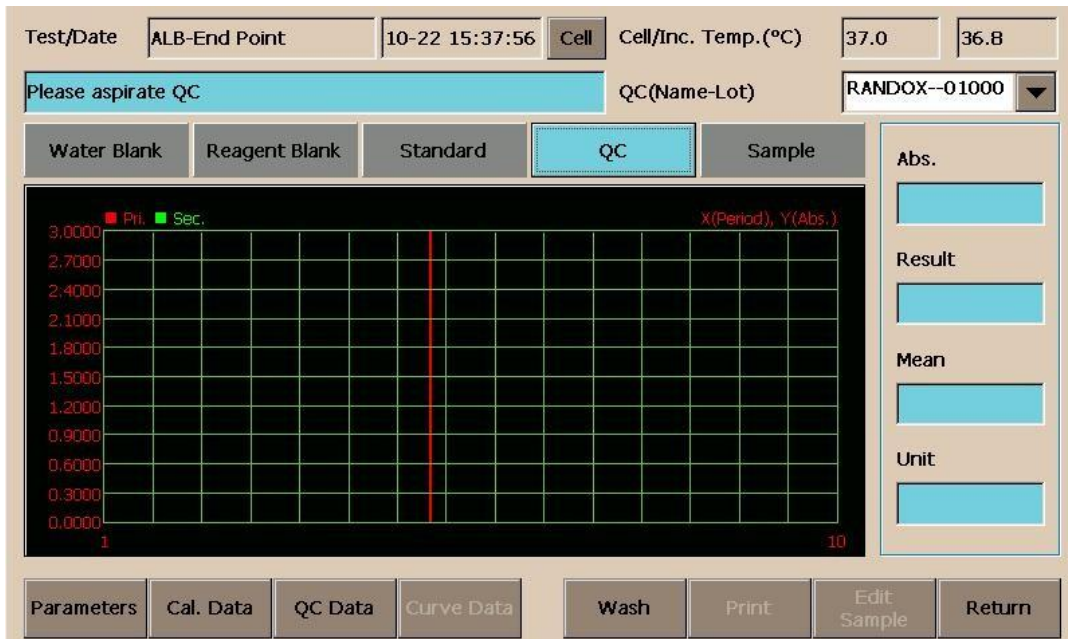
It is recommended that user should do standard test regularly. Wrong standard result or K value will cause test result unreliable.



Note

If on “Reagent setup” dialog, the “Calibrate Type” was 1 Point Linear. This Standard button is disable.

3.1.1.4. QC Test



This screen allows you to test QC absorbance and calculate result(concentration).

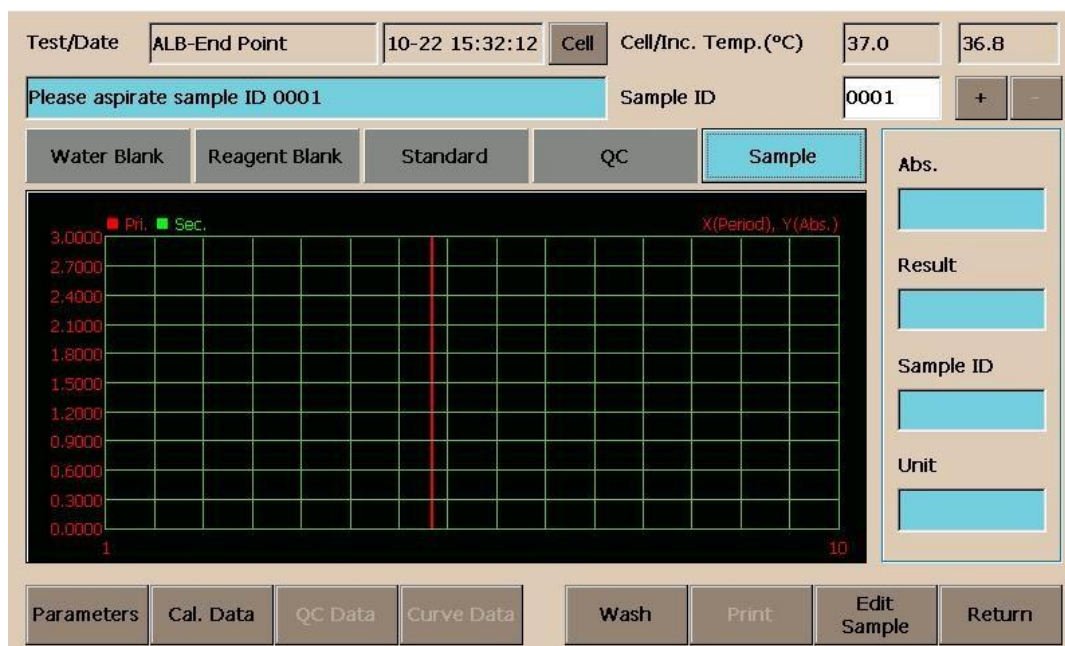
- **QC(Name-Lot):** Select a QC that you want to test.
- **Please aspirate QC:** Insert aspirate tube into QC then press aspirate button to aspirate QC, machine start testing QC absorbance.
- **Abs.:** Display QC absorbance after testing.
- **Result:** Display test result(concentration) after testing.
- **Mean Value:** Display man value of QC after testing.
- **Unit:** Display the unit of test result after testing.



Note

The QC button is disable if there is no QC information on QC setup dialog.

3.1.1.5. Sample Test



This screen allows you to test Sample absorbance and calculate result (concentration).

- **Sample ID:** Input sample ID that you want to test. It can be edit by clicking “+” or “-” button.
- **Please aspirate sample:** Insert aspirate tube into sample, then press aspirate button to aspirate sample, machine start testing sample absorbance.
- **Abs.:** Display sample absorbance after testing.
- **Result:** Display sample result after testing.
- **Sample ID:** Display sample ID of current completed test after testing.
- **Unit:** Display test result unit.
- **Edit Sample button:** Click this button to popup edit sample information dialog, in this dialog, you can edit sample's name, age, doctor...



Caution

- 0001 is the default first sample ID on current day, it can be edited by clicking “+” or “-” button.
- After testing, the sample ID number will be increased 1 automatically.
- Click “Wash” button and aspirate distilled water into flow cell to clean flow cell.
- If current sample result is abnormal. It is recommended to wash flow cell by water before next sample aspiration to prevent carry over.



Caution

It is necessary to wash flow cell immediately when finishing analyzer. The testing solution stay in flow cell long time will decrease the life of flow cell.

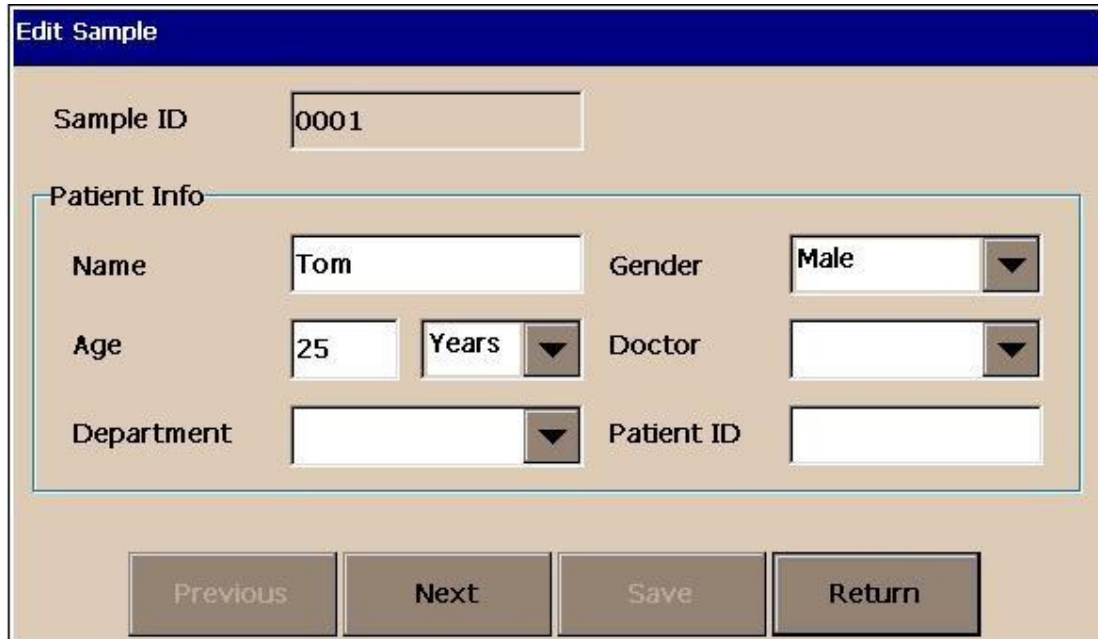
3.2.1.1. Search Sample



This screen allows you to search history samples and results according to search condition inputted.

- **Sample Reg. Date:** Search samples by the date or date range, the default date is 1 month recent.
- **Name:** Search samples by sample name.
- **Doctor:** Search samples by doctor name.
- **Department:** Search samples by department.
- **Confirm button:** Click this button to display the samples and results that matched condition.
- **Return button:** Click this button to return Sample Results screen.

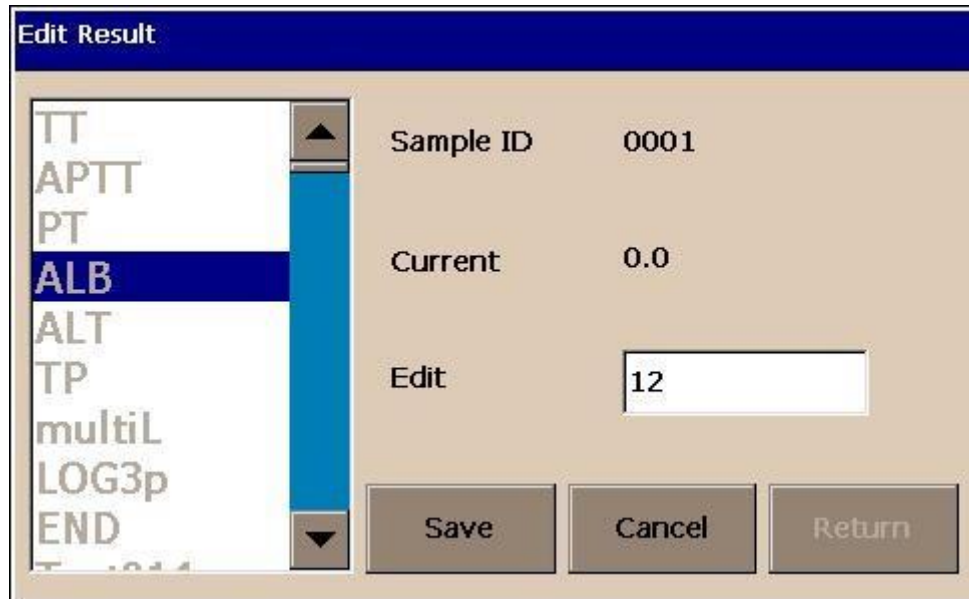
3.2.1.2. Edit Sample



This screen allows you to edit selected sample's information.

- **Sample ID:** Display sample ID for editing.
- **Patient Info:** Input sample's information:
 - **Name:** Input patient name.
 - **Gender:** Click the combo box to choose a gender.
 - **Age:** Input age, then click the combo box to choose age unit.
 - **Doctor:** Click the combo box to choose a doctor or input a new one.
 - **Department:** Select department or input a new one.
 - **Patient ID:** Input a patient ID.
- **Previous button:** Click this button to go to previous sample.
- **Next button:** Click this button to go to next sample.
- **Save button:** Click this button to save sample information.
- **Return button:** Click this button to return to sample results screen.

3.2.1.3. Edit Test Result

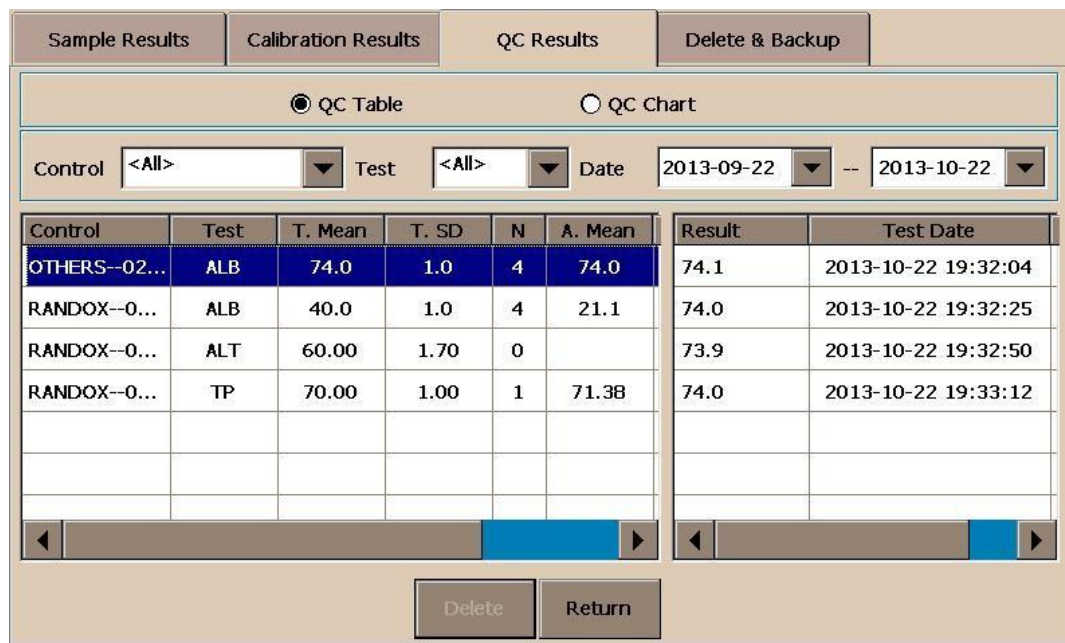


This screen allows you to edit sample test results by manual.

- **Test list:** Select a test that you want to edit it.
- **Sample ID:** Display sample ID that selected.
- **Current:** Display current test result.
- **Edit:** Input test result by manual.
- **Confirm button:** Click this button to update the test result.
- **Return button:** Click this button to return to sample results screen.

3.2.2. QC Results

3.2.2.1. QC Table

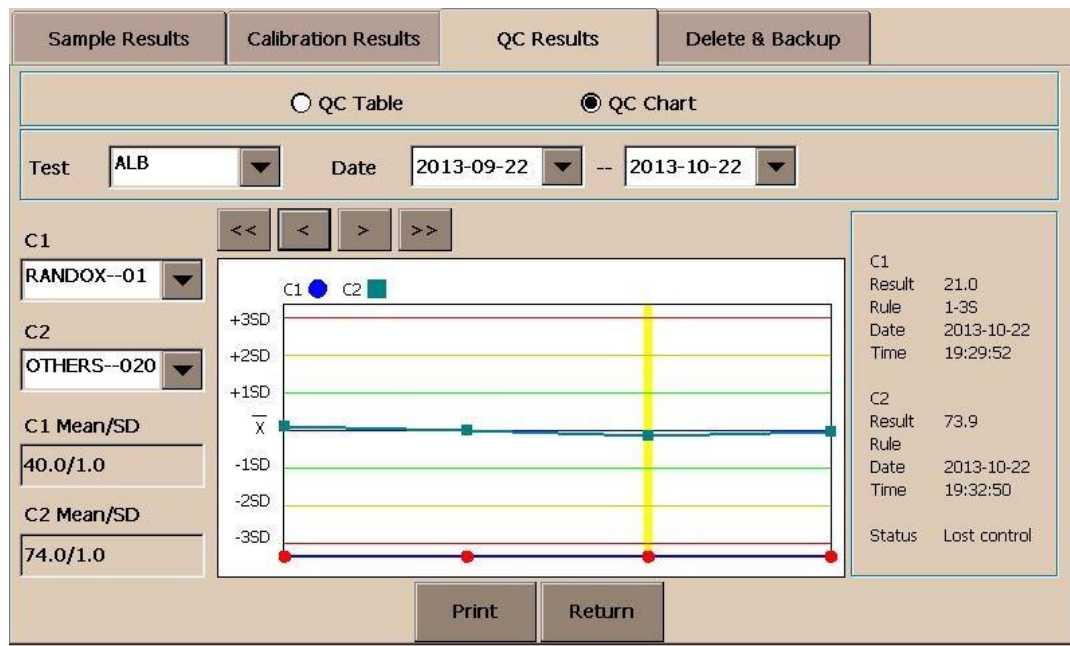


Control	Test	T. Mean	T. SD	N	A. Mean	Result	Test Date
OTHERS--02...	ALB	74.0	1.0	4	74.0	74.1	2013-10-22 19:32:04
RANDOX--0...	ALB	40.0	1.0	4	21.1	74.0	2013-10-22 19:32:25
RANDOX--0...	ALT	60.00	1.70	0		73.9	2013-10-22 19:32:50
RANDOX--0...	TP	70.00	1.00	1	71.38	74.0	2013-10-22 19:33:12

This screen allows you to search QC results.

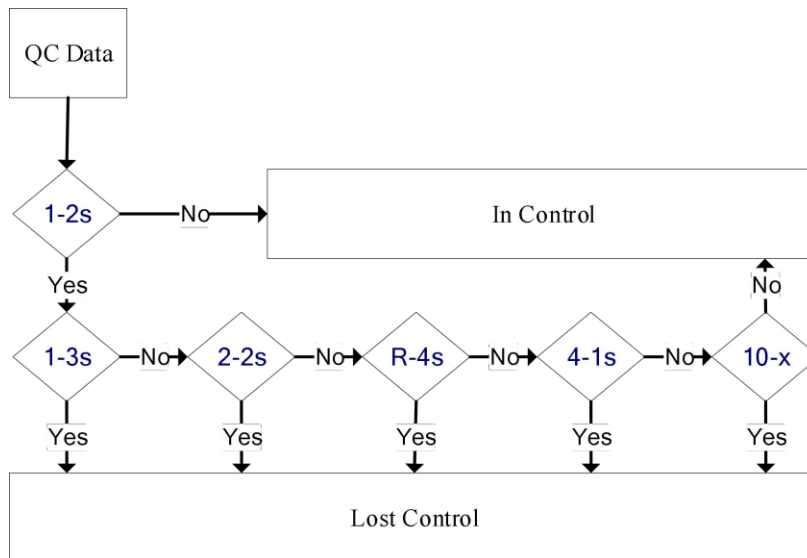
- **Control:** Choose a control that displayed on control list, the default is display all controls.
- **Test:** Choose a test that displayed on test list, the default is display all tests.
- **Date:** Choose a data range, the test results that matched the date will be displayed on result list, the default is 1 month recent.
- **Control list:**
 - **Control:** Display the control that matched control and test combo box.
 - **Test:** Display test of control.
 - **T. Mean:** Display mean value that setup on QC setup dialog.
 - **T. SD:** Display SD value that setup on QC setup dialog.
 - **N:** Display the result number of result list.
 - **A. Mean:** Display the mean value of result list.
 - **A. SD:** Display the SD value of result list.
 - **CV%:** Display the CV value of result list.
- **Result List:**
 - **Result:** Display QC test results that matched the date.
 - **Test Date:** Display the date of QC results.
- **Delete button:** Click this button to delete selected QC result.
- **Return button:** Click this button to return to main screen.

3.2.2.2. QC Chart



This screen allows you to view QC chart, check the QC status, and print the QC chart. The Quality control is according to Westgard multi-rule.

- **Test:** Choose a test.
- **Date:** Choose a date range to view QC chart.
- **C1:** Choose a Control to put on the QC chart.
- **C2:** Choose a Control to put on the QC chart.
- **C1 Mean/SD:** Display C1 Mean and SD value that setup on the QC setup dialog.
- **C2 Mean/SD:** Display C2 Mean and SD value that setup on the QC setup dialog.
- **C1 Result, Rule, Date, Time:** Display the detail information of the result on the QC chart.
- **C2 Result, Rule, Date, Time:** Display the detail information of the result on the QC chart.
- **Status:** Display the QC status, in control, warning, or lost control.
- **Print button:** Click this button to print current QC chart.
- **Return button:** Click this button to return to main screen.



● **Westgard multi-rule QC Conclusion flow**

- **1-2s:** One control result exceeds ± 2 standard deviations.
- **1-3s:** One control result exceeds ± 3 standard deviations.
- **2-2s:** Two consecutive control results exceeds ± 2 standard deviations.
- **R-4s:** The difference between two consecutive control results exceeds 4 standard deviations.
- **4-1s:** For consecutive control results for one level exceed ± 1 standard deviations.
- **10-x:** Ten consecutive control results for one level lie on one side of the mean.

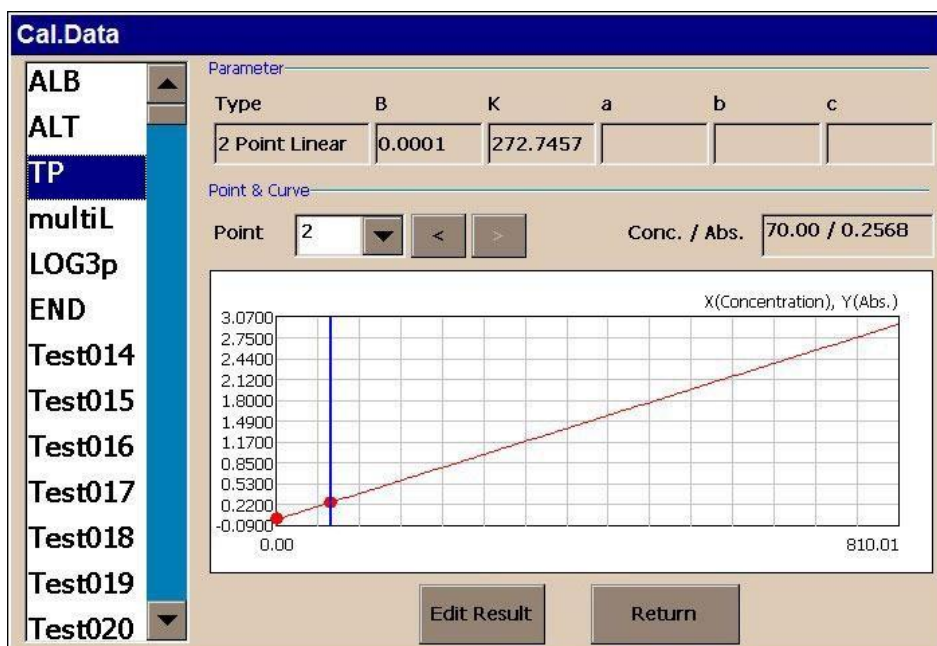
3.2.3. Calibration Results

Sample Results		Calibration Results		QC Results		Delete & Backup	
Test	B	K	a	b	c	Calibration Type	
ALB	0.0197	189.0000				2 Point Linear	
ALT	0.0000	1746.0000				1 Point Linear	
TP	0.0001	272.7457				2 Point Linear	
multiL	0.0075	6.05E-008	12.8794	-3.7202	0.3723	Exponential	
LOG3p	64213.5076	-64213.5306	2.78E-007			Logit-Log 3P	
END	0.0000	1.0000				1 Point Linear	
Test014	0.0000	1.0000				1 Point Linear	
Test015	0.0000	1.0000				1 Point Linear	
Test016	0.0000	1.0000				1 Point Linear	
Test017	0.0000	1.0000				1 Point Linear	

This screen displays the calibration parameters of each test.

- **Cal. Data button:** Click this button to popup calibration data dialog. In this dialog, you can view the detail calibration parameters and curve of selected test.
- **Cal. Trace:** Click this button to popup calibration trace dialog. In this dialog, you can view the history absorbance of reagent blank and each standard of selected test.

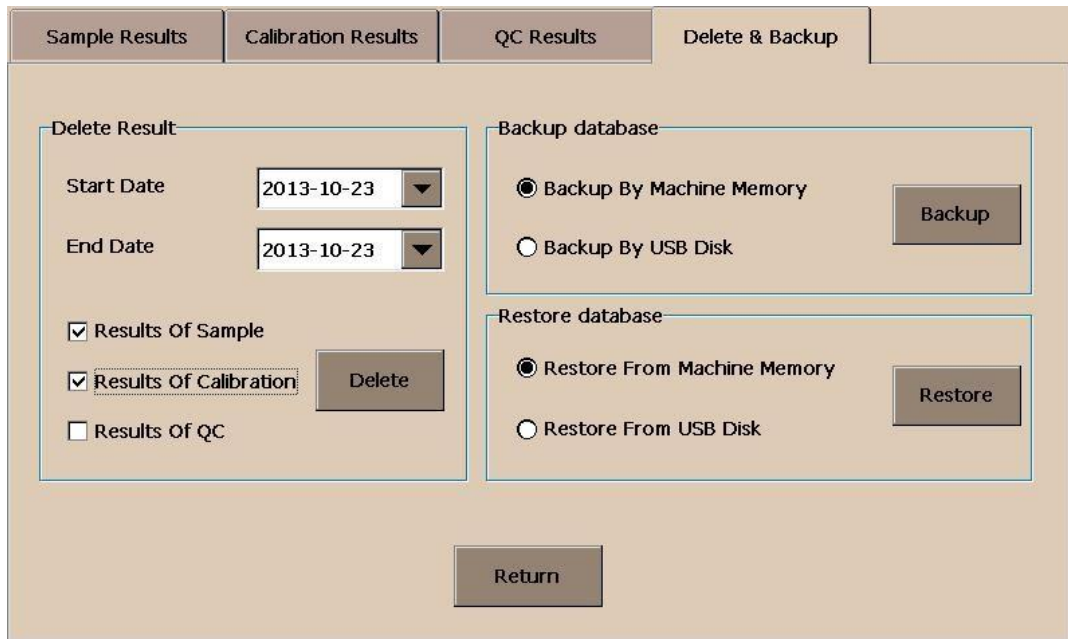
- Calibration Data



This screen allows you to view the detail calibration parameters and curve of selected test, and the absorbance of blank and each standard.

- **Type:** Display the calibration type.
- **B:** For 1 point linear and 2 point linear. If the Blank type (S0) is Reagent, it is the Reagent blank absorbance. If the Blank type (S0) is water, it is zero. For other calibration type, it is a parameters computed automatically of calibration curve.
- **K:** For 1 point linear, it is the K factor that inputted on Reagent Setup dialog. For 2 point linear, it is the K factor that computed automatically after calibration. For other calibration type, it is a parameters calculated automatically of calibration curve.
- **a, b, c:** It is the parameters calculated automatically of calibration curve, and it is only for non-linear calibration type.
- **Point:** Choose a standard, and it's concentration and absorbance displayed on the right.
- **Conc./Abs.:** Display the concentration and absorbance of selected standard on the left.
- **Edit Result:** Click this button to pop up Edit Result dialog. In this dialog, you can input standard absorbance value, the system will calculate calibration curve automatically.
- **Return button:** Click this button to return Calibration results screen.
- For more details about B, K, a, b, c, please refer to appendix 2 calibration type.

3.2.4. Delete & Backup



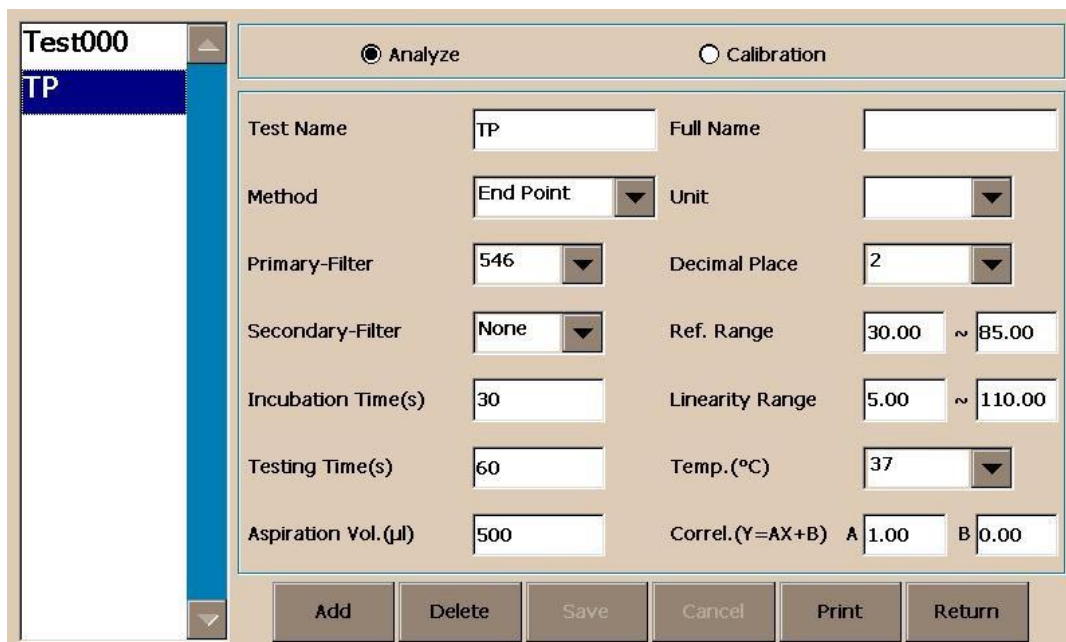
This screen allows you to delete history result, backup and restore the database.

- **Delete Result:**
 - **Start Date:** Choose a start date to delete result by clicking delete button.
 - **End Date:** Choose a end date to delete result by clicking delete button.
 - **Results of Sample:** Choose to delete results of sample or not by clicking delete button.
 - **Results of calibration:** Choose to delete results of calibration or by clicking delete button.
 - **Results of QC:** Choose to delete results of QC or not by clicking delete button.
- **Backup database:**
 - **Backup By Machine Memory:** Choose this radio button to backup the current database in machine memory by clicking backup button.
 - **Backup by USB Disk:** Choose this radio button to backup the current database in external USB disk by clicking backup button.
- **Restore database**
 - **Restore From Machine Memory:** Choose this radio button to restore database form machine memory by clicking restore button.
 - **Restore From USB Disk:** Choose this radio button to restore database form USB disk by clicking restore button.

3.3. Reagent Setup

3.3.1. Clinical Chemistry Assay Setup

Click Reagent Setup icon on main screen, the following dialog will be displayed:



- **Analyze:** Click this button to set the analysis parameters
 - **Test Name:** Input test code. Null code unaccepted.
 - **Full Name:** Input full name of the test. It can be void.
 - **Method:** Choose method. Including End point, Fixed-Time, Kinetics, 2 point end and Turbidity.
 - **Unit:** Choose or input result unit. You can define more options on “System Setup/Dictionary” screen.
 - **Primary-Filter:** Choose Primary wavelength to be used on the test.
 - **Decimal Place:** Choose decimal place of result(0-4).
 - **Secondary-Filter:** Choose Secondary wavelength to be used on the test. It is for End point method only, and must not be same with the main-filter.
 - **Ref. Range:** Input reference range. If the test result is out of this range, the results will be flagged with "H" or "L"
 - **Incubation Time(s):** Input incubation time (1-999 Sec).
 - **Linearity Range:** Input linearity range. If the test result is out of this range, the results will be flagged with "LINH" or "LINL"
 - **Testing Time(s):** Input testing time (1-999 Sec).



Caution

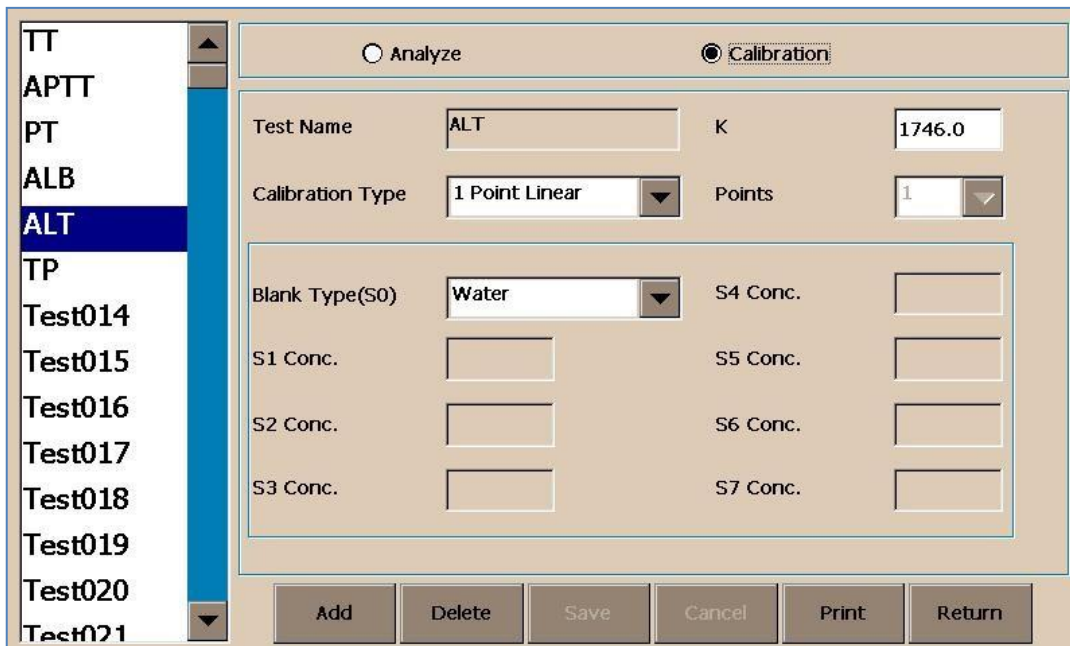
1. End point assay

Mix reagent and sample first, then put test tube or other container into incubator, when incubation time is finish, take out test tube out and aspirate into flow cell. Usually, Incubation time 3-5 sec and Testing time 3-5 sec.

2. Kinetics assay and Fixed time assay

Above 2 method, incubation time is short normally as 60 sec. It is recommended to aspirate sample solution after mixing reagent and serum, it is not necessary to put into external incubator. Incubation time set up 60 sec, and testing time set up 30 sec or 60 sec.

- **Temp.(°C):** Choose reaction temperature. Including 25 °C, 30 °C, 37 °C and room temperature. The default is 37 °C.
- **Aspiration Vol.(ul):** Input aspirate volume. The default value is 500ul.
- **Calibration:** Click this button to set the calibration parameters.



TT	<input type="radio"/> Analyze	<input checked="" type="radio"/> Calibration
APTT	Test Name: ALT	K: 1746.0
PT	Calibration Type: 1 Point Linear	Points: 1
ALB	Blank Type(S0): Water	S4 Conc.: <input type="text"/>
ALT	S1 Conc.: <input type="text"/>	S5 Conc.: <input type="text"/>
TP	S2 Conc.: <input type="text"/>	S6 Conc.: <input type="text"/>
Test014	S3 Conc.: <input type="text"/>	S7 Conc.: <input type="text"/>
Test015		
Test016		
Test017		
Test018		
Test019		
Test020		
Test021		

- **Test Name:** Display test code.
- **K:** Input K value of the test.
- **Calibration Type:** Click this combo box to Choose calibration type.
- **Points:** Click this combo box to choose number of standard points.
- **Blank Type(S0):** Click this combo box to choose the blank type including Water, Reagent.
- **S1-S7 Conc.:** Set the concentration of standard 1 to standard 7.

- **Add button:** Click this button to add a new test.
 - **Save button:** Click this button to save configuration.
 - **Cancel button:** Click this button to cancel changes.
 - **Delete button:** Click this button to delete a selected test.
 - **Print button:** Click this button to print selected test parameters.
 - **Cancel button:** Click this button to cancel editing test parameters.
 - **Return button:** Click this button to return to main screen.
-



Caution

Reagent parameters setup, please refer to instruction of reagent and do it step by step, Semi-auto chemistry analyzer is different with auto chemistry analyzer, many prepare works should be finished by manual. If you have any questions, please contact technical support.

3.4. QC Setup

Click QC setup icon on main screen, the following dialog will be displayed:

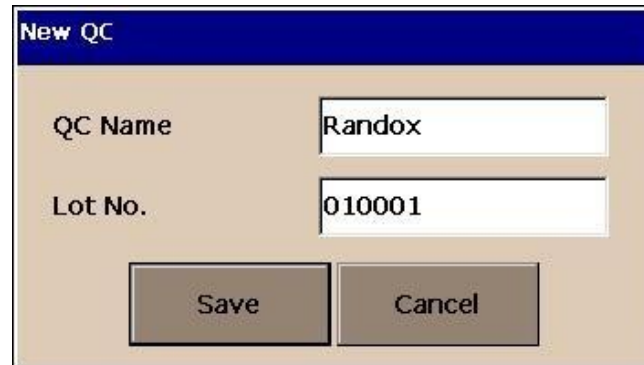
QC List		Test List		
QC Name	Lot No.	Test Name	SD	Mean
RANDOX	010001	ALB	1.0	40.0
OTHERS	020001	TP	1.00	70.00
		ALT	1.70	60.00

New QC	Edit QC	Delete QC	New Test	Edit Test	Delete Test	Return
--------	---------	-----------	----------	-----------	-------------	--------

This screen allows you to setup QC information and QC test information. Setup the Mean and SD value for QC results processing.

- **New QC button:** Click this button to popup ADD QC dialog box. In this dialog, you can add a new QC on QC List.
- **Edit QC button:** Select a QC from QC List, then click this button to popup Edit QC dialog box. In this dialog, you can edit the selected QC name and lot number.
- **Delete QC button:** Click this button to delete a selected QC from QC list.
- **New Test button:** Select a QC, then click this button to popup ADD test dialog box. In this dialog, you can add a new test on Test List.
- **Edit Test button:** Select a Test from Test List, then click this button to popup Edit Test dialog box. In this dialog, you can edit the SD and mean value.
- **Delete Test button:** Click this button to delete a selected QC test item from Test List.
- **Return button:** Click this button to return to main screen.

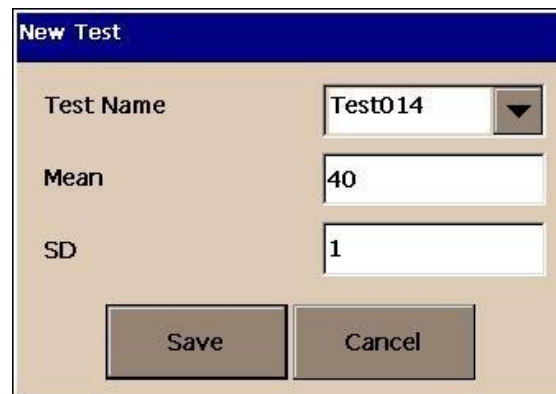
3.4.1. Add QC



This screen allows you to add a new QC to QC list.

- **QC name:** Input QC name
- **Lot No.:** Input QC lot number.
- **Save button:** Click this button to save the name and lot number.
- **Cancel button:** Click this button to return QC setup dialog box.

3.4.2. Add QC Test Item



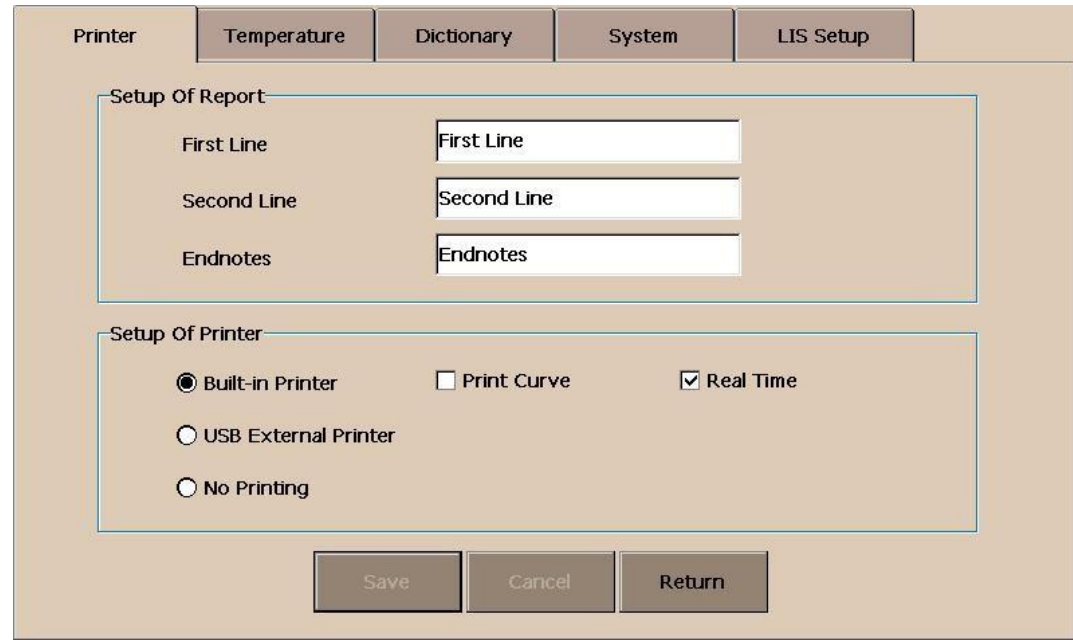
This screen allows you to add a new QC test and Mean, SD value on test list.

- **Test Name:** Choose a test.
- **Mean:** Input target value.
- **SD:** Input SD value.
- **Save button:** Click this button to save configuration
- **Cancel button:** Click this button to return QC settings screen.

3.5. System Setup

Click System setup icon on main screen, the following dialog will be displayed:

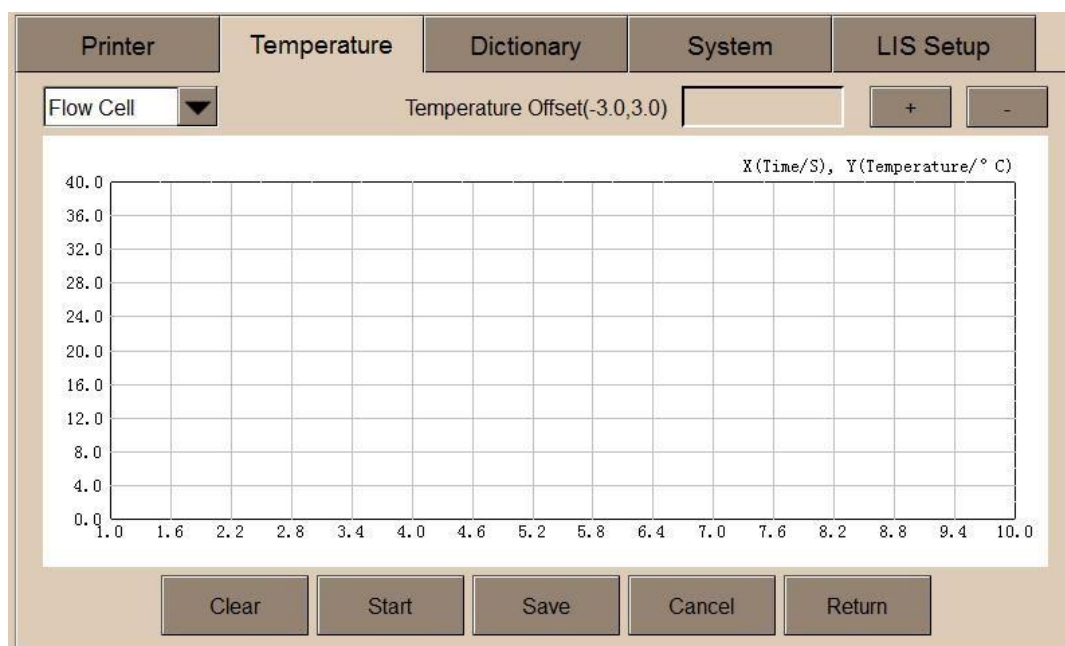
3.5.1. Printer



This screen allows you to set report header, and to choose inner or outer USB printer.

- **Setup Of Report:**
 - **First Line:** Input first line of the print report title.
 - **Second Line:** Input second line of the print report title.
 - **Endnotes:** Input the print report endnotes.
- **Setup Of Printer:**
 - **Build-in Printer:** Click this radio button to choose inner printer.
 - ◆ **Print Curve:** Auto print reaction curve with results or not
 - ◆ **Real Time:** Auto print test result or not after testing.
 - **USB External Printer:** Click this button to choose external USB printer.
 - **No Printing:** Click this radio button to choose no printer, print nothing.
- **Save button:** Click this button to save current configurations.
- **Cancel button:** Click this button to cancel the changes.
- **Return button:** Click this button to return to main screen.

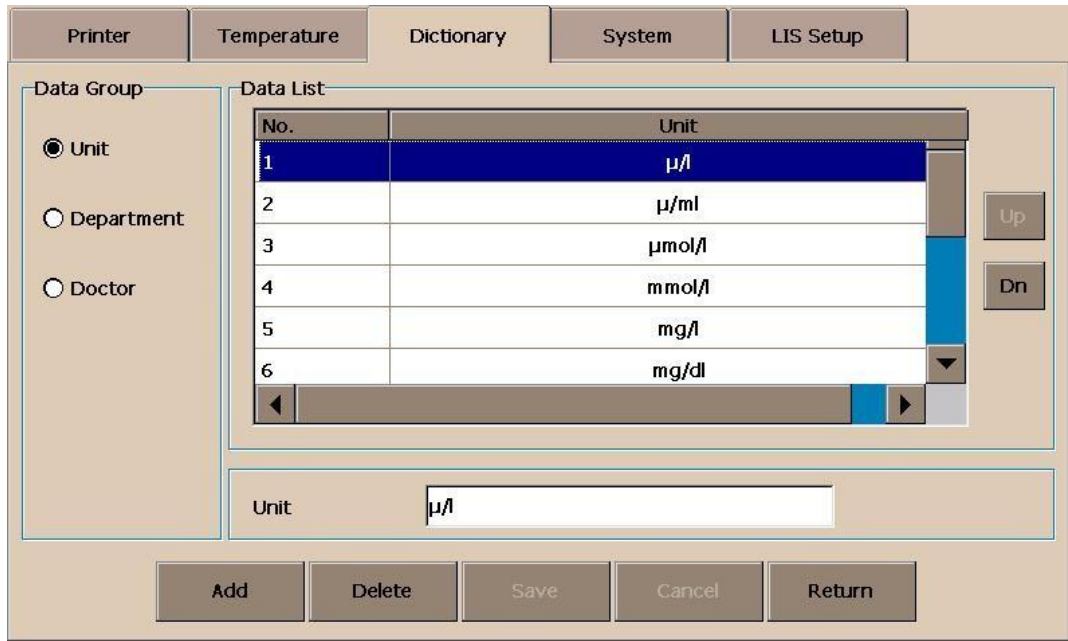
3.5.2. Temperature



This screen allows you to calibrate the temperature of flow cell and incubator.

- **Flow Cell:** Select flow cell or incubator to calibrate its temperature.
- **Temperature Offset(-3.0, 3.0):** Click “+” or “-” button to input the temperature offset value. The range of temperature offset is -3.0 - 3.0.
- **Clear button:** Click this button to clear real-time temperature curve of flow cell.
- **Start button:** Click this button to display real-time temperature curve of flow cell.
- **Save button:** Click this button to save the temperature offset.
- **Cancel button:** Click this button to cancel the changes.
- **Return button:** Click this button to return to main screen.

3.5.3. Dictionary



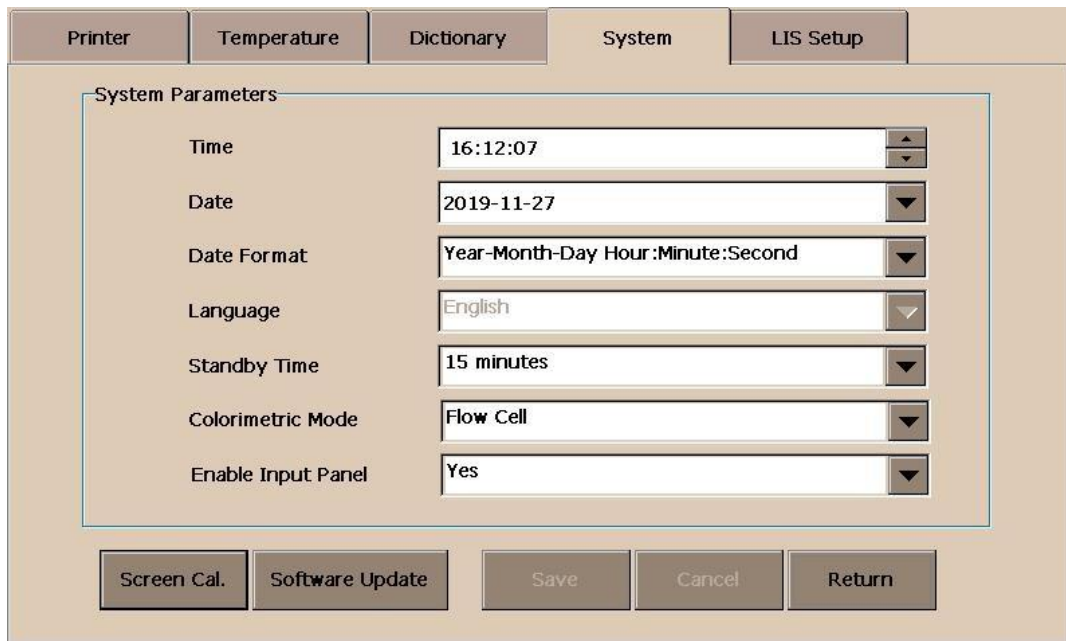
No.	Unit
1	μ/l
2	μ/ml
3	μmol/l
4	mmol/l
5	mg/l
6	mg/dl

Unit:

This screen allows you to set the content of combo Box.

- **Unit:** Set up unit list.
- **Department:** Set up department list.
- **Doctor:** Set up doctor list.
- **Add button:** Click this button to add a new item in the list.
- **Delete button:** Click this button to delete a selected item from the list.
- **Up button:** Click this button to move up the selected item.
- **Dn button:** Click this button to move down the selected item.
- **Save button:** Click this button to save current configurations.
- **Cancel button:** Click this button to cancel the changes.
- **Return button:** Click this button to return to main screen.

3.5.4. System



This screen allows you to set system parameters, to do touch screen calibration and to update software.

- **Time:** Input or click combo box to set up time.
- **Date:** Input or click combo box to set up date.
- **Date Format:** Click this combo box to choose date format.
- **Language:** Click this combo box to choose language.
- **Standby Time:** Click this combo box to choose sleep time. Machine will auto change to standby status while you don't use it.

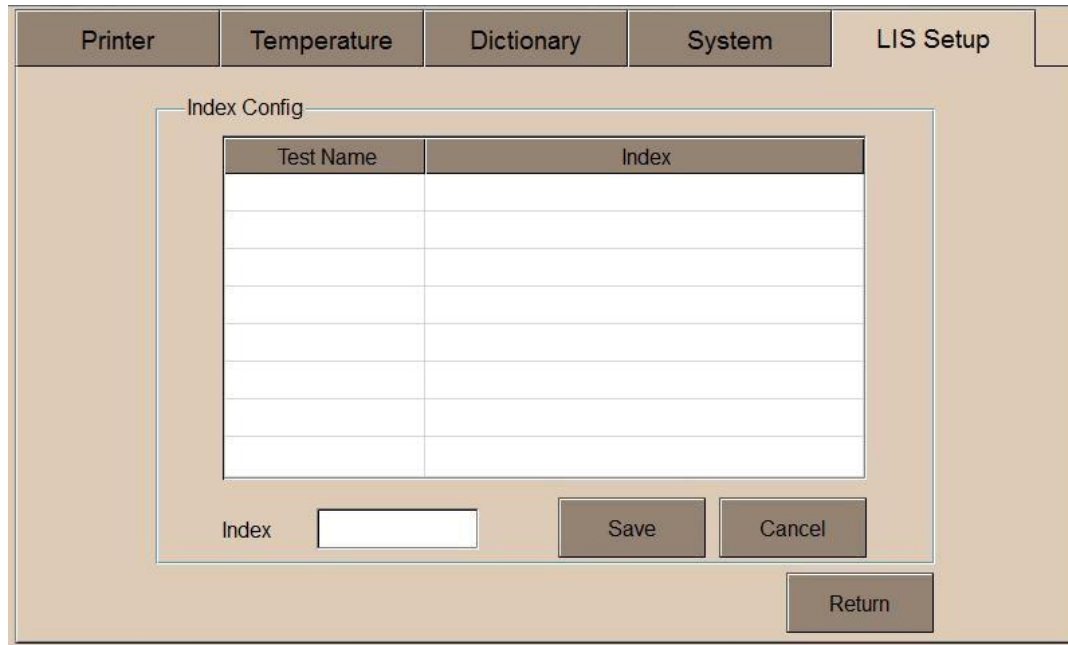
Note

Device goes to sleep will shut down the lamp for protection. Touch the screen, move external USB mouse or click USB keyboard will wake up the device and lamp; it is recommended to do analyze after 1 minute for lamp stability.

- **Colorimetric mode:** Click this combo box to choose flow cell mode or cuvette mode.
- **Enable Input panel:** Click this combo box to choose yes or no. If no, the input panel cannot be popped up automatically, you should use external USB keyboard for inputting.
- **Screen Cal. button:** Click this button to do touch screen calibration.
- **Software Update button:** Click this button to do software updating.

- **Save button:** Click this button to save system parameters.
- **Cancel button:** Click this button to cancel changes
- **Return button:** Click this button to return main screen.

3.5.5. LIS Setup



Test Name	Index

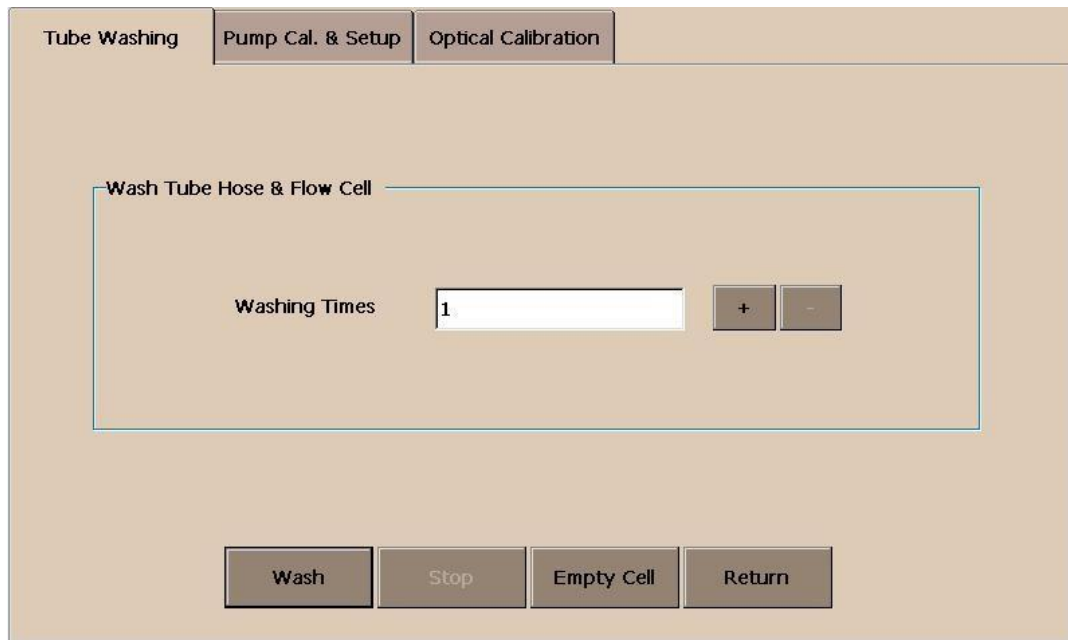
This screen allows you to set the index configuration of LIS.

- **Index:** Input a index value.
- **Save button:** Click this button to save index configurations.
- **Cancel button:** Click this button to cancel changes.
- **Return button:** Click this button to return main screen.

3.6. Maintenance

Click t Maintenance icon on main screen, the fowling dialog will be displayed:

3.6.1. Tube Washing



This screen allows you to wash tube and flow cell by water or detergent after working.

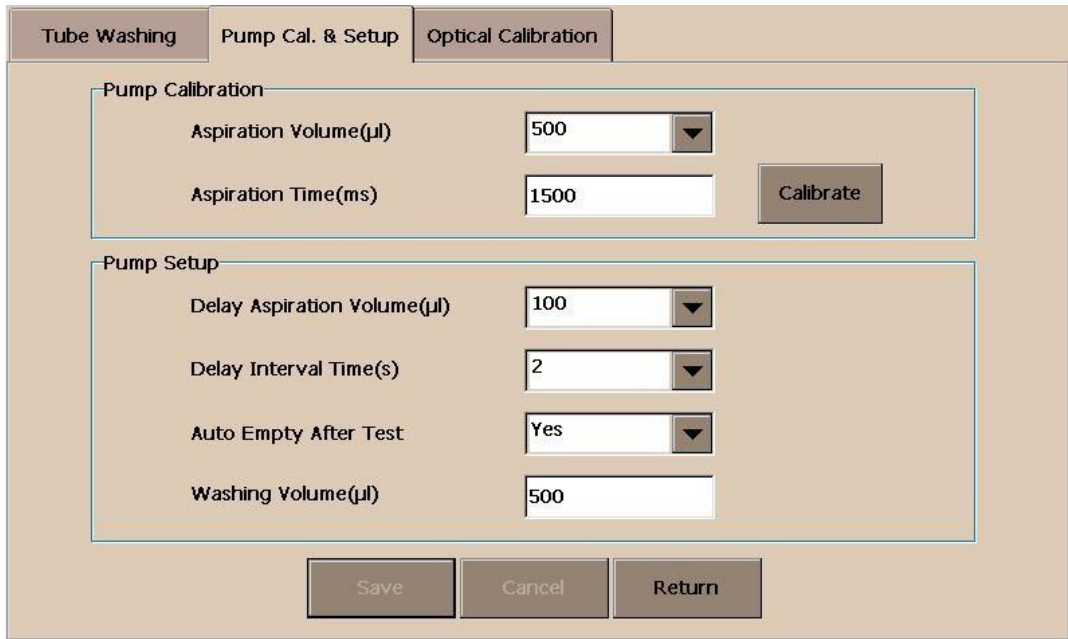
- **Washing times:** Use the +, - button to input washing times. The range is 1-10 times.
- **Wash button:** Click this button to wash flow cell and tube.
- **Stop button:** Click this button to stop washing immediately.
- **Empty cell button:** Click this button to empty flow cell by aspirating air.
- **Return button:** Click this button to return main screen.



Note

please click “Empty cell” button after washing flow cell and tubing hose, in order to move out water residues stay in the tubing system.

3.6.2. Pump Calibration



This screen allows you to calibrate aspiration time and setup pump.

- **Aspiration volume(ul):** Click this combo box to choose aspiration volume that for calibration.
- **Aspiration Time(ms):** Input aspiration time. It is recommended to click "Calibrate" button to calibrate the time.
- **Calibrate button:** Click this button to popup calibration dialog prepare for calibration. See next page.
- **Delay Aspiration Volume(ul):** Click this button to choose delay volume for aspiration.

It means pump will stop a short while(2 seconds and can be changed in Delay Interval Time box) and continue aspirate 100ul (as above figure shows) solutions which stay in the tube hose into flow cell. The purpose is to flush previous residuals, decrease carry over.

- **Delay Interval Time:** Choose a delay time that pump start aspirating the delay volume.
- **Auto Empty After Test:** Choose Yes or No, it means automatically empty the liquid stay in flow cell after testing.
- **Save button:** Click this button to save current configurations.
- **Cancel button:** Click this button to cancel the changes.
- **Return button:** Click this button to return to main screen.

Pump Calibration

New Aspiration Time(ms)

Pump Calibration Method

Pump Calibration Steps:

- 1.Pipette 500ul(1000ul;1500ul optional)water into cuvette
- 2.Push "Aspirate" button, Pump will start to aspirate water into flowcell
- 3.Watching up cuvette...
- 4.Push "Aspirate" button again to stop aspirating (the water in the cuvette almost finish)

Warning: No air bubble pump into flowcell;otherwise, Please re-calibrate again!

This screen allows you to do pump calibration after clicking “Calibrate” button.

Calibration steps:

- Please prepare a test tube.
- Drop distilled water (according to “aspiration volume” set) into test tube by using aspirate tube
- Click aspiration button, machine will auto aspirate water, when you find water in test tube almost finish, please click aspiration button again, pump will stop and auto remember aspiration time.
- Click “Confirm” button to save the aspiration time. Click “Return” button to return without saving.



Caution

- No aspiration air into aspiration tube, otherwise, recalibrate.
- Usually, manufacture setup everything well before shipping, but after use machine for a while, user should understand how to do pump calibration.
- Pump calibration purpose is that:
In order to use enough reagent and sample solution to flush previous residuals, and make sure get good results.

3.6.3. Optical Calibration

Filter	AD	Gain	Offset	New AD	New Gain	New Offset
340	49907	11	25			
405	50495	11	25			
450	49270	14	31			
505	48590	6	16			
546	49473	3	10			
578	49053	17	36			
630	50575	11	25			

Attention
 The red row means optical parameters are out of normal range.
 Normal range: 1. AD [35000, 59000] 2. offset [0, 4000].

Calibrate Stop Wash Save Cancel Return

This screen allows you to calibrate optical signal for all filters.

- **Calibrate button:** Click this button to popup a dialog box, prepare for calibration.
 Insert aspiration tube into water(at least 500ul) and then press aspiration button, Instrument will read all filters AD and Offset value automatically.
- **Stop button:** Click this button to stop optical calibration immediately.
- **Save button:** Click this button to save new AD value after automatically calibration.
- **Cancel button:** Click this button to cancel the changes.
- **Return button:** Click this button to return to main screen.
- **Wash button:** Click this button to wash flow cell and tube by water.



Caution

- The AD value of each filter should be within 35000-59000, and Offset value should be 0-4000, if this value are always out of range, please contact technical support.

3.7. Power Management

Click Power Management icon on main screen, there are three icons will be displayed:

- **Shut down icon:** Click this button to shut down software, and then switch off the power switch.
- **Standby icon:** Click this button to run standby mode, and lamp was off in this mode.
- **Return icon:** Click this button to return to main screen.



Note

Device goes to standby will shut down the lamp for protection. Touch the screen, move external USB mouse or click USB keyboard will wake up the device and lamp. It is recommended to do analyze after 90 seconds for lamp stability.

4. SERVICE AND MAINTENANCE

4.1. Wash Flow Cell

Please obey following maintenance steps.

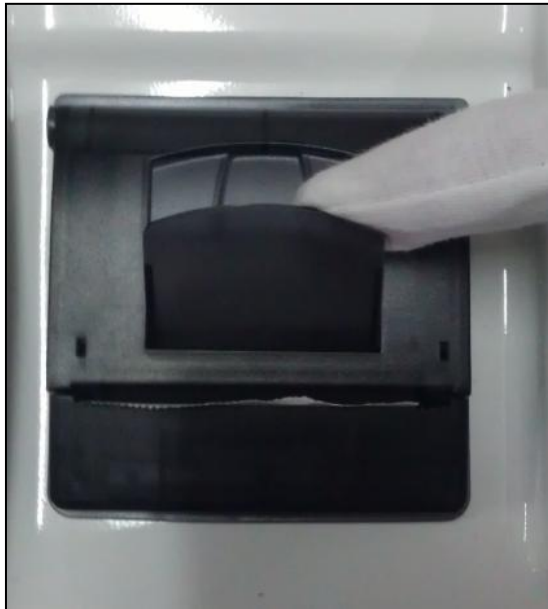


Caution

- Before the instrument works, flow cell should be washed with distilled water.
 - At the end of each working session, flow cell should be washed with distilled water immediately in order to clean peristaltic pump and remove dirt and solution sedimentation outside flow cell. Use the wash button and distilled water for this purpose.
 - After users finish a week's work. Use distilled water to wash flow cell, then clean it with sodium hypochloride or detergent. Allow the detergent to remain in flow cell for about 1-5 minutes, then empty, finally wash repeatedly with distilled water. Ensure thorough cleaning of the detergent.
 - It is not good to remain any liquid in the flow cell for long time, please wash by aspirating air to move any liquid out of flow cell.
-

4.2. Printer Paper Installation

If select inner printer on “Printer” dialog, it is necessary to install thermal printer paper, otherwise, program will alarm when printer working.



Installation steps:

- Open the printer cover like the above figure shows.
- Put the thermal paper into Printer paper slot, the carbon membrane layer of thermal paper should be direction down.
- Close the printer cover



Caution

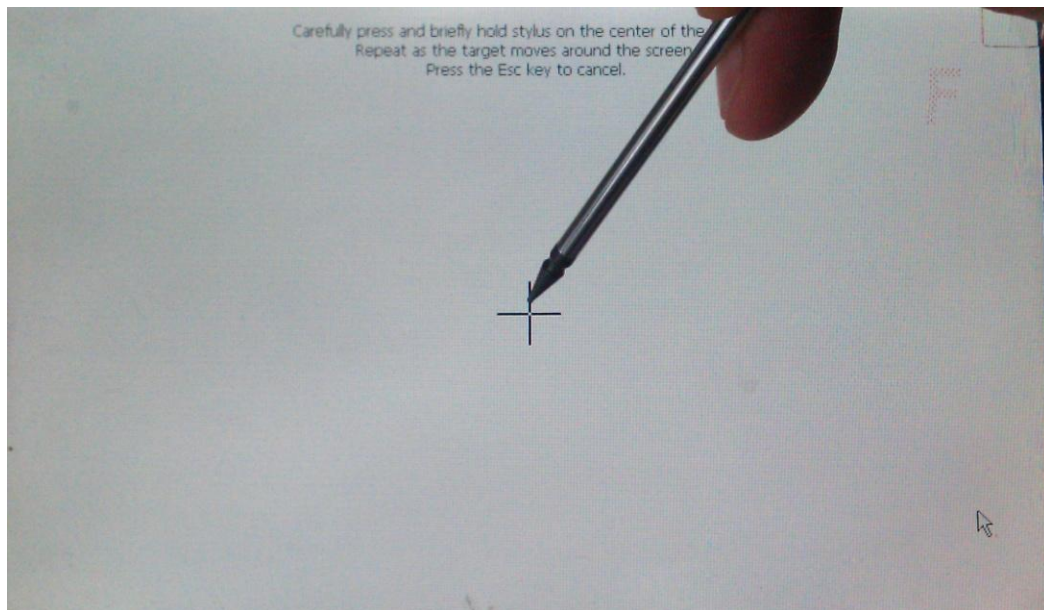
Please pay attention to the direction of print paper, if the direction is wrong, there is nothing on paper when printer working.

4.3. Touch Screen Calibration

Usually, Touch screen has been calibrated before shipping to Customer, but it need to re-calibrate when you change main board or upgrade software.

Below illustration will indicate you how to do re-calibration of touch screen.

Click " **System Setup→System→ScreenCal.**", machine will popup below dialog:



Please use touch pen to point onto the centre of the cross. Repeat it 5 times until the cross disappeared.



When touch screen lose its effectiveness, please use external USB mouse to enter above dialog box.

4.4. Pump Cassette Replacement

If there are something wrong about aspiration, maybe the pump cassette need to be changed.



Press the clip and take out the pump cassette from motor, and the replace a new one.

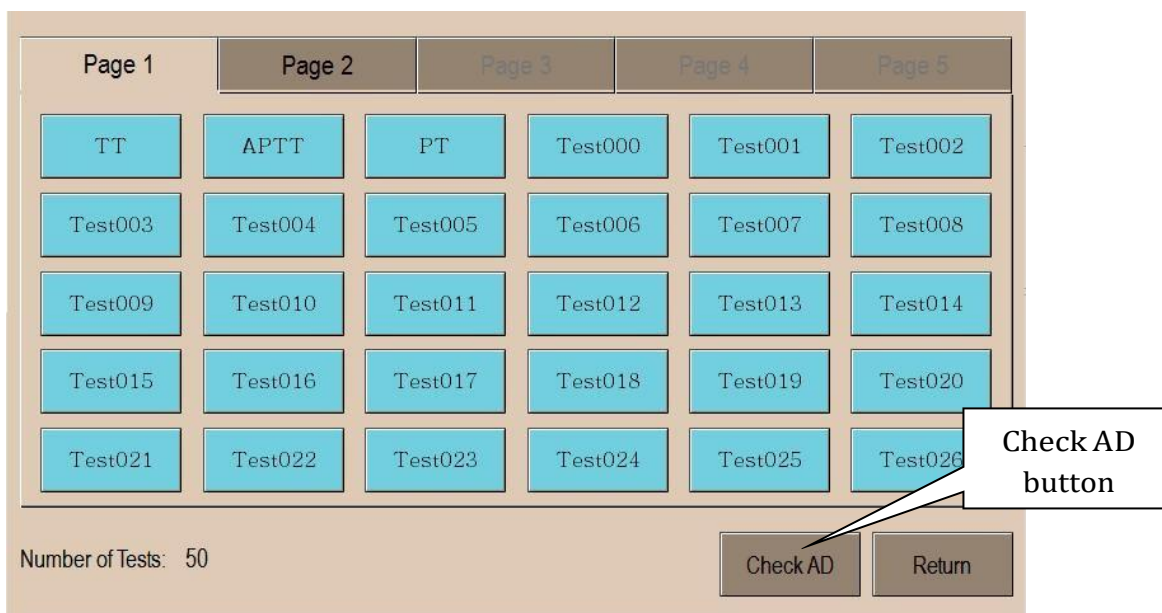


Biohazard

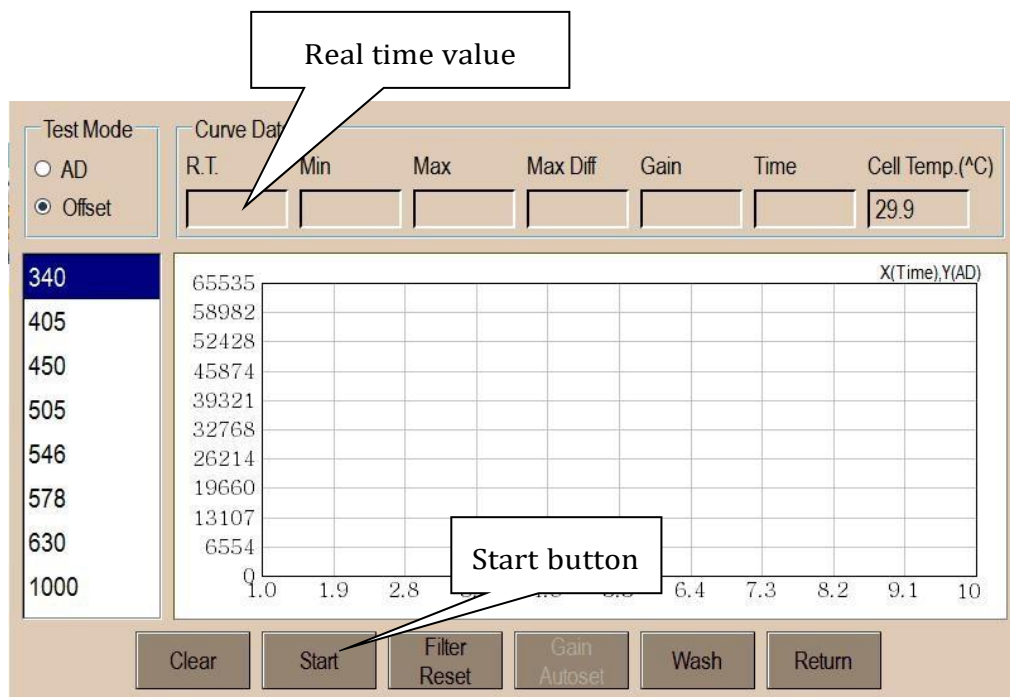
- Inappropriately handling waste solution may lead to biohazardous infection. Do not touch the waste solution with your hands. Wear gloves and lab coat, and goggles if necessary.
 - In case your skin contacts the waste solution, follow standard laboratory safety procedure and consult a doctor.
-

4.5. Offset value adjust

If the mainboard is broken, the engineer needs to replace it by the new one. After the engineer install the mainboard in the machine, there is some work to adjust



- Step4: Click the start button, the offset value will be shown in the graph and the current offset value will be shown in the text box: R.T.
- Step5: Adjust the offset value between 10 to 50 by rotate the potentiometer using screwdriver. The offset value will increase if rotate the potentiometer in clockwise direction and decrease in the count clockwise direction.



5. TROUBLE SHOOTING

The table below lists some simple way of trouble shooting. User can do it according to the steps. If cannot solve, please contact technical support.

Error phenomenon	Probable causes→ Correction actions
Instrument doesn't work or no lighting of the power indicator	<ol style="list-style-type: none"> 1. Socket loose or contact undesirable→ Reconnect and fixed socket and the power cable. 2. Power adaptor loose or contact undesirable → Reconnect and fixed power adaptor and the cable.
No aspiration	<ol style="list-style-type: none"> 1. Pump hose is aging or breakage → Replace pump hose. 2. Tube system was blocked → Get rid of blockages.
Build-in printer doesn't work	<ol style="list-style-type: none"> 1. Printer has no paper → Install thermal printer paper.
External USB printer doesn't work	<ol style="list-style-type: none"> 1. Printer socket loose or contact undesirable → Reconnect and fixed socket and the power cable; 2. USB cable loose→Reconnect and fixed USB cable; 3. Printer cannot support PCI 3 GUI print language → Replace printer that support PCI 3 GUI language.
Touch screen no response	<ol style="list-style-type: none"> 1. After upgrading program not calibration → Recalibration touch screen. 2. After replace main board not calibration → Reaction touch screen.
AD value is out of range(35000-59000).	<ol style="list-style-type: none"> 1. There are air bubbles in flow cell→Wash flow cell by detergent. 2. lamp house not bright→Replace a new lamp house.
Wrong result or bad repetition	<ol style="list-style-type: none"> 1. There are air bubbles in flow cell → Wash flow cell by detergent. 2. The sample is hemolytic or whether the reagent is expired.

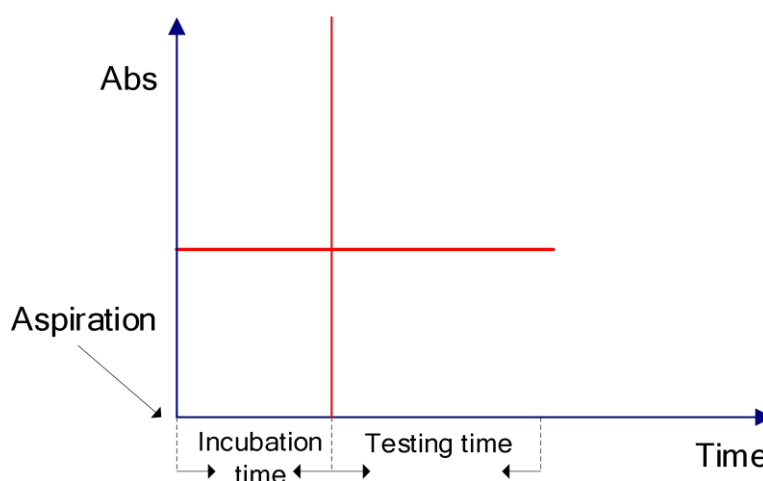
APPENDIX 1 CALCULATION METHODS

The system previous five methods for clinical chemistry assay measurements: End point, Kinetics, Fixed time, 2 point end, and turbidity, and clotting method for coagulation assay.

End Point

After aspiration, system read out the absorbance (one absorbance per second) in the incubation and testing time period, then calculate average of absorbance of testing time.

Reaction curve as below:



Absorbance calculation formula:

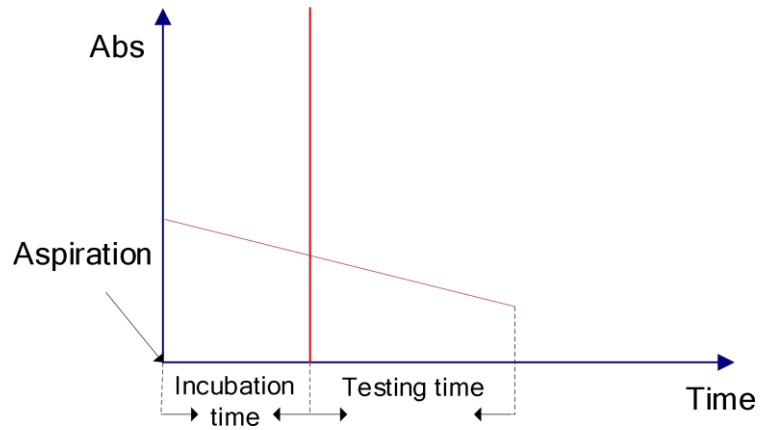
$$A_x = \frac{\sum_{i=1}^N A_i}{N}$$

N=Testing time

Kinetics

After aspiration, system read out the absorbance (one absorbance per second) in the incubation and testing time period, then calculate the rate of absorbance change per minute of testing time.

Reaction curve as below

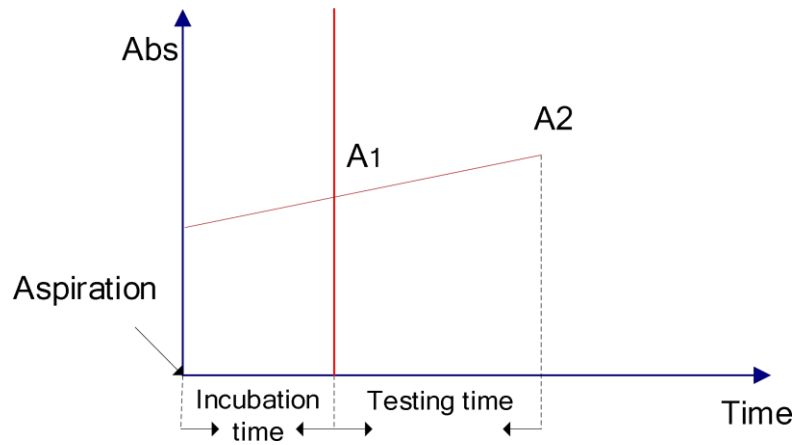


Absorbance calculation formula:

$$A_x = \Delta A / \text{min}$$

Fixed Time

After aspiration, system read out the absorbance (one absorbance per second) in the incubation and testing time period, read A1 at the beginning of testing time, then read A2 at the end of testing time, Calculate the difference between A2 and A1.



Absorbance calculation formula:

$$A_X = A_2 - A_1$$

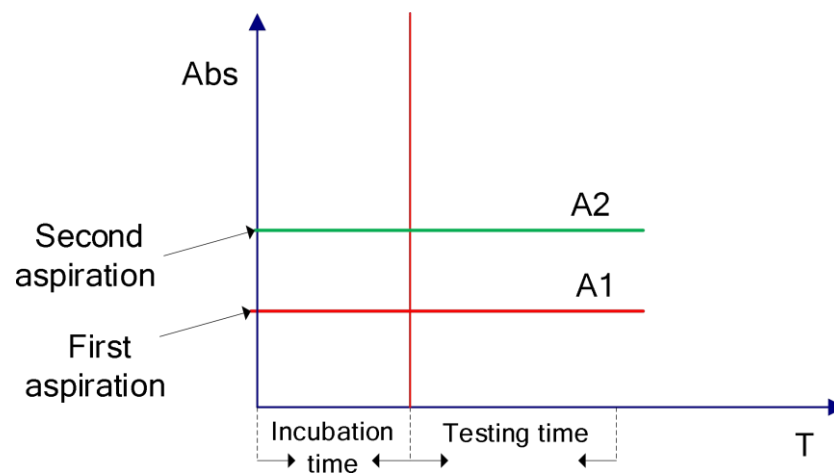
2 Point End

There are 2 steps of 2 point end method, need to do aspiration 2 times.

First step, after aspiration, system read out the absorbance (one absorbance per second) in the incubation and testing time period, then calculate average of absorbance of testing time as A1.

Second step, after First step, after aspiration, system read out the absorbance (one absorbance per second) in the incubation and testing time period, then calculate average of absorbance of testing time as A2.

Calculate the difference between A2 and A1



Absorbance calculation formula:

$$A_1 = \frac{\sum_{i=1}^N A_i}{N}$$

$$A_2 = \frac{\sum_{i=1}^N A_i}{N}$$

N=Testing time

$$A_X = A_2 - A_1$$

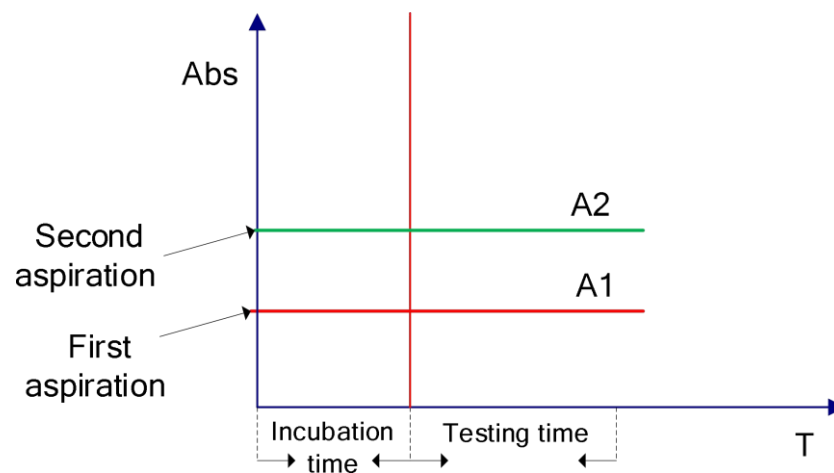
Turbidity

There are 2 steps of turbidity method, need to do aspiration 2 times.

First step, after aspiration, system read out the absorbance (one absorbance per second) in the incubation and testing time period, then calculate average of absorbance of testing time as A1.

Second step, after First step, after aspiration, system read out the absorbance (one absorbance per second) in the incubation and testing time period, then calculate average of absorbance of testing time as A2.

Calculate the ratio between A2 and A1



Absorbance calculation formula:

$$A_1 = \frac{\sum_{i=1}^N A_i}{N}$$

$$A_2 = \frac{\sum_{i=1}^N A_i}{N}$$

N=Testing time

$$A_X = A_1 / A_2$$

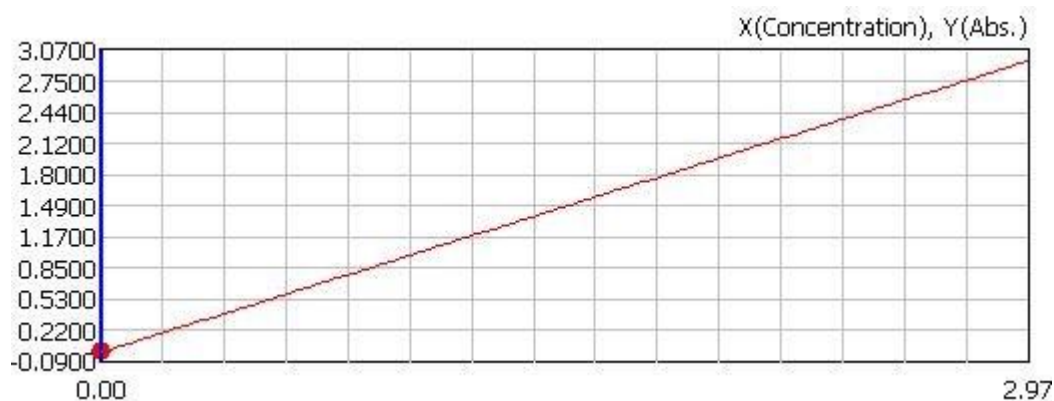
APPENDIX 2 CALIBRATION TYPE

Noun explanation:

- **Calculated value:** The value that calculated automatically by machine.
- **Measured value:** The value that measured by machine
- **Input value:** The value that inputted by user.
- **Ax:**
 - For end point assay, it is the absorbance measured when using single wavelength, the absorbance difference between primary and secondary wavelength when using double wavelength.
 - For kinetics assay, it is the absorbance change per minute of testing time.
 - For fixed time assay, it is the absorbance difference between last point and first point during testing time.
 - For 2 point end assay, it is the absorbance difference between first step (sample) and second step (sample blank).
 - For turbidity assay, it is the absorbance ratio between first step and second step

For more details, please refer to appendix 1 calculation method.

1 point linear



- **Calibration formula**

$$C_x = K \times (A_x - B)$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the A_x of samples.

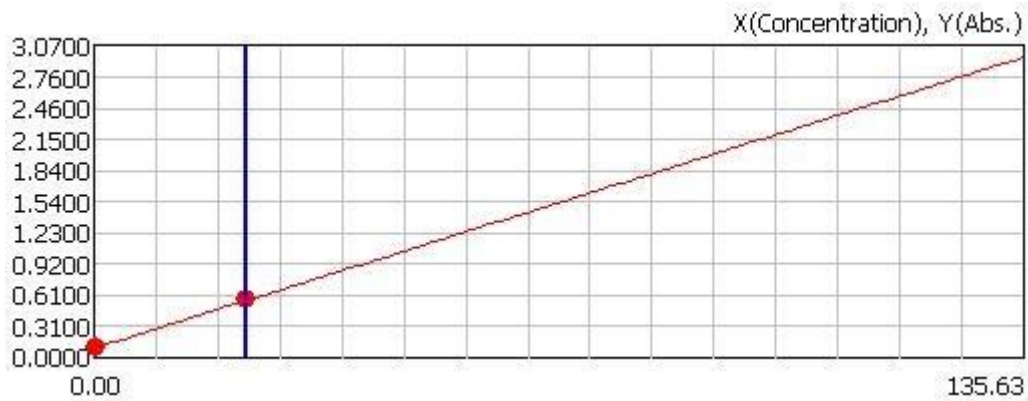
B : (measured value) the A_x of Reagent blank, If the blank is water, it is zero.

K : (input value) the value that inputted on Reagent setup dialog box.

- **Screen display**

B, K will be displayed on calibration data dialog box.

2 point linear



- **Calibration formula**

$$C_x = K \times (A_x - B)$$

$$K = \frac{C_1}{A_1 - B}$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the A_x of samples.

B : (measured value) the A_x of Reagent blank. If the blank is water, it is zero.

K : (calculated value) the value that calculated after calibration.

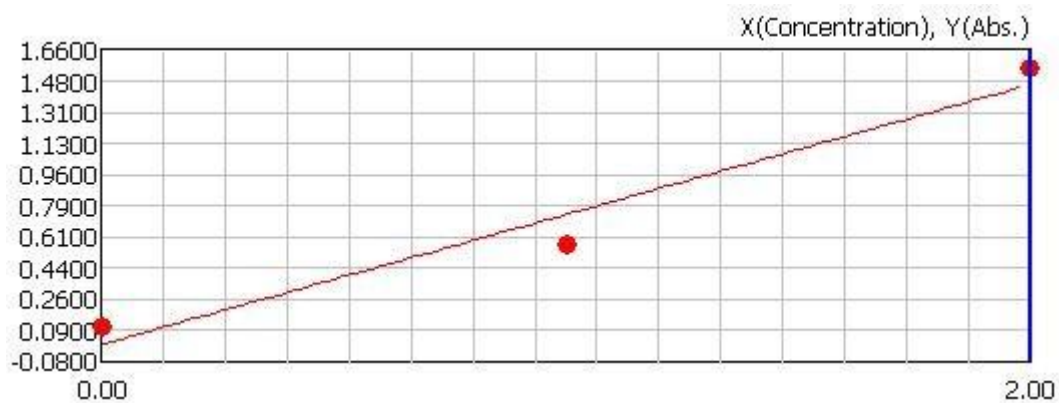
C_1 : (input value) the concentration of standard 1.

A_1 : (measured value) the A_x of standard 1.

- **Screen display**

B, K will be displayed on calibration data dialog box.

Multi point linear



● Calibration formula

$$B = \bar{A} - \frac{X \times \bar{Cr}}{Y}$$

$$K = \frac{Y}{X}$$

$$X = \sum_{i=0}^{n-1} (C_{ri} - \bar{Cr}) \times (A_i - \bar{A})$$

$$Y = \sum_{i=0}^{n-1} (C_{ri} - \bar{Cr})^2$$

$$\bar{A} = \left(\sum_{i=0}^{n-1} A_i \right) / n$$

$$\bar{Cr} = \left(\sum_{i=0}^{n-1} C_{ri} \right) / n$$

$$C_x = K \times (A_x - B)$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the A_x of samples.

B : (calculated value) the parameters of calibration formula.

K : (calculated value) the parameters of calibration formula.

C_{ri} : (input value) the concentration of standard i .

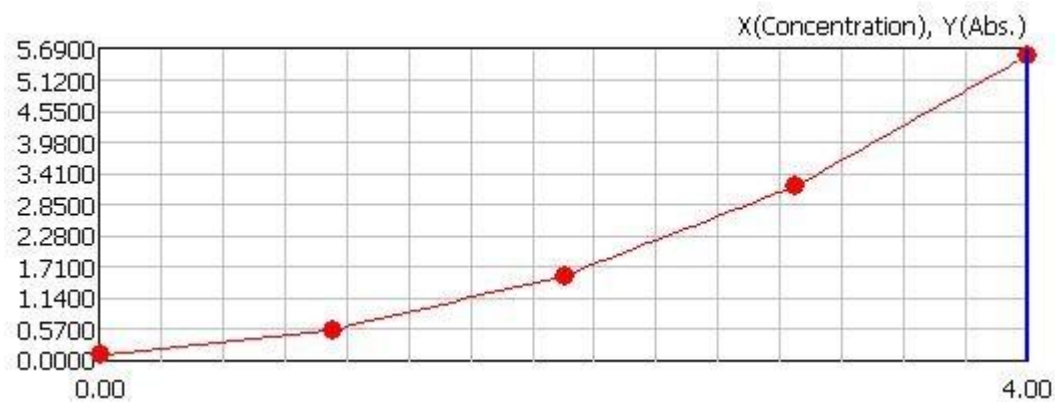
A_i : (measured value) the A_x of standard i .

n : (input value) the points of standard that inputted on Reagent setup dialog. It must be within 3-8.

● Screen display

B, K will be displayed on calibration data dialog box.

Line graph



● Calibration formula

$$C_x = K_N \times (A_x - A_N) + C_N$$

$$K_N = \frac{C_{N+1} - C_N}{A_{N+1} - A_N}$$

$$N = [0, n - 2]$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the A_x of samples.

A_{N+1} : (measured value) the A_x of standard $n+1$.

A_N : (measured value) the A_x of standard n .

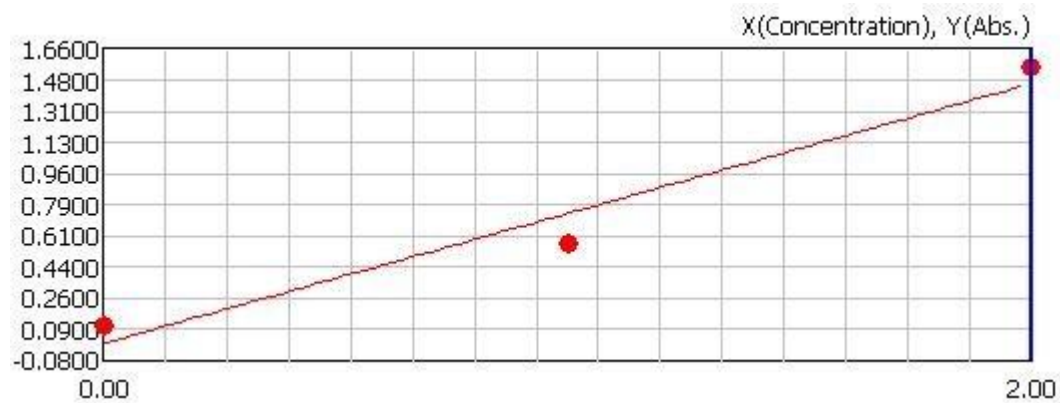
C_{N+1} : (input value) the concentration of standard $n+1$.

C_N : (input value) the concentration of standard n .

K_N : (calculated value) the parameters of calibration formula.

n : (input value) the points of standard that inputted on Reagent setup dialog. It must be within 3-8.

Logit-Log 3P



- **Calibration formula**

$$A_x = B + \frac{K}{1 + aC_x}$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the A_x of samples.

B : (calculated value) the parameters of calibration formula.

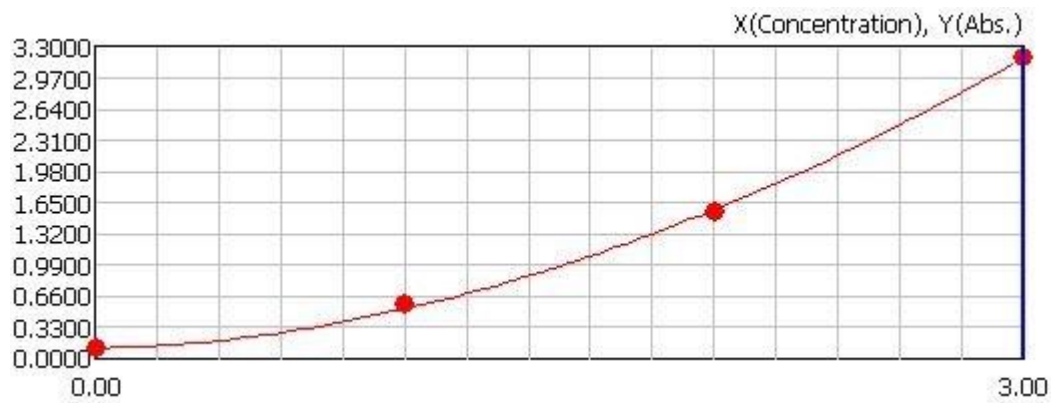
K : (calculated value) the parameters of calibration formula.

a : (calculated value) the parameters of calibration formula.

- **Screen display**

B, K, a will be displayed on calibration data dialog box.

Logit-Log 4P



- **Calibration formula**

$$A_x = B + \frac{K}{1 + aC_x^b}$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the A_x of samples.

B : (calculated value) the parameters of calibration formula.

K : (calculated value) the parameters of calibration formula.

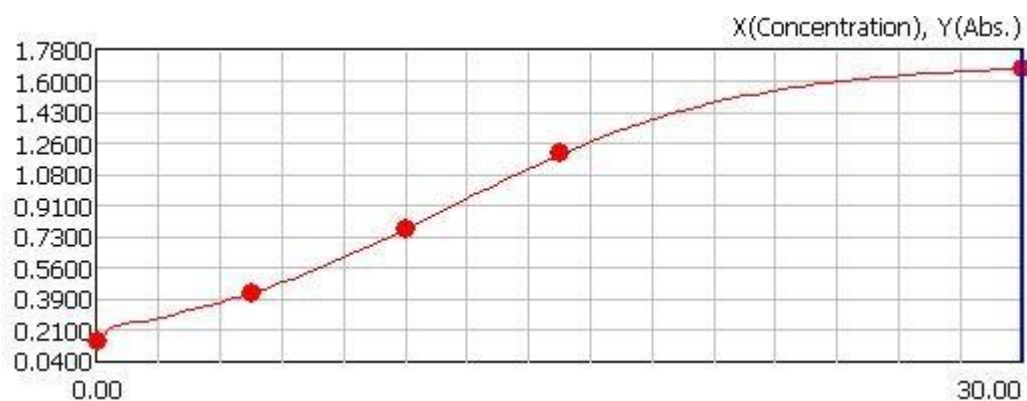
a : (calculated value) the parameters of calibration formula.

b : (calculated value) the parameters of calibration formula.

- **Screen display**

B , K , a , b will be displayed on calibration data dialog box.

Logit-Log 5P



- **Calibration formula**

$$A_x = B + \frac{K}{1 + \exp(-a - b \times \ln C_x - c \times C_x)}$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the A_x of samples.

B : (calculated value) the parameters of calibration formula.

K : (calculated value) the parameters of calibration formula.

a : (calculated value) the parameters of calibration formula.

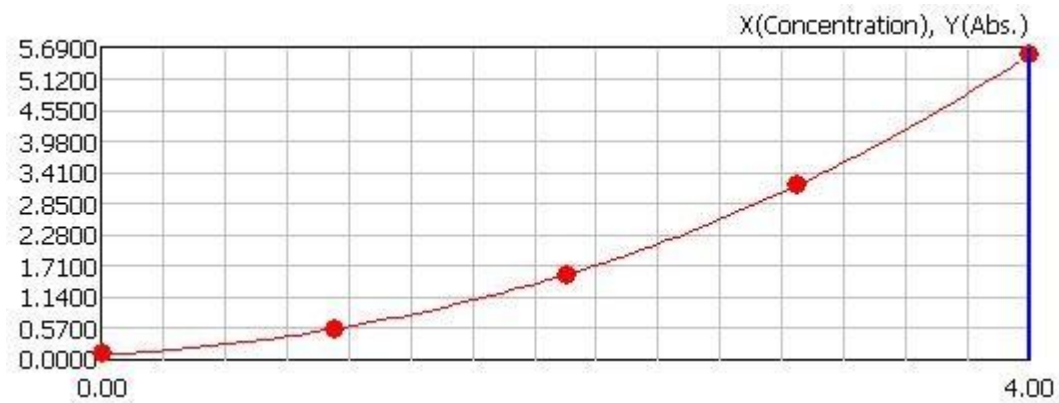
b : (calculated value) the parameters of calibration formula.

c : (calculated value) the parameters of calibration formula.

- **Screen display**

B, K, a, b, c will be displayed on calibration data dialog box.

Exponential



- **Calibration formula**

$$A_x = B + K \times \exp\{a \times (\ln C_x) + b \times (\ln C_x)^2 + c \times (\ln C_x)^3\}$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the A_x of samples.

B : (calculated value) the parameters of calibration formula.

K : (calculated value) the parameters of calibration formula.

a : (calculated value) the parameters of calibration formula.

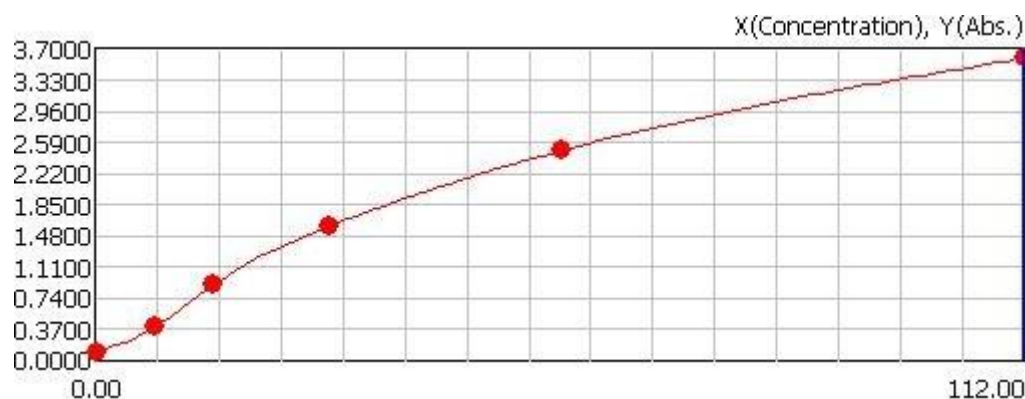
b : (calculated value) the parameters of calibration formula.

c : (calculated value) the parameters of calibration formula.

- **Screen display**

B , K , a , b , c will be displayed on calibration data dialog box.

Spline



- **Calibration formula**

$$A_x = a(I) + b(I) \times (C_x - C(I) + c(I)) \times (C_x - C(I)^2) + d(I) \times (C_x - C(I))^3$$

$$I = [0, n - 2]$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the A_x of samples.

$C(I)$: (input value) the concentration of standard I.

K_N : (calculated value) the parameters of calibration formula.

$a(I)$: (calculated value) the parameters of calibration formula.

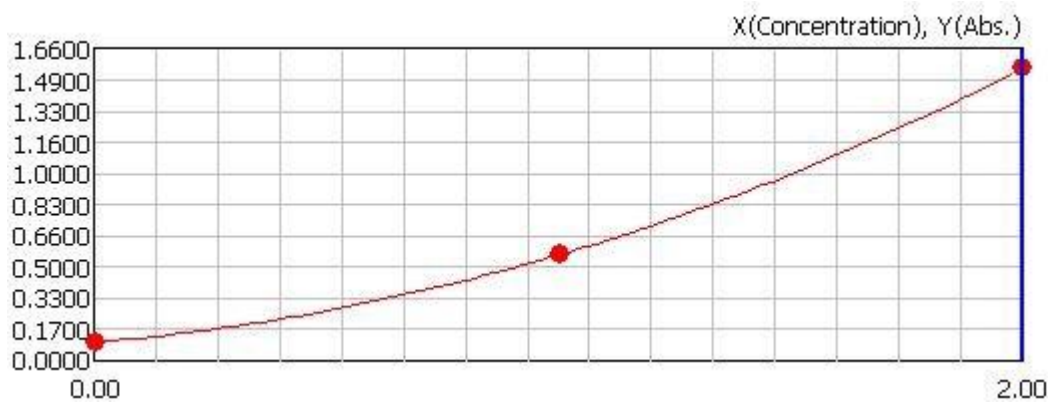
$b(I)$: (calculated value) the parameters of calibration formula.

$c(I)$: (calculated value) the parameters of calibration formula.

$d(I)$: (calculated value) the parameters of calibration formula.

n : (input value) the points of standard that inputted on Reagent setup dialog. It must be within 5-8.

Parabola



- **Calibration formula**

$$A_x = B + K \times C_x + a \times C_x^2$$

C_x : (calculated value) the concentration of samples.

A_x : (measured value) the Ax of samples.

B :(calculated value) the parameters of calibration formula.

K :(calculated value) the parameters of calibration formula.

a :(calculated value) the parameters of calibration formula.

- **Screen display**

B, K, a will be displayed on calibration data dialog box.

