

TC6030 Automatic Chemistry Analyzer User Manual



Please read operating manual before installation and operation.

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Preface

Thank you for purchasing TC series Chemistry Analyzer.

Before using the Chemistry Analyzer, please read this operation manual first, and understand the relevant operation instructions.

Please keep this manual properly for convenient use.

To ensure the safe operation, please read the following notes

- This user manual contains all the optional fittings and optional functions (sell separately), if you do not purchase them, you can just skip that content.
- Chemistry Analyzer TC6030 is intended for in vitro diagnostic use in clinical laboratories and designed for quantitative determination of clinical chemistry in serum, plasma, urine and cerebrospinal fluid samples. Please consult us first if you want to use it for other purposes.
- The Chemistry Analyzer is to be operated only by clinical professionals, doctors or experimenters trained by Drawell or appointed distributors.
- Please do not try methods not indicated by this manual, for it may lead to unreliable results and even device damage.
- While operating, please first check whether this analyzer works normally by testing QC material.
- Information on the storage requirement (both for sealing and unsealing), usage and precaution for reagent, QC materials and calibration liquid, please refer to this manual provided by Drawell.
- Please do not try to disassemble or reassemble the unit of Chemistry Analyzer TC6030 for it may lead to unreliable results and even device damage. To disassemble or reassemble the unit, please contact our Customer Service Department or appointed distributors
- Assembling, augment, reassembling, improvement and repair of the analyzer should be conducted by the technicians approved by Drawell. Otherwise, we shall not be responsible for the damage
- The power switch must be easy to reach and be convenient and safe to power the analyzer off. Do not place the analyzer at a site that is difficult to power on and off.
- The analyzer is not for family use.
- The analyzer is not for outdoor use.

Product Information

Sign	Meaning	Description
	In Vitro Diagnostic equipment	
	CE marking.	CE is the sign EU protect in accord, product should comply with the requirement of Directive 98/79/EC.
	Authorized Representative in the European Community	
	Serial Number	
	Date of Manufacture	
	Manufacturer	
	Warning: Admonish users pay attention to the potential dangers, electronic rubbish, easy to pollute environment.	Contact the manufactory to recycle or deal with them according to the demand of local government.
	Fragile mark	
	Guard against damp	
	This side up	
	Stacking layers limit	
	Temperature range	
	Environment-friendly use period	This electronic product contains certain toxic and hazardous substances. The environment friendly use period is 10 years. You can use it safely within the period. If exceed, it should enter the recycling system.

Copyright & Declaration

Drawell Science Corporation has the copyright of this unpublicized manual and has the rights to treat it as confidential data. This manual is only used as references for operating and maintaining analyzer or other Drawell products. Others have no rights to make it public.

This manual contains some proper data protected by the copyright law. It can not be duplicated, or translated into other languages without written consent from Drawell Science Corporation.

Drawell does not make any guarantee to this material, including guarantee responsibility of implied merchantability proposed to it for some specific purpose. Drawell is not responsible for the mistakes in the material and the accidental or indirect loss caused by the actual use of this manual.

The display figure in this book may be a little different from the actual one.

Due to the upgrade of products, sometimes there would be some situations in which products disagree with the content of this manual, please pardon us for not giving notice separately.

Drawell assumes no responsibility for the computer operating systems used by users or the use involved copyright of other enterprises.

Warranty Policy

Warranty period

One year from the date of complete installation or conforming to the contract stipulations.

Guarantee

Drawell should take responsibility for security, reliability and performance of analyzer while the following requirements are met:

1. Assembling, augment, readjustment, improvement and repair should be conducted by technician authorized by Drawell.
2. Concerning electric equipment meets national standard.
3. Chemistry Analyzer TC6030 is operated according to the operation manual.

Drawell will supply customers free repair service when the breakdown is caused by the defect of our design or manufacturing during the guarantee period, and adopt relevant maintenance solutions according to trouble.

Non-guarantee Items

If the following situations occur, it is not included in the guarantee range even within guarantee period:

1. The trouble caused by operating chemistry analyzer beyond the requirements of operating environment mentioned in this operation manual.
2. The trouble caused by improper maintenance or maintaining companies which are not appointed by Drawell.
3. The trouble caused by not replacing the consumables or spare parts that have life period in time.
4. The trouble caused by using hardware, software or assistant products not supplied by Drawell.
5. The trouble caused by using reagent not authorized by Drawell.
6. Circuit corrosion, optics component aging in evidence by strong corrosive gas in the air.
7. The trouble caused by using condemned instrument or buy secondhand instrument without connecting with Drawell.
8. The data loss caused by instrument damage (data backup or exporting are recommended).
9. The trouble caused by the methods of removing, transporting, installation of chemistry analyzer that go against with the operation manual.
10. The trouble caused by self disassembly or reassembly instrument.
11. The trouble caused by fire, earthquake, wind harm, flood, lighting strike, crime, terrorism, war and other irresistible natural disasters.
12. The trouble caused by other improper operations that go against with the operation manual.

Use and Storage Environment

The service department appointed by our company carries on the installation at purchasing time. Analyzer should only be used when the following conditions and the corresponding environment are met.

1. Safety conditions

- 1) Use indoor;
- 2) The temperature is between 5~40℃;
- 3) Instrument should stock in the environment with temperature of -10℃ ~ 55℃ , relative humidity ≤95%, Atmospheric pressure 500hPa ~ 1060hPa, no corrosive gas, good ventilation, clean room.
- 4) Typical transient over voltages appearing on the mains supply;
- 5) Class of pollution: class II.

2. Normally working conditions

- 1) Meet the requirement of safety conditions above
- 2) Power supply rating voltage fluctuation: $\sim (110-220V) \pm 10\%$ 50/60Hz ± 1 Hz;
- 3) The room temperature should be kept between 10℃~35℃, and the fluctuation of room temperature shall be within $\pm 2^\circ\text{C}$ during testing.
- 4) Work relative humidity (extended condition): ≤90%, no dew;

3. Others environment conditions

- 1) No perceptible vibration.
- 2) No acute fluctuation in power supply.
- 3) There is no device generated high frequency wave nearby (like centrifuge, discharge equipment etc.).
- 4) There is sole grounding terminal (the grounding resistance should be below 10Ω).
- 5) The instrument is disturbed by electromagnetic waves. The data and operation mistakes may occur, thus, it must keep instrument far away high intensity electromagnetic wave generator.

4. Transportation requirement

- 1) The instrument is shipped in accordance with the requirements of contract under package condition.
- 2) Take it lightly and put it in accordance with the stacking layers limit requirements.
- 3) Instrument should stock in the environment with temperature of -10℃ ~ 55℃ , relative humidity ≤95%, Atmospheric pressure 500hPa ~ 1060hPa, no corrosive gas, good ventilation, clean room.
- 4) Transport according to medical device transport requirements and avoid rain and sun exposure.

Reader

Before using the analyzer, please read and understand this manual first.

The below clinical laboratory professionals-----this manual's readers are as follows:

1. The person who operates TC series analyzer daily;
2. The person who maintains TC series chemistry analyzer and handles troubles;
3. The person who learns the operation of the TC series analyzer.



WARNING

This analyzer is operated by the people trained and authorized by Drawell company or our distributor only.

Usage of Operation Manual

This manual is TC series Automatic Chemistry Analyzer operation manual.

It mainly helps users to know the content covering operating principle, structure, operation, daily maintenance, simple trouble disposal, etc.

Analyzer should be operated according to this operation manual.

Safety Use Notes

Before using, please read "Safety Use Notes" and operation manual first and properly conduct the operation.

To ensure safe and proper operation and protect you and your possession from the damage, please read and understand below symbols and signs.

Please first fully understand their meaning, and then read the main body of this manual.

Signs & Meaning

Sign	Meaning	Description
o	Alternating current shut down(electrical source cut)	
I	Alternating current turn on(electrical source turn on)	
~	Alternating current source	
	Warning: risk of electric shock	Remind user to avoid shock
	Warning: risk of burn	Remind user to avoid scald
	grounding	
	equipotential	
	Attention	Explain the important information in the operating process and some special operating skills. Failure to observe the manual may lead to unreliable results or device damage.
	Warning	Read the statement following the symbol. The statement is alerting you to an operating hazard that can cause personal injury
	Biohazardous Warning	The statement is alerting you to a potentially biohazardous condition.
	Explanation	Helpful information during the operation process
	Importance	Some important information to ensure performance of the instrument and avoid damage

Safety Precautions

Observe the following safety precautions when using the Chemistry Analyzer. Ignoring any of these safety precautions may lead to personal injury or equipment damage.

	WARNING
	If the analyzer is used in a manner not specified by our company, the protection provided by the system may be impaired.

Preventing Electric Shock

Please observe the following instructions to prevent electric shock.

	WARNING
	When the MAIN POWER is on, users must not open the rear cover or side cover. Spillage of reagent or sample on the analyzer may cause equipment failure and even electric shock. Do not place sample and reagent on the analyzer. In case of spillage, switch off the power immediately, remove the spillage and contact our Customer Service Department or your local distributor.

Preventing Personal Injury Caused by Photometer Lamp

Please observe the following instructions to prevent personal injury caused by photometer lamp.

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

Preventing Personal Injury Caused by Moving Parts

Please observe the following instructions to prevent personal injury caused by moving parts.

	WARNING Do not touch such moving parts as sample probe, reagent probes, mixers and wash probe when the analyzer is in operation. Do not put your fingers or hands into any open parts when the analyzer is in operation. The moving parts will stop working when there is any mechanical faults; in order to prevent other faults, please switch off the power immediately, and contact our Customer Service Department or your local distributor.
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Preventing Infection

Please observe the following instructions to protect against the biohazardous infection.

	BIOHAZARD Inappropriately handling samples, controls and calibrators may lead to biohazardous infection. Do not touch the sample, mixture or waste with your hands. Wear gloves and lab coat and, if necessary, goggles. In case your skin contacts the sample, control or calibrator, follow standard laboratory safety procedure and consult a doctor.
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Handling Reagents and Wash Solution

	WARNING Reagents and enhanced wash solution are corrosive to human skins. Exercise caution when using the reagents and enhanced wash solution. In case your skin or clothes contact them, wash them off with soap and clean water. In case the reagents or wash solution spill into your eyes, rinse them with much water and consult an oculist.
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Treating Waste Liquids & Waste Parts

Please observe the following instructions to prevent environmental pollution and personal injury caused by waste.

	BIOHAZARD Some substances in reagent, control, enhanced wash solution and waste are subject to regulations of contamination and disposal. Dispose of the
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	waste in accordance with your local or national rule for biohazard waste disposal and consult the manufacturer or distributor of the reagents for details. Dispose of the waste parts, such as reaction cuvette, sample tube or the analyzer in accordance with your local or national guidelines for biohazard waste disposal. While disposing of the waste parts or entire analyzer, wear gloves and lab coat and, if necessary, goggles.
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Preventing Fire or Explosion

Please observe the following instructions to prevent fire and explosion.

	WARNING Ethanol is flammable substance. Please exercise caution while using the ethanol. The surface of instrument adopts antflaming material, when fire or explosion occurs; please use common civil products to quench the fire (using water or fire extinguisher).
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Preventing Empyrosis

Please observe the following instructions to prevent empyrosis.

	WARNING Please don't touch the heat devices such as the heating water pot when the instrument is operating. After switching off the power supply, please wait at least 15 minutes for analyzer to cool down, and then maintain the instrument or replace components.
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Precautions on Use

To use the Chemistry Analyzer safely and efficiently, please pay attention to the following operation notes.

- **Intended Use**

	WARNING
	The analyzer is an automated chemistry 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. Please consult us first if you want to use the analyzer for other purposes. To draw a clinical conclusion, please also refer to the patient's clinical symptoms and other test results.

- **Operator**

	WARNING
	The Chemistry Analyzer is to be operated only by experimenters trained by our company or our authorized distributors.

Environment

	CAUTION
	Please install and operate the analyzer in an environment specified by this manual. Installing and operating the analyzer in other environment may lead to unreliable results and even equipment damage. To relocate the analyzer, please contact our Customer Service Department or your local distributor.

Preventing Interference by Electromagnetic Noise

	CAUTION
	Do not install devices generating excessive electromagnetic noise around the analyzer. Do not use such devices as mobile phones or radio transmitters in the room housing the analyzer. Do not use other CRT displays around the analyzer. Electromagnetic noise may interfere with operations of the analyzer. Do not use other medical instruments around the analyzer that may generate electromagnetic noise to interfere with their operations.

Operating the Analyzer

	CAUTION
	Operate the analyzer strictly as instructed by this manual. Inappropriate use of the analyzer may lead to unreliable test results or even equipment damage or personal injury.
	Before using the analyzer for the first time, run the calibration program and QC program to make sure the analyzer is in proper state.
	Be sure to run the QC program every time you use the analyzer, otherwise the result may be unreliable.
	Do not uncover the sample/reagent disk when the analyzer is in operation. Keep the cover closed.
	The RS-232 port on the analyzing unit is to be used for connecting with the operation unit only. Do not use it for other connections. Only use the supplied cable from Drawell or our distributor for the connection.
	The operation unit is a personal computer with the operating software installed. Installing other software or hardware on this computer may interfere with the analyzer operation. Do not run other software when the analyzer is working.
	Do not use this computer for other purposes. Inappropriate use of the computer may lead to virus infection. Computer virus may spread and infect by floppy, software, network, etc.
	Do not touch the display, mouse or keyboard with wet hands or hands with chemicals.
	Do not turn the MAIN POWER to ON again within 10 seconds after placing it to OFF; otherwise the analyzer may enter the protection status. If it does so, place the MAIN POWER to OFF and place it to ON again.

Samples

	CAUTION
	Use samples that are completely free of insoluble substances like fibrin, or suspended matter; otherwise the probe may be blocked and lead to unreliable result. Check the hematocyte agglutinate or not before separate serum. Remove fibrin suspended before analyzing.

	If there are suspended matter in urine sample, sediment urine sample by centrifugation before analyzing. Medicines, anticoagulants or preservative in the samples may lead to unreliable results. Hemolysis, icterus or lipemia in the samples may lead to unreliable test results, so sample blanks are recommended. Store the samples properly. Improper storage may change the compositions of the samples and lead to unreliable results. Sample volatilization may lead to unreliable results. Do not leave the sample uncovered for a long period. Some samples may not be analyzed on the analyzer based on parameters the reagents claim capable of testing. Consult the reagent manufacturer or distributor for details.
	Certain samples need pretreatment before being analyzed by the analyzer. Consult the reagent suppliers for details. The analyzer has a specific requirement on the sample volume. Refer to this manual for proper sample volume. Load the sample to proper tube position on the sample disk before the analysis begins; otherwise you will not obtain correct results.

Reagents, Calibrators and Controls

	CAUTION Select appropriate reagents according to performance characteristics of the analyzer. Consult the reagent suppliers, our company or our authorized distributor for details, when you are not sure the reagent is available or not. Store and use the reagents, calibrators and controls strictly as instructed by the suppliers. Improper storage or use of reagents, calibrators and controls may lead to unreliable results and bad performance of the analyzer even in validity period. Perform calibration after changing the reagents. Otherwise, you may not obtain reliable results. Contamination caused by carryover among reagents may lead to unreliable test results. Consult the reagent suppliers for details.
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Setting up the Analyzer

	CAUTION To define such parameters as sample volume, reagent volume and wavelength, follow the instructions in this manual and the instructions of reagents.
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Backing up Data

	NOTE
	The analyzer automatically stores the data to the built-in hard disk. However, data loss is still possible due to deletion or physical damage of the hard disk or other reason. We recommend you to regularly back up the data to such medium as CDs.

Computer and Printer

	NOTE
	Refer to their operation manuals for details.

External Equipment

	WARNING
	Accessory equipment connected to the analyzer interfaces, e.g. computer, printer, must be complied with the requirement of IEC 60950 or EN 60950.

Chapter One. Installation

1.Preparation

The system should be installed by our authorized personnel only, and you should prepare a proper site for installation.

If you need to move the system to another site, please contact our Customer Service Department or your local distributor.



Warning

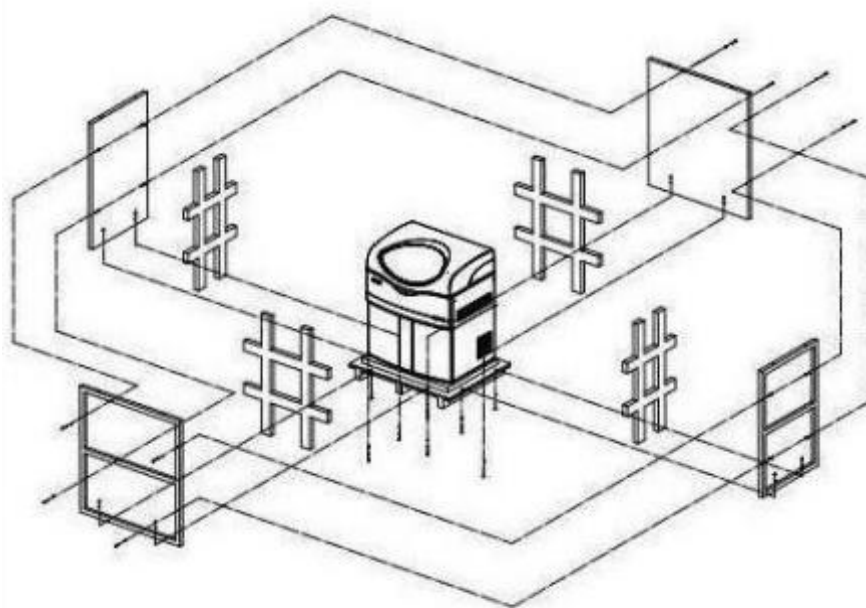
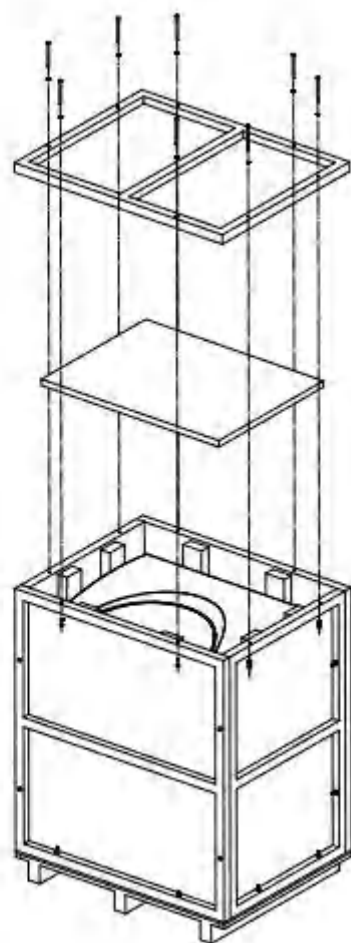
- The system should be installed by personnel authorized by Drawell only.

1.1 Check before installation

When you receive the system, carefully inspect the package. If you see any signs of damage, file a claim immediately with our Customer Service Department or your local distributor.

After opening the package, check the delivered goods against the packing list as well as the appearance of the system. If you find anything missing or damaged, alert our Customer Service Department or your local distributor immediately.





1.2 Installation Requirements



Warning

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

1.2.1 Installation Environment Requirements

- The system is for indoor use only.
- The bearing platform (or ground) should be level (gradient less than 1/200).
- The bearing platform (or ground) should be able to bear 220Kg weight.
- The installation site should be well ventilated.



Warning

- The risk of falling down may lead to instrument damage, when inclination more than 8 degree. The protective measurement should be implied during storage, transit, etc.

1.2.2 Power Requirement

- Power supply: AC 100-240V, 50/60Hz, with voltage fluctuation of $\pm 10\%$. Three-wire power cord should be grounding properly.
- The system should be connected to a properly-grounded power socket.
- The distance between the power socket and the system should be less than 3 meters.



Warning

- Make sure the power socket is grounded correctly. Improper grounding may lead to electric shock and/or equipment damage.
- Be sure to connect the system to a power socket that meets the above-mentioned requirements and has a proper fuse installed.

1.2.3 Temperature and Humidity Requirements

1.2.3.1 Storage Temperature and Humidity

- Storage temperature: $-10^{\circ}\text{C}\sim 55^{\circ}\text{C}$, with fluctuation less than $\pm 2^{\circ}\text{C}/\text{H}$;
- Storage relative humidity: $\leq 95\%\text{RH}$, no dew.



- The system will be damaged in the environment that temperature and relative humidity is beyond requirements mentioned above.

1.2.3.2 Working Temperature and Humidity

- Working temperature: $10^{\circ}\text{C}\sim 35^{\circ}\text{C}$, with fluctuation less than $\pm 2^{\circ}\text{C}/\text{H}$;
- Working relative humidity: $\leq 90\%\text{RH}$, no dew.



- Operating the system 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.

1.2.3.3 Water Supply and Drain Requirements

- The water must meet requirements of the GB-6682 III grade water.
- The water temperature should be $5\sim 50^{\circ}\text{C}$.
- If water-purifying equipment is used, the pressure at water source should be within $49\text{kPa}\sim 392\text{kPa}$.



- Be sure to dispose of the waste according to the local regulations.

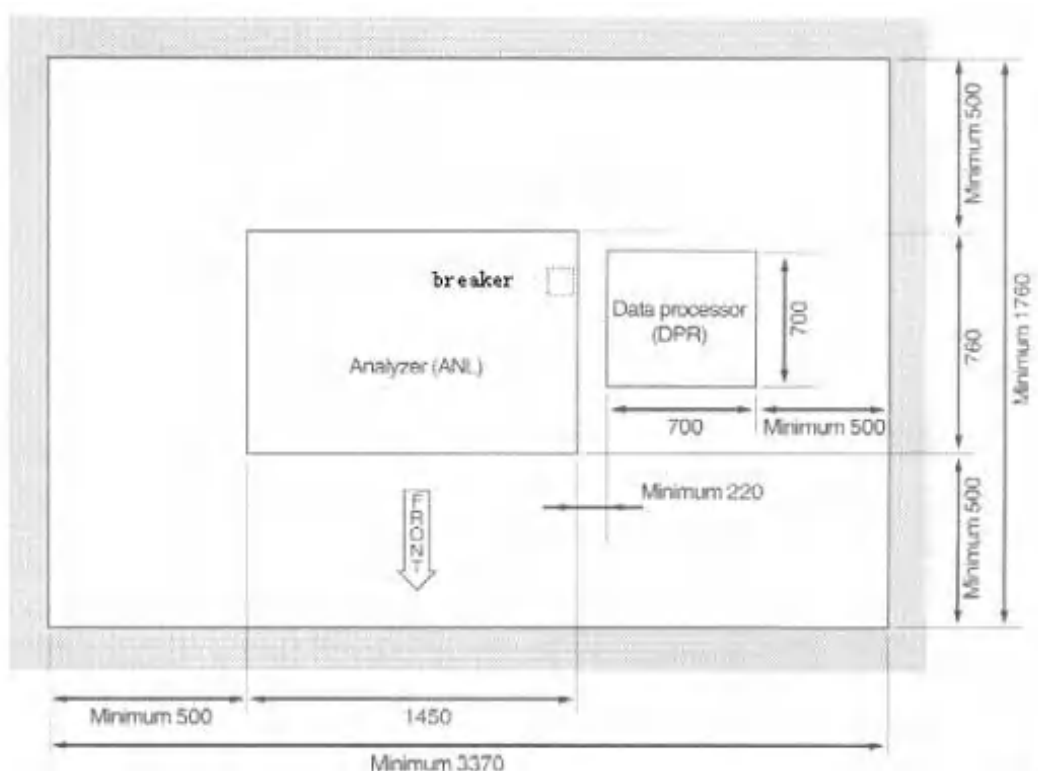


Caution

- The water must meet requirements of the GB-6682 III grade water; otherwise insufficiently purified water may result in misleading measurement.

1.2.3.4 Space and Accessibility Requirements

The system should be installed and used meeting the space and accessibility requirements as shown below. The laboratory should be large enough, so that the analyzer and computer will not be crowded.



2. Installation

2.1 Connecting Water Supply Bucket



Biohazard

- Wear gloves and lab coat and, if necessary, goggles.



Caution

- Keep the top of water bucket is not higher than the bottom panel of the upper part of instrument.
- To keep the outlet tubing smooth, do not bend or twist it.

2.2 Connecting Waste Bucket



Biohazard

- Wear gloves and lab coat and, if necessary, goggles.



Caution

- Keep the top of waste bucket is not higher than the bottom panel of the upper part of instrument.
- Ensure all the waste tubing is above the top of waste bucket and smooth without bending or twisting. Otherwise liquid may overflow from panel due to unsmooth drainage. The analyzer may be damaged if the problem gets serious.

Ensure the power supply is off.

Choose an appropriate site in the right side cabinet to place the waste bucket.

Plug the three-hole to outlet on the bottom panel.

Insert three short tubes into the bucket.

2.3 Installing/Removing Sample-Reagent Disk



Warning

- Before installing/removing the sample-reagent disk, make sure the system is power off and the sample-reagent disk has stopped.



Biohazard

- Wear gloves and lab coat and, if necessary, goggles.

To install the sample-reagent disk, align the hole of the disk to the pin of the rotor, gently lower the disk all the way down and tighten (clockwise) the two retaining screws on the sample-reagent disk to secure it to the rotor.

To remove the sample-reagent disk, loosen (counterclockwise) the two retaining screws on the sample-reagent disk to separate it from the rotor, then grab the handle and pull the disk upward to remove it.



Caution

- The sample-reagent disk may be contaminated when being used. If samples spill in the compartment or on the disk, wipe them with cloth soaked with water or disinfectant after placing the Power to OFF.

2.4 Installing/Removing Sample Tubes



Warning

- Before installing/removing the sample tubes, make sure the sample-reagent disk and sample probe have been stopped and the system is in Standby status.
- Do not use sample tubes other than the specified.



Biohazard

- Wear gloves and lab coat and, if necessary, goggles.

To load sample tubes, insert the tube into the tube holder until the bottom of the tube contacts the groove of the tube rack.

To remove sample tubes, grab the tube and pull it upward to remove it from the tube holder.

2.5 Installing/Removing Reagent Bottles



Warning

- Before installing/removing the reagent bottles, make sure the reagent disk and reagent probes have been stopped and the system is in Standby status.
- Do not use reagent bottles other than the specified.



Biohazard

- Wear gloves and lab coat and, if necessary, goggles.

To load reagent bottles, insert the bottle into the bottle holder until the bottom of the bottle contacts the groove of the holder.

To remove reagent bottles, grab the bottle and pull it upward to remove it from the bottle holder.

2.6 Installing/Removing Reaction Cuvette



Biohazard

- Wear gloves and lab coat and, if necessary, goggles.
- Be sure to dispose of the waste according to the local regulations.

To load reaction cuvette, insert cuvette into one of the cuvette holder arc until the edge of the cuvette contact the arc. Then align the hole of the arc to the pin of the rotor, gently lower the arc down and tighten (clockwise) the two retaining screws on the arc to secure it to the rotor. Finally load others like that.

To remove reaction cuvette, loosen (counterclockwise) the two retaining screws on the holder arc to separate it from the rotor, and pull the arc upward. Then pull cuvette upward from the arc separated to remove them. Finally remove others like that. To replace old cuvette with the new one, please refer to above operation instructions.

2.7 Installing/Removing Fuse



Turn off the power of the instrument, use a Phillips screwdriver to unscrew the back cover of the fuse holder, remove the broken fuse, insert the new fuse of the same type into the back cover of the fuse holder, and tighten the rear cover of the fuse holder with a Phillips screwdriver. The fuse is specified type with its model specification $\Phi 5 \times 20$, F10AL 250V.



Warning

- When replacing the fuse, it is necessary to cut off the power and replace the fuse of the same specification to prevent electric shock and accident.
- There is a risk of electric shock so the fuses need to be replaced by a professional person.

Chapter Two. System Introduction

1. Instrument introduction

1.1 Appearance

TC6030 chemistry analyzer



1.2 Parts & Consumables

To ensure your safety and system function, please use the spare parts which manufactured or recommended by Drawell. Please contact with Service Department of Drawell or your local distributor if necessary.

Description	Position	Note
Light bulb (20W 12V halogen lamps)	Light source	Change regularly Running time >2000 hour or system alarms

Description	Position	Note
Syringe piston assembly (PLUNGER ASSEMBLY 24400 500μL PG 'KLOEHN')	Syringe	Change regularly Running time >3 months or 100,000 times or has visible damage
Syringe shim	Connecting between syringe and three-way	Change regularly Replace when syringe have been disassembled for 2-3 times
Sample probe assembly	Sample probe arm	Change regularly Running for one year or bended
Sample probe shim	Sample probe	Change regularly Replacing when sample probe has been disassembled for 2-3 times
Stirring probe	Stirring probe arm	Change regularly Replace when it is damaged
Reaction cuvette	Reaction disc	Consumable
24ml reagent bottle	Reagent disc	Consumable
Reagent bottle cover	Reagent disc	Consumable
A4 paper	Printer	Consumable

1.3 Technical Specification

Throughput	260 tests/h
Parameter	At most 40 testing items online
Analysis method	End points, Fix-time (two points) , Kinetic, Colorimetry, Turbidimetry, Two wavelength, Double reagent, multi-standard and so on
Sample disc	40 sample positions (can be expanded); sample can be placed randomly; include standard QC, emergency , can use original tube or serum cup
Reagent disc	40 sample positions (can be expanded) , 24ml reagent bottle with refrigerated compartment
Sample volume	1-50μl, 0.1μl step
Reagent volume	10-400μl, 1μl step

Emergency sample	Insert emergency sample randomly and can be tested with priority
Sample probe	Automatic liquid level detection; collision protection; probe block detecting
Cleaning system	8-steps cleaning, cuvette dry automatically, spring style internal/external auto cleaning, cross-contamination rate less than 0.1%
automatic dilute retest	Support
Mixing System	Independent stirring arm, stirring immediately when sample is added; For double reagent, stirring immediately after R2 is added
Reaction disc	90 cuvette
Reaction Temperature	37±0.1°C, temperature fluctuating is ±0.1°C
Reaction cuvette	5mm×6mm×25mm, optical path :6.1mm
Reaction liquid volume	150~500μl
Reaction time	8-14 min
Optical system	Static optical fiber transit system; back light style
QC	Multi QC function, can insert QC randomly; QC diagrams can be stored, displayed and printed; Can pre-set up different QC material; every test can take 3 different QC material.
Light source	12V, 20W halogen lamp, halogen lamps, tungsten iodine lamp
Wavelength	9 wavelengths: 340nm, 405nm, 450nm, 510nm, 546nm, 578nm, 620nm, 660nm, 690nm.10,12 and 16 wavelength can optional.
Measuring period	9 seconds
Absorbency linearity	0.0000~5.0000Abs
Wavelength accurate	±1.5nm
CV%	≤1.5%
Stability	the change of absorbance is less than 0.01
Power	~100-240V, 50/60Hz, three-cores power cord, good grounding
Fuse	F10AL 250V
Input Power	Max 1000VA
Software	Window system,friendly interface with Chinese/English
Data processing	Can edit and store more than 300 testing parameter.Storage volume of patient information is based on capacity of computer hard disk.1GB capacity can store about 1.2 million date and available for date import and export.

Printer	Multi-format printing modes are available
Storing environment	See " Use and Storage Environment " in Preface
Working environment	Atmospheric pressure: 70.0kPa~106.0kPa. For others, please refer to safety introduction-use and store environment.
Main Unit Dimension	700mm (W) *650mm (L) *530mm (H)
Main Unit Net Weight	61.7kgs(N.W.) + 46.3kgs (T.W.)
Water Consume	<4L/H
Exporting accessory	PC keyboard
	PC mouse
	Printer
	Screen
Communication port	Instrument / computer : RS-232C,LAN port (can be expanded)
Safety class	Against electric strike style: external electrical supply Against electric strike level: B Hazardous liquid protection: general equipment Sterilization 、 disinfection : not application Not suitable for environment with inflammable anesthetic gas Continuous running equipment

2.Reagent

Reagent use please refer to the operation manual, and we will give the simple introduction on reagent classification and its principle

2.1 Reagent classification

Reagent can be divided into below types.

Powder reagent

Reagent need to be dissolved with buffer solution or distilled water (deionized water) in operation, then start testing

Single liquid reagent

Reagent can be directly used without any prior treatment and only one style is enough

Double (multi) reagent

Reagent can be directly used without any prior treatment, but need two or more reagents are used together

The superiorities of double reagent are as follows

- 1.2.1.3.1 Storage stability can be improved;
- 1.2.1.3.2 Two-point method can be used;
- 1.2.1.3.3 In some tests, interference of non-specific chemical reaction can be eliminated.
- 1.2.1.2.4 The double reagents method can eliminate non-specified chemistry:

For example: when testing serum ALT, the original keto-acid in serum can react with reagent LDH to lead to result on the high side. However, you add non α -ketoglutaric acid reagent (R1) firstly getting the original keto-acid reacting with LDH, then you add reagent with α -ketoglutaric acid (R2) and ALT enzyme catalysis begins and pyruvic acid is created. The pyruvic acid will react with LDH, and the consumed NAD^+ can reflect the ALT activity, so the interference will be eliminated.

2.2 Reaction Principle of Reagent

2.2.1 End Point

Common Reagent for this method

Total bilirubin, conjugative bilirubin, total protein, albumin, glucose, uric acid,

CHOL(cholesterol), triglyceride, high density lipoprotein cholesterol, low density lipoprotein, calcium, phosphorus, magnesium etc.

Analyte turns to product in the reaction, and when it reaches reaction end point, we could get the concentration of this substance based on the magnitude of absorbance. This is called end point.

Actually, it would be more proper to name it balancing method. In the curve of time—absorbance, when it reaches end point or balancing point, the absorbance does not change any more. It is easy to set parameter, and the longer the time of reaction, the more accurate the result is.

Determination of time of end point

Based on curve of time—absorbance

Based on reaction end point of analyte and the reaction situation of chaff interferent.

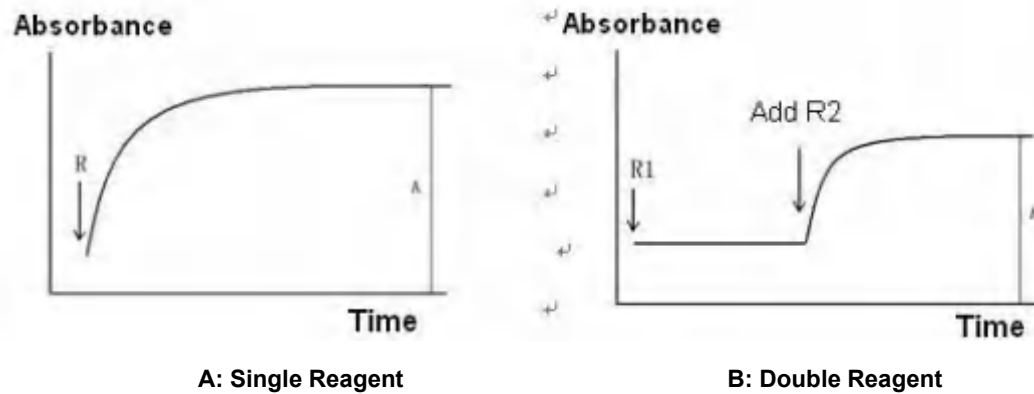
One Point End Assay

When the reaction reaches the end point, say the absorbance does not change any more on the curve of time—absorbance, choose a value of end point absorbance on the curve to calculate the result.

The formula is: the concentration of analyte $C_U = (\text{analyte absorbance } A_U - \text{reagent blank absorbance } A_B) \times K$

K—calibration factor

Chart 1 Reaction Curve of One Point End Assay



Two Points End Assay

Before the reaction of analyte, choose the first absorbance, and when the reaction reaches end point or balancing point, choose the second absorbance, calculate the result based on the difference between the two points.

The formula is: the concentration of analyte $CU = (A_2 - A_1) \times K$

K—calibration factor

Chart 2 Reaction Curve of Two Point End Assay

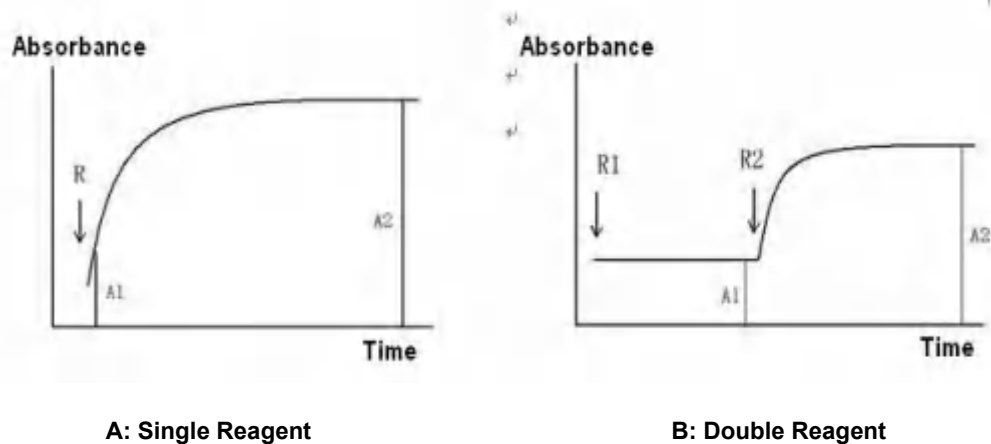
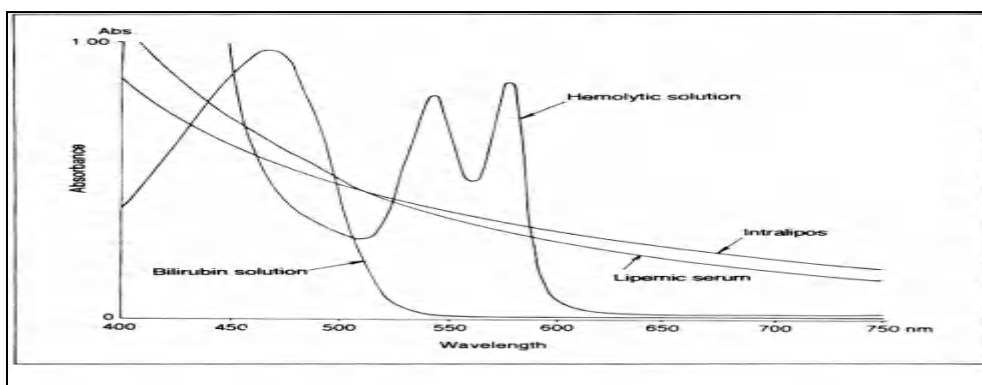


Chart 3 Light Absorption Curve of Hemoglobin, Bilirubin and Lipo-turbid



This method can effectively eliminate the interference caused by the light absorption of such samples as hemolysis, icterus and lipo-turbid.

2.2.2 Fixed Time

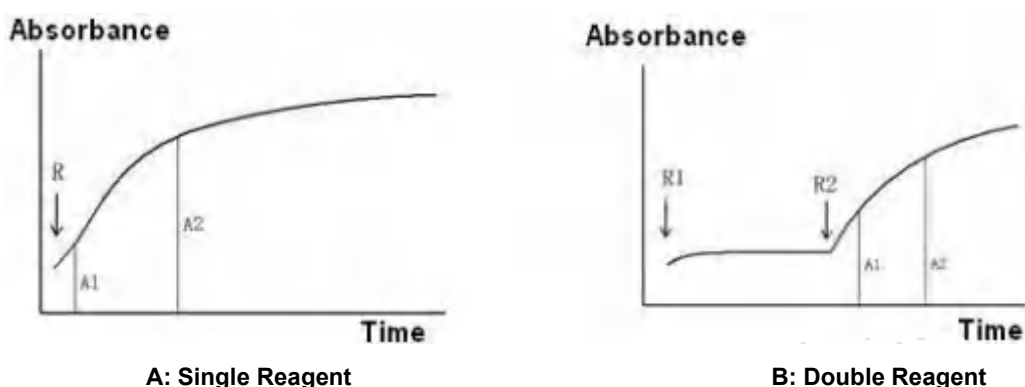
Reagent for this method: creatinine, urea, bile acid.

Choose two photometry point on the curve of time—absorbance. The two points are neither beginning absorbance nor end point absorbance. The difference between absorbance of the two points is used to calculate the result. This method is sometimes called two points. Formula is the same with two points end assay:

$$CU = (A_2 - A_1) \times K$$

K—calibration factor

Chart 4 Reaction Curve of Fixed Time



(This method helps to solve the problem of some reaction non-specificity)

For example: the creatinine test of picric acid. Set blank rate to eliminate the influence of bilirubin. If set the reagent blank rate within a period of time after adding the first reagent, due to the picric acid hasn't react with creatinine yet in this period, and the bilirubin has been converted by oxidation in the alkaline environment of the 1st reagent, so can eliminate the negative influence of bilirubin after the rate change of 2nd reagent minus the change of reagent blank rate. Please refer to the following chart:

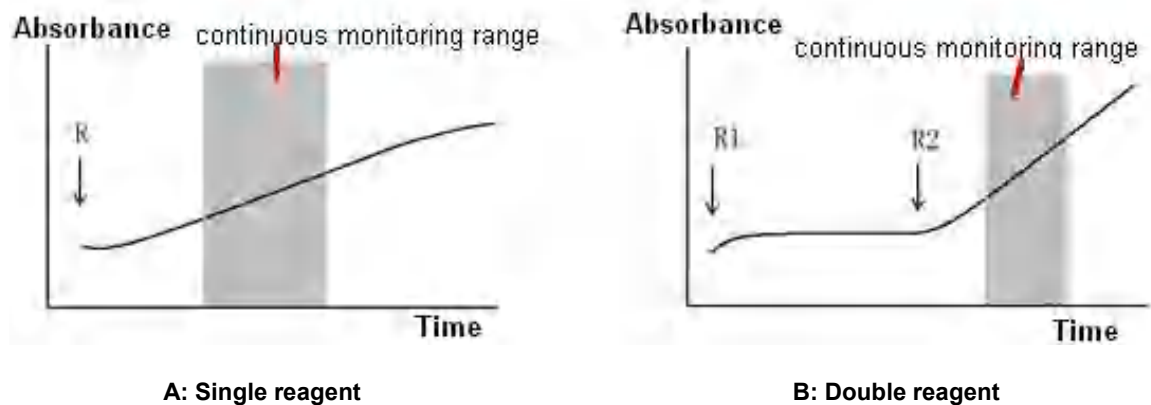
Chart 5 Blank rate method eliminate the influence of creatinine test caused by bilirubin

2.2.3 Rate Method

Generally adopt continuous monitoring method (also called rate method) for enzyme assay, such as alanine aminotransferase, aspartic transaminase, lactic dehydrogenase, alkaline phosphatase, Pancreatic enzyme acyl transfer γ ammonia, amylase, HBDH, cholinesterase, acid phosphatase, CKMB and creatine kinase and so on.

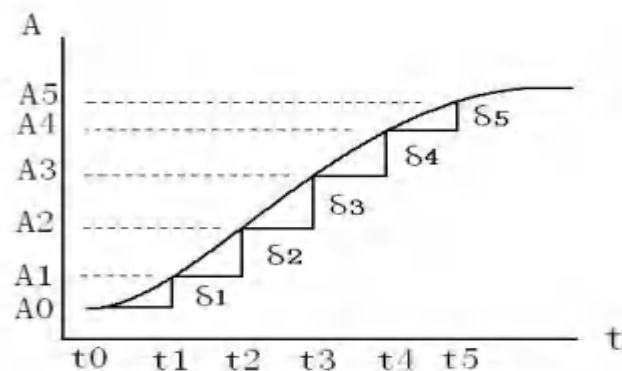
Rate method, is to choose the absorbance value continuously in time-linearity section in the absorbance curve (the D-value between every two point is the same) when test enzymatic activity or test the metabolin by enzyme, and calculate result based on the change rate of unit absorbency($\Delta A/\text{min}$).

Chart 6 Reaction curve of rate method



① Linearity section of enzymatic reaction

Chart 7 Linearity section of enzymatic reaction



$\delta 1$ and $\delta 5$ value slants small, and $\delta 2 = \delta 3 = \delta 4$, so from A1 point to A4 is linearity section

② Advantages of rate method:

Can confirm the linearity period and calculate $\Delta A/\text{min}$, and to calculate the enzymatic activity accurately according to this value; so this make the automatic chemistry analyzer observably superior to the manual method when test the enzymatic activity. Continuous monitoring method is also used for testing the concentration of linearity reaction metabolin which are normally resulted by some enzyme test.

enzymatic activity (U/L) = $\Delta A/\text{min} \times \text{theory (o calibration) K value}$

concentration of metabolin CU = $\Delta A/\text{min} \times \text{calibration K value}$

③ Theory K value

It is usually used for enzyme assay, for there have no recognized calibration substance for enzymatic activity. We can get the formula of enzymatic activity according to the international definition of unit enzymaticity:

enzymatic activity (U/L) = $\Delta A/\text{min} \times \text{calibration K value}$

In this formula use K, theory K value, as analysis parameter to input to the analyzer equipment

a. The premise of adopting theory K value:

The dosage of sample and reagent must be accurate; the light diameter of the colorimetric cuvette is accurate; the temperature control is accurate and the wavelength is accurate. But actually, due to the difference of the stepping motor accuracy and width of the optical filter between different models instruments, this may cause the error of sample and reagent volume and absorbance testing; and the influence of temperature is large sometimes.

b. Actual Moore absorptivity and K value testing

Due to the Moore absorption coefficient is influenced by cuvette light diameter and wavelength, so the Moore absorptivity in this manual or which is provided by the reagent manufactory maybe are a little different from the actual Moore absorptivity tested by instrument. So it is necessary to get the actual Moore absorptivity, and then calculate the theory K value accordingly.

NADH (NADPH) Moore absorptivity testing:

NADH (NADPH) has no standard pure product, and the stability of the solution is not so good, so we can't directly use NADH or NADPH standard liquid to calibrate the instrument. Must do NAD⁺(NADP⁺) reaction.

When use hexokinase (HK) or glucose-6-GD method to test the glucose, the consumption of glucose keeps equal Moore relations with NADH. The glucose has standard pure product. According to the formula $A = \epsilon bC$, the cuvette's light diameter and glucose standard liquid's concentration, to test the absorbance of glucose standard liquid A, and then to calculate the NADH's (NADPH) Moore absorptivity ϵ is A/bC .

The concentration of the glucose standard liquid is 10mmol/L(0.01mol/L), the adding volume of the standard liquid is 3.5 μ L, the add volume of enzyme reagent is 335 μ L, the

light diameter of the cuvette is 0.7cm, the absorbance is 0.465 at the 340nm, then the actual tested NADH Moore absorptivity is 6424. That means at the wavelength of 340nm on this instrument, the tested Moore absorptivity is 6424, but on theory NADH's (NADPH) ϵ is 6220.

The Moore absorptivity test of "Chromogen" substrates at 405nm wavelength

Many enzymes substrates are synthetic "chromogen" substrate by artificially synthesized, they are colourless. And they will liberating out colored reaction product after enzyme action, at the wavelength of 405nm, it has absorption peak. ALP substrate: phosphoric acid p-nitroaniline (4-Nitrophenyl phosphate, 4-NPP) liberate out yellow p-nitrophenol (4-Nitrophenol, 4-NP) after enzyme reaction; GGT substrate: γ -L- glutamyl- p-nitroaniline (γ -L-Glutamyl-p-nitroanilide) or γ -L- glutamyl-3- oxhydroxy- p-nitroaniline (γ -L-Glutamyl-3-carboxyl-p-nitroan) liberate out yellow p-nitrophenol after enzyme action (p-Nitroaniline, 4-NA) or p-nitryl-5- benzaminic acid (2-amino-nitrobenzoic acid, ANBA).

Take the Moore absorptivity test of p-nitroaniline as a sample:

- 4-NP standard stored liquid (10mmol/L)
- 4-NP standard application liquid (2.5mmol/L, produced by diluting 0.84mol/L AMP buffer solution)
- Substrate buffer solution (15mmol/L 4-NPP dispensed in 0.84mol/L AMP-HCL buffer solution, 37°C, pH 10.09 $\pm$ 0.02)

Test method: 4-NP standard liquid qty. is 5 μ L, Substrate buffer solution qty. is 350 μ L, wavelength is 405nm, light diameter is 0.7cm, temperature is 37°C, absorbency tested is A1; and use distilled water instead of 4-NP standard liquid, then can get absorbency is A2 and absorbency of 4-NP standard liquid is $\Delta A = A1 - A2$, according to above method. If get ΔA of 0.460, thus get real test 4-NP Moore absorptivity = 18662

④ Calibration K value:

Analyzer calculates automatically after enzyme activity calibration substance be calibrated. During enzyme testing, if the testing terms change, such as temperature, sample reagent qty. and absorptivity test error etc. all can affect calibration substance and sample untested, thus remedy with calibration substance. Generally, better use calibration K value, but should satisfy with two preconditions: ① must use matched reagents; ② must use matched and high qualified calibration substance, which should be traceable.

2.3 Transmittance Turbidimetry

It can be used for testing the items which generates turbidity reaction, and most are immune turbidity methods, apolipoprotein, immune globulin, alexin, antibody "O", rheumatoid factors, and other protein in serum such as prealbumin, haptoglobin, transferrin and so on.

The immune complex, which is formed by the antigen combined with the relative antibody, has certain turbidity in the reaction liquid, can be tested by common spectrophotometry method with transmittance turbidimetry testing; can be used for some protein and drug concentration testing. This method needs multi-point calibration, and then conduct non-linear regression to calculate the content of the antigen and antibody.

2.3.1 Reagent Blank Testing

2.3.1.1 Each bottle reagent should automatically test its reagent blank absorbency before testing;

2.3.1.2 Each sample should test the reagent blank absorbency.

2.3.2 Monitoring the Rate of the Reagent Blank

By set-up this function, analyzer will deduct the reagent blank rate in calculating the result.

In monitoring the activity of the enzyme testing which uses NAD (p) H decreasing as indication, rate-blank can be monitored and eliminate the effects of absorbency reducing which cause by the NADH's self-oxidation reaction

2.3.3 Sample Information Monitoring

Hemolysis, icterus, lipid of the sample will interfere the non-chemical reaction, so usually sample will be just its affecting level of the hemolysis, icterus, lipid at 600nm/570nm、700nm/660nm and 505nm/480nm, then automatically deduct this part to improve the reliability.

2.3.4 Reliability Monitoring

- ① End point monitoring
- ② Linearity monitoring

A: Conduct linear regression for all kinds of continuously monitored absorbance value.

Calculate variance of all points. Judge whether it presents linearity according to magnitude of variance:

B: Compare the shift of some points at the beginning of continuous monitoring with that in the end to judge whether it is linear phrase.

2.3.5 Substrate Consumption Monitoring

When determining the enzymatic activity by continuous monitoring assay, if during the monitoring period, the up or down of absorbance exceeds its substrate consumption value, it means that enzymatic activity of this sample is very high. When the substrate is to be used up, absorbance during the monitoring period will deviate the linear, which will make the result unreliable. This monitoring is vital for analyzing enzymatic activity by negative reaction.

2.3.6 Method Range of Linearity Monitoring

Every kind of analysis has a measurable concentration and activity range, if the result of sample exceeds the range, analyzer will give clues that result exceeds the linearity range. Most analyzers would automatically retest the sample decrement or increment.

2.4 Single Wavelength & Dual Wavelength

2.4.1 Conception

By using a wavelength to detect the light absorption strength of analyte is called single wavelength. It can be employed when the reaction liquid contains a kind of component or the absorption peak of analyte component in the mixed reaction liquid is no overlapping with the absorption wavelength of other coexistence material.

The method using a dominant wavelength and secondary wavelength is called dual wavelength. It would be better to employ this method when reaction liquid occur large absorption of interferent, which would affect the accuracy of testing result.

2.4.2 Function of Dual Wavelength

2.4.2.1 Eliminate the disturbance of noise;

2.4.2.2 Reduce the impact of stray light;

2.4.2.3 Reduce the impact of light absorption of sample: when sample contains interferent beyond chemical reaction, such as triglyceride, hemoglobin, bilirubin etc, nonspecific light absorption would be generated. But dual wavelength can eliminate this kind of disturbance.

2.4.3 Determination of Secondary Wavelength

When the dominant wavelength of analyte is decided, choose secondary wavelength according to the features of interferent absorption spectrum. Make interferent show similar light absorption value at the dominant and secondary wavelength, whereas analyte show obviously different light absorption value.

Generally speaking, secondary wavelength should be 100nm longer than dominant wavelength. Result is calculated based on the absorbance difference between dominant wavelength and secondary wavelength.

2.3.5 Reagent Package and Service Life

2.3.5.1 Concerning reagent package, attention should be paid to the manufacturer mark, which is supposed to meet the requirements of law and regulations.

2.3.5.2 Package should meet the requirements of industrial standard and enterprise standard.

2.3.5.3 Reagent should have proper service life, which should be indicated clearly and conspicuously on the package.

2.3.6 Precautions of Reagent

2.3.6.1 Reagent should be used within the expiration date.

2.3.6.2 Reagent should be used together with analyzer to form integrated system.

2.3.6.3 Reagent should be stored properly under the storage condition required by manufacturer.

2.3.6.4 Reagent should be used in accordance with service conditions and range of application required by manufacturer.

2.3.6.5 Reagent is only for in vitro diagnostic use.

3. Calibrator & Control

3.1 Conception

Calibrator: Calibrate with 2nd standard substance, decide value with conventional method. It is used for calibration of conventional method and instrument.

Control: it is characterized with brought in line with detection process. Its ingredients is the same or similar to matrix of detection sample. Control should be of good stability. The variation between several bottles should be less than expectant variation of observation system. Its conventional detection helps to confirm the report range.

Potential difference of result is likely to occur due to different detection principles and reagent quality adopted by analyzers produced by different manufacturers. Especially for some special specimen, the value got from different detection systems sometimes would be different with the true value. Therefore, manufacturer and distributor of analyzer have the responsibility to chronically and stably provide the special specimen of this detection system, detection result and other relevant information. Besides, to keep this traceability for good, all detection systems in this traceability system should be ensured under stable state every year, day and hour. So once all detection systems enter traceability system, it is necessary to actively conduct control indoor and among doors.

3.2 Packages and Expiration Date of Calibrator and Control

3.2.1 Concerning reagent package, attention should be paid to the manufacturer mark, which is supposed to meet the requirements of law and regulations.

3.2.2 Package should meet the requirements of industrial standard and enterprise standard.

3.2.3 Reagent should have proper service life, which should be indicated clearly and conspicuously on the package.

3.3 Precautions of Calibrator and Control

3.3.1 Reagent should be used within the expiration date.

3.3.2 Reagent should be used together with analyzer to form integrated system.

3.3.3 Reagent should be stored properly under the storage condition required by manufacturer.

3.3.4 Reagent should be used in accordance with service conditions and range of application required by manufacturer.

3.3.5 Reagent is only for in vitro diagnostic use.

Chapter Three Instrument Description

1. System Structure

This Part mainly describes the structure and interface and other basic operations of TC6030 automatic chemistry analyzer

The full name of the system is TC6030 Automatic Chemistry Analyzer , It is intended for in vitro diagnostic use and quantitative determination of clinical chemistries in serum, plasma, urine or cerebrospinal or pleuroperitoneal fluid samples.

Warning: if the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.



Note

- Some samples may not be analyzed on the system based on parameters and the testing reagents .For these sample, you can consult the reagent manufacturer or distributor for details.

1.1 Analyzing Unit

The analyzing unit consists of the sample-reagent disk, aspiration system, reaction disk, photometer for analyzing operation.

The cabinet below the analyzing unit is optional.

1.1.1 Sample-reagent disk

Sample-reagent disk holds sample and reagent. The outer circle positions hold sample and QC. The inner circle positions hold single/dual reagent.

The sample position can holds the following container:

Micro tube, Centrifugal tube

Blood collecting tube $\Phi 12 \times 75$

The Drawell reagent tubes are used only.

The volume of reagent container is 20ml

Sample-reagent disk places in the sample-reagent storage. The storage supports refrigeration to keep temperature between 2~8℃.



Note

- The reagent positions are for Drawell reagent bottles only. Please use specified sample tubes; otherwise, it may cause system damage.

1.1.2 Sample dispenser

The sample dispenser is composed of a sample probe, probe arm, probe rotor. It aspirates certain amount of sample or reagent from the designated sample tube and reagent bottle and then dispenses it into the designated reaction cuvette on the reaction disk.

After each aspiration and dispensing, the sample dispenser moves automatically to probe washing well for cleaning.

Volume of sample: 1.0~50µl, 0.1µl step;
Volume of reagent: 10~400µl, 1.0µl step.

Dispenser system is capable of pre-heating, liquid level detection and tracking, vertical collision protection.



Warning

- When the analyzing unit is in operation, do not place any part of your body or any obstacle in the route the arm moves. Otherwise, it may lead to personnel injury or equipment damage.

1.1.3. Mixer Assembly

The mixer assembly consists of mixer, mixer arm and rotor. It stirs the reaction liquid evenly in the reaction cuvette until reacting completely.

For single-reagent test, the mixer works once sample is dispensed.

For double-reagent test, the mixer works after dispensing sample and R2 respectively.

When stirring is finished, the mixer moves automatically to the wash well for cleaning.



Warning

- When the analyzing unit is in operation, do not place any part of your body or any obstacle in the route the arm moves. Otherwise, it may lead to personnel injury or equipment damage.

1.1.4 Reaction Disk Assembly

The reaction disk holds the cuvette. The cuvette are designed for reaction of sample and reagents, and colorimetric measurement.

In analyzing, the reaction disk carries the specified cuvette to dispensing position (mixing position the same) for dispensing and stirring, and then carries it to the axis of corresponding light path for absorbency measurement.

The cuvette is able to use permanently and is replaced manually if necessary.

The reaction disk is placed in temperature-controlled storage provided the steady temperature at $37 \pm 0.1^\circ\text{C}$.

The exchange of Cuvette cup:



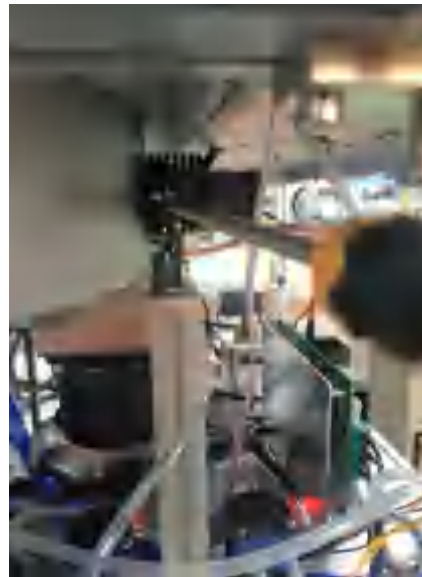
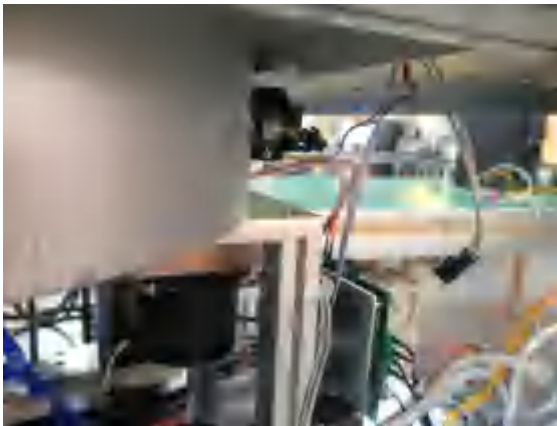
BIOHAZARD

- Wear gloves and lab coat is a must to replace reaction cup to avoid to be infected.
- Be sure to dispose of the used cuvette according to the local regulations.

1.1.5. Photometer Assembly

The photometer assembly, which locates in the analyzing unit, measures the absorbance of the reaction mixture in the cuvette.

The exchange of Halogen Lamp:



Biohazard

- Light sent by the photometer lamp may hurt your eyes. Do not stare into the lamp when the system is in operation.
- If you want to replace the photometer lamp, first switch off the MAIN POWER and then wait at least 30 minutes for the lamp to cool down before touching it. Do not touch the lamp before it cools down, or you may get burned.

1.2 Operation System

The operation system is a computer, installing control software for running, operation and data processing



Warning

- External device connected to the system, e.g. computer, printer, must be complied with the requirement of IEC 60950 or EN 60950.

1.3 Output System

Output System is a printer for printing data.



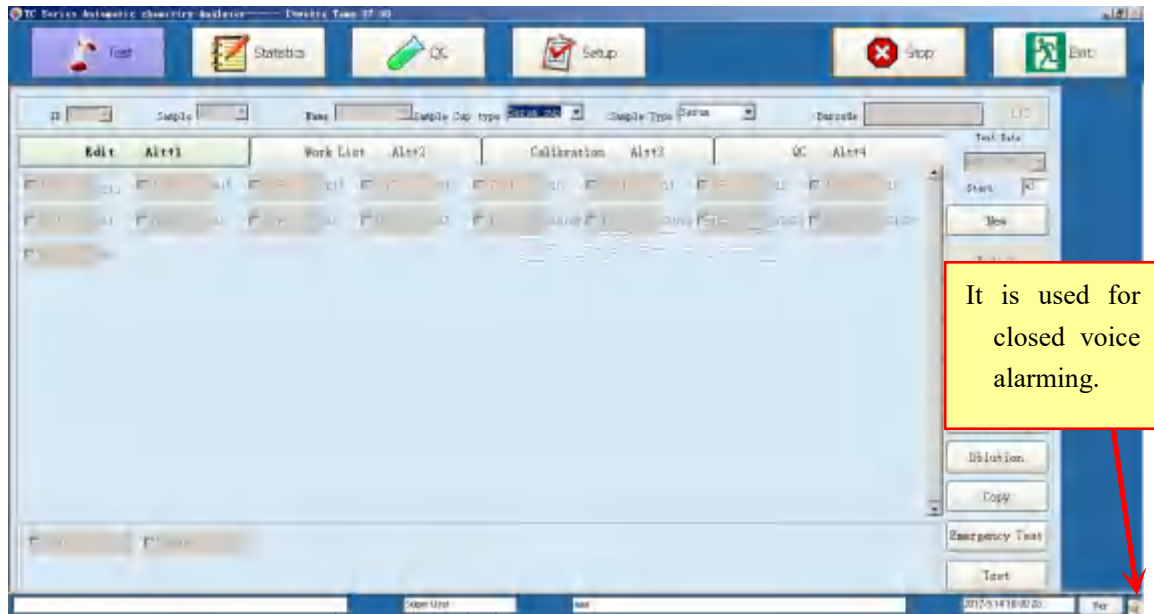
Warning

- External device connected to the system, e.g. computer, printer, must be complied with the requirement of IEC 60950 or EN 60950.

2. Software Operation

2.1 Screen Layout

The main interface of the software is displayed below:



Software main interface

Functional button area

It lies on the top of interface, including "User, Parameter, QC, Report, Statistic and Maintenance" submenus. When you click one of them, the relevant working interface will display.

Working status area

The area under the Functional Button Area is working status area, which displays time, sample ID, ID cup No and Patient information

Biochemical test area

It is set on the leftmost and rightmost columns of screen, designed for both regular and emergency test.

Working interface area

It displays the value and graph of parameters, process, result and etc on the interface of selected button. At the bottom of the interface is the note area, where the items listed on the current interface is described.

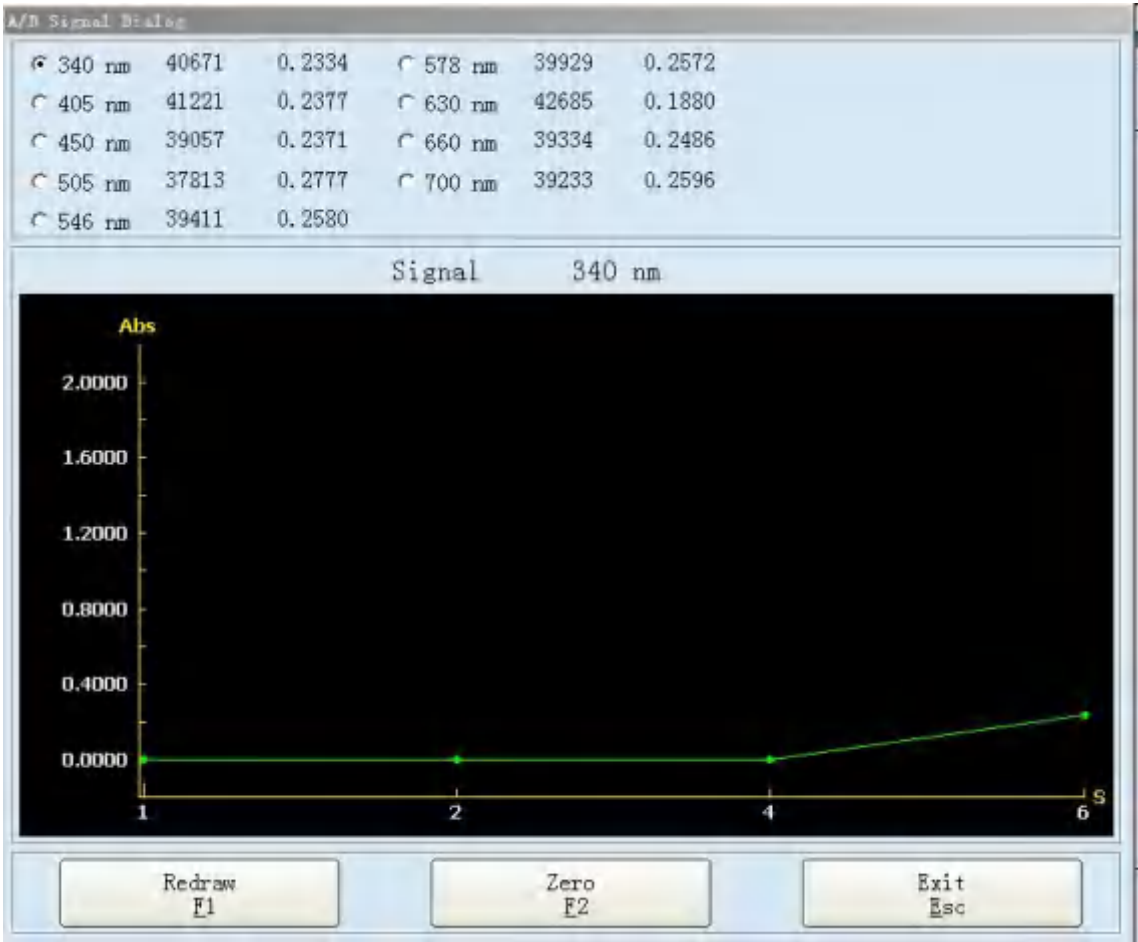
Operator area

The bottom area is operator area, which displays current operator's information

2.2 Screen Elements

Dialog box

The dialog box is one of the most common interfaces for man-machine interaction. Please see the following example.



Dialog box

Tab

Click a tab and you will enter its corresponding index working interface. See the figure below for an example.



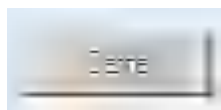
Drop-down list box

Click , and a list will display, as the figure below shows. Click the desired item to select it.



Button

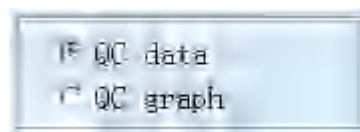
Click a button and you can access the function it indexes, as the figure below shows.



Option button

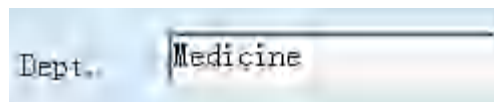
Click a radio button to select the option it represents.

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



Edit box

You can input characters in the edit box through the keyboard. See the figure below. Two edit boxes are provided, In one box, only character can be input on the box, in the other box, apart from input of character, the left button of the mouse can be used to click the right icon of edit box  or  to select



Scroll bar

When the content is beyond the size that screen can display, scroll bar will appear. Move the pointer on the scroll bar, press left button of the mouse and hold it, then you move the mouse to drag the scroll bar to see the hidden contents

Edit Alt+1		Work List Alt+2				Calibration Alt+3				QC Alt+4					
No.	Sample	Design	Sample	Sample Name	1	2	3	4	5	6	7	8	9	10	11
1	1	1	1	Serum cu	GLU	ALT	GGT	TP	ALB	BUN	cre	Ca			
2	2	1	2	Serum cu	GLU	ALT	GGT	TP	ALB	BUN	cre	Ca			
3	3	1	3	Serum cu	GLU	ALT	GGT	TP	ALB	BUN	cre	Ca			
4	4	1	4	Serum cu	GLU	ALT	GGT	TP	ALB	BUN	cre	Ca			
5	5	1	5	Serum cu	GLU	ALT	GGT	TP	ALB	BUN	cre	Ca			
6	6	1	6	Serum cu	GLU	ALT	GGT	TP	ALB	BUN	cre	Ca			
7	7	1	7	Serum cu	GLU	ALT	GGT	TP	ALB	BUN	cre	Ca			
8	8	1	8	Serum cu	GLU	ALT	GGT	TP	ALB	BUN	cre	Ca			

List

The list displays the name of one or multi items or combination of them. The example is showed as below. Click to select it, and click it again to cancel your selection. Number stands for the position of reagent.

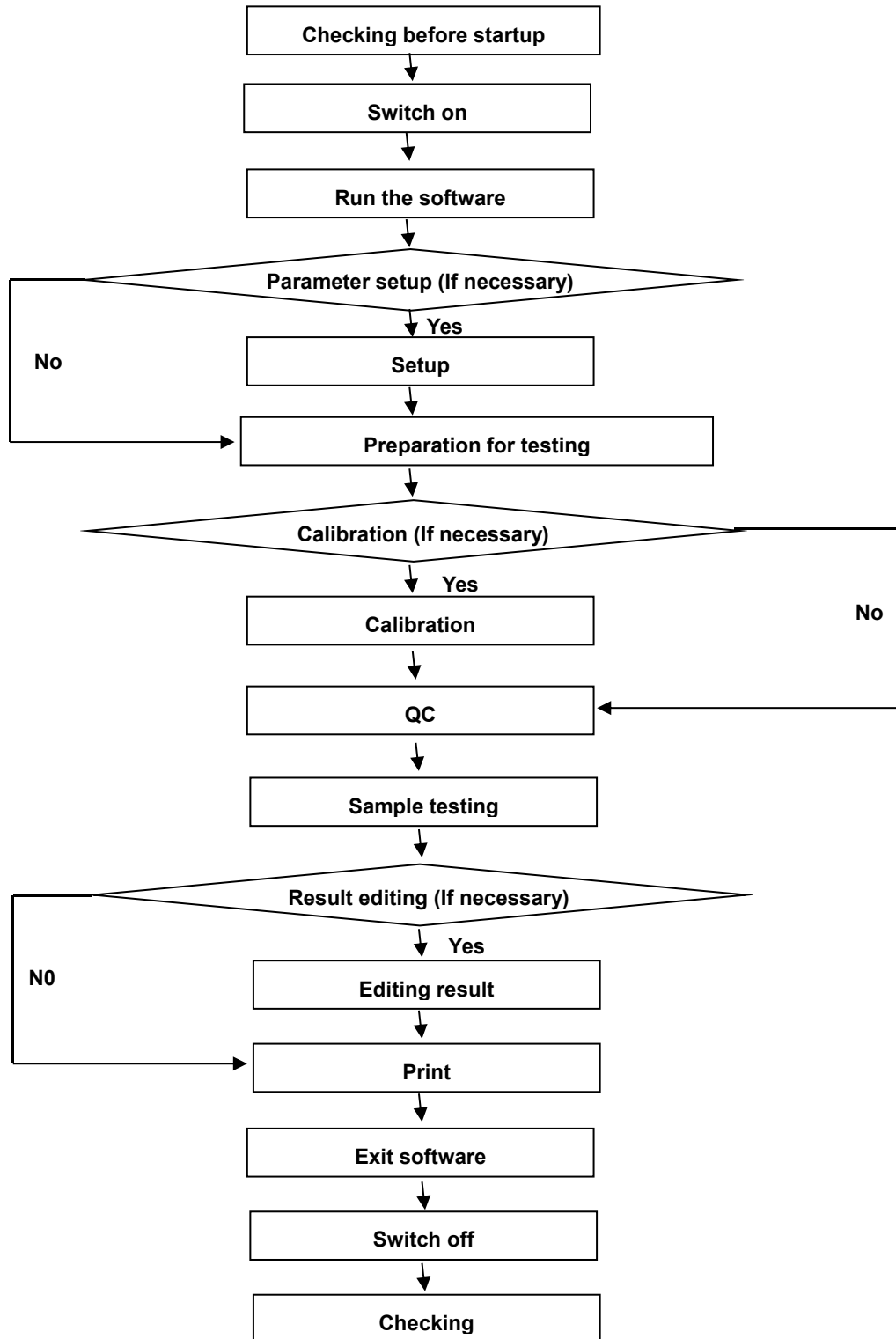
Edit		Alt+1		Work List		Alt+2		Calibration		Alt+3		QC		Alt+4	
☒ ALT	2/3	☒ AST	4/8	☒ ALP	9/17	☒ GGT	5/9	☒ TP	10	☒ BUN	11	☒ TP	12	☒ ALB	13
☒ GLU	14	☒ BUN	15	☒ creat	16	☒ UA	17	☒ TC	18/19	☒ TC	20/21	☒ HDL_C	22/23	☒ LDL_C	24/25
☒ Ca	26														

☒ All

☒ Group 1

Chapter Four Basic Operations

1.General Operation Procedure



2.Operation Rule

2.1 Preparation for Testing

2.1.1Checking before Startup

To ensure that the system can works normally after switching on, please check what stated below before startup.



BIOHAZARD:

- Wear gloves and lab coat and when doing the following inspections; if necessary, please also wear goggles.

1)	Check the power supply, ensure power supply and voltage is ok.
2)	Check the communication cable (which connect the analyzer, computer and printer) line and the power line, ensure they are ok and not loose.
3)	Check whether the printing paper is enough; please add printing paper if necessary.
4)	Check the detergent is placed properly. Note: Drawell recommends the following types detergents: • Strong acidity detergent: 0.1mol/l muriatic acid. • Strong alkalescency detergent: 0.5%(V/V) hypochlorous acid. • Do not mix the about two detergents together. • Drawell recommends to use the two detergents interchangeably, For example this time use Strong alkalescency detergent, then next time use Strong alkalescency detergent
5)	Make sure the sample probe is at the right position (cleaning position).
6)	Make sure the stirring probe is at the right position (cleaning position).
7)	Make sure there is enough distilled water in the water bucket.
8)	Emptying the waste bucket.
9)	Prepare enough reagents for daily tests.

2.1.2 Switch On

Connect the power supply and switch on each part orderly as follows:

1	Analyzer Power Supply
2	Computer Screen Power Supply
3	Computer (Mac Pro) Power Supply
4	Printer Power Supply

2.1.3 Run Software

- 1) After startup Windows (windows XP and win7) Operation System, you can startup control software by double clicking the shortcut icon of the software on the desktop or from software package.
When startup, system will check the operation system, screen resolution, close screen protection program, check color configure, initial database, check printer.
After checking, a dialog box will pop-up and then you can input administrator name and password and click “OK” to enter into the software.



Note: The temperature showed on the main interface, the data is captured every 10s; if on the temperature set up interface, the data is captured every 3s.



Note:

- The screen resolution must be more than 1024x768; color setup must be 8 digits or above.
- The system administrator name is “8888” and the initial password is “8888”.

- 2) Click “MAINTENANCE” button, and then click “Initialize” button to reset the moving parts and the screen is shown as below.



Note:

- To ensure accurate testing results, please power on the system for at least half an hour before starting the testing.

2.1.4 Parameters Setup

Only when the parameters are set properly and rationally, the analyzer can carry out the testing and other functions.

Please setup the parameters when first time operates the analyzer. During the daily operation, the user can setup the parameters according to the specific needs.

Before the testing, please at least setup the following parameters:

- 1) Hospital data setup
- 2) Doctor data setup
- 3) Calibration Setup
- 4) QC setup
- 5) Items setup

2.1.5 Preparing the Reagent

Load the reagent bottles to their designated positions on the reagent disk, and then open the bottle covers.



Warning:

- Exercise caution to prevent puncture wound by the probe tip.



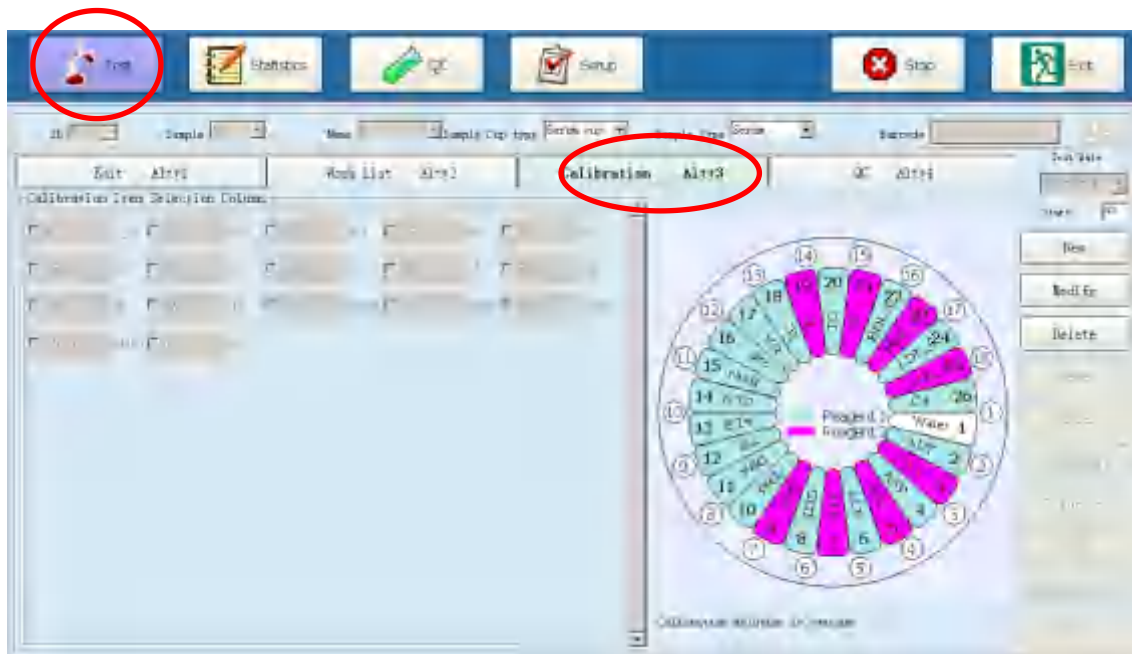
BIOHAZARD

- Wear gloves and lab coat are must to avoid to be infected and, if necessary, goggles.

3. Start Testing

3.1 Calibration

Do calibrations before testing; and select refer to the following picture:

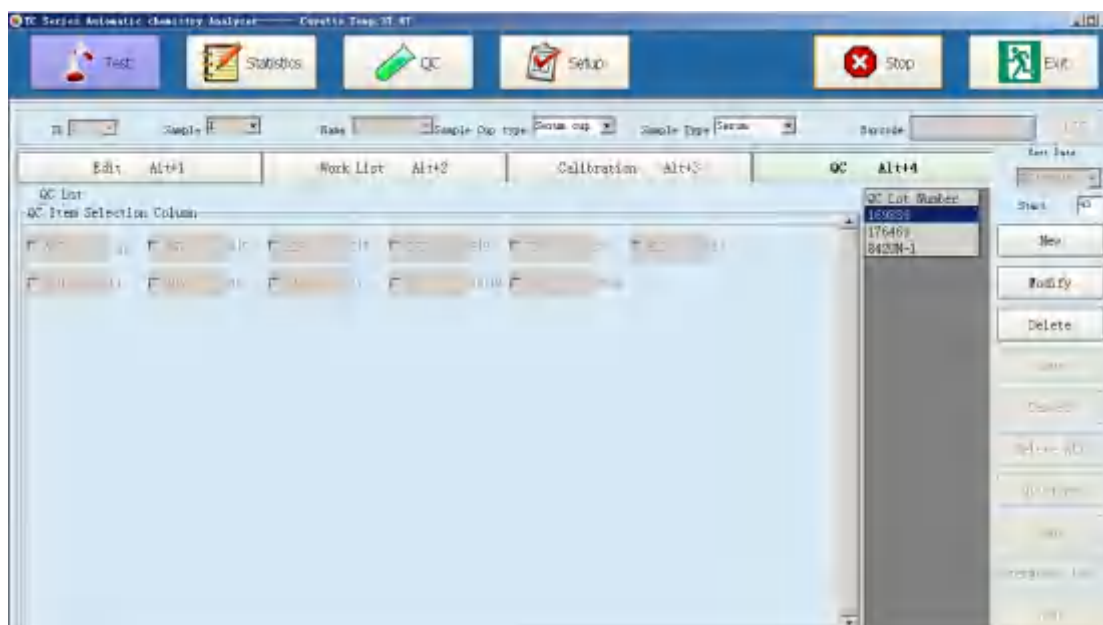


Note:

- Please re-perform the calibration if you change the reagent lot No., test parameter, source lamp (or other analysis conditions will result in measurement situation change).

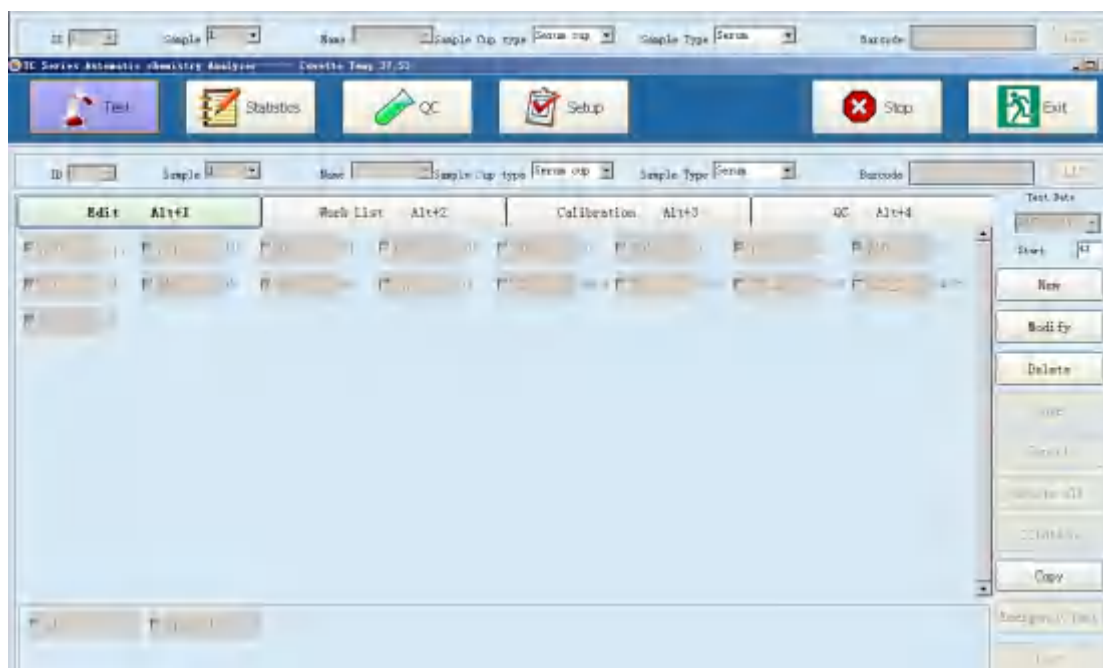
3.2 QC

Put the QC (as the sample) together with the samples for testing. Also can compiled the QC chart.



3.3 Sample Testing

Setup the samples parameter as the below picture. Load the samples into the corresponding positions after requesting the samples; and then click “test” to start the testing.



Note:

- The requesting of emergency testing is similar with the requesting of common samples; the only difference is to click “emergency testing” at requesting time in necessary.
- Ensure the samples are placed in the correct positions, otherwise it may cause unreliable testing results.

4. Result Follow-up

4.1 Editing the Sample Testing Results



Note:

- The testing results can only be edited when guided by authorized superior doctors.

4.2 Printing the Testing Results



Important:

- The system automatically stores the data to the built-in hard disk. However, data loss is still possible due to deletion or physical damage of the hard disk or other reason. We recommend you to regularly back up the data to such medium as CDs.

5. Finishing the Testing

5.1 Exit the Operation Software

When all tests are finished and the system is in standby status, the user can click "EXIT" button to exit the operation software.

5.2 Shut Down the Analyzer

After exiting the Windows operating system, please switch off the powers orderly as below:

1)	Printer Power Supply
2)	Computer Power Supply
3)	Analyzer Power Supply

5.3 Checking after Powering Off



BIOHAZARD:

- Wear gloves and lab coat are must to avoid to be infected and, if necessary, goggles.

1)	Cap the sample/reagent tube/bottle on sample/reagent disks and cover the disks.  Note: • If the MAIN POWER of the analyzer is power off, please take the reagents from the reagent disk and put them into an external refrigerator.
2)	Remove the calibrators, controls, samples and reagents in the sample/reagents disc.
3)	Empty the waste bucket.
4)	Check the surface of the analyzer, if any stains, wipe them off with clean soft cloth. If necessary, with neutral reagent

Chapter Five Advanced Operations

1.Work menu sheet

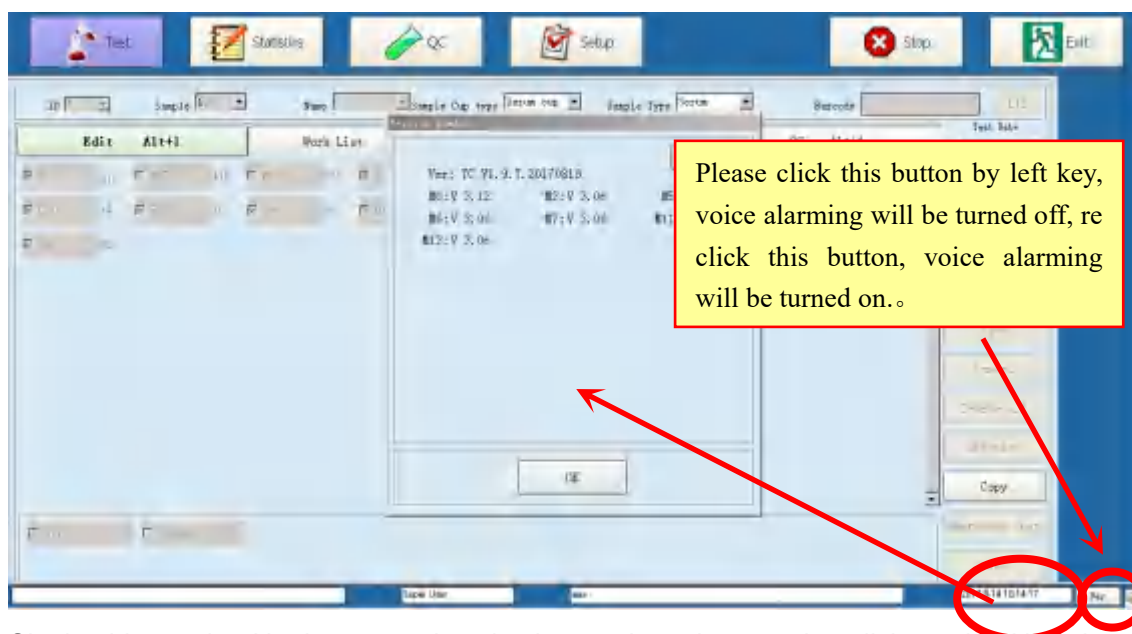
1.1 Work menu

Main menu	First class menu	Second class menu	Remarks
1 、 Customer data	Customer section setup		Display hospital name when printing.
	Operators setup		Display operators name when logging and printing.
	Data dictionary setup		
2 、 Biochemistry parameters	Biochemistry items parameter setup	Item basic parameter Samples and reagents volume Item reference range Calibrator results	Setup biochemistry parameters
	External items parameter setup		Add other instruments test into printing.
	Counting items setup		
	Combined items setup		Select bulk items fast.
	Item test sequence setup		To avoid cross pollution.
	Item print sequence setup		
3、 Indoor QC	QC serial No. setup		
	QC data display		
	QC within a day		QC data process within a day 。
	QC daytime		QC data process on different days。
4、 Test report	Patient information registration		
	Test results display		
	Real-test graph display		
5、 Query & Stat.	Modify results		Modify test results
	Historical data display		
	Charge Stat.		
	Query		
	Patient historical		
6 、 Instruments maintenance	Instruments initialization		
	Instruments speciality setup		
	Cuvette maintenance		Wash cuvette and test cuvette quality
	Instruments parameters setup		Instruments move parameters setup
	A/D signal test		Test signal value

	Movement assembly test		Test valve and pump's work condition.
	Temperature& pressure		Display and setup temperature & pressure.
	Print format setup		
	LIS parameters setup		
	Cuvette working time		This is used for recording using time of cuvette, it will show in red if the use time excess rated, to remind user to change cuvette.
7、Biochemistry test	Item edit		
	Item view		
	Calibrator setup		
	QC		
8、Performance test	Calculator		
	Reagents volume test		Test reagents volume
	Dilution setup		Condition setup while automatically retest
	ISE setup		Select" Instruments specialty setup" then display。
	Barcode scan setup		Select" Instruments specialty setup" then display。
9、Stop test			Stop all order and initialization。
10、Exit			Exit software.

1.2 Software version number

Click bottom right side of main interface "version no.", will see version no. information. See below picture.



Single chip version No. is automatic selection, and you just need to click version no. when it is the first time to run this software.



This is for “turn on”



This is for “turn off”

2 Menu Introduction

2.1 Customer data

Click” Customer data” button, enter into below interface. Using for hospital setup、operator setup and data dictionary setup.

The screenshot shows the 'Setup' menu of the 'TT Series Automatic Analyzer' software. The 'Setup' button is circled in red. Below it, the 'Customer Data Setup' button is also circled in red. The interface shows various setup options like Reagent Parameter Setup, Reference Range Setup, Character Setup, etc.

The 'Customer Data Setup' interface is shown below, with three tabs: Customer Data, Operator Setup, and Data Dictionary Setup. The 'Customer Data' tab is active, showing fields for Hospital, Address, Tel, and Report title. The 'Operator Setup' tab is also visible, showing fields for Department, Doctor, and Note. The 'Data Dictionary Setup' tab is also visible, showing a table with columns for Department, Dr, and Note.

Department	Dr	Note
Medicine	fff	
Surgery	ddd	

2.1.1 Customer unit setup

“Customer unit setup” interface see above picture, use for setup hospital name、address、telephone、section name、patient name and so on.

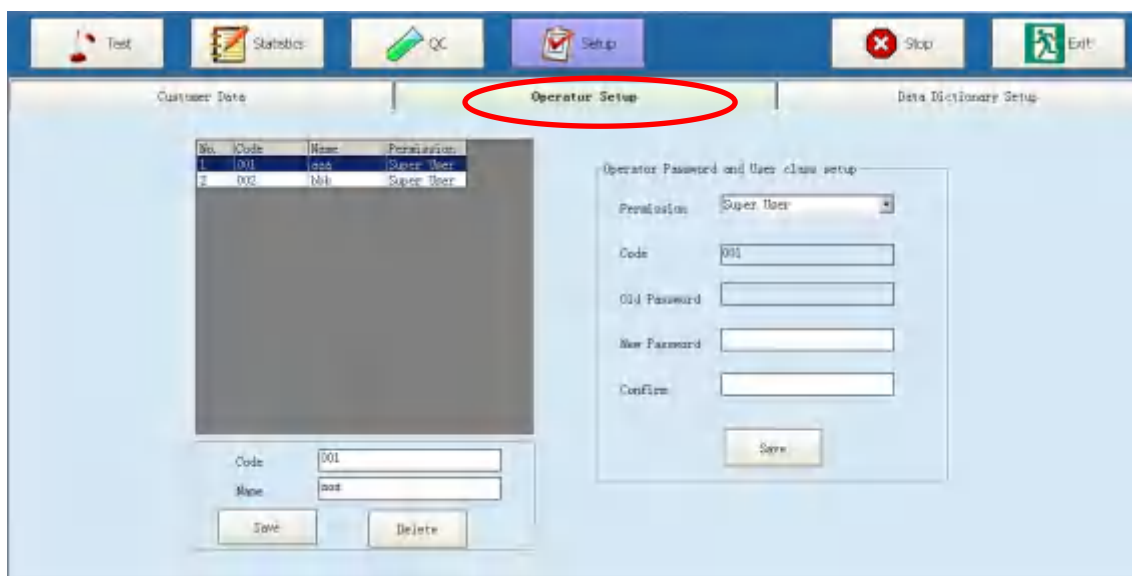
Parameters	meanings
Hospital name	Hospital's name. Can display when printing.
Hospital address	Hospital's address.
Telephone	Hospital's telephone
Section name	Samples section name。
Doctor name	Doctor's name who diagnostic patient。
Remark	Explain above parameters that can't describe。

Button	Function
Save	Save input information
Delete	Delete input information

2.1.2 Operator setup

Select" Operator setup" option, enter into below interface:

Super user can edit chemistry parameters, ordinary user can't edit.



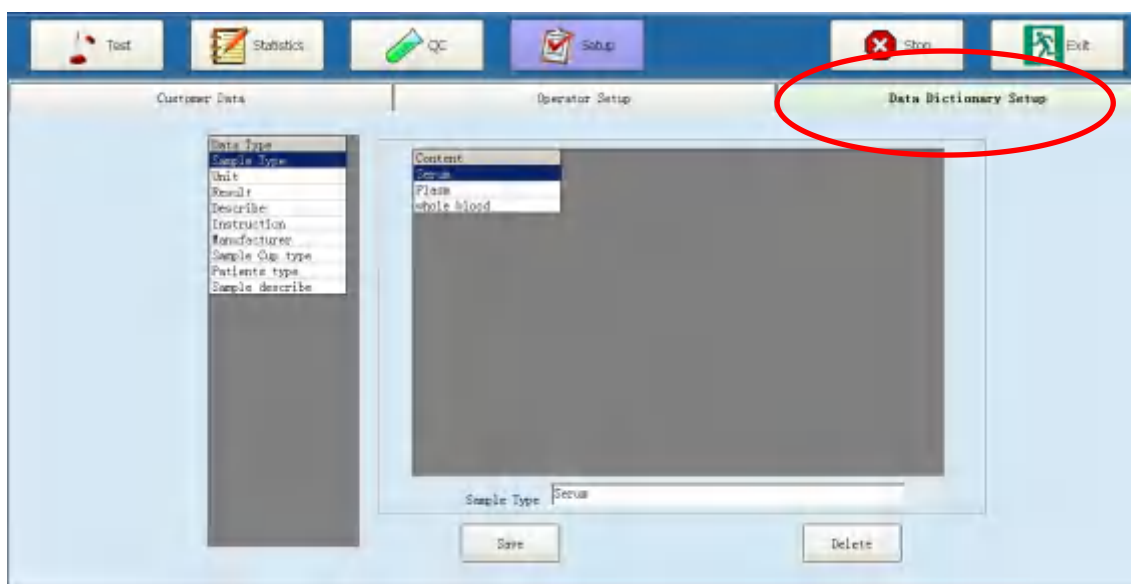
Parameters	Meanings
Operator's code	Setup operator's code instead of name。
Operator's name	Setup operator's name。
Operator's old password	Operator's setup password before。
Operator's new password	Operator's change old password to new one。

Parameters	Meanings
Confirm new password	Input new password again to confirm。

Buttons	Function
Save	Save input information
Delete	Delete input information

2.1.3 Data dictionary

Select "Data dictionary" option, enter into below interface:



Parameters	Meanings
General data	Input needed contents in this column 。
Sample type	In sample type column add related contents。
Related contents	Add related contents in sample type, will display in related contents。

Buttons	Function
Save	Save modified contents
Delete	Delete selected contents

2.Biochemistry parameters

Click "Parameter" button, enter into following interface, use for biochemistry test items parameter setup. This is the most main steps that instrument can test correct results.

The screenshot shows the Series 8000000i Rheology Analyzer software interface. The top menu bar includes buttons for Test, Statistics, QC, Setup, Stop, and Exit. The main area contains a grid of buttons for various setup functions. The 'A. Reagent Parameter Setup' button is circled in red.

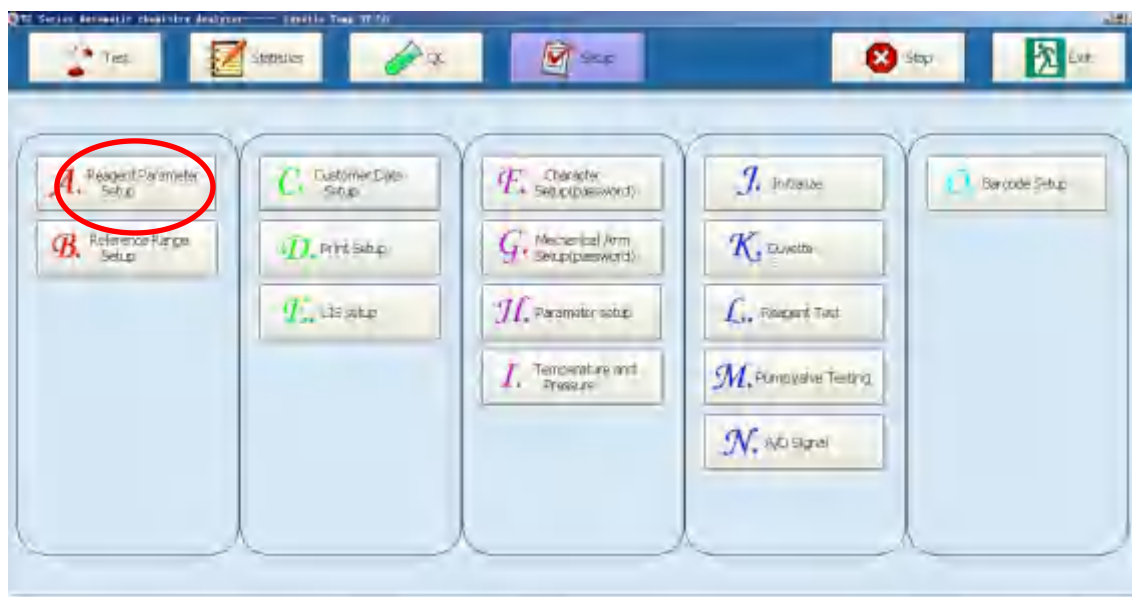
Function	Function	Function	Function
A. Reagent Parameter Setup	C. Customer Data Setup	F. Character Setup (password)	J. Initialize
B. Reference Pump Setup	D. Print Setup	G. Mechanical Arm Setup (password)	K. Cuvette
	E. LIS Setup	H. Parameter Setup	L. Reagent Test
		I. Temperature and Pressure	M. Pump/Valve Testing
			N. I/O Signal
			O. Barcode Setup

[illegible]

System needs setup sample volume、 reagent volume、 wavelength.To setup these parameters please check this user manual and reagent user manual.

Click “Parameter” button, enter into following interface, use for biochemistry test items parameter setup. This is the most main steps that instrument can test correct results.

66



Important:

System needs setup sample volume、 reagent volume、 wavelength.To setup these parameters please check this user manual and reagent user manual.

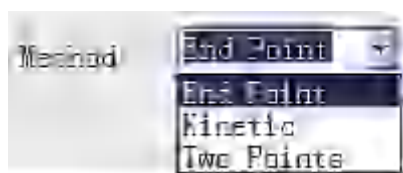
2.1.1 Biochemistry items parameters setup

“Biochemistry items parameter setup” interface see above picture. Using for setup biochemistry test items basic parameter、 reagents and samples 、 reference range and so on.

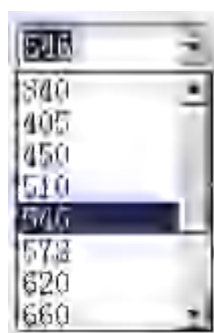
2.1.1.1 Basic parameters

This place can setup test methods, main wavelength, subsidiary wavelength, decimal points, unit amend factors and standard setup.

Setup method can reference user manual's parameter requests to setup.



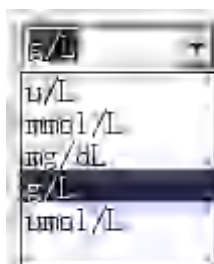
Click test method's right side scroll bar , select correct method.



Click main wavelength's right side scroll bar , select correct main wavelength.



Click subsidiary wavelength's right side scroll bar, select correct subsidiary wavelength.



Click unit right side scroll bar, select correct unit.

Parameters	meanings
method	According to test items, select suitable methods by scroll bar 。 For example, ALT is kinetic.
Main wavelength	Main wavelength must setup。

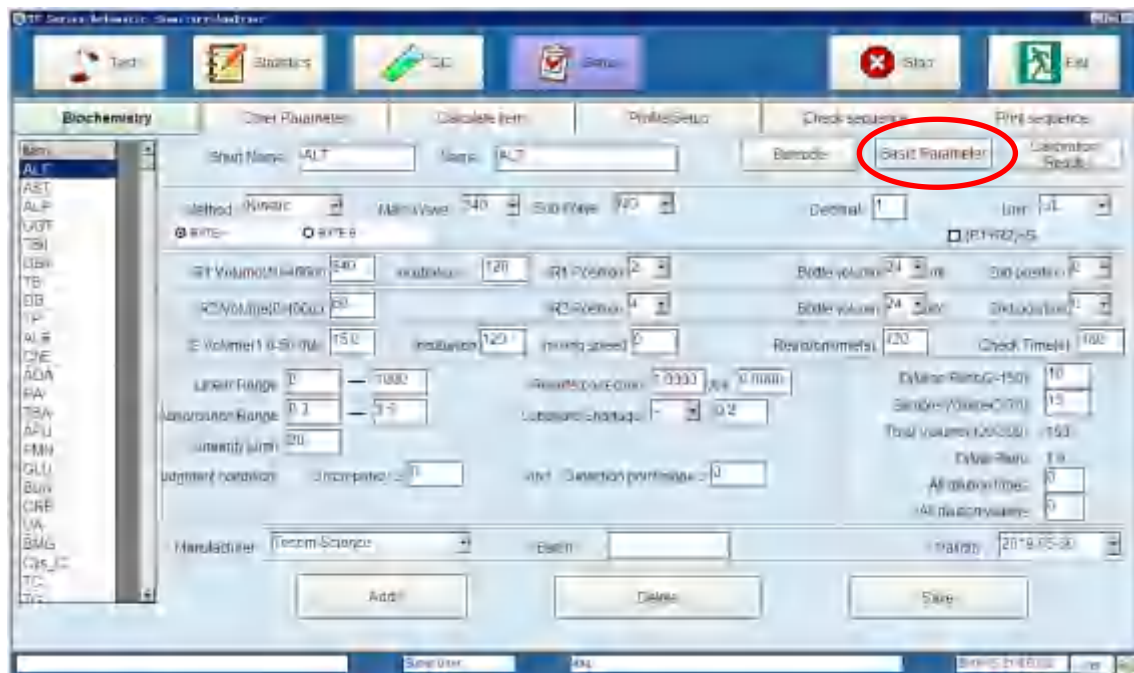
Parameters	meanings
Subsidiary wavelength	Delete disturbed wavelength, setup depends on needs.
Decimal points	Results need save decimal points. For example, setup "0", doesn't need save decimal points.
Unit	Test items units.
Linear Range	The max testing value for Chemistry testing, if the result exceeds the linear range, it will dilute automatically and retest.
Linear limit	It is only effective for rate method, used to determine whether reaction curve of rate method is smooth, if beyond linear limit, it will automatically diluted for retest.
Absorbance Range	Used to determine reaction curves is within normal range, if beyond absorbance range, it will automatically dilute for retest.
Substrate Shortage	Substrate Shortage Parameter is set to absorbance is greater than or less than set value, to be judged as consumed.
High value: Slope 1 Slope 2	High value judgment, Only suitable for "law of absorbance falling rate" : 1. slope1 means: "Difference","Difference"="The slope before four points"-“check-point slope”. This parameter filled by user, and "Difference value = linear high limit/theory K value" 2. slope1 means: “check-point slope”, “check-point slope”. Means: slope between read points, This parameter filled by user, and "Check point slope" = normal value high limit/theory K value" 3. “The slope at front four points”, among them the first point as to be judgement of Absorbance peak after” R1. sample.R2” filled over and add subsequent three points. 4. Should be taken as High value, for conform to two conditions at same time. “slope 1$\geq$ set value and slope 2$\leq$set value.
Manufacture	Fill in the manufacturer of Chemistry reagent
Batch	Fill in the batch No. of Chemistry reagent
Autodilute times	Used to set defaulted dilution factor while the item automatically retest
Sample Volume	To set up the item's sample volume while automatically retest.
Total Volume	To display the total sum of sample volume and water volume, it will be calculated automatically.
Dilute Ratio	To display the ratio of sample volume to water volume, it will be calculated automatically.

Parameters	meanings
Mixing speed	To set up stirring speed need hardware supporting. Used to set up the project of stirring speed during the test, Note: In the case of hardware is not supported, this parameter does not work, Users don't need to pay attention to this parameter.

Buttons	Function
Add	Click add, enter into next parameter setup.
Delete	After click, delete setup items.
Save	Save setup.

2.1.1.2 Basic Parameter

Click “Biochemistry Basic Parameter” enter into following interface:



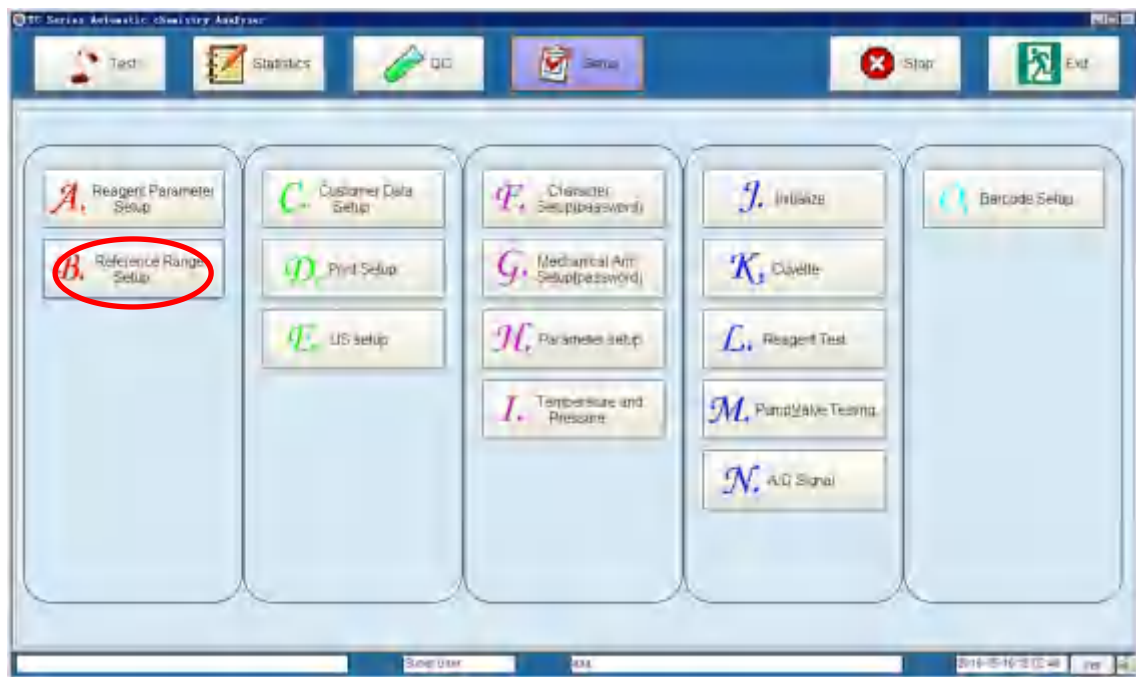
Here can setup R1 volume and position, R2 volume and position, R1&R2 incubation time, Setup sample volume and test points.

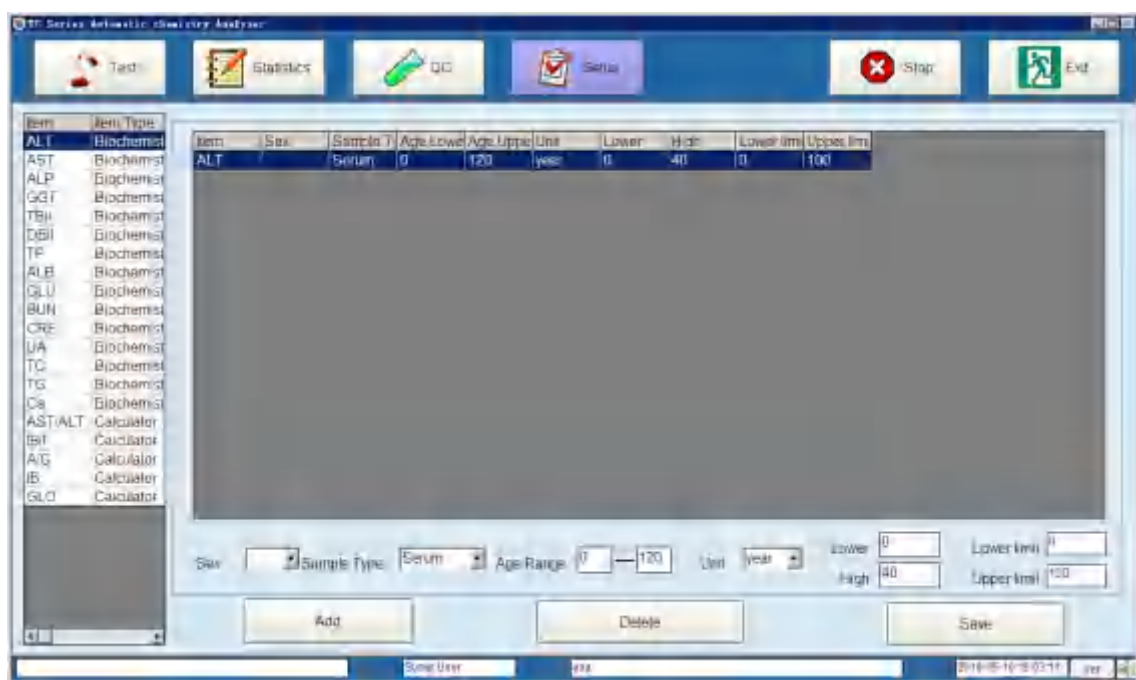
Parameter	Meaning
The First Reagent Setup	
Volume	R1 volume。 Range:10~400, 1.0step, unit: μl 。
R1 Position	The position of R1 on reagent disk.
Bottle volume	Select the actual reagent volume
2nd position	Make one same test item can use two bottles of reagent, after select

Parameter	Meaning
(1#disk)	the “standby reagent position”. When the reagent in “1st position” is used up, the analyzer will suck reagent from “2nd position” automatically, this expands reagents volume intelligently.
The Second Reagent Setup	
Position	R2 reagent position in the reagent disc
Incubation Time(s)	The incubation time after add the R1, Sample and R2
Bottle volume	Select the actual reagent volume
2nd position (2#disk)	Make one same test item can use two bottles of reagent, after select the “standby reagent position”. When the reagent in “1st position” is used up, the analyzer will suck reagent from “2nd position” automatically, this expands reagents volume intelligently.
Sample and Check Time Setup	
Sample Volume	Sample needed volume。Range:1~50, 0.1step, unit: μl 。
Check Time(s)	Test time use points display。

2.1.1.3 Item reference range

Select one of biochemistry items, click” reference range” option, can appear this item reference range and also can edit.



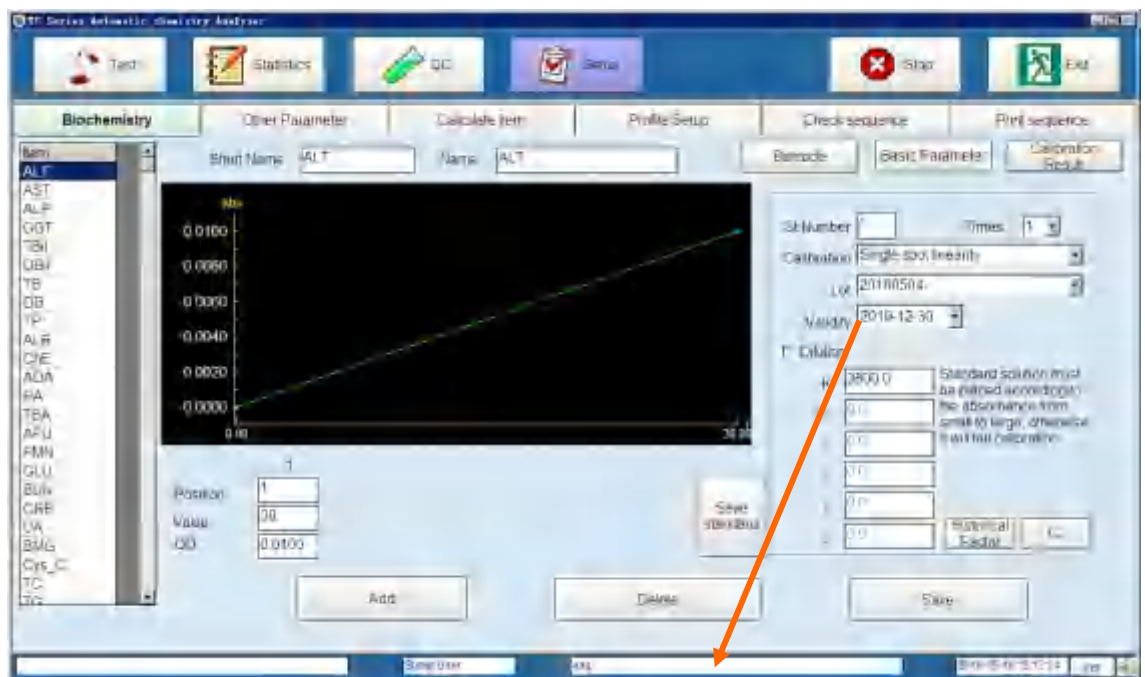
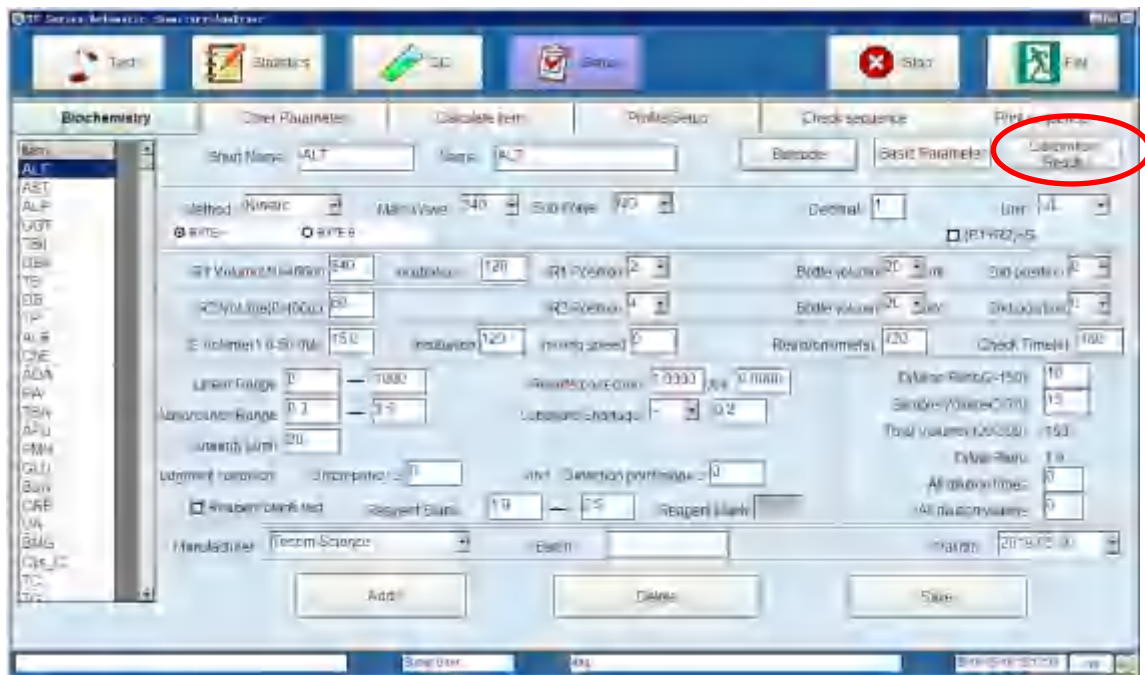


Parameters	Meanings
Sex	Patient sex.
Sample type	The sample which is tested, for example, serum or urine.
Age	Patient age.
Unit	The unit of concentration or activity of a sample.
Lower	Normal value's lower limit value.
High	Normal value's upper limit value.
Lower limit	Setting alarm range of lower limit value
Upper limit	Setting alarm range of upper limit value

Buttons	Function
Save	Save setup results
Add	Add patient's parameter.
Delete	Delete setup results.

2.1.1.4 Calibrator results

If setup calibrator in item parameters, in this interface will appear calibrated results curve.



The Validity of standard fluid can be modified, beyond the validity, it will not be shown on this page, a.k.a. it cannot be used to do calibration

Parameters	Meaning
St.Number	While selecting standard method, it will appear the corresponding standard fluid No.
Dilution	Only use 1 calibrator, make calibrator after dilute according to setup dilute times.

Position	Calibrator in samples position.
Value	Calibrator marked value
OD	Calibrator test absorbance value
Compute	Click button“Compute” , according to the value of standard solution and its absorbance, the software will automatically display the value of K、R0、a、b、c、d。

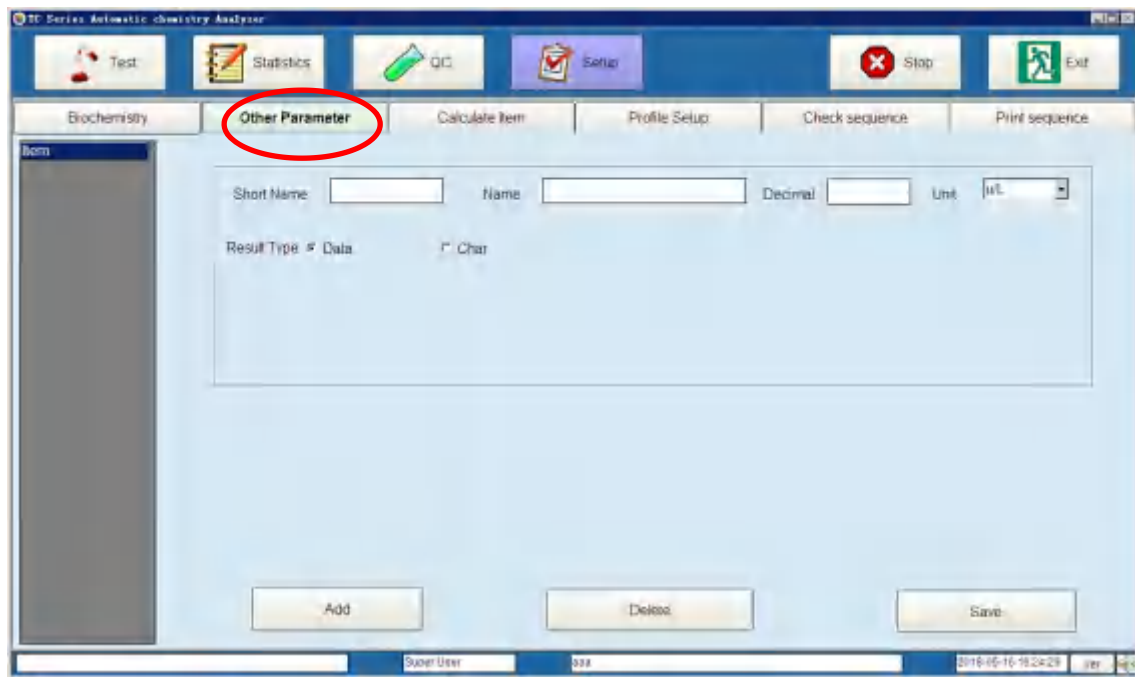
Buttons	Function
Save	Save setup results
Add	Add patient's parameter.
Delete	Delete setup results.

Standard method please see below chart:

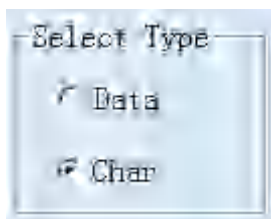
Serial No		Type of Standard fluid	Standard Qty	Standard Parameter
Linear Stand ard	1	Single spot linearity	1	K
	2	Double spot linearity	2	a、b
	3	Multiple spot linearity	3~6	a、b
Non-li near Stand ard	1	Logistic-Log 4P	4	K、R ₀ 、a、b
	2	Logistic-Log 5P	5	K、R ₀ 、a、b、c
	3	Exponential 5P	5	K、R ₀ 、a、b、c
	4	Polynomial 5P	5	a、b、c、d
	5	Parabola	3	a、b、c
	6	Spline	4	R ₀ 、a、b、c

3. External item parameter setup

Click” external item parameter setup” enter into following interface, check or edit items.



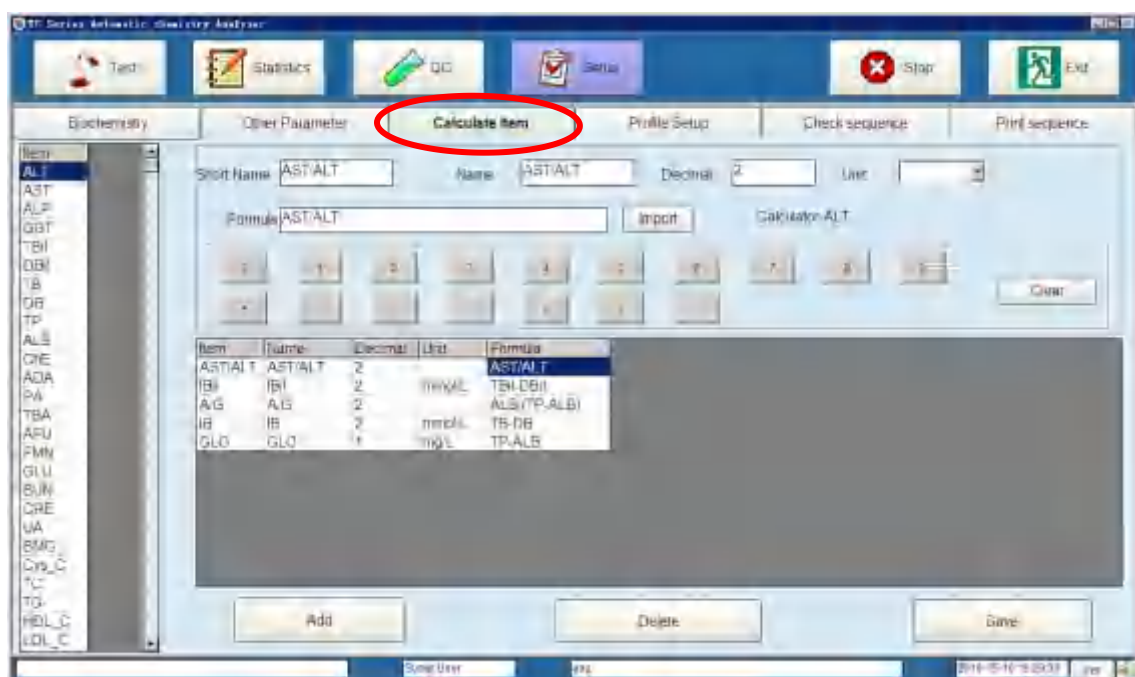
This use for patient test by other instruments, need results print together in same report.



Result can display by figure or character.

3.Counting items setup

Some biochemistry items don't need test. Can count by other items. For example, GLO=TP-ALB.



Parameter	Meaning
Name	Chinese names of computation items
Short Name	English names of computation items
Decimal	The saved decimals of computation items results
Unit	The unit of computation items
Formula	The calculating formula
Calculator	Select and lead the items which are related to the selected computation items in biochemistry items listing
Clear	Eliminate the current expression by clicking this button
Import	After select the items in the upper box, lead the items into the expression by clicking this button
0~9	To input numbers into expression by clicking these buttons
+ - * /	To input "+", "-", "*", "/" operational symbols into expression by clicking these buttons
. ()	To input decimal point or bracket into expression by clicking these buttons

Buttons in this dialog box:

Button	Function
Save	Save the setting results
Add	Add patients' parameters
Delete	Delete the setting results

4.Profile setting

- 1) Click "Items combination setting" will enter into below interface, edit combined items.
- 2) Click "Add" button, input needed combined item in combined item name, then click needed combined items in items column, after click "save", will display in combined items.
- 3) Biochemistry items combination, can operate easily in biochemistry testing, only click biochemistry combined items will display needed test items, please see "biochemistry test" in details.



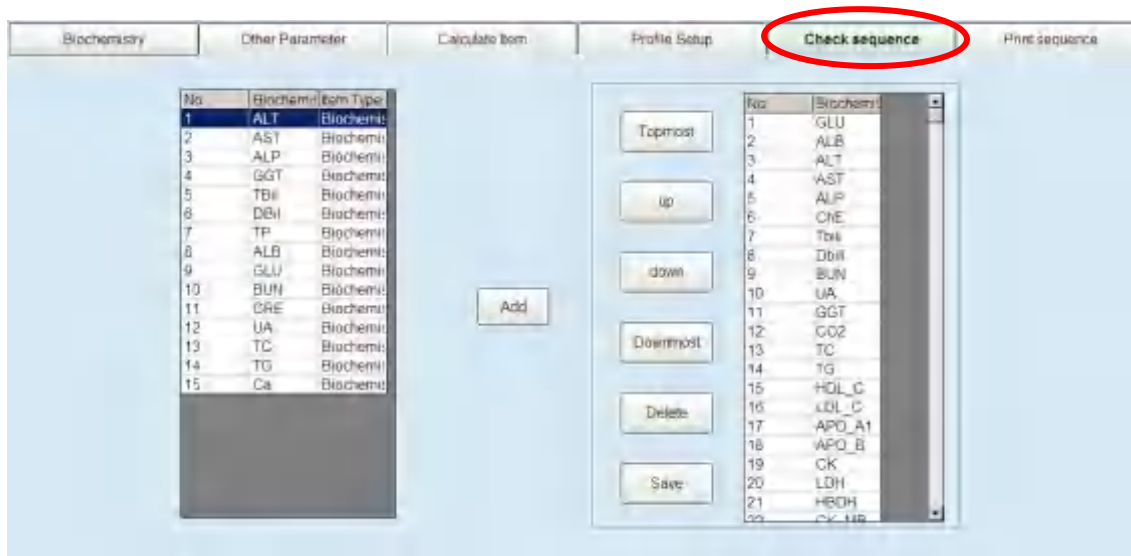
5. Test sequence setting

5.1 Here can set up item test sequence, left list is all chemistry items, right is going to test items.

5.2 Choose one of left items, click "add", can add this item to the bottom of right list, if setting right list items sequence, choose one of items, then click

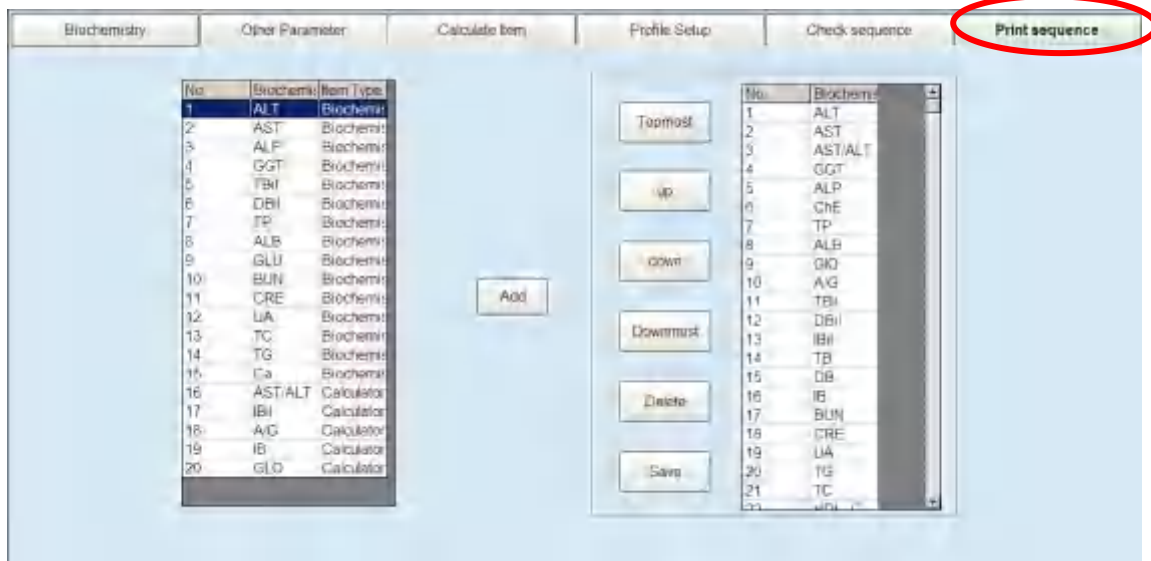
"up", "down", "top", "bottom" buttons. "up", "down" buttons, click one time, move one position.

5.3 According to setting sequence, will test from No.1.



6.Item print sequence setting

Here can also setting item print sequence, left list is all chemistry items, right list is needed print chemistry test items. Choose one of left items, click “add”, can add this item to the bottom of right list, if setting right list items sequence, choose one of items, then click “up”、“down”、“top”、“bottom” buttons. “up”、“down” buttons, click one time, move one position.



Below introduce “parameter” interface buttons

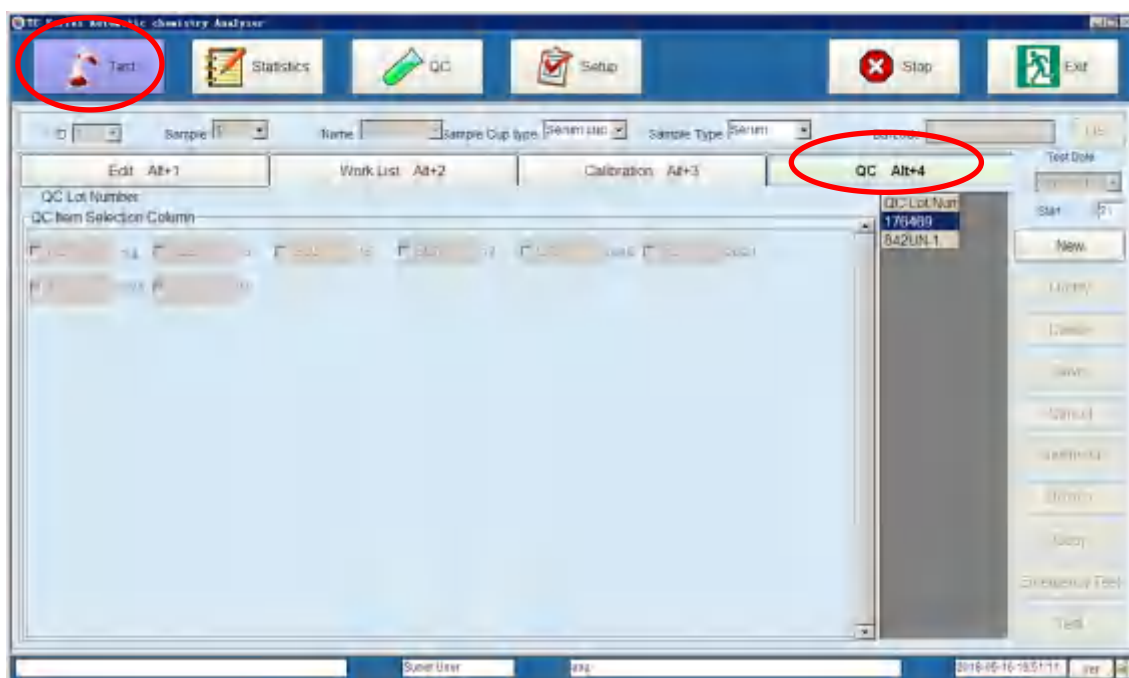
Buttons	function
Add	Click this button, add new items.
Delete	Choose item, then click delete ,delete this item.
Save	Choose item and setting, then click will save setting.
Topmost	Choose item then click, this item will on the top.
up	Choose item then click, this item will move up one position.
down	Choose item then click, this item will move down one position.
Downmost	Choose item then click, this item will on the bottom.

3. Indoor QC

1) QC sample input

1.1 Sample input of chemistry test interface

Click “Test” button , will enter into chemistry test interface. Click “QC” can enter into QC interface. Choose can do chemistry test items in this QC, click “add” button, will see behind “calibration” option have “QC” option, choose one group of items, click “add”, “save”, can do “test”. See picture. This interface use QC tests.



Remarks:

- In item list, item's background color indicates condition:
 - Yellow means this item have been choose;
 - Red means this item can be selected

2)、Indoor QC

Click “Quality Control” button, enter into QC interface. This interface use QC LOT setting、QC data display and QC chart analysis。

2.1、 QC LOT setting

You can set each item's QC number、 target value、 Expiry date and deepness. See below Picture.

QTY Series Software: Quality Analyzer

QC Lot Number setup
 QC Data
 QC in same day
 QC in different day
 QC value print

QC Lot Number:
 Item: ALT
 Density: 1.000
 Validity: 2016-12-31

QC Target: 11
 SD: 12
 QC:

Composite Sum Check
 R Value: Comm Limit:
 T-X(1) BSD: X-2 TSD
 P-X(1) BSD: X-3 BSD
 T-X(1) BSD: X-5 TSD
 Westgard Multi-Rule
 T-1.2S: T-R-4S
 T-1.3S: T-4.1S
 T-2.3S: T-10X
 Deviation with QC Rule
 Range Value E: 0
 X-R QC Rule
 SDR Value: 0
 Range: 0 — 0

Biological Unit	Decimal	QC Target	SD	1SD	2SD	Lower	High	QSC	WMR	WMI
ALT	uL	11	12	-1-23	-13-35	0	0	1	0	0
AST	uL	1	1							
ALP	uL	1	1							
GGT	uL	1	1							
TRH	mmol/L	2	2							
DBI	mmol/L	-2	-2							
TP	g/L	1	1							
ALP	g/L	1	1							
GLU	mmol/L	-2	-2	4.4-5.2	4.4-5.2	0	0	1	0	0
BUH	mmol/L	2	2	5.01-5.52	4.75-5.79	0	0	1	0	0
CRP	mmol/L	1	1	5.55-7.22	6.21-7.77	0	0	1	0	0
UA	mmol/L	1	1	255-294	252-335	0	0	1	0	0
TC	mmol/L	2	2	2.0-2.54	2.18-2.91	0	0	1	0	0
TS	mmol/L	2	2	1.21-1.41	1.3-1.46	0	0	1	0	0
Ca	mmol/L	-2	-2	1.99-2.15	1.91-2.23	0	0	1	0	0

Sample:
 Unit:
 Print:

QC RULES

1、There are four QC rules as below:

- 1、Westguard multi-rule
- 2、Cumulative sum check
- 3、 $\bar{X} - R$ rule
- 4、error accumulation rule

2、Judgment method of QC rules:

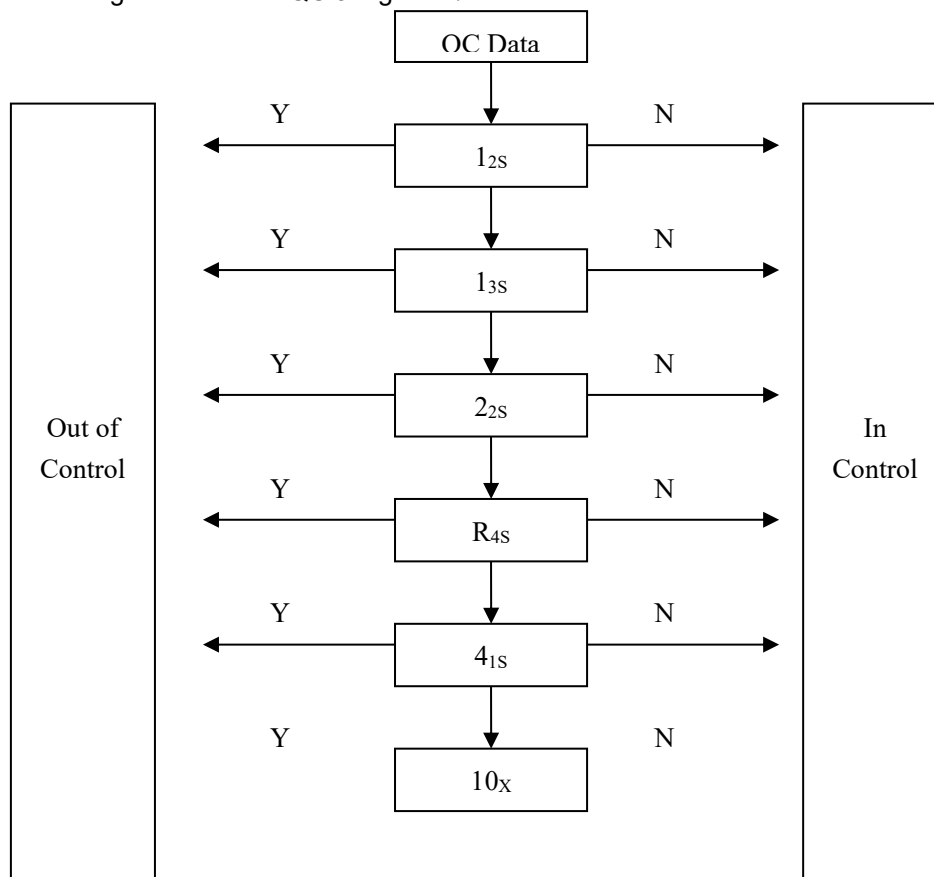
1、Westguard multi-rule

Including sub rules as below:

code symbol	Definition	QC Judgment
1 _{2s}	1 point falls outside +2SD or -2SD of the mean.	warning
1 _{3s}	1 point falls outside +3SD or -3SD of the mean.	Out of control (Random error, System error)
2 _{2s}	2 points continuously fall outside +2SD or -2SD of the mean.	Out of control (System error)
R _{4s}	Difference of 2 continuous values is greater than 4SD	Out of control (Random error)
4 _{1s}	4 points continuously fall outside +1SD or -1SD of the mean.	Out of control (System error)
10 _x	10 points continuously fall on the same side of the mean.	Out of control (System error)

Parameters: 1-2S、1-3S、2-2S、R-4S、4-1S、10X、multi-selection

Figure Westgard Multi-rule QC Judgment:





2、Cumulative sum check

- 1、Calculating Threshold K and Control Limit h according to the setting rules;
- 2、When the QC value is not beyond Threshold K, ignore it;
- 3、At the data point which QC value is beyond Threshold K(higher than high limit or lower than low limit), calculating of cumulative sum is starting.;
- 4、For the following data points, continue calculating cumulative sum;
- 5、When cumulative sum start changing the symbols(from + to -, or from -to +), calculating ended, cumulative sum becomes zero, and for the following data points, continue calculating cumulative sum.
- 6、When cumulative sum is beyond Control Limit h(higher than high limit or lower than low limit), it is out of control.

Three methods are as below:

	Threshold K	Control Limit h
Method 1	$X \pm 1.0SD$	$X \pm 2.7SD$
Method 2	$X \pm 1.0SD$	$X \pm 3.0SD$
Method 3	$X \pm 0.8SD$	$X \pm 5.1SD$

3、 $\bar{X} - R$ rule

According to the comparison of different value R which is from twice tests (X_1 and X_2) of same QC liquid and entered SD_R , beyond $2SD_R$ or $-2SD_R$, it is out of control. Here is the requested way to get SD_R value: via pre-testing, continue testing 20 days, testing the same lot samples before and after once everyday, calculating the SD_R of different value R based on twice tests (X_1 and X_2).

P: SD_R value, it is entered by user.

4、error accumulation rule

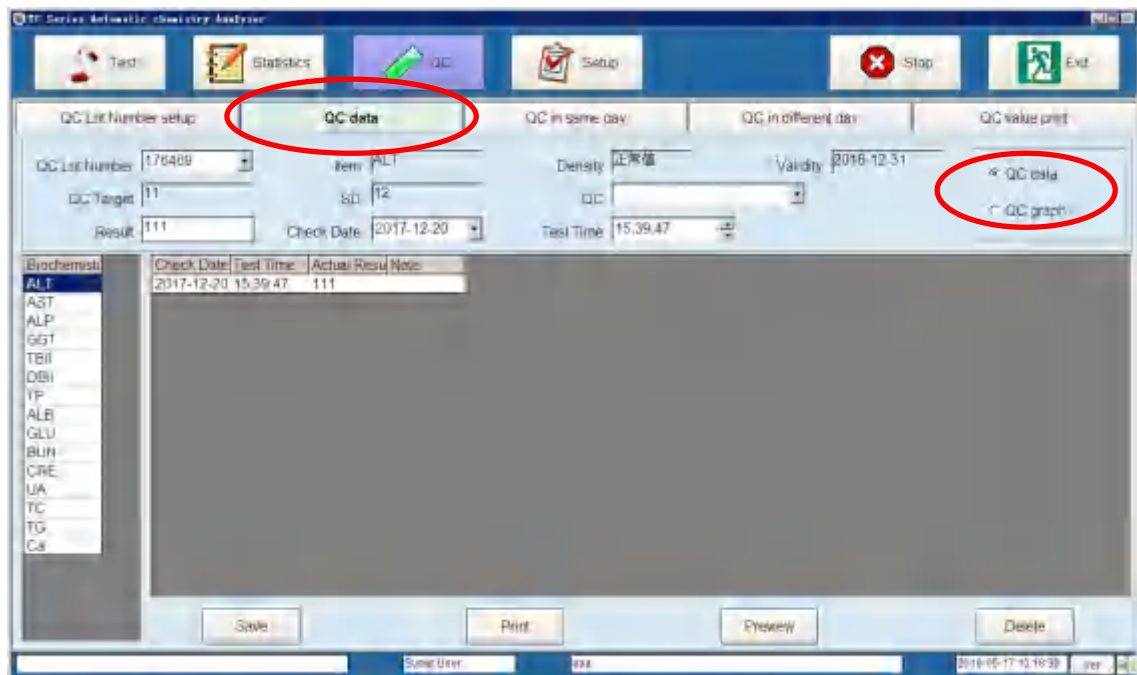
Calculating the different value of one QC liquid one project testing result X and target value(error, +/-), the sum error of 1 is error 1, the sum error of 2 is error 1 plus error 2, the sum error of 3 is sum error 2 plus error 3, the sum error of N is sum error n-1 plus error n, the sum error is beyond sum error limit E or $-E$, it is out of control.

P: limit value E, it is entered by user.

2.2、 QC data display

In this option can check QC value. See below picture.

Select “ QC data display” , as below picture:



Select “ QC chart”, will display QC chart curve. See below picture.



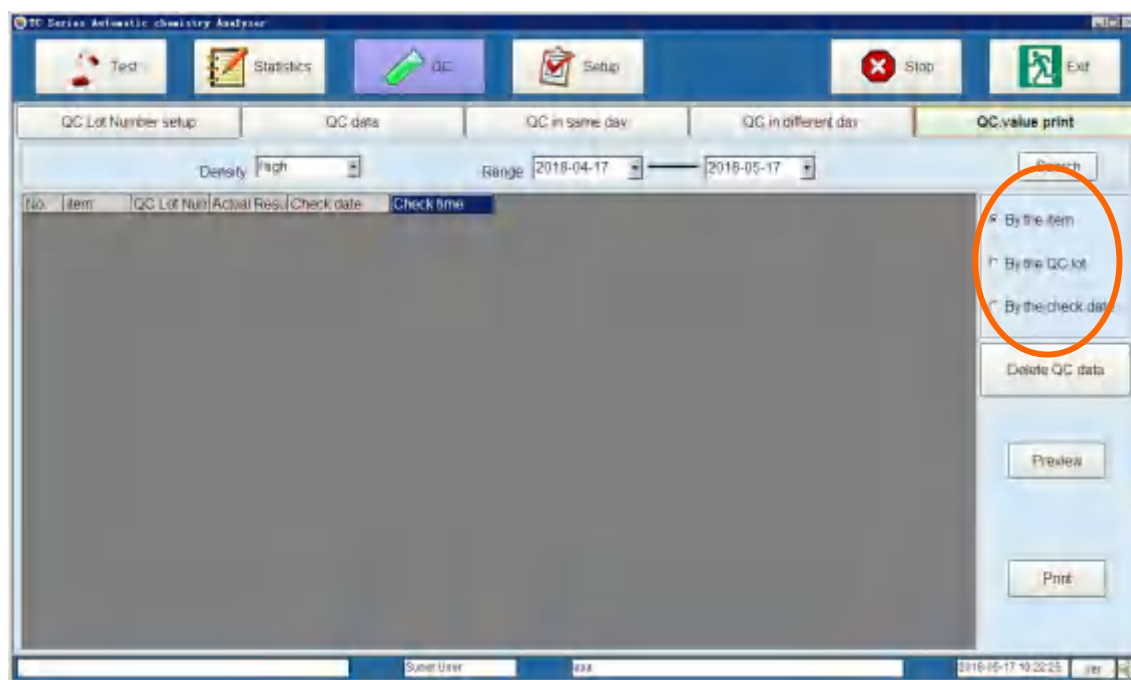
2.3、Day QC & daytime QC:

QC in same day: QC performed in the same day.

QC in different day: QC performed in the different day:

2.4、QC value print

It can print according to item, Lot No. and test time.



Below is introduction interface's button.

Button	Function
Redraw	Refresh the interface
Print	Print QC chart.
Print view	View the interface before printing



Attention:

- Setting QC liquid's valid date exactly, so that system can judge if it in valid or not.

4.Test report

Click“report” button, enter into interface, input patient’s information, “Save”information, User can “view” print format, select suitable format, “Print”, can print patient test report.

1) Patient information registration

During testing, can input patient full information, click“test report”button, enter into“Patient information registration” interface, see below picture,This interface use for register and edit samples information.

Also in interface can check patient test result, and display real-time test chart.

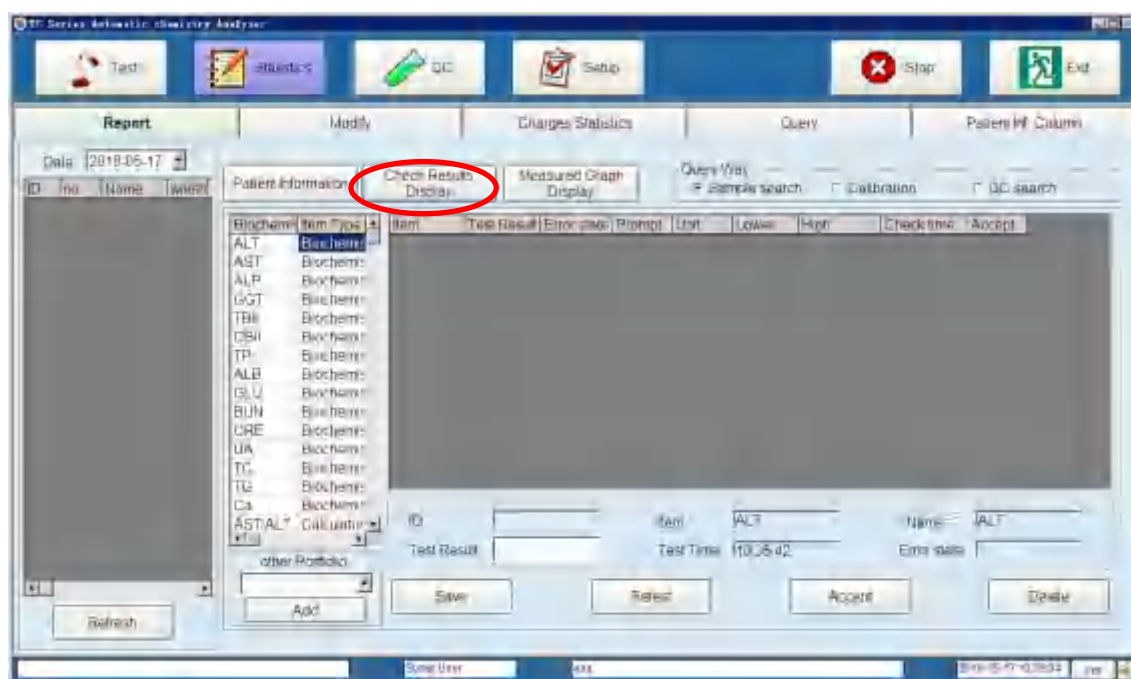
Below introduce “Sample information” dialog box’s parameter.

Parameter	Meaning
Serial No.	Software will increase serial no automatically.
ID	Operator input ID No. for tell different samples.
Select	“No” not selected. “Yes” selected.
Name	Patient name
Gender	Patient sex
Age	Patient age
Outpatient No.	Patient case history No.
In-patient No.	Patient in-patient No.

Parameter	Meaning
Area No.	Patient sick area.
Bedroom No.	Patient sickbed No.
QA INSPECTOR	The qty of inspector
Submitting department	Inspector's department.
Submitting doctor	Inspector name
Sample type	"Serum", "Plasma", "Urine", "Others"
Print date	Revise inspect date manually
Clinic impression	Basic description of patient samples.
Barcode No.	Samples barcode information.

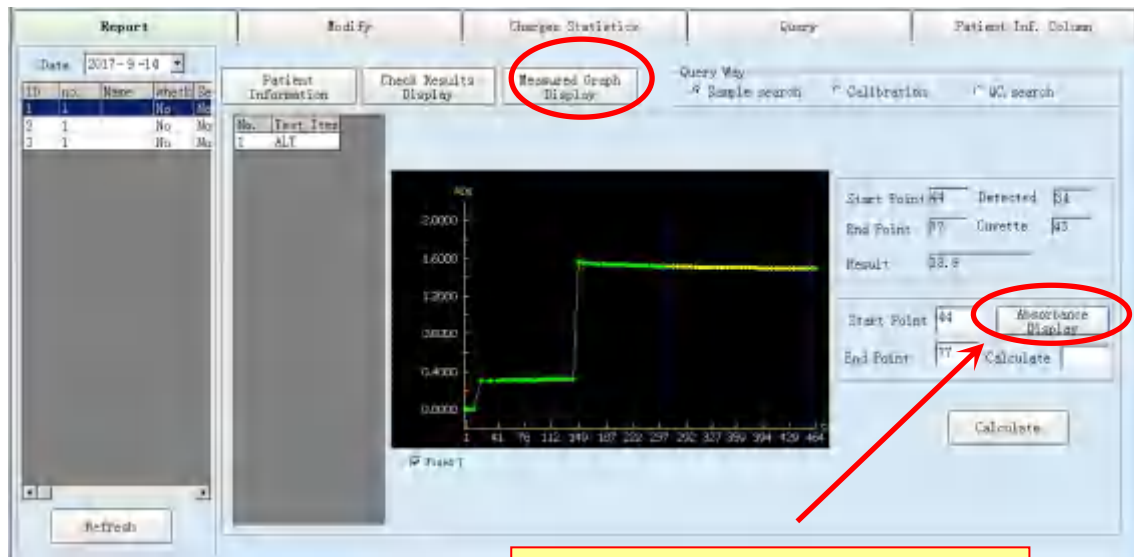
2、Test results display

Here can check patient test results and modify them.



3、Measured chart display

3.1、Inspector can check test chart here, and according to chart to confirm instruments or reagents have problem or not, patients test results trustiness or not.



Click this bottom, absorbance of all points on the curve can be displayed here.

3.2、Inspector can use real-time chart to check reagents parameter setting right or not, if not correct, change test points and resetting.

No.	Time	OD
1	5182078	.056
2	5197078	.0511
3	5211375	.0505
4	5226312	.0517
5	5241437	.0525
6	5252937	.0532
7	5265609	.0516
8	5280781	.0519
9	5296016	.0523
10	5312125	.0573
11	5327328	.1535
12	5342297	.1855
13	5356094	.202
14	5371234	.2167
15	5386359	.2282
16	5401453	.2381
17	5416594	.2451
18	5431734	.2529
19	5446875	.2588
20	5461984	.265
21	5477109	.2709
22	5492250	.2756
23	5507375	.2792
24	5522312	.2845
25	5537422	.2886
26	5552562	.2924
27	5567531	.2943
28	5582687	.2975

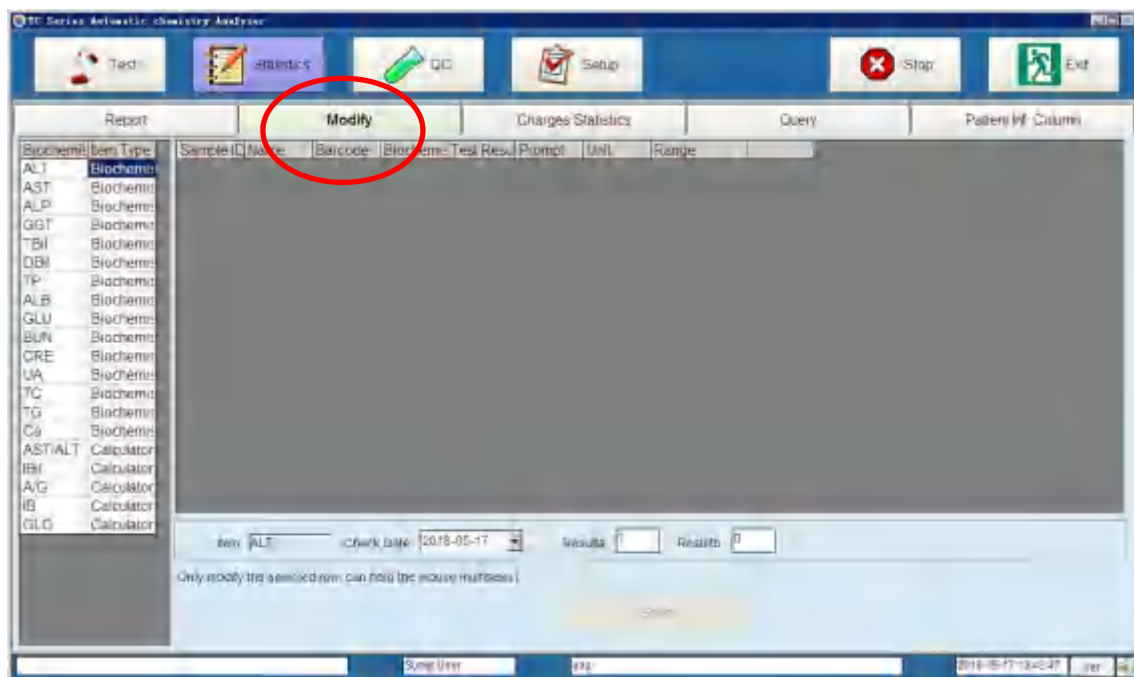
Back

Time is acquired by computer software, unit is “milisecond”, please keep in mind do not change time of computer system while testing. During actual verification, the time on second point minus that on first point, the difference is the time of first cycle, other cycles can be done in the same manner.

5.Query and Statistics

Click“Statistics” button enter to main interface. See below picture.

- In menu can check historical data.
- In menu can edit historical data.
- In menu can make charge statistic for test items.
- Have different kinds of query mode.
- Query and edit results can print.



1.Results modification

1.1、Click “Results modification”, then enter to interface below. This is use for editing results.

The interface shows a list of biochemical items on the left and a table of results in the center. The 'Modify' tab is selected. The table has columns: Sample ID, Name, Barcode, Biochemia Test, Rem, Prompt, Unit, Range, and a final column. The bottom section includes a 'Item' dropdown (set to ALT), a 'Check Date' (2017-9-14), and two 'Results' input fields (one with '1', one with '0'). A 'Save' button is at the bottom right.

Report	Modify	Charges Statistics	Query	Patient Inf. Column
Biochemia Item Type	Sample ID Name Barcode Biochemia Test Rem Prompt Unit Range			
ALT Biochemia	1 ALT 18.9 u/L 0.0 - 40.0 1			
AST Biochemia	2 AST 19.4 u/L 0.0 - 40.0 2			
ALP Biochemia	3 ALT 19.7 u/L 0.0 - 40.0 3			
GGT Biochemia				
TPBil Biochemia				
DBil Biochemia				
TP Biochemia				
ALB Biochemia				
GLU Biochemia				
BUN Biochemia				
cre Biochemia				
UA Biochemia				
TC Biochemia				
TG Biochemia				
HDL_C Biochemia				
LDL_C Biochemia				
Ca Biochemia				
AST/ALT Calculate				
IBil Calculate				
A/G Calculate				
IB Calculate				
GLO Calculate				
HIV Other Par				
HAV Other Par				
HCV Other Par				
ESR Other Par				
TT Other Par				
PT Other Par				

1.2、Select the desired items and click the Sample ID, then input the correct value in “Result” edit box and click “Save”.

This screenshot is identical to the one above, showing the 'Results modification' interface. A red circle highlights the 'Modify' tab, and another red circle highlights the 'Results' input field at the bottom. The interface shows a list of biochemical items on the left and a table of results in the center. The 'Modify' tab is selected. The table has columns: Sample ID, Name, Barcode, Biochemia Test, Rem, Prompt, Unit, Range, and a final column. The bottom section includes a 'Item' dropdown (set to ALT), a 'Check Date' (2017-9-14), and two 'Results' input fields (one with '1', one with '0'). A 'Save' button is at the bottom right.

Report	Modify	Charges Statistics	Query	Patient Inf. Column
Biochemia Item Type	Sample ID Name Barcode Biochemia Test Rem Prompt Unit Range			
ALT Biochemia	1 ALT 18.9 u/L 0.0 - 40.0 1			
AST Biochemia	2 AST 19.4 u/L 0.0 - 40.0 2			
ALP Biochemia	3 ALT 19.7 u/L 0.0 - 40.0 3			
GGT Biochemia				
TPBil Biochemia				
DBil Biochemia				
TP Biochemia				
ALB Biochemia				
GLU Biochemia				
BUN Biochemia				
cre Biochemia				
UA Biochemia				
TC Biochemia				
TG Biochemia				
HDL_C Biochemia				
LDL_C Biochemia				
Ca Biochemia				
AST/ALT Calculate				
IBil Calculate				
A/G Calculate				
IB Calculate				
GLO Calculate				
HIV Other Par				
HAV Other Par				
HCV Other Par				
ESR Other Par				
TT Other Par				
PT Other Par				

Parameters in this interface.

Parameter	Meaning
Biochemistry item	This box shows all the biochemistry items. You can check and edit them by selecting items.
Item type	Used for indicating if the item is testing item or computation item
Item name	Item's English name
Check date	Show the done biochemistry items orderly at testing date.
Result a	Test item selected, whose test result will be multiplied by correction factor, batch of test results can be revised.

2. Historical Data

2.1、In historical data, can query sample、calibrator、QC result separately, also can display different date's result. As following figure:



Do not select a fixed Y-axis, absorbance of curve on ordinate will be the maximum absorbance of reaction

2.2、Display the reaction curve of item result, and the reaction curve can be edited and calculated

2.3、To modify the start point and end point to re-calculate the results; it is mainly used for the operator to analysis the testing results.

Parameters in this interface:

Parameter	Meaning
Check date	Only when testing date is set, you can query the testing items on that day
Query method	There are two methods: sample query and QC query
SN. and sample ID	Show the S.N. and sample ID of biochemistry items done on that day. Select by mouse.
Test item	After choose sample ID, testing ID will be shown. Showing reaction curve of that detection item by mouse.
Results	By setting parameters, the results tested by analyzer
Testing points No.	Reaction point No. participating calculation when setting parameter
Start point	When you need to re-edit the results, it is the testing point which is used for calculating the time the reaction begins
End point	When you need to re-edit the results, it is the testing point which is used for calculating the time the reaction finishes
Result	The new results after editing the beginning and end testing points
Fixed Y-axis	If you don't select this option while observing reaction curve, the ordinate is the maximum absorbance in reaction curve. If you select, ordinate is fixed at value of 2.0000.

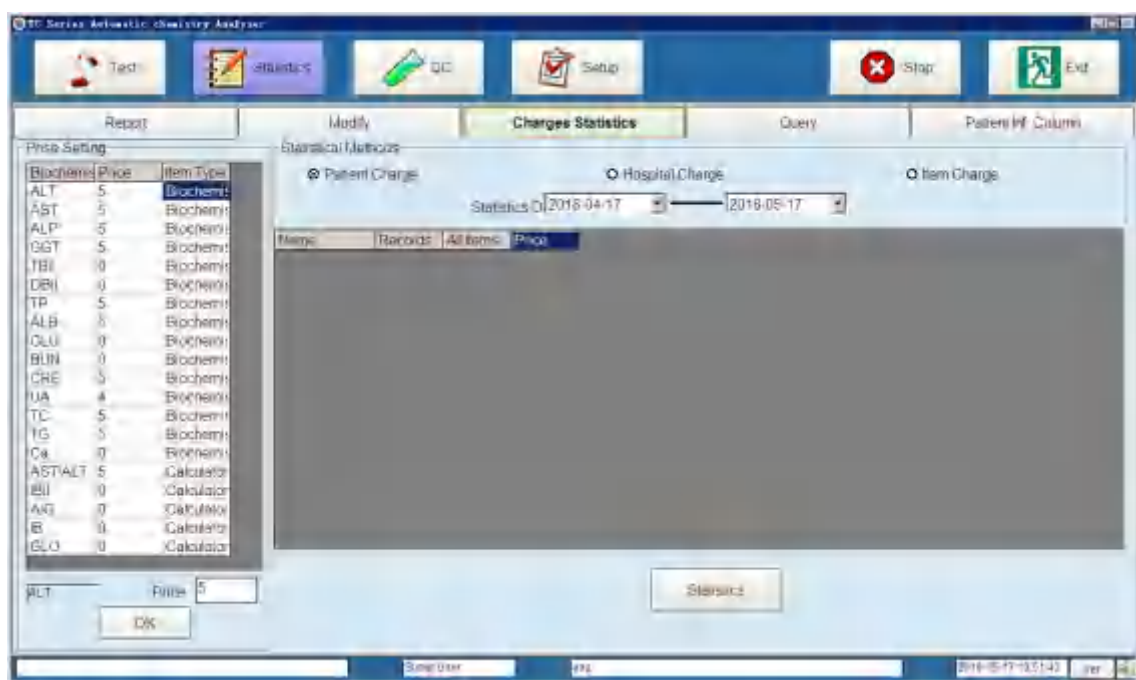
Buttons in this interface:

Button	Function
Calculate	Calculation results will display the edited results by clicking "calculation" button
Save	To save the edited results by clicking this button

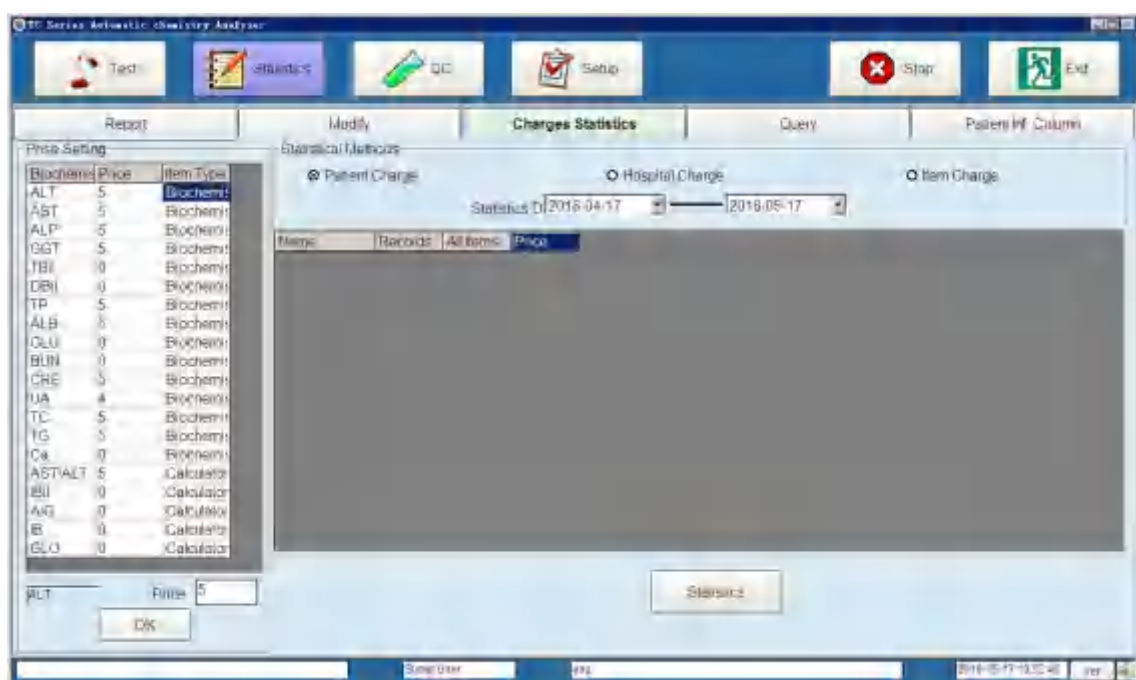
3.Charges Statistics

Click "Charges Statistics" tab to check total charge. It helps to get charge statistics. The window is displayed below.

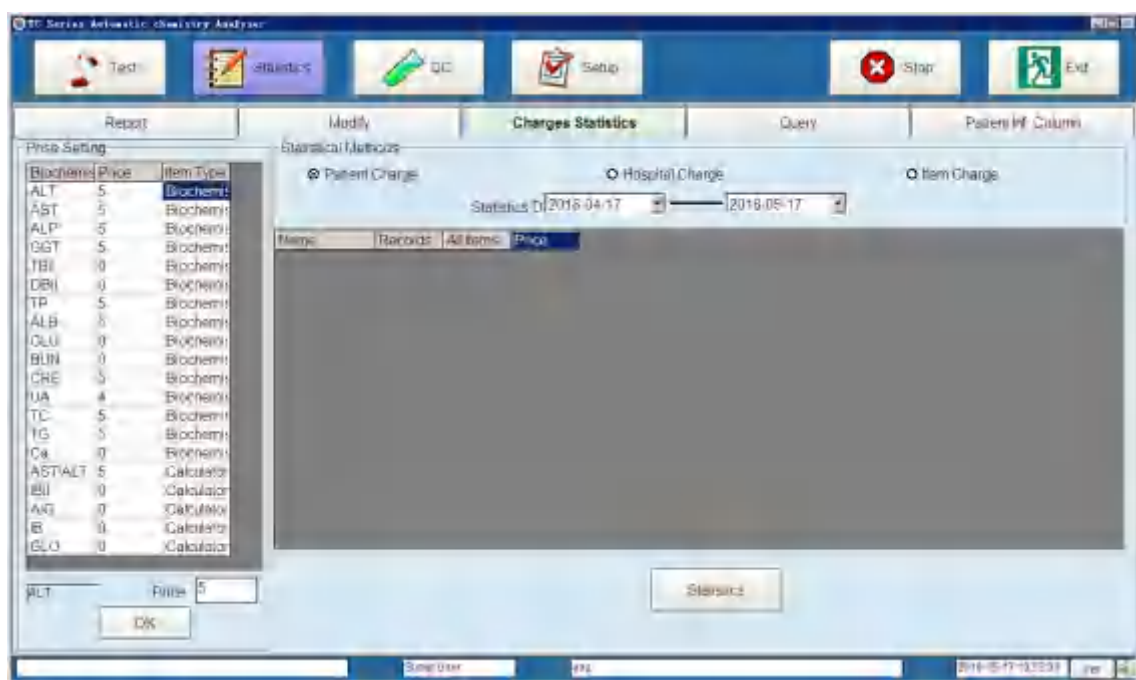
3.1、Please review **Patient Charge** Statistics, **Hospital Charge** Statistics, or **Item Charge** Statistics by selecting corresponding tab and then click **Statistics**.



3.2. *Statistics*—Charges Statistics—Item charge



3.3. *Statistics*—Charges Statistics—Hospital charge



Parameters in this interface:

Parameter	Meaning
Price	Input the testing price of certain testing item
Patient charge	Show the testing items of a patient, and the charges he has to pay
Hospital charge	The charge of all biochemistry testing items from different departments
Item charge	The charge of certain items in the statistics date
Statistics date	Query charge statistics according to statistics date
Price	Input the price of selected item into the price box

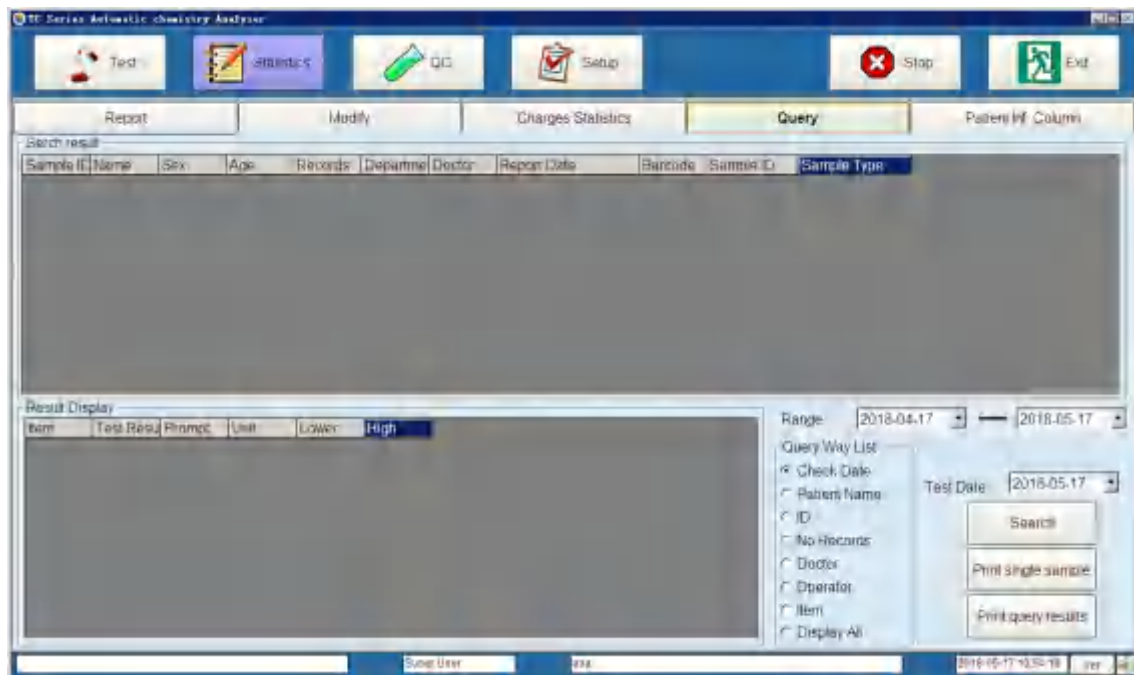
Buttons in this interface:

Button	Function
OK	Confirm the inputted price
Statistics	Statistics the prices

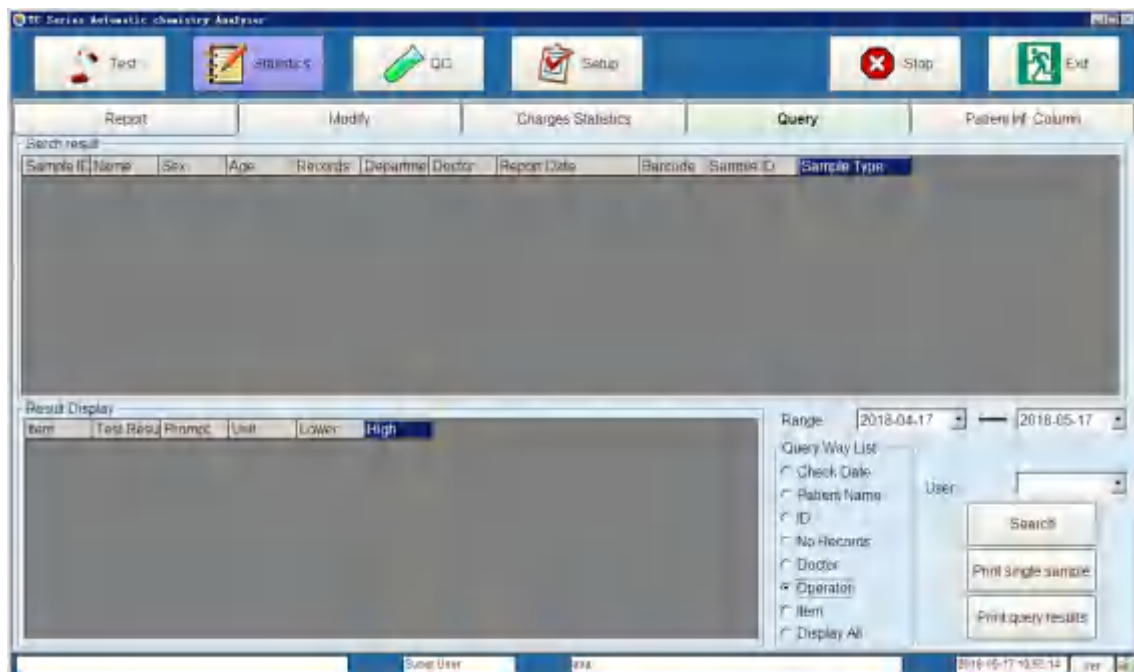
4.Query

Select a desired query way and click “Search” to index to results. The window is displayed below

4.1、Statistics — Query — Query way list — Check date



4.2、Statistics — Query — Query way list — Operator:



Parameters in this interface:

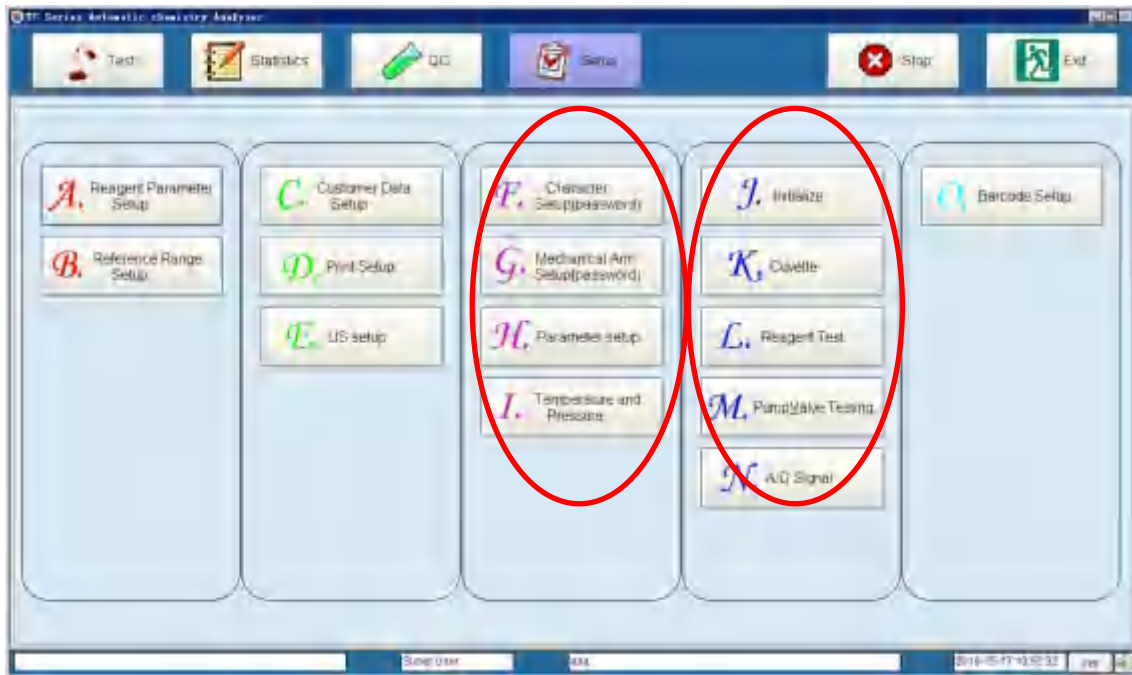
Parameter	Meaning
Search result	Click the items in "Search result" to show in the "Result display" column
Result display	Display the results from the "query results column"
Doctor	Show test results done by certain doctor
Query way list	Five methods: date, patient name, medical record No., testing doctor, all results.

Buttons in this interface:

Button	Function
Search	After selecting "query builder", click it to search the results that meet your requirements

5.Maintenance

Click “Maintenance” button to enter into the below interface. This is mainly used for maintaining the system and data.



1、Initialize

Click “Initialize” button to get the following dialog box; and then click “Initialize” button again to initialize the instrument; it is adopted when the user can’t ensure whether the instrument has returned to the beginning point.



Buttons in this interface:

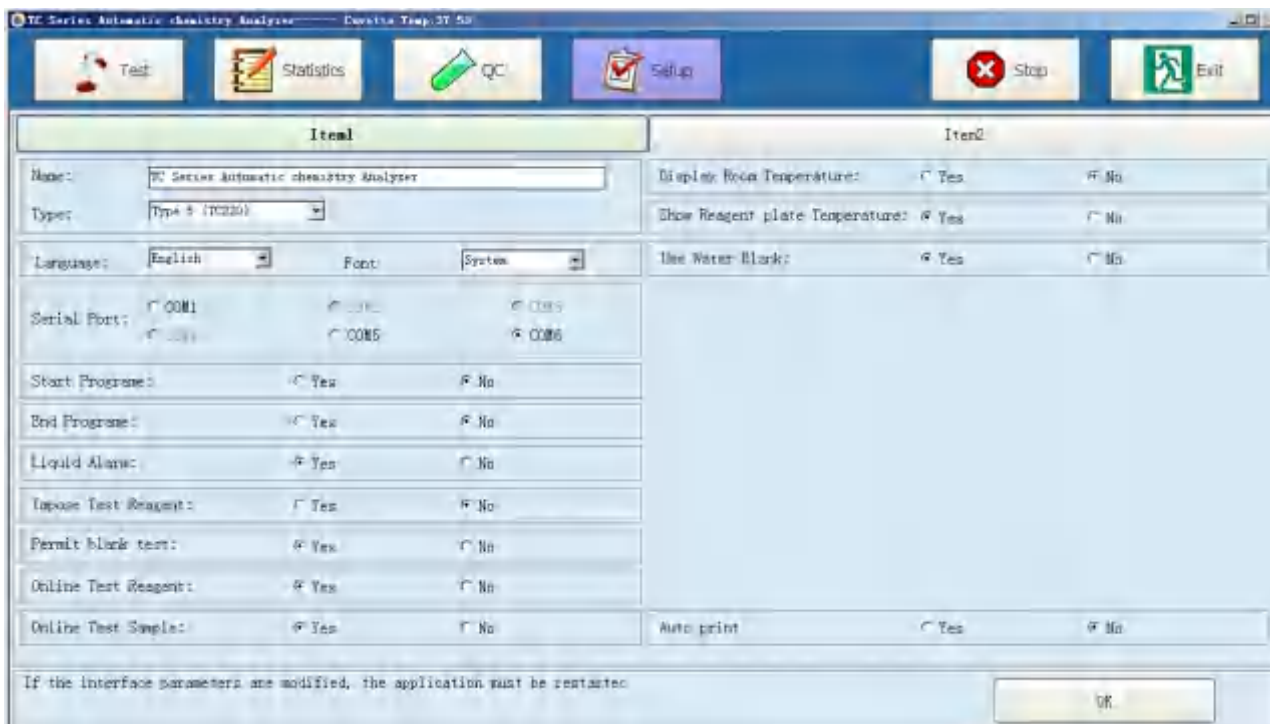
Button	Function
Initialize	To initialize the instrument by clicking this button, and the moving parts will return to start position
Back	To return to the maintenance main interface by clicking this button

2、Character Setup

Click “Character setup” button to enter into the following interface, It is used for system setup:



Input password “777” to enter into the interface. Choose instrument model and software language, and set communication serial port.



Parameters in this interface:

Item	Meaning
Name	The name of the device will be displayed in the title bar of the main interface
Type	Type 1 is Chemistry Analyzer TC6030
Language	English and Chinese are available here. “Debug” is used to locate the position of every menu name in Data Base. Two other languages are reserved, and you need to edit language data base before using them.
Font	Please select corresponding Font available in your country, otherwise it will cause display problem.
SIZE	Please select the size of font
Serial port	The serial port between analyzer and computer, which is usually set by engineer
Start program	After selection of “yes, the instrument will wash all cuvette automatically once switching on of the instrument, then detect temperature and pressure
End program	After selection of “yes, the instrument will wash all cuvette automatically once switching on of the instrument, then dispense distilled water into cuvette
Liquid alarm	The liquid alarm can be used only when selection of “yes”, please select “no” if the liquid alarm is not furnished.
Impose test reagent	After selection of “yes, the instrument will carry out detection of reagent volume, if you need to skip this detection, please select “no”
Permit blank test	If select YES, when machine tests there is no reagent, it will do test as usual, not stop automatically.
Online test reagent	Click “yes”, in the course of testing, after sipping reagent , it will show balance reagent volume on time.
Online test sample	After selection of “yes, if sample is in shortage, the analyzer will pause testing the residual items under the sample.
Serum residue times	After filling times, the sample online test result is 0, the times of continuing testing
Display room temperature	If select YES, will display the room temperature. Because this function needs hardware support, if main control panel single chip version before V2.05, please select NO.
Show Reagent plate temperature	The reagent plate temperature can be displayed only when selection of “yes”, please select “no” if the refrigerating function of reagent plate is not furnished.
Use water blank	After selection of “yes”, the signal value of testing cuvetts is saved as

Item	Meaning
	blank value of the absorbance. After selection of “no”, the default signal value of the cuvette the analyzer detect is saved as blank value of the absorbance
Auto print	By selecting “YES”, the results will be printed out automatically

3、Cuvette

Clicking “Cuvette” button under the “Maintenance” interface to enter into the below interface:



- 3.1、Wash cuvette: used for washing the selected cuvette
- 3.2、Stop wash: used for stopping the current cleaning action
- 3.3、Wash all cuvette: used for cleaning all the cuvette
- 3.4、Add water: used for fill the 60cuvettes with distilled water
- 3.5、Pump water: Used for emptying the 60 cuvette
- 3.6、Testing cuvette: to check whether the cuvette is broken or not by observing the blank absorbance of the water; also change the cuvette by observing the absorbance
- 3.7、Save cuvette: used for saving the signal values of the tested quality of the cuvette

Note : please pump cuvette before testing everyday; and please inject distilled water after test is finished

3.8、Light source tracker: recording the signal value of every tests, and judge the situation of lamp

3.9、Detergent Record: recording the times of using detergent

3.10、Use Record: recording the working time of lamp every day

3.11、Sign Bad:After the test quality of cup, it will appear red while signal value is less than 30000 and reaches 65535, this cuvette will automatically mark as bad cuvette, in the course of test, it will jump this cup and to test next one . If user want to change between “good cup” and “bad cup”, you can click number of cuvette, then click”mark”, so you can change them.

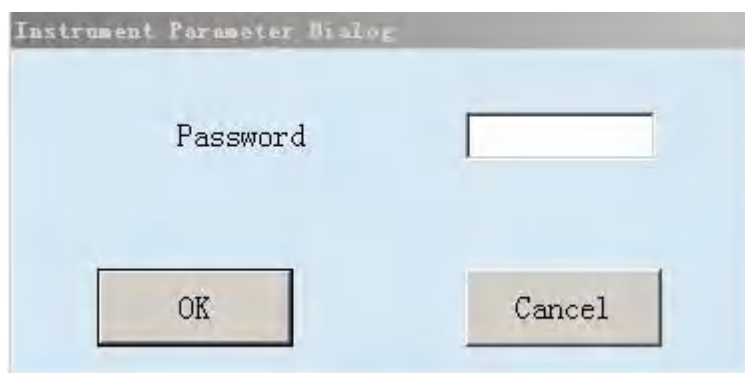
3.12、Sign all good:All mark “good cup” and “bad cup”: if cuvette display bad cup and user don't want to change cup and want to continue to test,then you can click a button which mark all cuvette “good cup” for user convenience.

3.13、Sign no water: If user make “add distilled water” operation, under the condition of “evacuation cuvette cup” or “cleaning all cuvette cup” the software will regard cuvette cup as having water, so it will alert user that “there is water in cuvette cup” in the course of test. If user have known that there is no water in cuvette cup, then click this button, the cuvette cup will display no water, the software will not alert user.

4、Parameter Setup

Clicking “Parameters setup” button to enter into the following interface; Input password “999” to enter into the “moving parameters setup” dialog box. Here the user can setup the parameters of the mechanical arm, and detect the mechanical arm. This is usually done by engineer authorized by our company

。



Instrument Parameter Dialog

Password

OK Cancel



NOTE:

- The parameter setup must be done by engineer authorized by our company.
Otherwise, it may lead to unexpected damage

Input the password and enter into the following interface. It is used to modify the settings when first time installation, mechanical arm replacement or site changes.



Operation Instruction

Arm Setup Columne

Wash Position 500

Cuvette 1250

1# sample 1350

1# reagent 1810

2800

Str Arm Setup Columne

Wash Position 800

Cuvette 1620

Stir Needle 1 on 80 20

Wash Arm Setup

depth 1 80

Time Setup

Detergent Volume

Add Water Volume

Water Pumpback

Wash Time

Blank Water

Stir Time

Stop time add reagent

Safe Operation Select

Save Back

Parameters in this interface:

Parameter	Meaning
Arm setup columne	
Wash position	Use sample mechanical arm at the washing position as the starting point
Wash depth	Clicking this button, Reagent sample needle position in the cleaning pool by

Parameter	Meaning
	descend steps
Cuvette	The steps numbers of sample mechanical arm probe start from washing position to reaction cuvette in reaction disk
Cuvette depth	The steps numbers of sample mechanical arm probe get into the depth of reaction cuvette. When the probe touched the bottom of the cuvette, please hold up 10 steps, that means to reduce 10 cuvette depth.
1# sample	The steps numbers of sample mechanical arm probe start from washing position to No1 sample position
Sample depth	The steps numbers of sample mechanical arm probe get into the depth of sample position
1# reagent	The steps numbers of sample mechanical arm probe start from washing position to 1# reagent position
Reagent depth	The steps numbers of sample mechanical arm probe get into the depth of reagent positions
Wash arm setup	
Depth 1	The position of washing mechanical arm probe get into the depth of reaction cuvette in reaction disk
Depth 2	The depth of washing mechanical arm probe down to the rim of cuvette, when adding water
Stir arm setup column	
Wash position	Use stirring mechanical arm at the washing position as the starting point
Wash depth	The steps numbers of stirring mechanical arm probe get into the depth of washing position
Cuvette	Clicking this button, Reagent sample needle turn to cuvette position.
Cuvette depth	The steps numbers of stirring mechanical arm probe get into the depth of reaction cuvette in reaction disk. When the probe touched the bottom of the cuvette, please hold up 10 steps, that means to reduce 10 cuvette depth.
Time setup	
Add water Volume	The volume of injecting distilled water
Water pump back time	The time of water pump back
Wash time	The time of probe washing
Blank water volume	The volume of distilled water when testing the cuvette blank
After reagent 1 time	The waiting time to next step after adding reagent into cuvette.

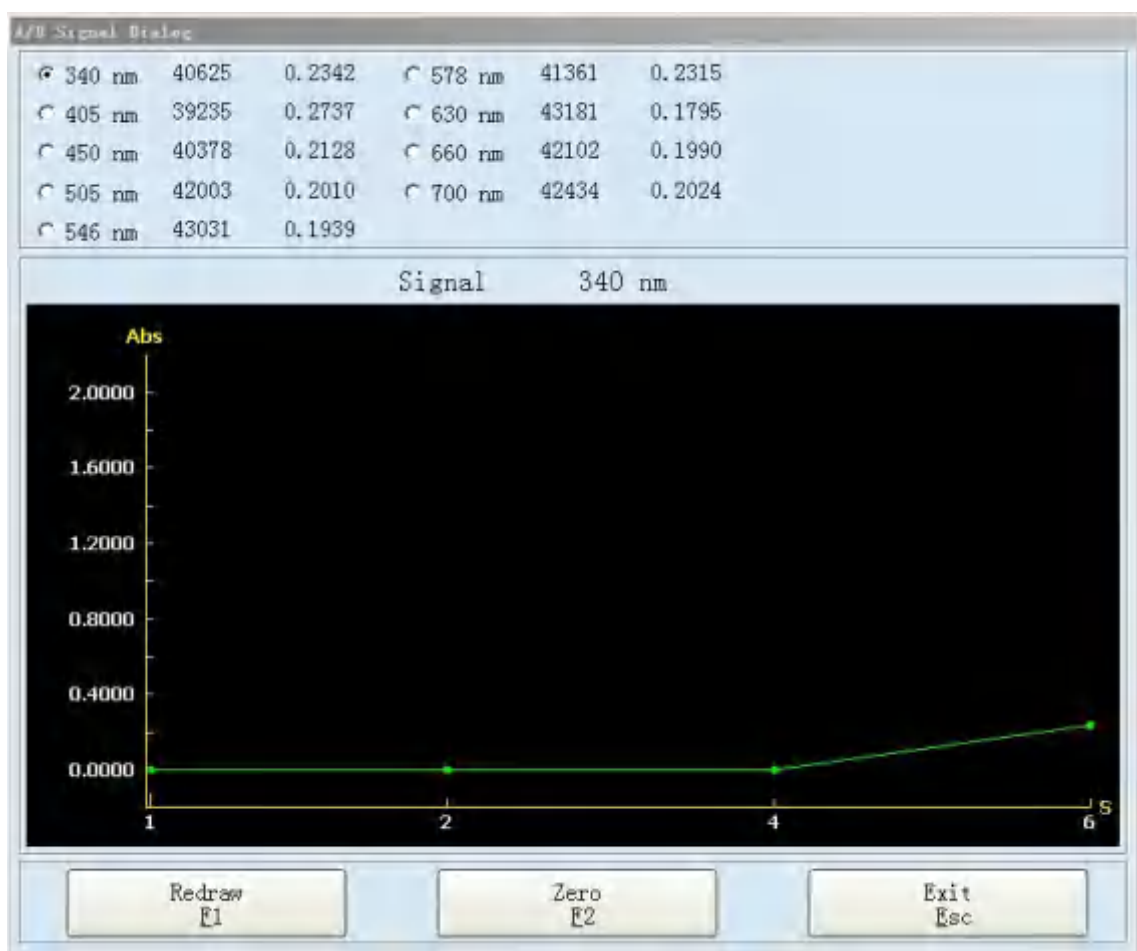
Parameter	Meaning
Stir time	Rotary time of the stirring stick
Vacuum drain	Used to setup the time to drain the vacuum completely.

Buttons in this interface:

Button	Function
Save	To enter into the dialog box by clicking this button after input the password
Hoist	To make the mechanical arm moving up and down at the original position
Reposition	To make the arm moving right and left by clicking this button, and stop at the original position
Save	To save the modified settings by clicking this button
Back	To return to the “maintenance “ main interface by clicking this button

5、A/D Signal

- 1) Click “A/D Signal” button to enter into the following interface. It is used to check the stability of each wavelength.
- 2) If the instrument moved to another place where there is not sure a grounding wire, then you can check whether there has the grounding wire or not by fluctuation of wave in this interface
- 3) The interface can also observe the linear range of different wavelengths of the instrument.。



Buttons in this interface:

Button	Function
Redraw	Re-draw the signal chart
Zero	Return the signal value to zero
Back	To return to the “maintenance” main interface by clicking this button

6.Arm Test

Click “Arm Test” to pop up the window below.

The Defecting Components Dialog window displays the status of various system components. It includes sections for Syringe detected column, Reagent valve defect, Sample and reagent plate defect, Liquid Alarm, and Motor Defect. Each section has buttons to toggle the component on or off. The Liquid Alarm section shows 'Del.' and 'Waste' status with green bars. The Motor Defect section has a 'Back' button.

Buttons: Reagent syringe, Reagent valve on, Vacuum pump on, Affusion valve On, Wash needle valve on, Det. Pump On, Stir Needle 1 on, triple valve on, Discharge pump On, Reposition, Cuvette, Reagent Plate, Sample Plate, Liquid Alarm, Del., Waste, Water, Test, Back

**Warning:**

- When the system is in operation, don't touch the moving parts including sample-reagent dispenser, mixer and wash unit.
- When system is in operation, don't place your finger or hand into the open parts.

Parameters in the interface

Parameter	Meaning
Syringe detect column	
Reagent Syringe	Check R1 Reagent Syringe
Reagent vale detect column	
Reagent valve on	Check Reagent valve
Wash needle valve on	Check Wash needle valve
Vacuum pump on	Check Vacuum pump
wash pump on	Check wash pump
Stir on	Check Stir
Affusion valve on	Check Affusion valve
Backwater valve on	Check Backwater valve
Drainage pump on	Check Drainage pump
Sample, reagent Plate detect column	
Arm restoration	
Reaction cuvette	Check Reaction cuvette
Sample plate	Check Sample plate
Reagent plate	Check Reagent plate
Buttons in this interface:	
Test	Test the liquid level alarm
Back	Exit from this interface

7. Temperature and Pressure

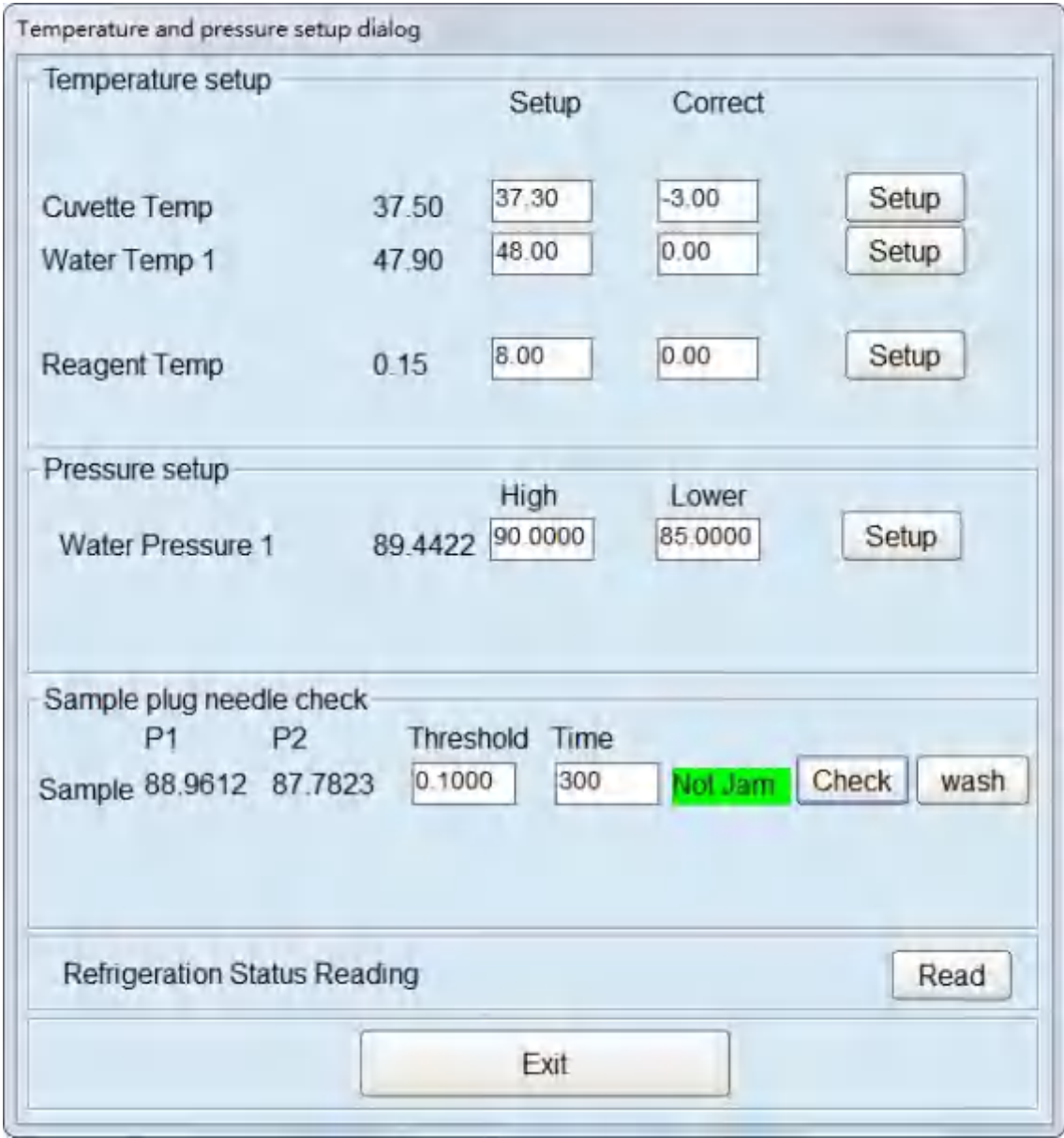
Click “temperature and pressure” button to setting the temperature and pressure

The correction factor is used for calibrating the temperature value when there is any error between the temperature in the instrument and the thermometer.

And only when the temperature is balanced, then the correction factor can be modified.

Please set the correction factor to “0” if you don’t have micro thermometer for measuring.

The temperature displayed = instrument temperature measured + correct coefficient



The dialog box is titled "Temperature and pressure setup dialog" and is divided into several sections. The "Temperature setup" section contains three rows of data for "Cuvette Temp", "Water Temp 1", and "Reagent Temp". Each row has a "Setup" button. The "Pressure setup" section contains one row for "Water Pressure 1" with "High" and "Lower" pressure values and a "Setup" button. The "Sample plug needle check" section displays "P1", "P2", "Threshold", and "Time" values, along with a "Not Jam" status, "Check", and "wash" buttons. The "Refrigeration Status Reading" section has a "Read" button. An "Exit" button is located at the bottom center.

Temperature setup				
		Setup	Correct	
Cuvette Temp	37.50	37.30	-3.00	Setup
Water Temp 1	47.90	48.00	0.00	Setup
Reagent Temp	0.15	8.00	0.00	Setup

Pressure setup				
		High	Lower	
Water Pressure 1	89.4422	90.0000	85.0000	Setup

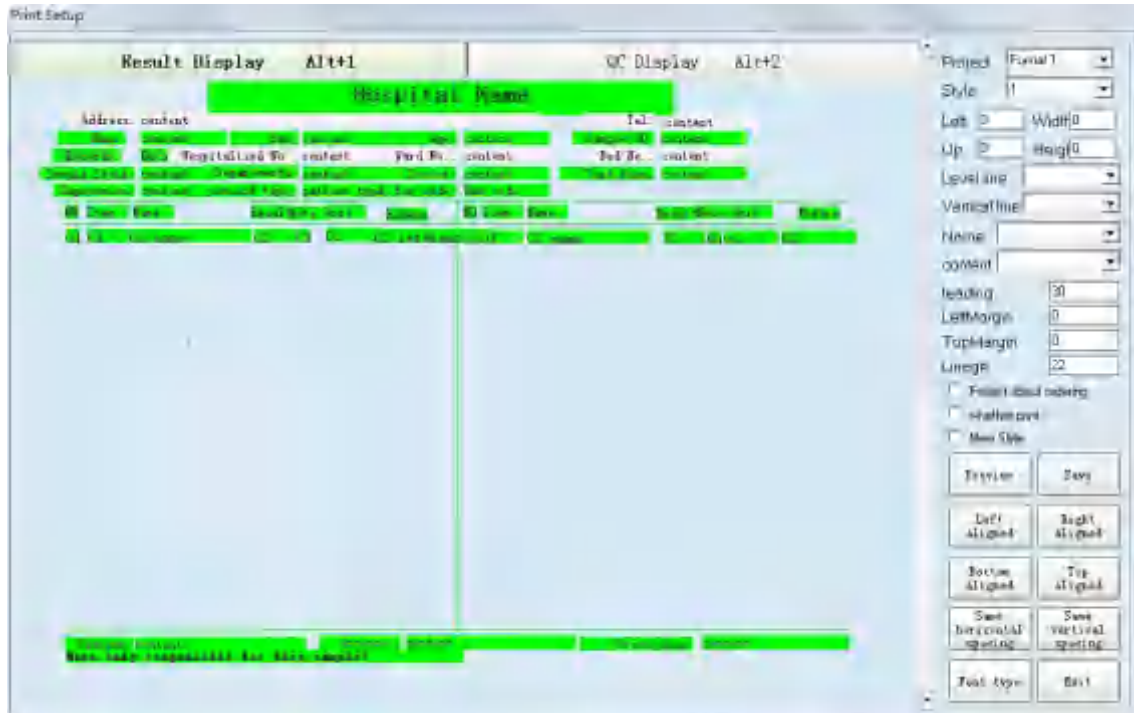
Sample plug needle check				
	P1	P2	Threshold	Time
Sample	88.9612	87.7823	0.1000	300

Not Jam Check wash

Refrigeration Status Reading Read

Exit

8. Print Setup



- 1) 、 Project: Used for selecting the print format
- 2) 、 Apply: To make the selected format as current print format by clicking this button
- 3) 、 Preview: To preview the current format by clicking this button
- 4) 、 Save: To save the current modifications to the format by clicking this button
- 5) 、 left aligned, right aligned, bottom aligned and top aligned: firstly select the items which need to be operated, and then click the corresponding button to carry out the corresponding operation.
- 6) 、 Same horizontal spacing and same vertical spacing: firstly select the items which need to be operated, and then click the corresponding button to carry out the corresponding operation.
- 7) 、 Font type: Used for modifying the size and type of the selected content.
- 8) 、 Exit: to exit the current interface by clicking this button

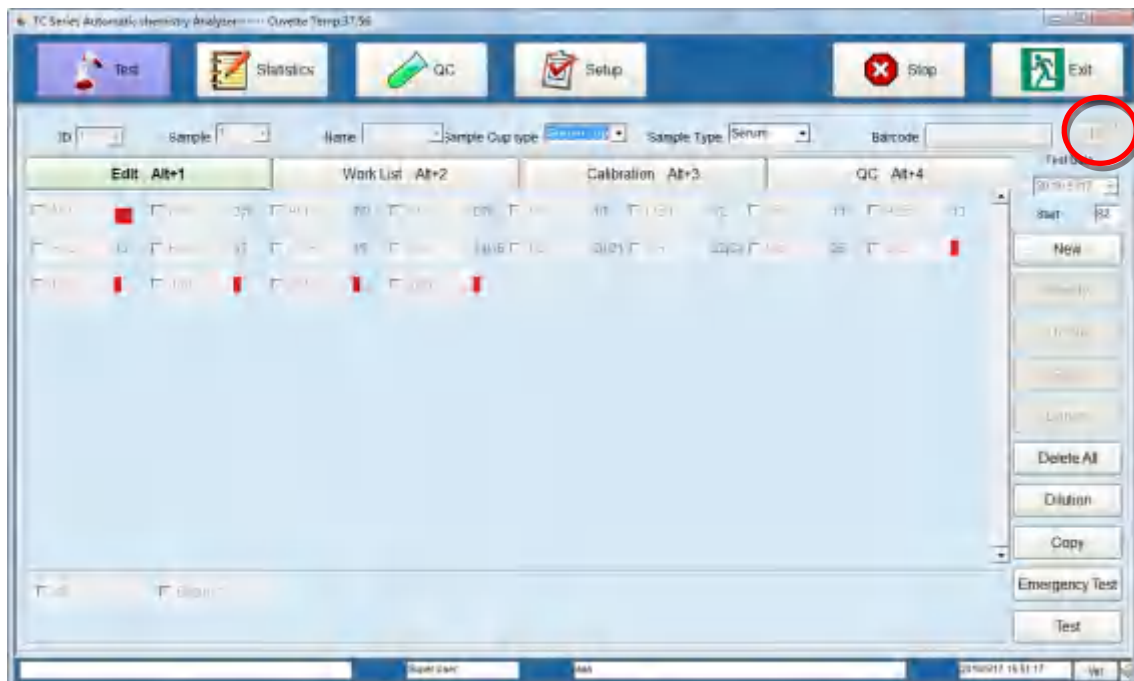
9.LIS Parameter setting: can choose whether use LIS transmission function. See below picture.



LIS function switch, when need LIS transmission function, tick “√” in front pane.

Please choose correct LIS agreement.

When tick LIS“√”, you can see LIS button under testing menu. Please check below picture. This button will send Barcode No. to LIS system, and then send the patient information of this Barcode No. in LIS system to the operation software.



6.Test

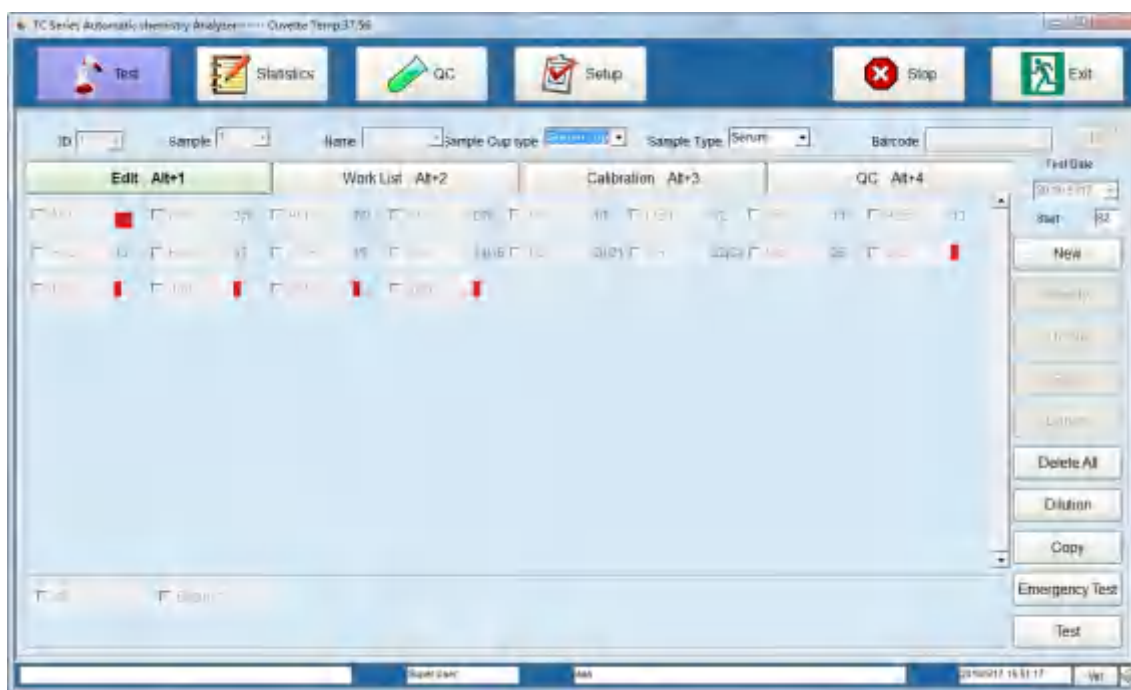
The input and testing of sample are proceeded in “biochemistry testing” interface.

1)、 Bio-test

Click the “Test” button in the main menu to enter into the biochemistry test interface. There are four tabs: Edit, Work list, Calibration setup and QC.

1.1、 Edit

As is shown in the below chart, input sample ID, sample disc No., start cuvette No. and end cuvette No. (It will increase progressively automatically, and don't need manual intervention). Select the test item, click “Add” button. If you want to continue inputting, please click “New” button; and the sample ID will add 1 automatically. Select test item, and click “Add”. While inputting sample ID, you can not input the same No. repetitively, otherwise the latter sample result will cover the former one.

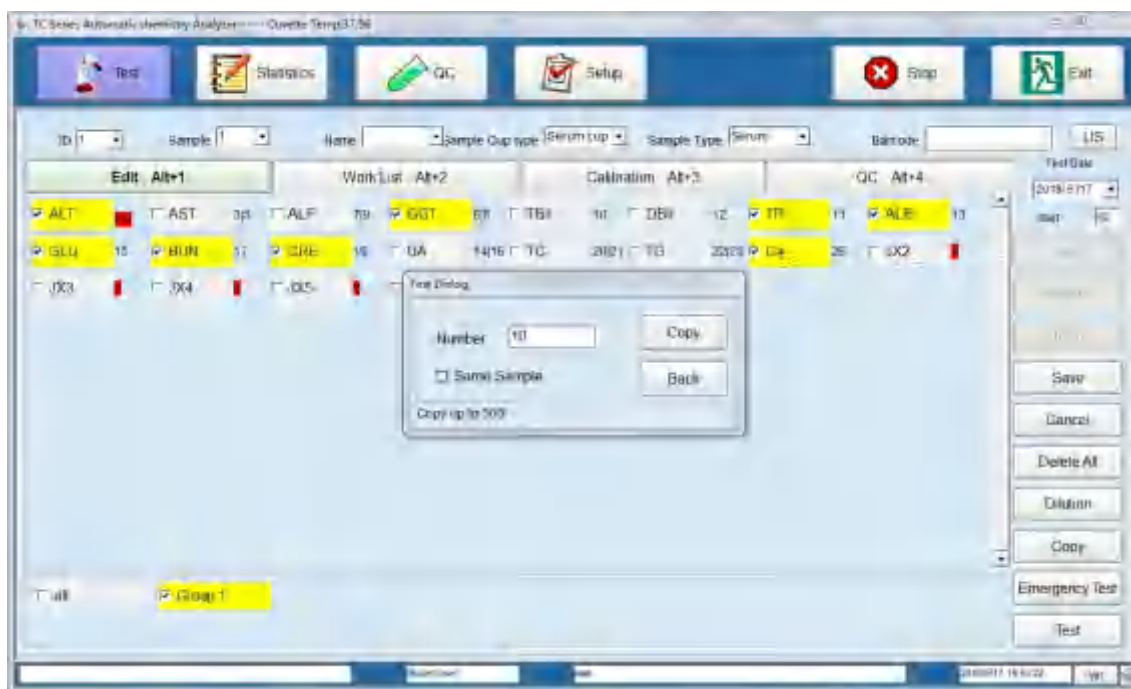


NOTE:

- In the list of biochemistry item, the button status of the items reflects the current status of this item.
 - If the button is sunk; it means this item is selected.
 - If the button is bulgy; it means this item can be selected.
 - The colors shown in “item combination list” and “manual item list” in the parameter menu is the same as that in “biochemistry item” list.
-

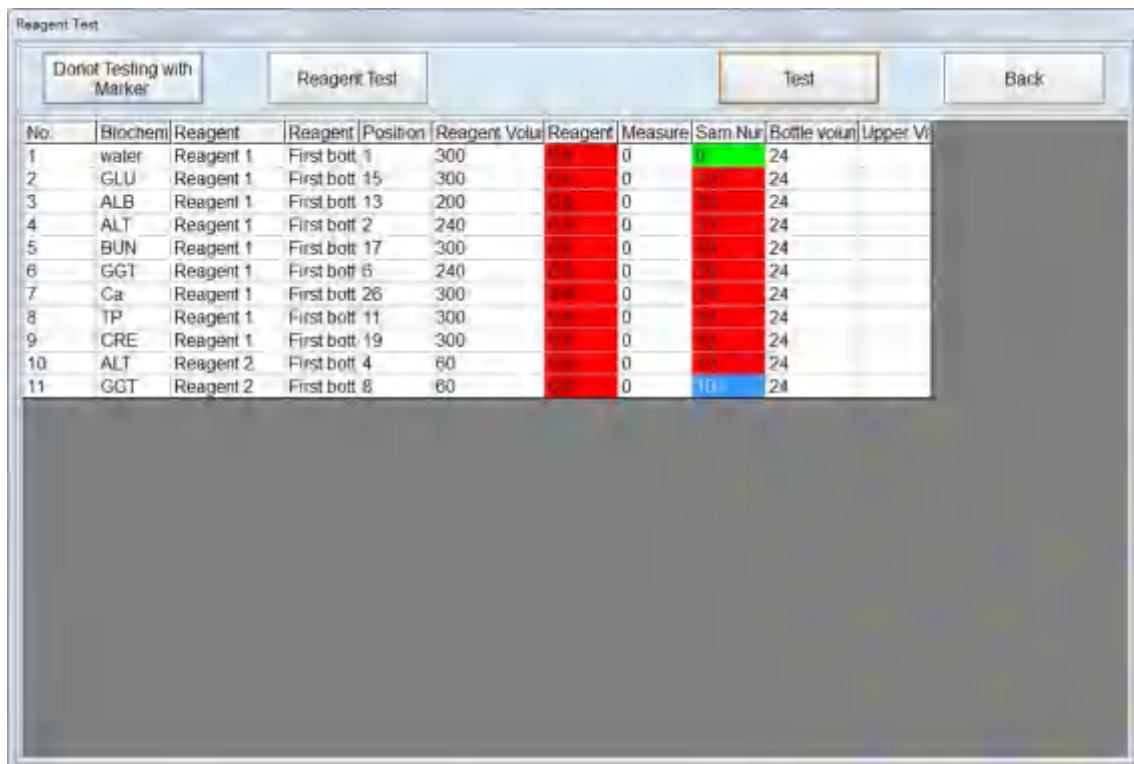
1.1.1、 Test - Edit - Copy:

After selecting test item, click “Copy” button in the interface to enter into the chart (as is shown below). You can conduct the same testing for different samples, or conduct tests many times for the same sample according to the options. For details, please refer to the meaning of “copy” in the “parameter/function” of this chapter.

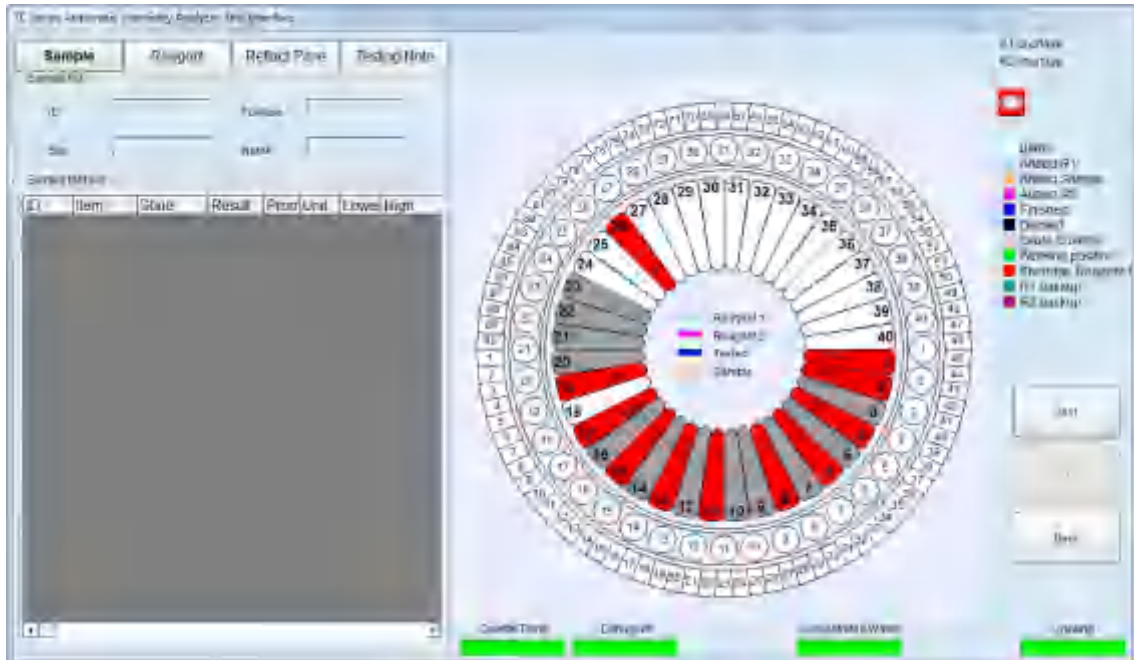


1.1.2、 Test – Edit -Test

After choosing the test items, please click “Test” button to enter into the following interface. This menu is the interface for confirming conventional testing, QC testing and calibrating testing before the final testing, and also for the detecting of needed volume of reagent for this testing.



1.1.3、 The instrument will detect whether the reagent is enough or not. And then click “Item check” to enter into the following testing interface; and then click “Test” button to test the sample automatically.



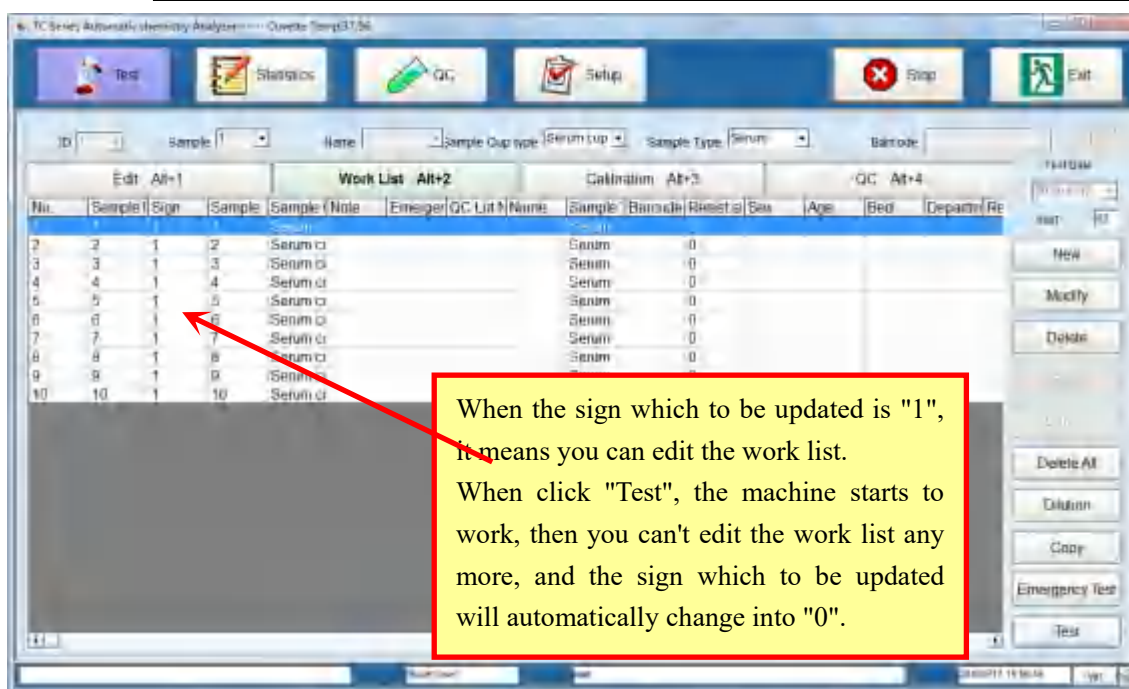
1.2、 Work List

This is the supplementary menu of biochemistry item menu. Before setting the Biochemistry items, click “work list” button to check whether there have test items in current page; If have, you need to delete all the test items from the list. Then set the biochemistry items which need to be tested in the “Work list”. After setting, you can view the test items of

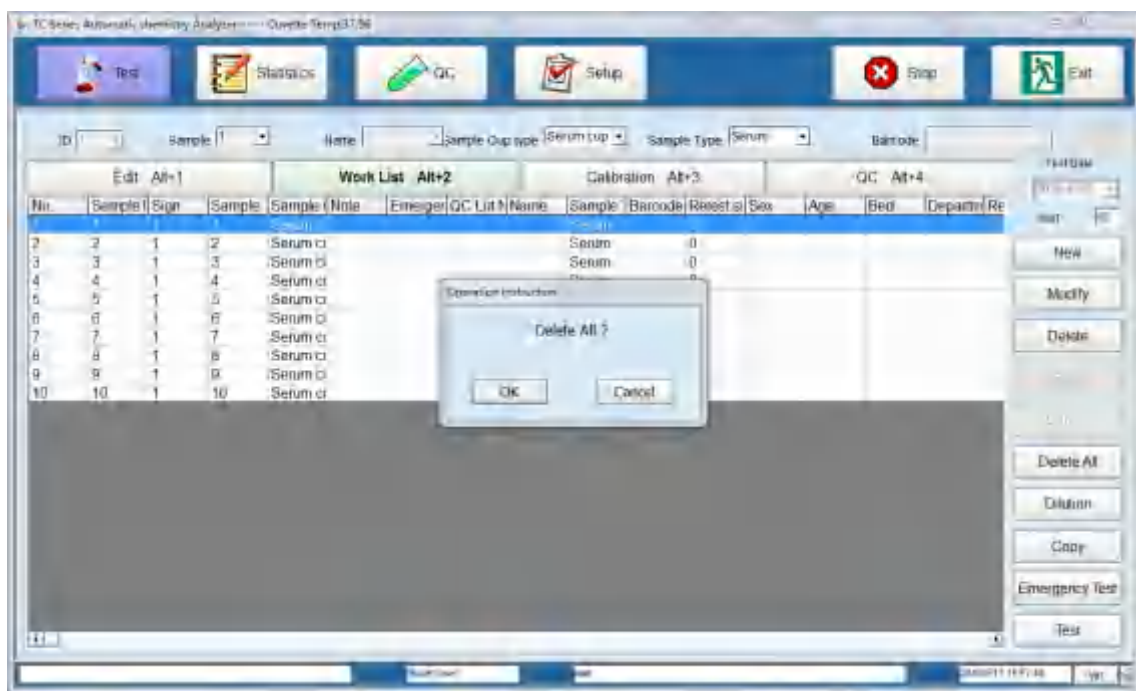
inputted sample ID in “Work list” list. Look at the test item list interface as below:

NOTE

- After finishing the previous test item, and if you want to conduct or set the next test item, you should delete the previous detection item list. Otherwise, the previous detection item would be done again.

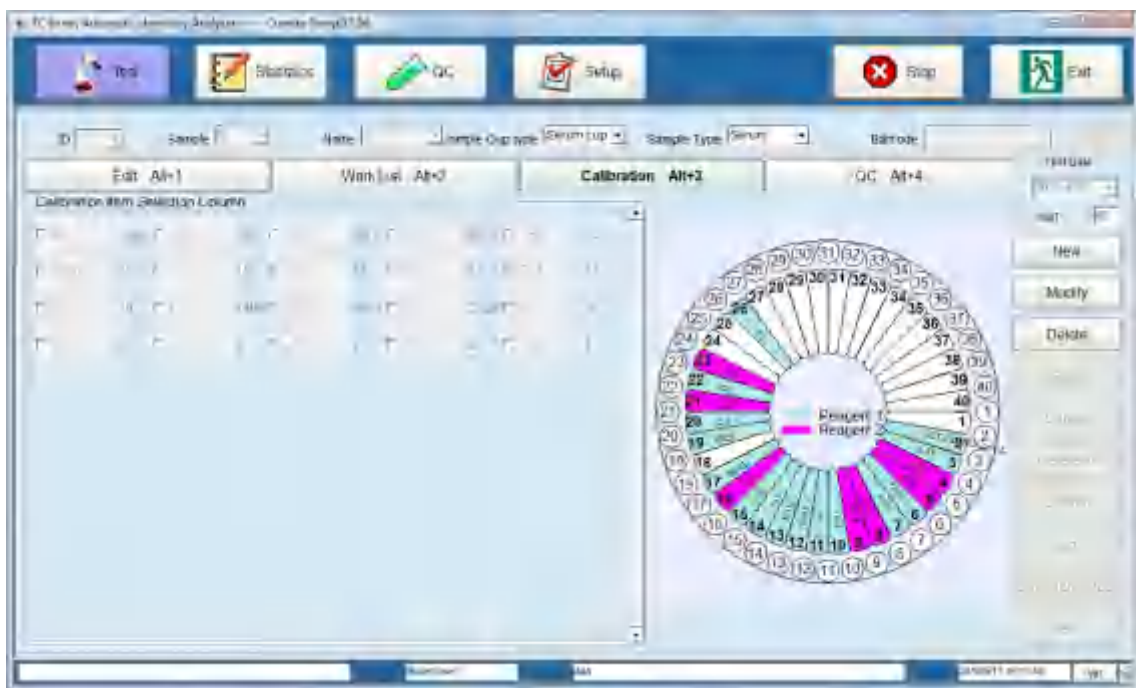


1.2.1 Test — Work list —click “Delete all” and the below chart is shown. Click “OK” to finish deleting, and click “Cancel” to cancel the delete.



1.3 Calibration Setup

It is used for editing the items which need calibration, shown as the below chart:



1.4 QC

Please refer to the following explanations for the parameters and buttons in this interface:

Parameter/Function	Meaning
--------------------	---------

Parameter/Function	Meaning
Sample ID	The unique No. of every sample. The sample ID is unique in the same day's testing
Sample cup No.	User can choose the position of each sample.
Starting Cuvette	The first cuvette to be tested, which can be started from any cuvette.
New	select the test items into the work list, click "New", then they will be added into the work list.
Modify	Edit work list
Delete	Selected the items which need to be deleted with mouse to blacken it, click "Delete", then the selected item can be deleted.
Save	Save the edited items.
Cancel	Cancel the finished modification
Delete All	Delete all the edited items.
Dilution	set up the multiple factor of pre-dilution items
Copy	If there are N samples will be done under the same item, click [copy] after choosing item, and input N under the [copy No.], meanwhile, "same serum disc No." should not be chosen. If choose "same serum disc No." simultaneously, it means detect the same sample under the same item N times.
Emergency Test	Insert emergency testing sample, and then the emergency sample can be tested prior.
Test	To start the biochemistry testing by clicking this button

1.5、Emergency Test

The "Emergency test" button is the same as the "Work list". The emergency sample testing can be inserted randomly during the biochemistry testing is conducting.

1.6、Revising the sample test information

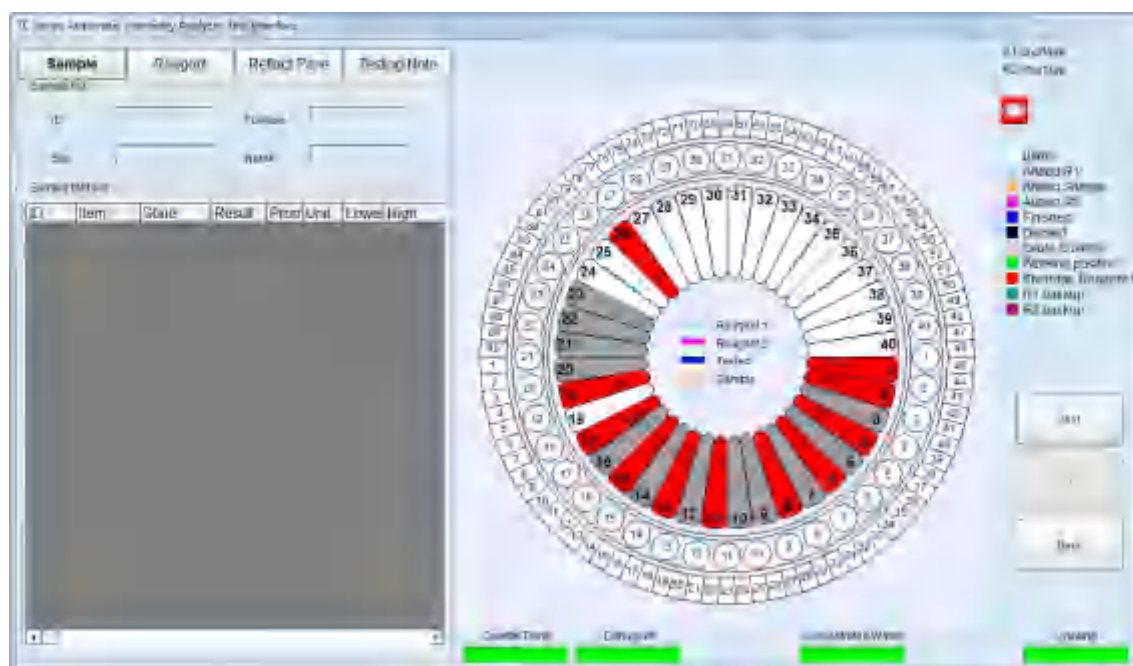
Input the sample ID that needs revising in "Work list" interface in the biochemistry testing menu. Change the sample testing information, and then click "Add", (if testing has started, you are unable to modify the information).

1.7、Test

1.7.1、Sample test interface

After inputting sample and QC in the "Work list" and "emergency test" menu, click "Test"

button, biochemistry detection interface will be shown as below:

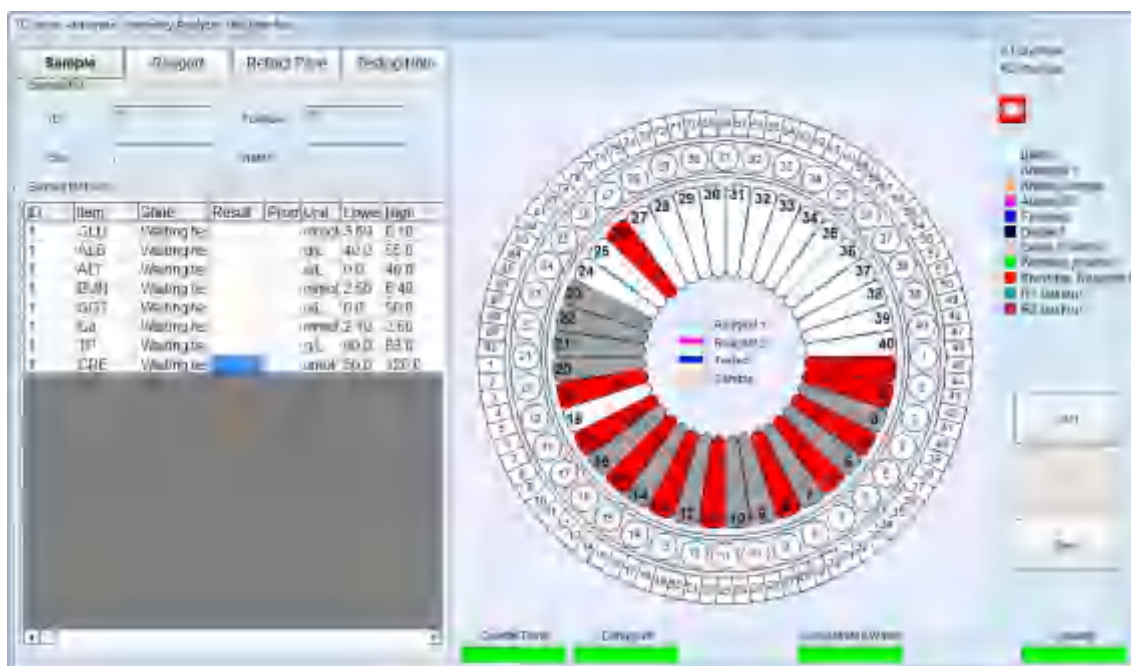


NOTE

- Before clicking “Detect” button, please ensure that sample, calibrator, QC liquid and reagent are placed at the right positions.

1.7.2、Sample testing interface

Click “Test” button again in this interface, then test will begin. “Sample, Reagent, Reflect pane” taps will appear on this interface, and click any tap, you can To know each factor’s working state by clicking each option, such as click “Reflect pane”, then click any reaction cuvette on the virtual chart, you may know the current state of that cuvette.



1.7.3、Test result inquiry in the testing interface

When testing is finished, the “Sample test list” box under “Sample” tap will show current test result as well as the state of reaction disc cleaning. Also the washing status of reaction disc can be shown here.

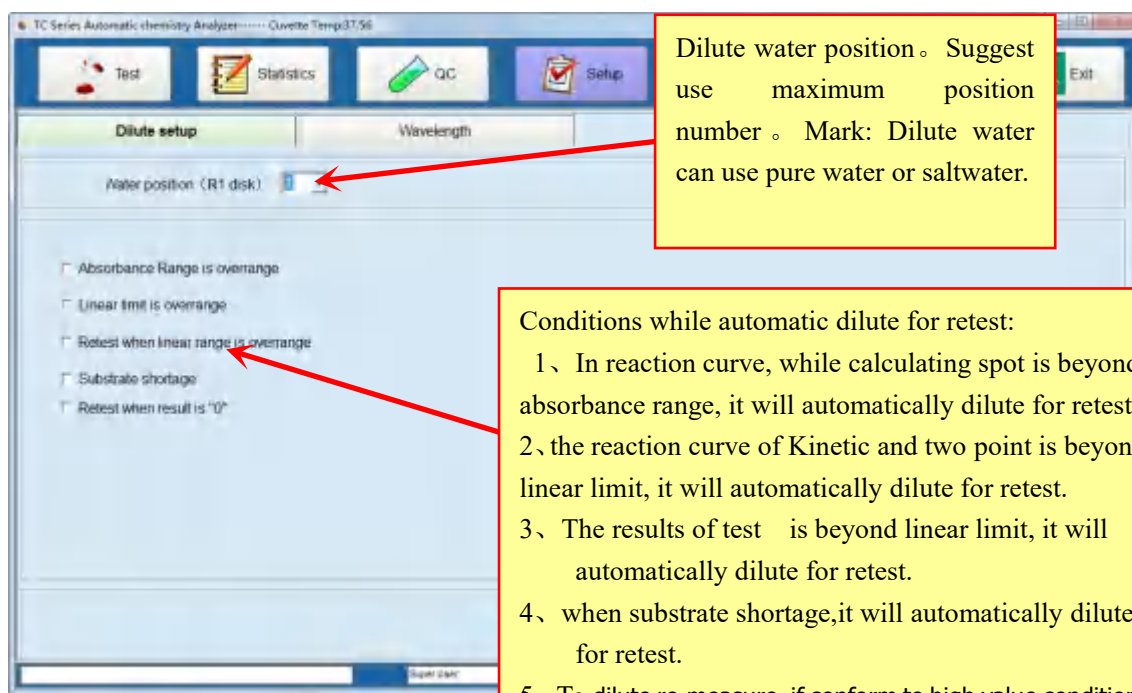
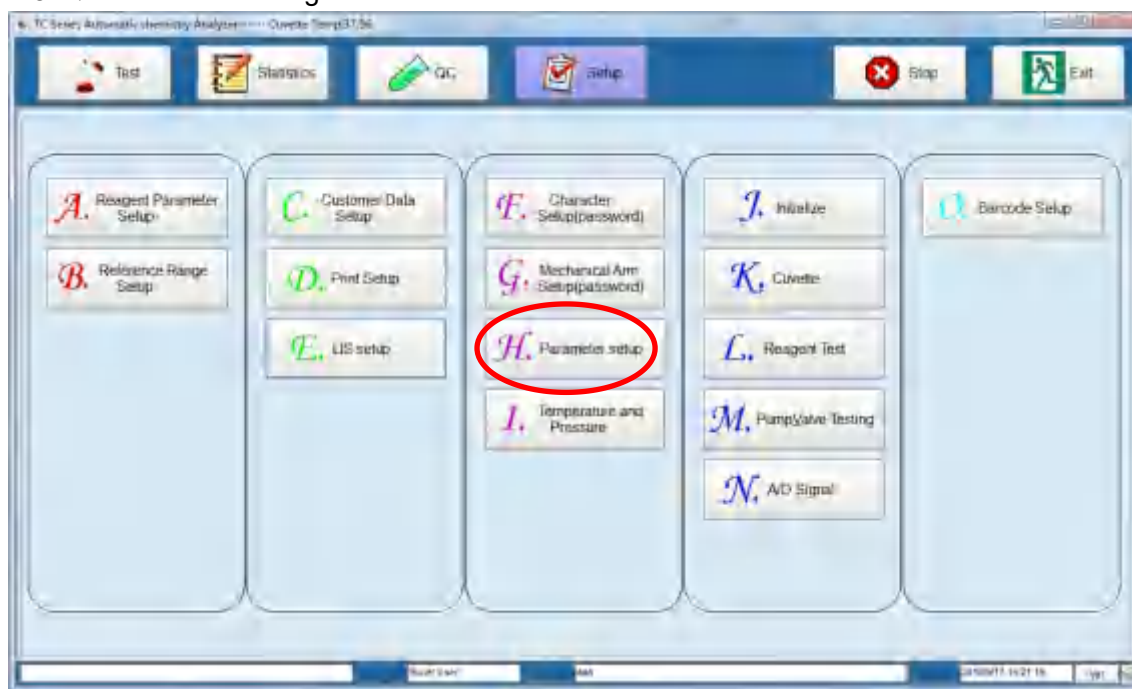
Beside, you can also check the current result under “Statistics” function tap.

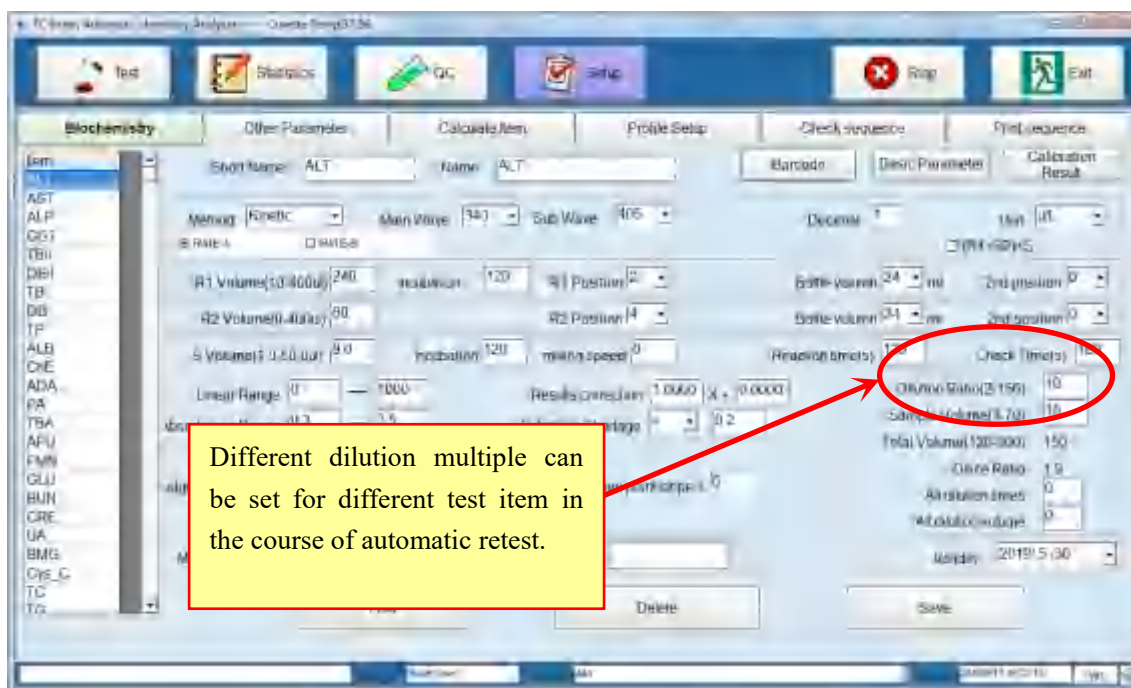
Option functions in this interface:

Option	Function
Sample	Display the information of each sample
Reagent	Display the reagent information of each reagent cuvette
Reaction Cuvette	Display the information of each reaction cuvette
Pause/Continue	To pause or continue the instrument's testing; Please don't click this button adarbitrium, for the biochemistry reaction is running all the time
Return	When the detection is finished, click this button to back
Distilled Water	Liquid level alarm. “have” means the distilled water is enough; “no” means the distilled water need to be changed
Waste	Liquid level alarm. “not full” means it is normal; “full” means it need to be cleaned

1.8 Dilution retest user manual

1.8.1、Parameter setting





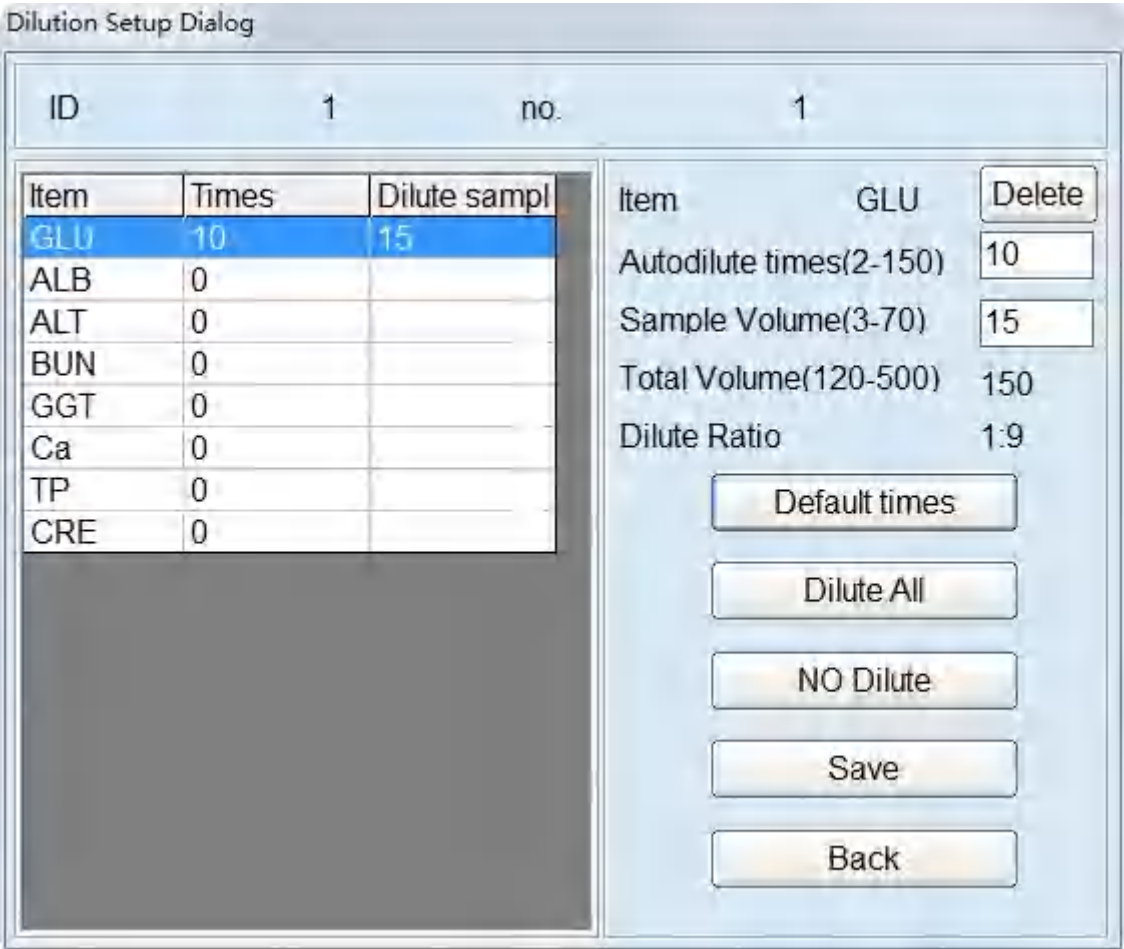
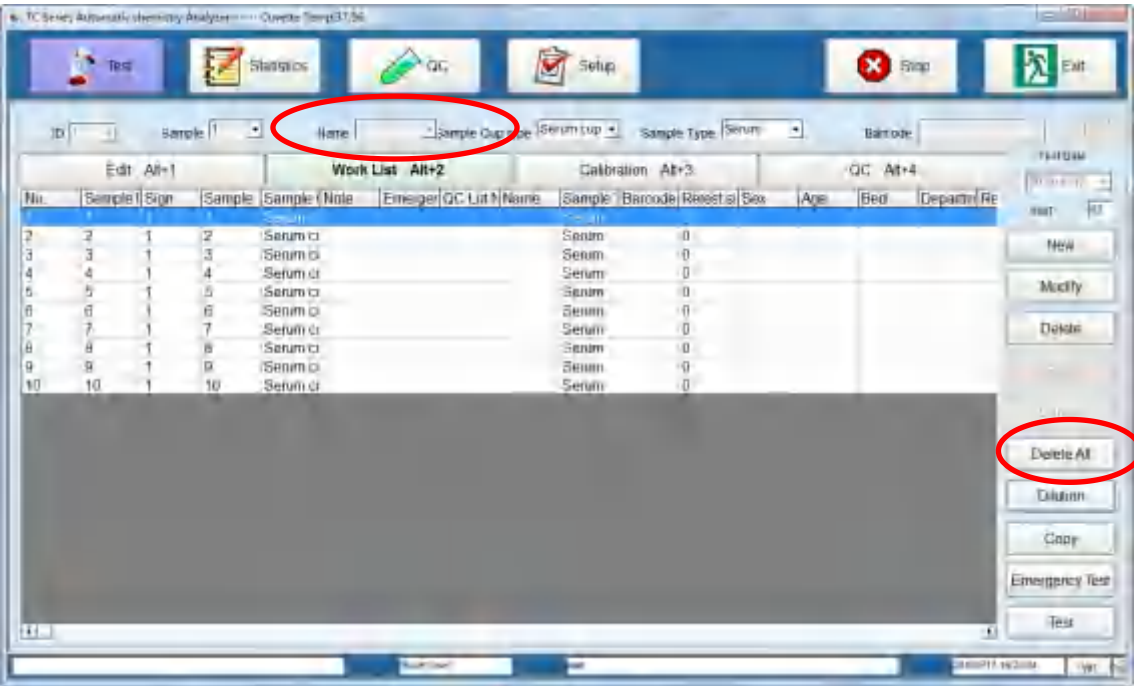
Linear limit:

- 1) Kinetic and two points methods valid, end point method is invalid .
- 2) Test point ≤ 3 : not counting linearity range.
- 3) $4 \leq \text{Test point} \leq 8$: linearity = (First three absorbance change rate — last three absorbance change rate) / All test points absorbance change rate
- 4) Test point ≥ 9 : linearity = (First six absorbance change rate — last six absorbance change rate) / All test points absorbance change rate
- 5) (Linear limit 's judge method: the value more less, curve more higher. If reaction curve is not smooth, will auto dilute retest.
- 6) Substrate shortage: when the absorbance in the reaction curve is greater or less than the set value, the substrate is judged to be in shortage.

Absorbance Range:

Judgement method: If absorbance is not in the setting range, will auto dilute and retest. When appear high value, will over range the setting range. Setting range depends on user during the tests.

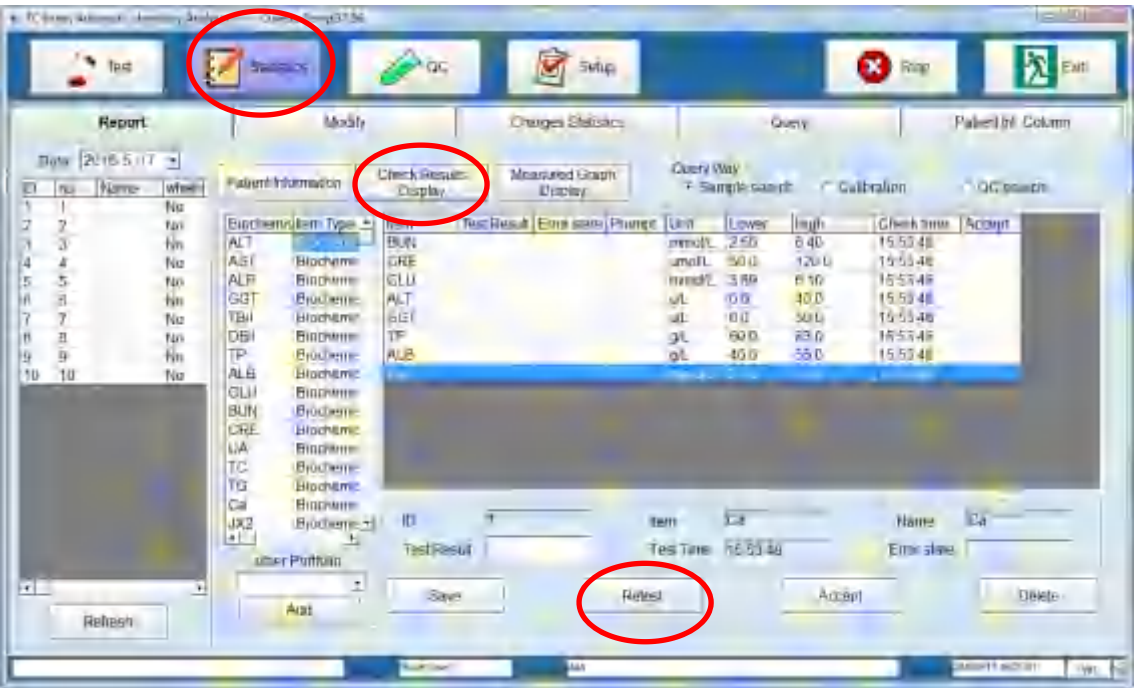
1.8.1、 Pre-dilution using method:



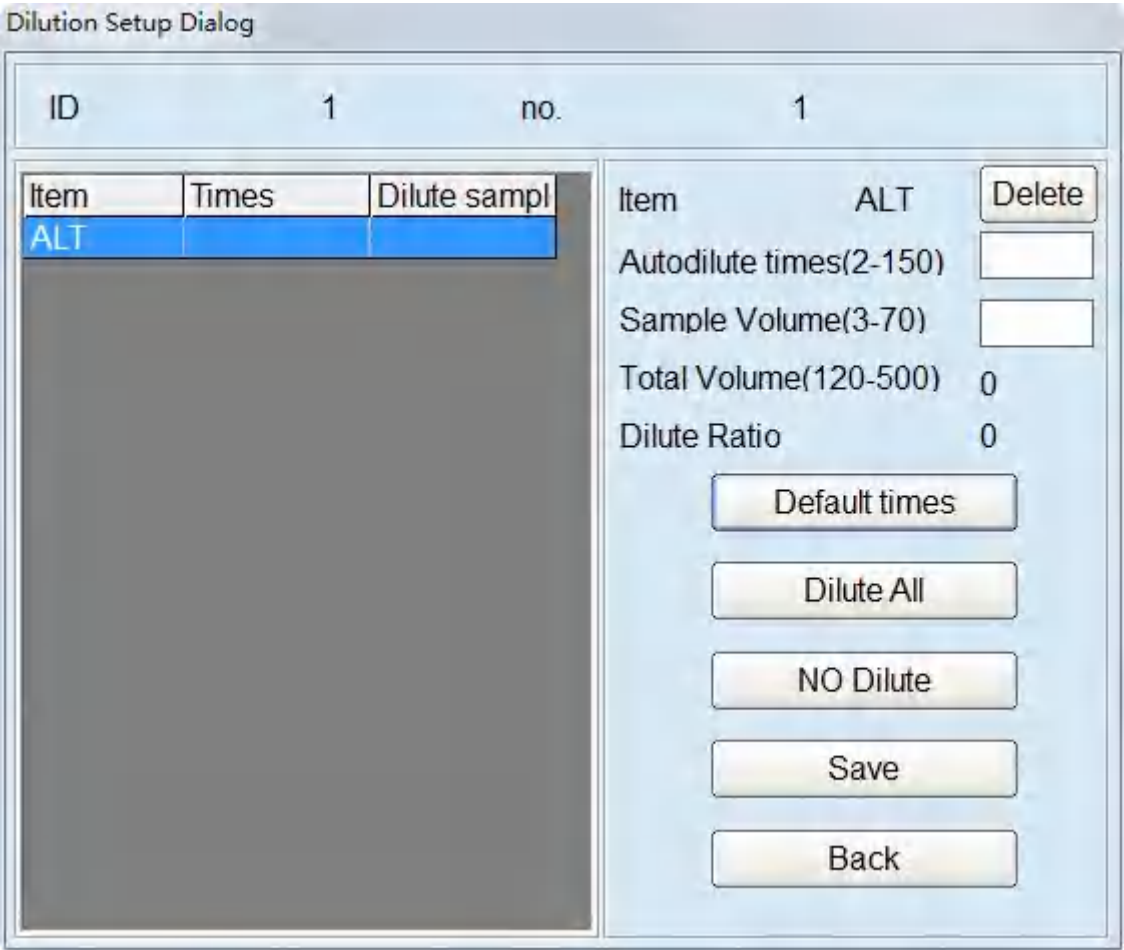
1、 1、 Auto dilute: Fill in the pre-dilution multiples, The number is 2-150 times

- 2、 Sample Volume: Fill in the syringe sample volume of per-dilution, the number is 3-70ul
- 3、 Total Volume: 为 The software automatic computation .Refer to the volume of sample and dilution water ,will not exceed the cuvette volume
- 4、 Dilute Ratio: The software automatic communicates. Refer to the proportion of sample volume and dilution water volume when pre-dilution
- 5 、 Default times : After the choice, All selected items will use the default dilution multiple.(The default dilution multiple setting is in “Biochemistry parameter” - “Biochemistry parameter setting” –“Basic parameter “
- 6、 Dilute All: After the choice, the all current sample will use the default dilution multiple to pre-dilution
- 7、 No Dilute: After the choice, the current sample will not pre-dilution, you can quickly cancel the pre-dilution that you have already chosen
- 8、 Save: Save the modification
- 9、 Back: Return to the last interface

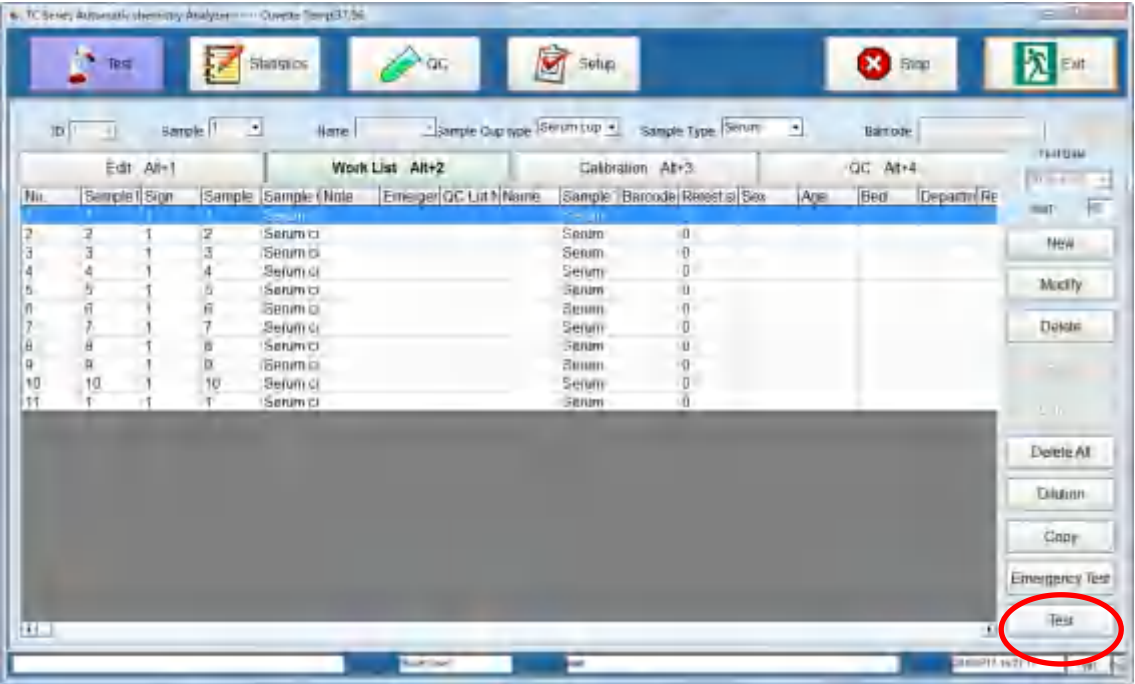
1.8.3、Test result retest:



In report menu, you can click rerun button, will appear below dialog.

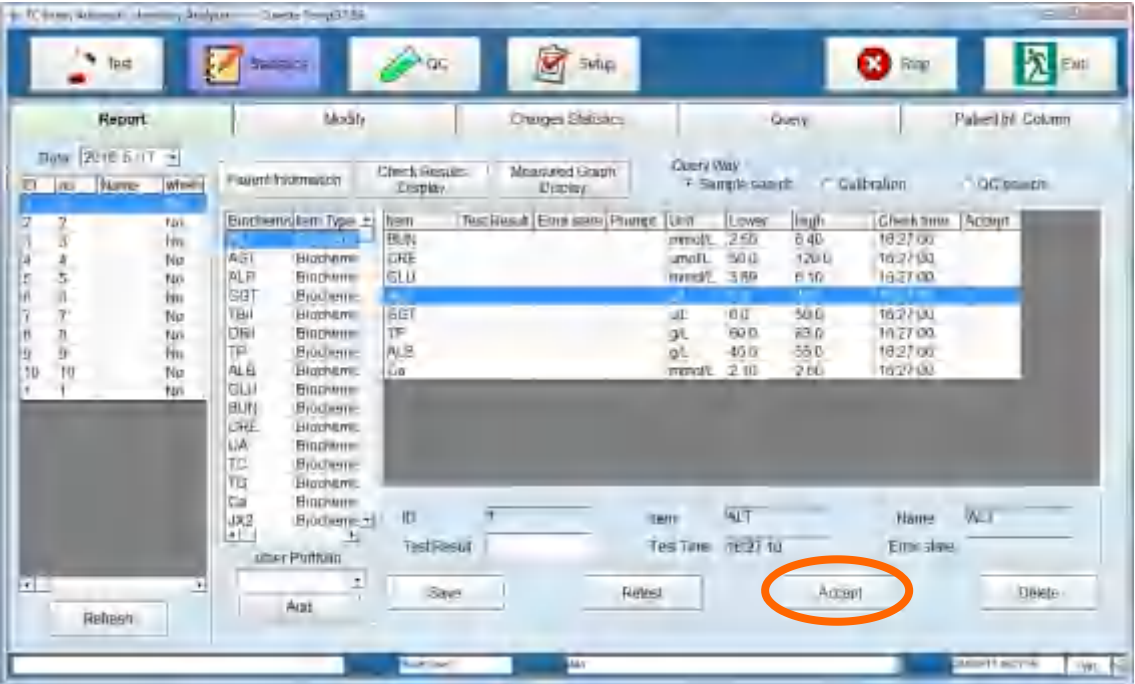


Rerun can choose dilute times or no dilute retest. Click OK, will add your chosen items to test list automatically. Then click test button, will auto dilute retest. Please see below picture.



1.8.4、Rerun result option:

After rerun , will appear two results. When printing, only choose one of results. Software default the last result. If user want to use frontal result, can choose in below picture. Choose frontal result then click “accept”.



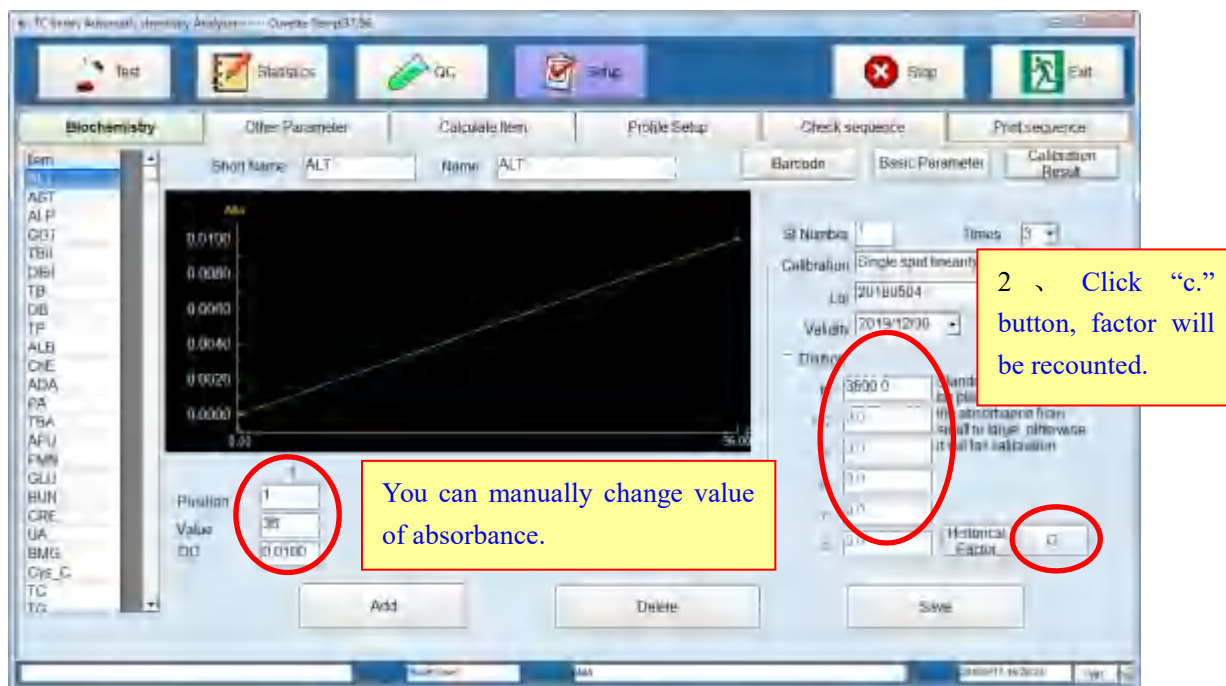
2. Calibration

Click “Parameter” button to enter into the following interface. It is mainly used for biochemistry test, QC and calibration.

2.1、 Calibration Setup

Conduct the “position setup for calibration liquid” in this interface:

Click “Parameter” button, and select “biochemistry” button; and then click “Basic parameter” to get the below chart.



Please select one item under the list of “item name”, then set calibrator method, standard qty, standard position, standard value. The initial value of absorbance is “0.0000”, After Calibrating, the value of absorbance will be automatically got and fill in, Meanwhile K、R0、a、b、c、d factor can be automatically calculated, or you can manually change value of absorbance, click “compute” button, K、R0、a、b、c、d factor will be recomputed.

Parameters in this dialog box:

Parameter	Meaning
St. Number	Input the standard No. of this project, more than one is acceptable.
Position	Set the position of calibration liquid on sample disc
Value	The corresponding standard value of calibration liquid
OD	The absorbance value of instrument calibration

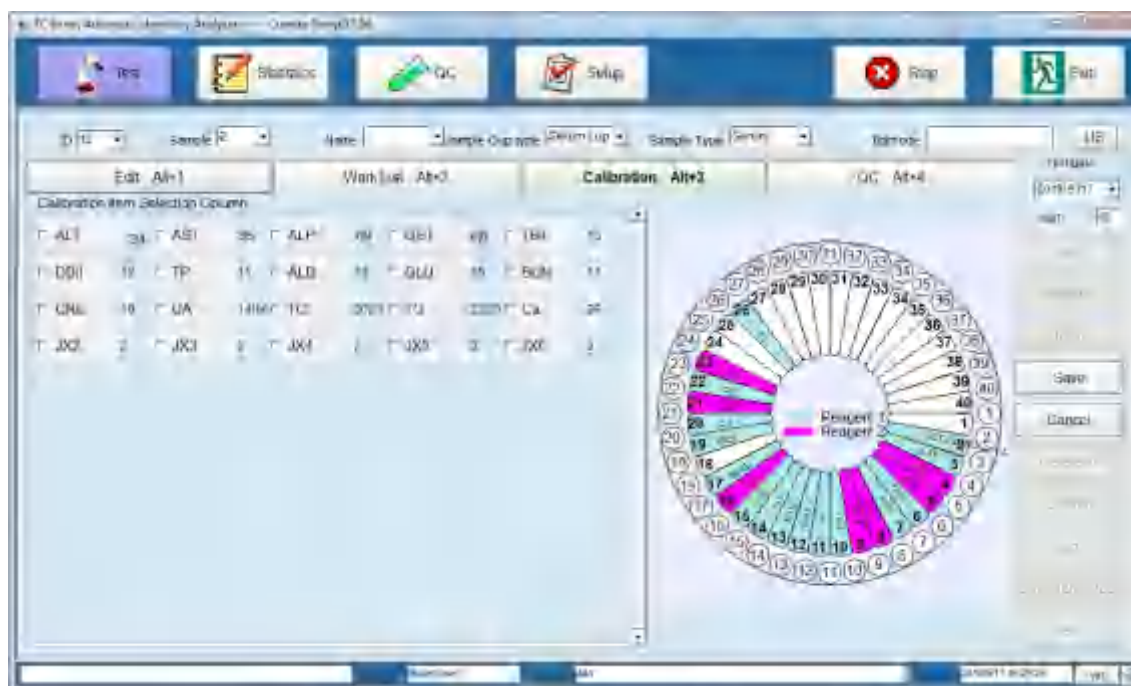
Parameter	Meaning			
Calibrator method	Please see below picture, there are 3 kinds of linear calibration and 6 kinds of Non-linear calibration, which corresponds to different standard qty and calibration parameter.			
Serial No:		Calibration type	Standard fluid no.	Calibrator parameters
Linear Calibration	1	Single spot linearity	1	K
	2	Double spot linearity	2	a、b
	3	Multiple spot linearity	3~6	a、b
Non-Linear Calibration	1	Logistic-Log 4P	4	K、R ₀ 、a、b
	2	Logistic-Log 5P	5	K、R ₀ 、a、b、c
	3	Exponential 5P	5	K、R ₀ 、a、b、c
	4	Polynomial 5P	5	a、b、c、d
	5	Parabola	3	a、b、c
	6	Spline	4	R ₀ 、a、b、c

Button in this interface:

Button	Function
Save	Save the settings

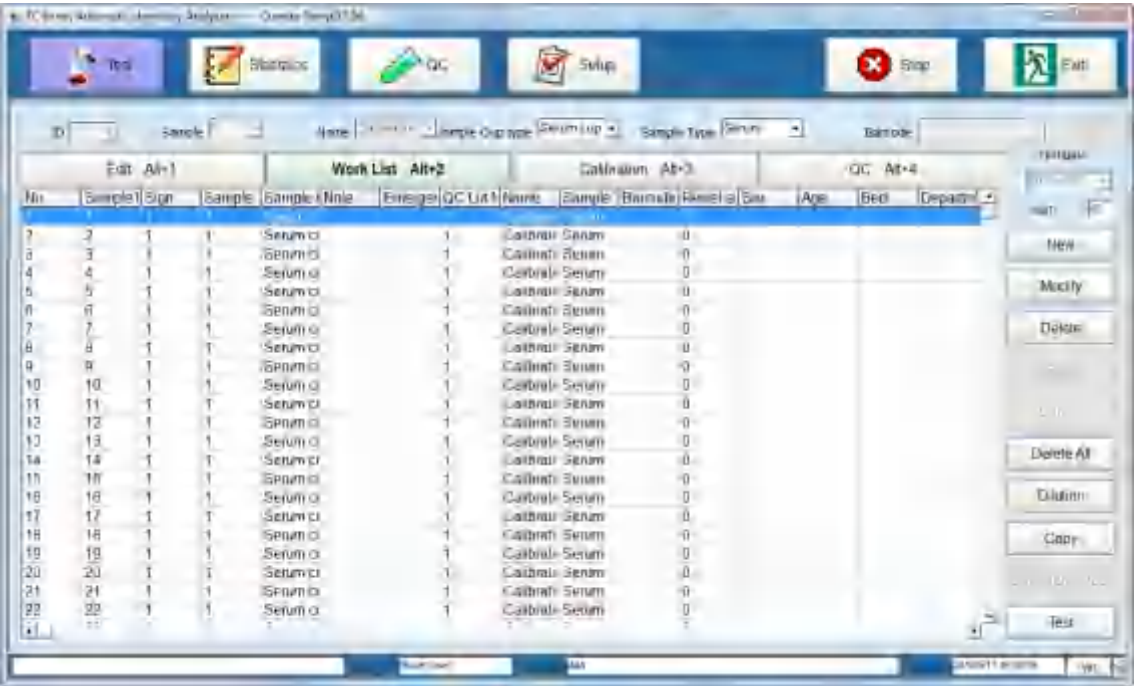
2.2、Calibration Test

Click “calibration setup” option in “Test” interface to get the following chart:



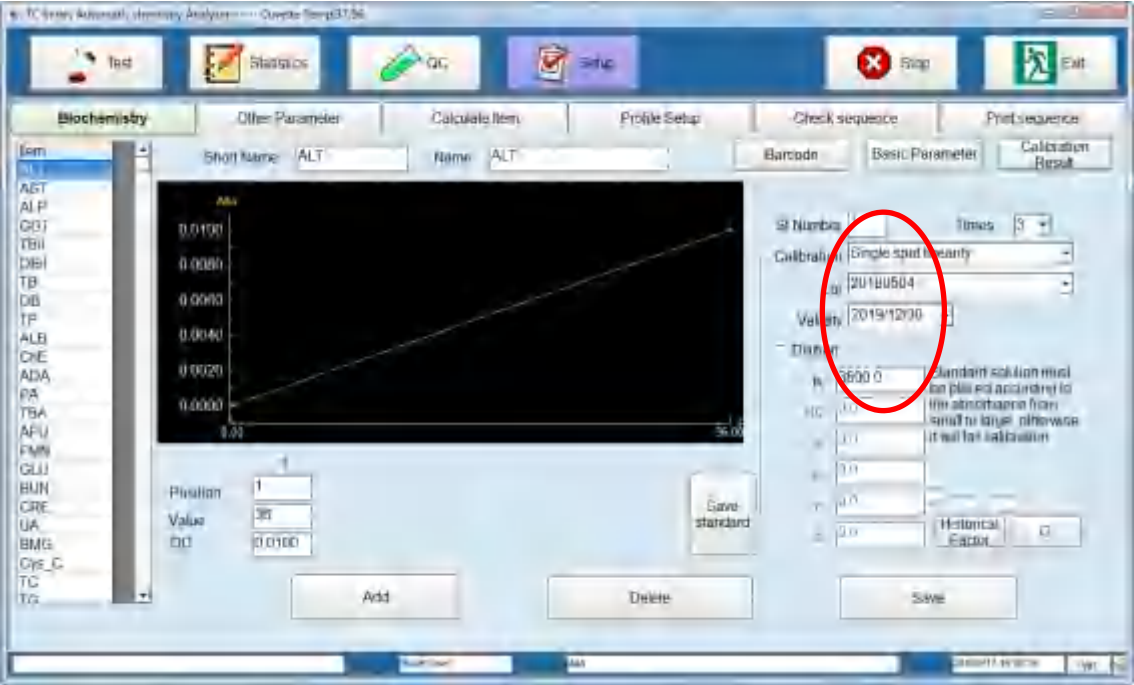
Select the item which needs to be calibrated, and then click “Add” button. To start the

calibration test by clicking “Test” button after “Item preview” interface is confirmed.



2.3、Calibration Result Check

The results from calibration is new factor for K、R0、a、b、c、d, you can check under “bio-chemistry parameter”-bio-chemistry item parameter setup—calibrator results. The value of K、R0、a、b、c、d as below picture is calibrated results.



NOTE

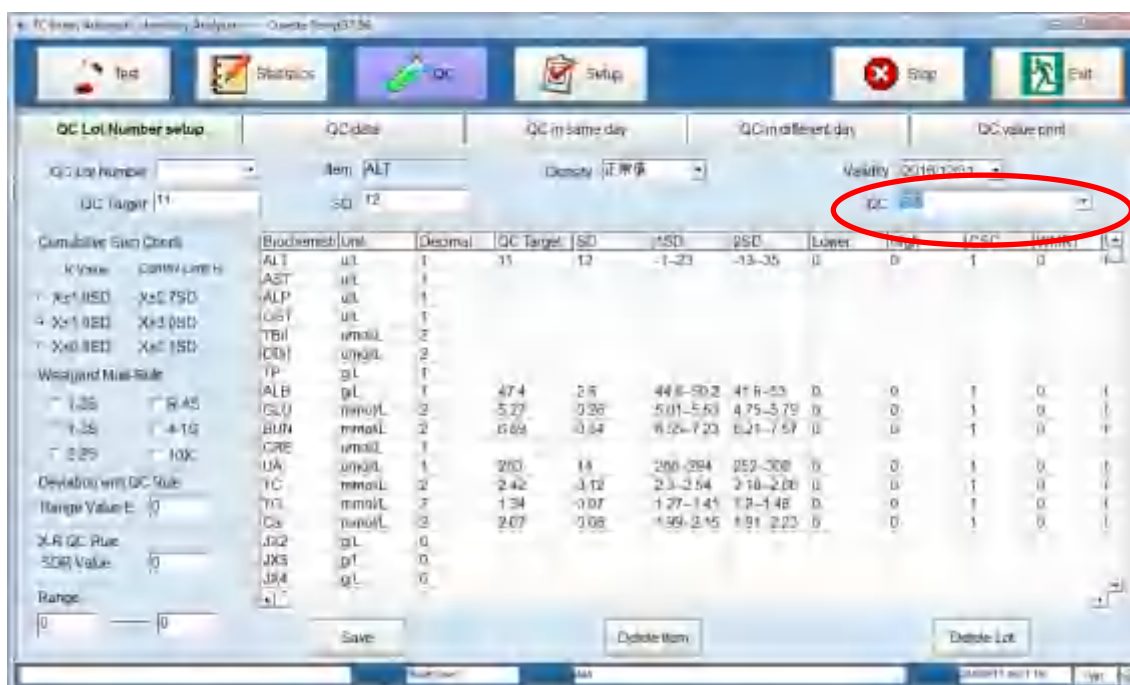
- The system will adopt the current default calibration factor to calculate the concentration of the sample.
- The system will set the newest calibration factor (including the calibration factors which are got from calibration test and calibration edit) as the default factor.

3.QC

3.1、QC Setup

Click “QC” button to enter into the “QC” interface, select “QC SN. setup” button to set the SN.number, density and validity of the control.

Select the item which is included in this control, and then input the target value and SD value of the item. Item's unit and name are set in “Parameter”. After setting, click “Modify” button firstly, and then click “Save” button.

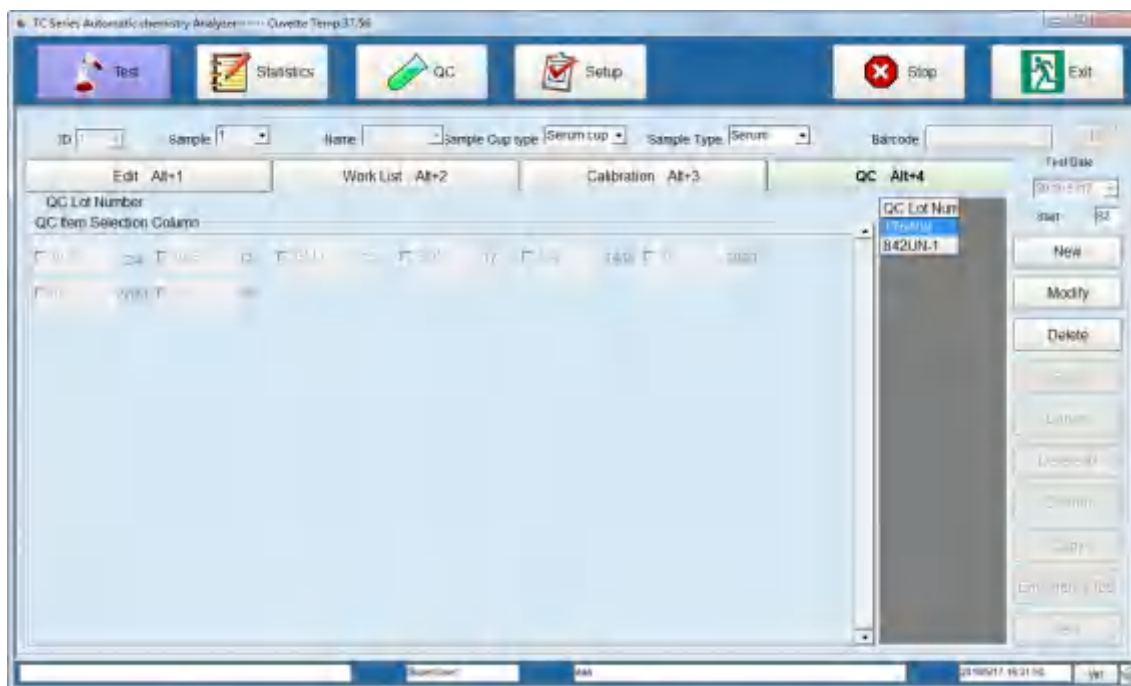


3.2、QC Test

Enter into “Test” interface, select “QC” button, and choose the SN. Number of QC liquid and the items need to be done.

And then click “Add”. After the item preview is finished, please click “Test” button to start the

QC testing.



3.3、QC Results Review

To query the QC results in “QC” interface after the QC testing is finished.

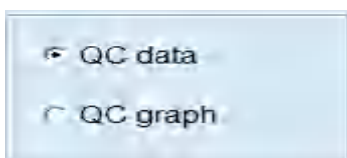
All the QC results are shown in “QC data”.

“QC in same day”: displays all the QC results in the selected date.

“QC in different day”: displays the last QC result of each day in the selected date range.



The QC results can be viewed both in data listing or QC chart.



Parameters in this interface:

Parameter	Meaning
Item name	The name of the QC item
QC SN. Number	lot No. of the QC liquid
Density	Choose high, middle, and low level for the QC liquid
QC target value	The target value of this QC item in this lot No. , it is set in the “QC setup” interface
SD	The standard deviation of this QC item in this lot No. , it is set in the “QC setup” interface
Validity	Expired date of QC
Real time test result	QC test result
QC Test date	Date of the QC
QC Test time	Time of the QC test, the QC result in the last moment of the day is used as the daytime QC value
QC graph	Display the QC result in QC chart
QC data	Display QC results in data list

Buttons in this interface:

Button	Function
Save	Save the settings which have be done
Print	Print the QC chart
Delete	Delete the current QC result

8、Function

The “Performance test” menu includes “Reagent Vol.” and “Calculator” in our software of biochemistry instrument.

1. Reagent Vol.

Click “Reagent Vol.” button to detect the set reagent in all the parameters. It is convenient for adding the reagent in time.

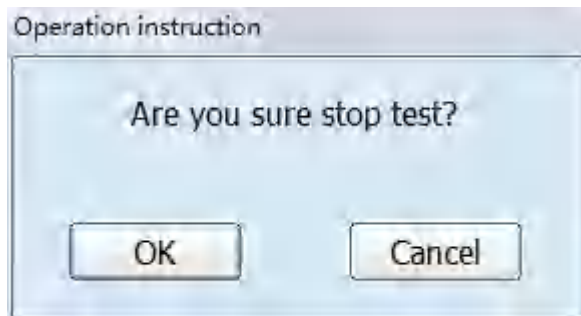
Under this menu, it will display the reagent remaining volume of last analysis, after current analysis, data will be updated automatically.

Reagent Test

No.	Biochem	Reagent	Reagent	Position	Reagent Volu	Reagent	Measure	Sam Nur	Bottle volun	Upper Vi
1	water	Reagent 1	First bott	1	300	0.0	0	0	24	
2	GLU	Reagent 1	First bott	15	300	0.0	0	0	24	
3	ALB	Reagent 1	First bott	13	200	0.0	0	0	24	
4	ALT	Reagent 1	First bott	2	240	0.0	0	0	24	
5	BUN	Reagent 1	First bott	17	300	0.0	0	0	24	
6	GGT	Reagent 1	First bott	6	240	0.0	0	0	24	
7	Ca	Reagent 1	First bott	26	300	0.0	0	0	24	
8	TP	Reagent 1	First bott	11	300	0.0	0	0	24	
9	CRE	Reagent 1	First bott	19	300	0.0	0	0	24	
10	ALT	Reagent 2	First bott	4	60	0.0	0	0	24	
11	GGT	Reagent 2	First bott	8	60	0.0	0	0	24	

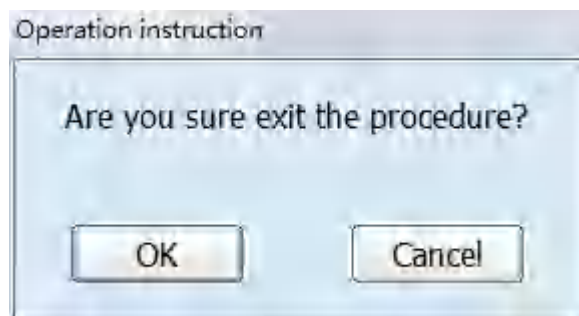
9、 Stop

Used for stopping the current testing. The software will cancel all the orders and start to initial after click this button



10、 Exit

Click “Exit” button in the main menu, and then click “OK” button in the dialog box to exit the operation system. There have “Return” buttons in each sub menu, by click these “Return” button to return to the previous menu.



Chapter SIX. Maintenance

To ensure reliability, good performance and service life of the system, regular maintenance is required.

6.1 Maintenance

6.1.1 Method and instruction for operating and maintaining

1. Keep the instrument power on for 30 minutes before analysis every morning.
2. Check and make sure the reagent and serum are enough. Check and make sure the pump pipe is at the bottom of the distilled water bucket, and can pump enough water for analysis. After emptying the waste and moving the waste bucket back, make sure that the drain pipe is in the waste bucket
3. Clean the cuvette no less than twice before testing every day.
4. Put the reagent, standard substance and QC serum to external refrigerator after tests every day.
- 5.To prevent injury and damage, please do not touch the moving arm (moving parts) during the test.
6. Add distilled water to the cuvette to keep them wet after test is finished.
7. Check to ensure that the distilled water and detergent in buckets are enough and waste bucket is not overflow every day.
8. Regularly check if the sample needles are blocked. Method: Click "Temperature and Pressure Settings" in the "Parameter Settings" menu

You should click "reagent valve on". If you find "reagent needle" no water pulling out, you should use acupuncture make them clear. If there is no effect, please contact with us,we will arrange worker to your company.

You are supposed to choose “syringe pump”, and then click “test”. If the two probes (reagent and sample probes) do NOT inject water, please unblock the probe with thin wire.

Please contact us when you need help.

9. If you find wash unit can not drained the cuvette completely or no water is injected in, please contact us.

10. The flaw or stain on the light-pass surface of the cuvette will influent the measurement of absorbency; please replace it with a new one.

11. QC serum should be tested to calibrate the precision of the instrument.

12. Choosing the Position 40 cuvette as the beginner of the test is recommended, because the Position 40 cuvette is already dry when washing procedure is finished.

13. Do not switch the instrument power on and off frequently, it should cause damage to the power module.

14. Stabilized voltage supply should be used when the net voltage is not steady or on the low side.

15. The reagent stored in the refrigerator should be waited to warm up to the room temperature before test.

16. Cap the reagent bottles in the disk when the instrument is in the idle status and uncap it before test.

17. Please pay attention when printing report:

test will stop immediately.

21. Replace with distilled water when detergent is used up. Please insert detergent pipe into the distilled water bucket in that case.

22..Please check the working of mechanical arm after repair instrument, if normal , then process QC, and ensure instrument working properly.

Chapter SEVEN. Troubleshooting

7.1 Initialization

Faults	Causes analysis	Solutions
1.Can not initialize after start the system	a. The serial port wire is not connected rightly b. The serial port is not selected rightly c. Software setting faults	a. Check whether the serial port line is connected. b. Select the serial port in communication setting. Select the needed serial port in computer device manager if there is not serial port in communication setting. c. Re-setting the software
2.The reaction disc can't rotate when initialize, and act on other actions after a period of time	a. the 0# motor signal wire is not inserted rightly b. The main control board is broken, or the line contact is not good c. Software program faults	a. Re- insert and extract 0# motor signal wire b. Replace the main control board, weld the serial port wire c. Replace the software
3.The motor lock is not tight after initialization	a. The voltage of 5V power supply is not stable or not enough b. The drive board of motor is broken	a. Replace the power board b. Replace the drive board of motor
4.the reaction disk position are different between initializing and parameter setting	a. The installation position of optocoupler of the reaction disc is wrong	a. Re-adjust the optocoupler of the reaction disc
5.Friction noise from the colorimetric disc when initialize	a. The colorimetric disc is not assembled rightly, or the rotary axis is not in	a. Disassemble the colorimetric disc and reposition

7.2 Mechanical

Faults	Causes analysis	Solutions
1.The mechanical arm can't detect initial position	a. The signal wire of optocoupler sensor is not connected to motor pinboard well. b. The retainer ring of optocoupler is not installed rightly c. Weld position of optocoupler is loosen	a. Check and connect to right position b. Re-adjust the position and fix c. Take down the optocoupler and re-weld
2.The mechanical arm can't uplink and downlink smoothly	a. There is a wire on the bottom side, or the upper and under mechanical arms are caught on the pipeline b. The friction between the axis and components is too big	a. Check and re-arrange the light path b. Daub silicone grease lubrication on the axis
3.The mechanical arm rock	a. The rotary synchronousbelt is too lax b. The synchronizing wheel and motor rotary axis do not occlusion tightly c. The voltage of 5V lock motor is not enough	a. Adjust the synchronousbelt to suitable tightness value b. Tighten the fastening screw on the rotary synchronizing wheel c. Check and replace 5V power supply
4.Obvious noise from the motor when running	a. Stepping motor line is loosened b. Dialing error of motor drive board	a. Electrode Cable. Find out the uncompacted parts and re-press the connecting plug b. Re-adjust the dialing of motor drive board
5.Reagent arm can't reach the designated position when testing	a. Motor board faults b. The rotary belt is too lax	a. Replace the No. 8 and 9 motor boards b. Adjust the synchronousbelt to suitable tightness value
6.Mechanical arm can't work normally	a. Motor board faults b. The optocouplers is broken c. Mechanical arm faults d. Internal 3P data lines burn up, external 232O data line is fall off	a. Replace the motor board b. Replace the optocouplers c. Replace the sample mechanical arm d. Replace the 3P data line and weld

7.3 Waterway System

Faults	Causes analysis	Solutions
1.Can't draw water but inject water when cleaning	a. The plus-minus of peristaltic pump power line is inversed	a. Swop the power-supply wiring heads of the peristaltic pump
2.Obvious residual water stain at the bottom of cuvette after cleaning	a. The apocenosic pump can't work b. The bottom of cleaning probe is projecting in the rinse block c. The cleaning needle can't reach to the bottom of the cuvette	a. Repair and replace the apocenosic pump b. Re-adjust the position of the cleaning piece c. Re-adjust the steps numbers of fluctuation to make the cleaning piece reach the bottom of the cuvette in "motion parameter settings"
3.Can't inject water well-distributed	a. The magnetic valve or water inlet are blocked	a. Replace the magnetic valve or clean the pipeline
4.The water level of pressure tank rise ceaselessly	a. The sealed cap of pressure tank is not tightened b. The seal ring of pressure tank leak air	a. Tighten up the sealed cap b. Replace the seal ring and sealed cap
5.The pressure of apocenosic pump is not enough	a. The apocenosic pump is blocked by foreignmatter b. The heating tank leak air	a. Disconnect the apocenosic pump and eliminate the foreignmatter b. Reassemble the heating tank
6.The detergent pipeline can't inject liquid	a. Peristaltic pump or pipeline problems b. The liquid takes time to upstream when the pipeline is empty c. The injecting time setting of detergent is wrong	a. Check the peristaltic pump and pipeline, please replace if necessary. b. Clean the cuvettes several times and the liquid will upgoing until fill the pipeline c. Re-setting the time
7.During clean the cuvette, the clean probe crash it	a. The cleaning arm is not well adjusted b. There is no chamfering on cleaning piece c. The installation angle of optocoupler is wrong d. Reaction discis loosen(a. the three fixing bolts on the reaction disc are not tightened; b. the cuvette bracket is not clasped; c. The bottom bearing of reaction disc is not tightened) e. The coded disc of reaction	a. Adjust the clean arm to the centre of the cuvette b. Take down the needle with cleaning piece, and take chamfering processing on cleaning piece c. Adjust the position of optocoupler slightly to make the green and red lights are bright d. Find out the reason of looseness and eliminate it e. Replace with qualified coded disc

	disc is unqualified	
8.The cleaning probe drip water	a. The magnetic valve is not closed well	a. Disconnect and clean, calibrate the optic parameters

7.4 Light Path

Faults	Causes analysis	Solutions
The signal value is lower than the allowed range	a. The voltage of lamp is not enough b. The voltage of AMP is too low c. The fiber optic is not installed correctly.	a. Adjust the lamp to suitable voltage b. Adjust the voltage of AMP to 3.6V after inject the distilled water c. Re-install the fiber optic
2.The signal is unqualified when the gain is on the max. or min. value	a. The fiber optic is break off b. Circuit board faults	a. Replace the fiber optic b. Check the weld condition of the circuit board to confirm whether the fuse is wrong selected
3.The signal value is not stable	a. The voltage is not stable b. The lamp is unqualified c. The photosensitive diode Is unqualified d. The fiber optic is not installed correctly. e.The circuit board is not grounded well f. The power source is unqualified	a. Adjust the lamp's voltage to rated voltage, we suggest to use stabilized voltage supply, b. Replace the lamp c. Replace the photosensitive diode d. Shorten the light path of the optic fiber to enhance the light intensity. And put the light beam (which is with the strongest light intensity) at 340nm wavelength e. The oxidation treatment at the junction of the screws may cause bad contact; Polishing the screw junctions of each circuit boards. And weld another grounding wire if necessary. f. Replace with qualified power supply

7.5 Test

Alarm prompt	Causes analysis	Solutions
1.Test results are not correct	a. The voltage is not stable b. The stirring depth is not enough c. The circuit board is not grounded well d. The voltage of AMP is too low e. The colorimetric cuvette is dirty f. The reagent is invalid g. Software faults h. The parameter settings of reagents are wrong	a. Adjust the lamp's voltage to rated voltage, we suggest to use stabilized voltage supply b. Re-adjust the stirring depth c. The oxidation treatment at the junction of the screws may cause bad contact; Polishing the screw junctions of each circuit boards. And weld another grounding wire if necessary d. Adjust the AMP's voltage to 3.6V after adding distilled water e. Replace the reaction cuvette f. Replace the reagents g. Re-install computer system and software h. Re-inspect the parameters settings

7.6 Temperature and Pressure

Faults	Causes analysis	Solutions
1.No heat	a. Check whether the heating power supply is inputted b. Check whether the reaction disc and water-heating temperature sensor are in normal condition c. The main control board is connected to temperature control board d. Check whether the wire is ok	a. Check +24V heating power source b. Check reaction disc and water-heating temperature sensor c. Check the connector wire between main control board and temperature control board d. Check whether the temperature setting is in normal condition
2. No pressure	a. Liquid inlet pump b. Pressure sensor	a. Check whether the pressure setting of the operation software is in normal condition b. Replace the waterway board
3.No refrigerate	a. The temperature setting is wrong b. Refrigeration power supply c. Check the refrigeration temperature sensor	a. Check whether the refrigeration temperature of the instrument is right b. Check +12 refrigeration power supply c. Check whether the refrigeration temperature sensor is in normal condition

NOTE: The user can solve the problems/faults (which are mentioned in the user manual) according to the user manual. If there is any problems/faults that can't be solved or not mentioned in the manual, please contact our company or your local distributor.

Product name: TC6030 Automatic Chemistry Analyzer

Product Model: TC6030L ☐ TC6020L ☐ TC6010L ☐

Input supply: $\sim$ 100-240V 50/60Hz

Input power 1000VA

Overvoltage classify: class II

Pollution class: 2

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