Copyright and Declaration

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Congratulations you have become a VIP client for Guilin URIT Medical Electronic Co., Ltd., and welcome to use Spincell 5plus Auto Hematology Analyzer, it will bring you the new experience and convenience.

Declaration

All contents in this manual were strictly compiled according to related laws and regulations in China, as well as the specific condition of Spincell 5plus Auto Hematology Analyzer, covering all the updated information before printing. URIT Medical Electronic Co., Ltd. is fully responsible for the revision and explanation of the manual, and reserves the right to renovate the relevant contents without separate notification. Some of the demonstration pictures are for reference and subject to real object if any differences.

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All instructions must be followed strictly in operation. In no event should URIT Medical Electronic Co., Ltd. be responsible for failures, errors and other liabilities resulting from user's noncompliance with the procedures and precautions outlined herein.

Limited Responsibility for Quality Warranty

From here on URIT is equivalent to URIT Medical Electronic Co., Ltd..

The manual for Spincell 5plus Auto Hematology Analyzer, defines the rights and obligations between the URIT and the customers about the responsibility for quality warranty and after-sale service, also the related agreements on commencement and termination.

URIT warrants the Spincell 5plus sold by the URIT and its authorized agents to be free from defects in workmanship and materials during normal use by the original purchaser. This warranty shall continue for a period of one year since the date of installation. The analyzer life is ten years.

Must meet the following requirements.

1. According to this manual to operate the instrument.

2. The software and hardware which installed on the instrument must comply with the provisions of this manual.

3. Only the engineers who authorized by URIT can do the maintenance and repair, and only the spare parts which approve by URIT can be used.

4. Laboratory power supply in line with national or international laws and regulations.

5. The samples are collected and storage under normal clinical laboratory l conditions.

6. The reagents comply with the provisions of this Operation Manual.

7. Use the right tools to do the instrument Maintenance or troubleshooting.

URIT assumes no liability in the following situations even during the period of warranty.

Failure due to abuse the analyzer or neglect the maintenance.

Use reagents and accessories other than manufactured or recommended by URIT.

Failure due to operation not under the instructions described in the manual.

Replace accessories not specified by URIT, or after maintenance or repair by a service agent not approved or authorized by URIT.

CAUTION

THE ANALYZER IS FOR PROFESSIONAL AND PRESCRIPTION USE ONLY.

Technical service and troubleshooting are provided by URIT Customer Support Center. Professional technician and sale representative will be sent to offer you timely service when necessary.

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Chapter 1 Introduction

1.1 Overview

Welcome to read the Spincell 5plus 5-Part-Diff Auto Hematology Analyzer's manual, this manual includes instrument operation, maintenance instructions and matters needing attention. In order to keep the instrument in a good performance, you should do operation and maintenance according to this manual.

Spincell 5plus 5-Part-Diff Auto Hematology Analyzer is an in vitro diagnostic medical device. It can analyzer and output 34 parameters of the specimen (including 6 graphics). The Optical detection section uses four angle laser scattering flow cytometry to analyzer the five part differential of white blood cells, Coulter theory to analyzer red blood cells，platelet, and uses non-cyanide colorimetry for hemoglobin concentration.

NOTE

- Read this instruction carefully before operating, especially the safety information. Please keep this manual properly for future reference.
- If the user does not operate the instrument according to this manual, misemployment will lead to inaccurate measurement and cause misdiagnosing, delaying patient's treatment or doing harm to the operator himself, even damaging the instrument.
- Any attempt to brief, optimize, improve or elide expected activities which listed in operation manual will be likely to cause some negative impact on the precision of instrument.
- User must follow the instruction strictly when he operating the URIT medical instrument.

1.2 How to Use This Manual

This manual contains general information, which is the best guidance for new operators. Please read it thoroughly at the first use. You can use contents to quickly find the required information in daily use. All related personnel should read this manual.

1.3 Hazard Sign

This manual uses the following warning conventions.

symbol	meaning
WARNING	Denotes the operator should follow the instruction under this symbol, or it may have a personal injury.
CAUTION	Denotes potential hazards that could result in a minor injury, also used for conditions or activities which could interfere with proper function of the analyzer.
NOTE	Prompts to operate according to symbols, emphasize the important information in operation procedures and the contents needed to pay attention to.
WARNING	Denotes potential bio-hazard.
WARNING	Denotes a laser hazard, if non-compliance with procedures or engineering controls, may result laser damage to eyes.
20	The environment-friendly use period is 20 years, within which can be rested assured to use. It should be carried to a recovery system if more than environmental protection use period.

Declaration

- Spincell 5plus complies with the requirements of *Emission and Immunity of GB / T 18268.26-2010.*
- Please make electromagnetic environmental assessment before using it.

1.4 Guidance

Operator can find the information needed according to the chapters

Information	Reference
Parameters	Chapter 1 Introduction
Notices for Operation	Chapter 2 Safety Information for Operation
Structure and Use	Chapter 3 System and Function
Installation	Chapter 4 Installation
Measurement Principle and Procedure	Chapter 5 Principles of Operation
System Parameter Setting	Chapter 6 Settings
Daily Operations	Chapter 7 Daily Operation
Requirement and Method of QC	Chapter 8 Quality Control
Requirement and Method of Calibration	Chapter 9 Calibration
Maintenance	Chapter 10 Maintenance and Care
Troubleshooting	Chapter 11 Troubleshooting
Detailed Specification	Appendix A
Communications Protocol	Appendix B
Metrical Information	Appendix C
Name and content of poisonous and harmful substances or elements	Appendix D
Daily operation procedures	Appendix E
Key components	Appendix F

1.5 Parameters

Item	Content	Explanation
Test Parameter	34 parameters(with graphics)	Scatter diagram, histogram, three dimensional stereogram
Operation	Enclosed puncture sampling, continuous sampling, 50 pcs sampling processing per batch, do emergency sample test at any time	No need for operators to contact with samples
Language	English & Chinese	Software supports online and U disk upgrade.
Display Setting	Equipped with brand computers and LCD monitors.	Data management and networking are convenient.

Data Storage	≥ 200,000 test results (with graphics)	
Speed	Whole blood single (emergency) sampling ≥60 / h, whole blood automatic (batch) sampling ≥60 / h	
Output Mode	External printer, choose to print the histogram. Different warning signs prompt probable abnormalities of specimen.	Reference range can be printed out in English&Chinese report format.
Blood Volume	whole blood automatic (batch) sample mode 20μL	Anticoagulation with EDTA-K2/EDTA-K3.
	Whole blood single (emergency) sample mode 20 μL	
	Diluent Sampling Mode 20 μL	
Reagent	Diluent, Detergent, Lyse (non-toxic environment-friendly reagents), Sheath	
Sample Aspiration Probe Rinsing	Use the automatic washing device to flush the inside and outside surface of sample aspiration probe.	Avoid samples cross contamination and operators contact the samples.
Unit Selection	With two units selection for WBC, RBC, HGB, PLT and other items.	Meet the parameters unit requests for different countries and places.
HGB Test	Cyanide-free quaternary ammonium salt hemoglobin.LED light source, 540nm wavelength colorimetry.	Environmental regents can avoid the effects of operators' health, and be good for environmental protection. If use the toxic reagents, you need to purchase specialist processing equipment, which will increase costs.
Control and Calibration	With standard, blood and manual calibration, With L－J, X, X－R, X－B control modes.	
Structure	Adopt separately	Enhance accuracy and

	removable syringe structure.	maintain easily
Maintenance	With automatic monitoring function to prompt the operator to perform automatic maintenance or troubleshooting procedures.	Improve the lifetime of equipment, and maintain the best working conditions
Reference Range	With 9 different groups normal range parameter setting function.	Can be adjusted according to different geographical groups, and the instrument will automatically identify and match the best reference.
Flush	High-voltage cautery. Removable ruby aperture plate is easy to clean. Positive and negative pressure recoil and intelligent automatic cleaning.	
Security	Have a good electrical security with the flow electricity isolation system.	
Host Size	L580mm×H550mm×W705mm	
Power	300VA	
Fuse	250V/3.15A	
weight	73kg	

Chapter 2 Safety Information for Operation

2.1 Overview

In addition to the safety use information, the general matters of operators in terms of security are also shown in this chapter. Please read this chapter carefully before operation.

2.2 Special Requirements

- Spincell 5plus 5-Part-Diff Auto Hematology Analyzer is for blood cell count, WBC five part differential and hemoglobin concentration measurement in clinical laboratory.
- Only allow to use the reagents and detergents mentioned in this manual. Operating requirements also include regular cleaning and maintenance.

2.3 General Requirements

- Read the operation manual before using. Understand all the important signs. Please keep manual for future reference.
- Following the manual instructions to start the analyzer, otherwise its function loss might be caused due to accidental mechanical damage and undesirable environment.
- The analyzer must be operated strictly in accordance with the methods mentioned in this manual.
- Keep long hair, fingers and clothes away from rotating parts.
- Turn off the power and unplug the power cord immediately if the analyzer gives off odor or smoking, otherwise it causes fire, electric shock or injury. If this happened, please contact the after-sale service department.
- Do not spill the samples or reagent and do not make other things falling into the analyzer, otherwise it causes short circuit. If this happens, turn off the power, unplug the power cord and contact the after-sale service department immediately.
- Do not touch the circuit, especially by wet hand, which causes electric shock.
- Make sure to connect the analyzer with correct voltage and grounding.

- Avoid damaging the power cord. Do not put any devices upon the power cord, and do not pull the power cord.
- Turn off the power before connecting other devices (host computer, printer).
- The analyzer is connected with AC power. There is a hazardous voltage symbol in the interface. Using power adapters of other brands may cause wrong test results due to the substandard technique data.

2.4 Electromagnetism Security

- The motor, which is inside the analyzer, produces alternative electric field and magnetic field.
- The analyzer is unable to run normally due to the strong electromagnetic interference.
- Data conversion errors and incorrect results are caused due to strong electromagnetic interference and poor grounding.

2.5 Installation

- The analyzer must be installed in dry and dust-free place. Do not place it in a wet, dirty, with poor ventilation or salt and sulfur place. Shell material is ABS + PC, it is corrupted if being placed in a high pH environment.
- Avoid splashing water on the analyzer.
- Do not expose it to the place with large temperature difference and direct sunlight.
- Avoid vibration. Put it into a box with foam to prevent damages during storage and transportation. Improper package may lead to abnormal operation of the analyzer.
- Installation site must be well ventilated.
- Although the analyzer does not produce ionizing radiation, but we should take other equipments generated strong ionizing radiation into consideration, such as X-ray and γ-ray. This may cause test results errors.
- Do no install it in the place with chemicals and generating gas.
- The frequency and voltage required should be consistent with those described in the manual and have the ability to allow current. The analyzer should be equipped with precision power supply or UPS.

- The equipment is about 73kg. Careful handling to avoid injuring.
- Wrong reagent or incorrect operation may cause wrong results.

2.6 Infection Prevention

- Analyzer surface and components have potential infectivity, so keep an appropriate distance between sample probe and surrounding objects in order to facilitate running.
- Wear protective clothing and rubber gloves during operation, maintenance and repairing. Wash hands with disinfectant after work.
- Do not contact the waste and its components with free hands.
- If accidentally exposed to infectious material or surface, thoroughly clean the skin with water immediately, and then operate according to the laboratory disinfection procedures.
- Analyzer uses blood as samples. Blood may contain microbial pathogens which can cause infection easily. Therefore, operation must be done carefully, if necessary, wear protective gloves to prevent the operator himself and people around being infected by pathogenic microorganisms. Even the control and calibrator can be infectiously, we should wear protective clothing and rubber gloves during calibration.

2.7 Reagent

- Check marks on the package.
- Avoid direct contacting with reagents, since the reagents may irritate eyes, skin and mucous membranes.
- If skin contacts with the reagents, wash with water immediately.
- If eyes contacts with the reagents, wash with water and seek medical advice immediately. Please read reagent safety instruction.
- Establish a set of emergency measures in laboratory is very necessary.
- Protect the reagents from being polluted by dust, dirt and germs.
- Reagents must be used within the validity period.
- Handle the reagents properly to prevent bubble. Do not shake! The reagent cannot be used immediately after transport.
- Do not make the reagents spilt. If it happened, wipe away with a cloth.

- If you swallow reagents accidentally, please seek the medical advice immediately.
- Diluent is a kind of good conductor, if being spilt next to the wire or device, it may cause electric shock. Please turn off the power, unplug the plug and clean the diluent.
- The probe cleaning solution or detergent is strongly alkaline cleaner. Do not let it contact the skin or clothes. If that happens, rinse the skin and clothes with plenty of water immediately.
- Probe cleaning solution contains sodium hypochlorite. If it contacts the analyzer surface, wipe up with a cloth immediately, otherwise it will corrode the surface.
- Ensure that the reagents keep the same level with the analyzer or lower. Do not put reagents on the top of the analyzer.

2.8 Maintenance

- As a precision electro-optical analyzer, maintenance is necessary for normal operation. The test data may have small deviations without regular cleaning. In rare case, operator might be infected due to poor cleaning.
- To prevent infection, electric shock and burn, operator must wear rubber gloves in maintenance work. Wash hands with disinfectant after work.
- Use special tools for maintenance.
- All the cleaning and maintenance procedures must be in accordance with the manual operation.
- Do the daily, weekly and monthly maintenance in accordance with the manual operation.
- If the analyzer is not used for a long time, empty the rinsing flow according to the procedure before disuse. Ensure the analyzer is in a good working condition before reuse.
- Reinstallation can only be done when replacing standby parts.

2.9 Laser

The analyzer uses semiconductor laser which is protected by a shield. If you remove the shield, the laser may burn your eyes and cause harmful radiation. Only the service technician assigned by URIT can open the lid.

2.10 Consumables

The disposal of residual reagents, cleaning agent and all waste must comply with local laws and regulations. Used samples and reagents should be separated from ordinary waste, or they may cause environmental pollution. Pollutants may also make the equipment unable to work.

2.11 Security Sign

	Beware of electric shock
	Protect from heat and radioactive sources
	Equipotentiality
	Alternating current
IVD	In vitro diagnostic medical device
LOT	Batch code
SN	Serial number
	Use- by date
MC	Metering License
	Date of manufacture
	Manufacturer

	Consult instructions for use
	Non recycling
	Watch your finger and hand

2.12 Operators

- This medical analyzer must be operated by well-trained personnel exclusively. If being operated incorrectly by non-skilled staff, misemployment will lead to inaccurate measurement and cause misdiagnosing, delaying patient's treatment or doing harm to the operator himself, even damaging the analyzer.
- Failing to operate in accordance with instruction would lead to incorrect operation, such as test parameter setting error. It may damage the analyzer and result in wrong diagnosis results.
- Maintenance should be carried out by professional technicians. It will cause test errors result from unauthorized technicians and nonstandard maintenance.
- Invalid hardware / software would affect the accuracy of test results. The operator needs to contact the after-sale service personnel as soon as possible.

2.13 Computer Virus

CAUTION

Although our software has been checked to make sure there is no computer virus, some measures must be considered in the daily operation. Here are some checking procedures, but not completed. Depending on your working conditions to choose appropriate measures.

1. Use a virus checker program for regularly checking.
2. Do not install other application programs except virus checker program.
3. Do not open unknown email attachments.
4. Do not download any file which has nothing to do with the software program.
5. Check files in the folder for anti-virus.
6. Do not use U disk or other storage media on the computer to prevent them bringing virus to the computer.

Chapter 3 System and Function

3.1 Overview

Spincell 5plus 5-Part-Diff Auto Hematology Analyzer, which is a vitro diagnostic medical device, is used for blood cell count, WBC five part differential and hemoglobin concentration measurement in clinical tests. The analyzer provides accurate test data of human venous blood, which provides necessary reference for clinical diagnosis.

The analyzer provides a fast count, all operations (including sampling, measurement and results output) are fully automatic. The analyzer automatically starts counting when putting the sample box on the sample platform. Three-dimensional graphics data and results can be displayed in the LCD screen after 60 seconds. Results can be printed or transmitted to the LIS system.

The characteristics are puncture sampling automatically and cleaning blood on the sample probe. There's no need for operators to contact with blood sample.

3.2 Parameter

The analyzer can analyze and arrange the sample data automatically and give five part differential count of blood cell and white blood cell respectively. It also generates the three-dimensional plot and scatter diagram of white blood cells and histogram of red blood cells and platelet.

The Spincell 5plus generates the following test parameters in Table 3-1(including two histograms, two three-dimensional plots and two scatter diagrams).

Table 3-1 Parameters

Abbreviation	Full Name	Unit
WBC	White Blood Cell Count	10^9/L
LYM%	Lymphocyte Percent	%
MON%	Monocyte Percent	%
NEU%	Neutrophil Percent	%
EOS%	Eosinophil Percent	%
BASO%	Basophil Percent	%
LYM#	Lymphocyte Count	10^9/L
MON#	Monocyte Count	10^9/L
NEU#	Neutrophil Granulocyte Count	10^9/L

EOS#	Eosinophil Granulocyte Count	10^9/L
BASO#	Basophil Granulocyte Count	10^9/L
RBC	Red Blood Cell Count	10^12/L
HGB	Hemoglobin	g/L
RETIC_ABS	Reticulocyte absolute number	10^9/L
RETIC	Reticulocyte	%
IRF	Immature Reticulocyte Fraction	%
HCT	Hematocrit (relative volume of erythrocytes)	%
MCV	Mean Corpuscular Volume	fL
MCH	Mean Corpuscular Hemoglobin	pg
MCHC	Mean Corpuscular Hemoglobin Concentration	g/L
RDW_CV	Red Blood Cell Distribution Width repeat precision	%
RDW_SD	Red Blood Cell Distribution Width STDEV	fL
PLT	Platelet Count	10^9/L
MPV	Mean Platelet Volume	fL
PDW	Platelet Distribution Width	fL
PCT	Plateletcrit	%
P_LCC	Large Platelet Count	10^9/L
P_LCR	Large Platelet Percent	%

Remark: PCT and PDW are the inferred parameters, which are provided for laboratory use only.

3.3 Structure

CAUTION

- The analyzer needs several people work together to move since it is relatively large. Please use proper tools and follow relevant safety code when moving.
- Take out the analyzer and then check whether the appearance is intact. Ensure there is no damage during transport.

The analyzer is consisted of host, computer, software, consumables, accessories and an external printer (optional).

Host is mainly composed of laser parts, automatic sampler, Syringe Mechanism, A/D and the central control panel, the WBC measurement unit,

RBC/PLT measurement unit, flow system and other parts, accessories includes the power cord, ground wire, etc. (See Appendix G)

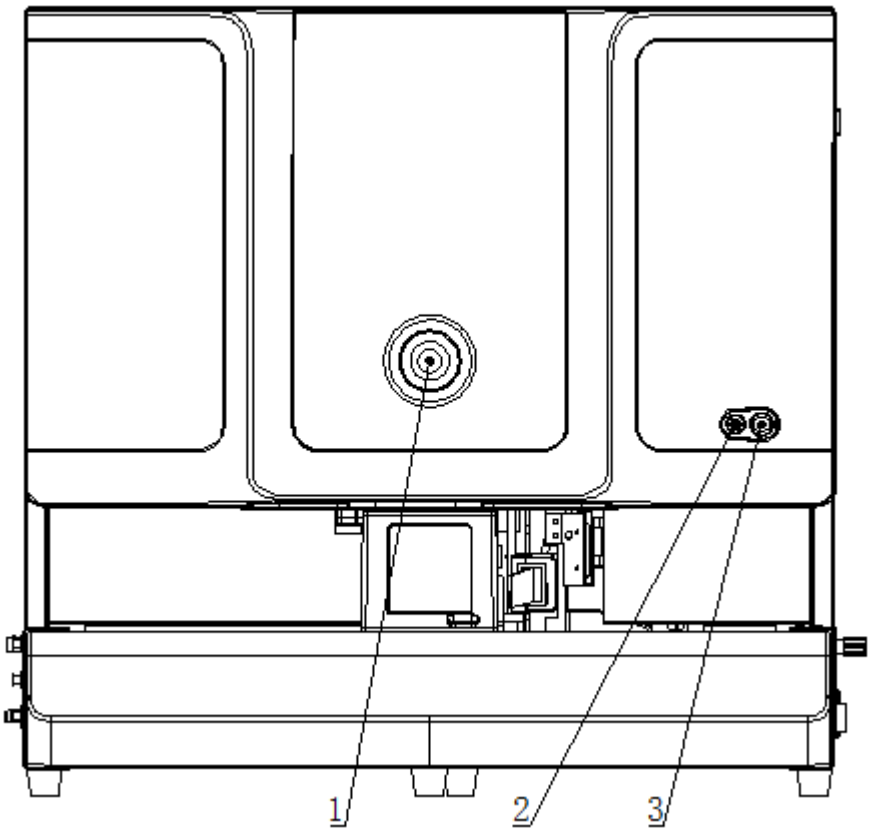


Figure 3-1A Front View

1--- Working Status Indicator
2--- Flush
3--- Count

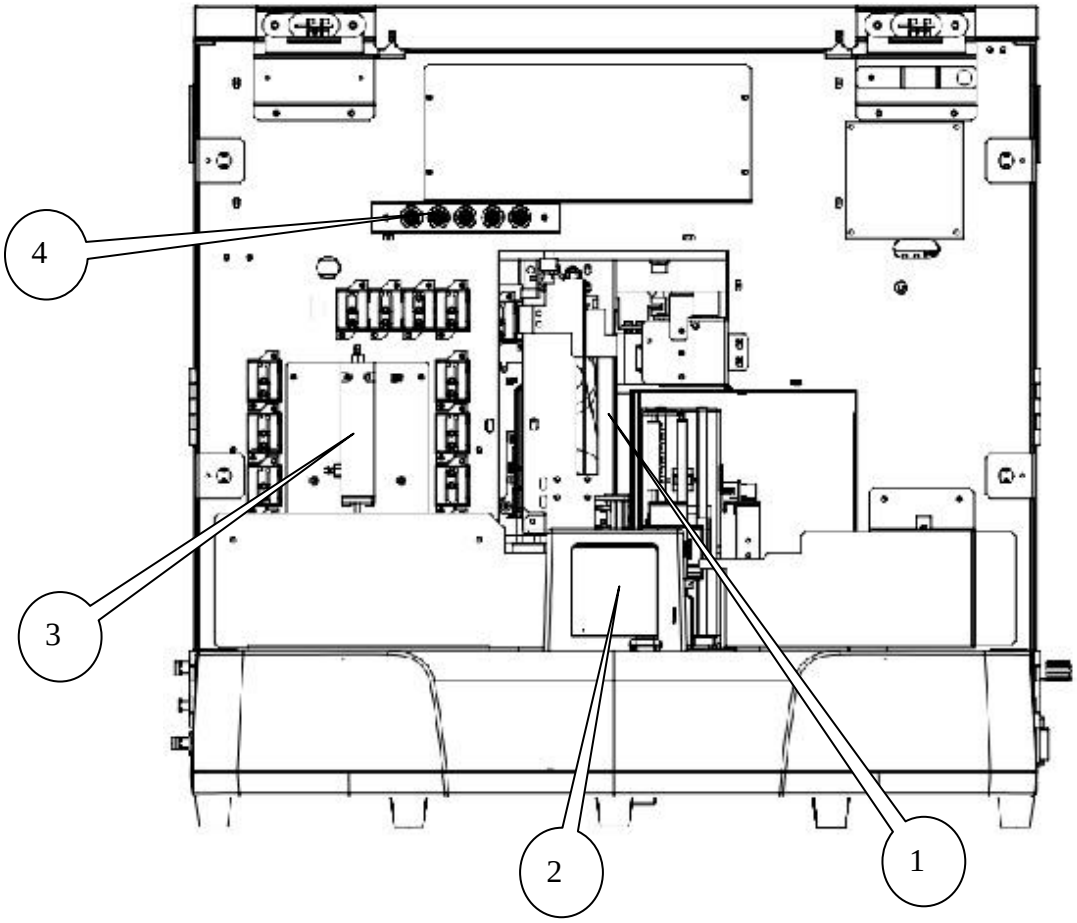


Figure 3-1B Front View (Remove the front housing)

1--- Sampling Unit
2--- Single Sampling
3--- Syringe Mechanism
4--- Optical Liquid Interface

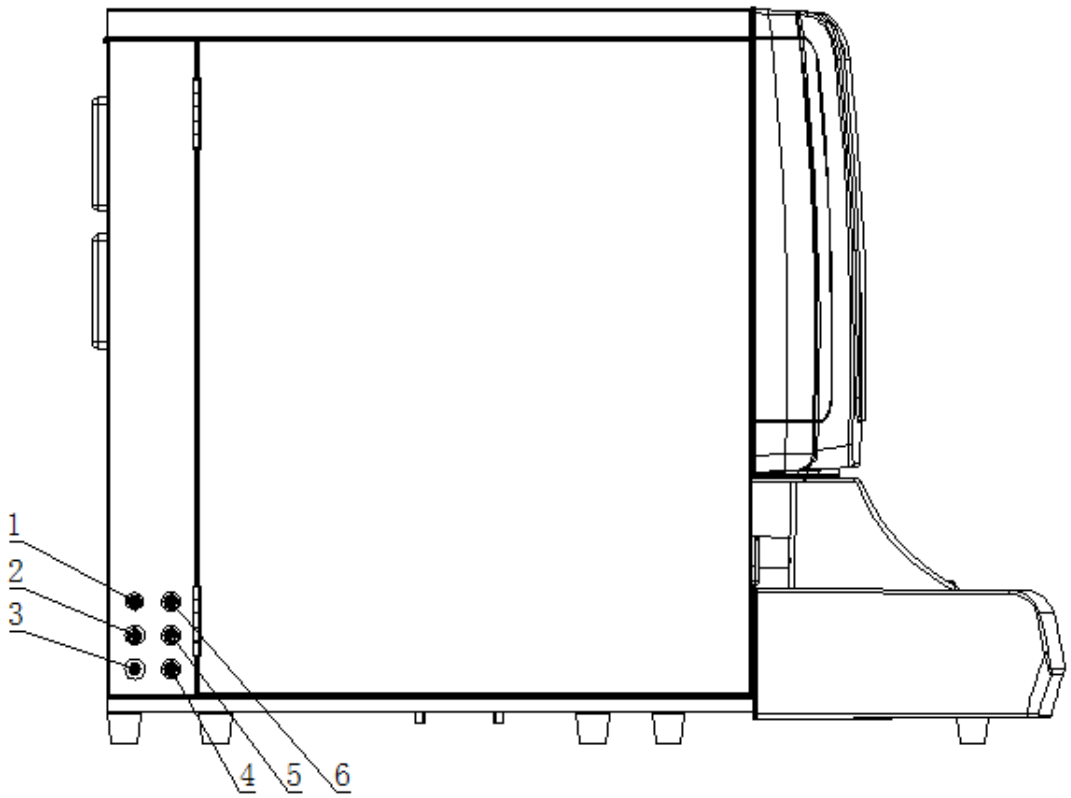


Figure 3-2A Left Side View

1--- SENSOR
2--- LYSE
3--- WASTE
4--- DETERGENT
5--- SHEATH
6--- DILUENT

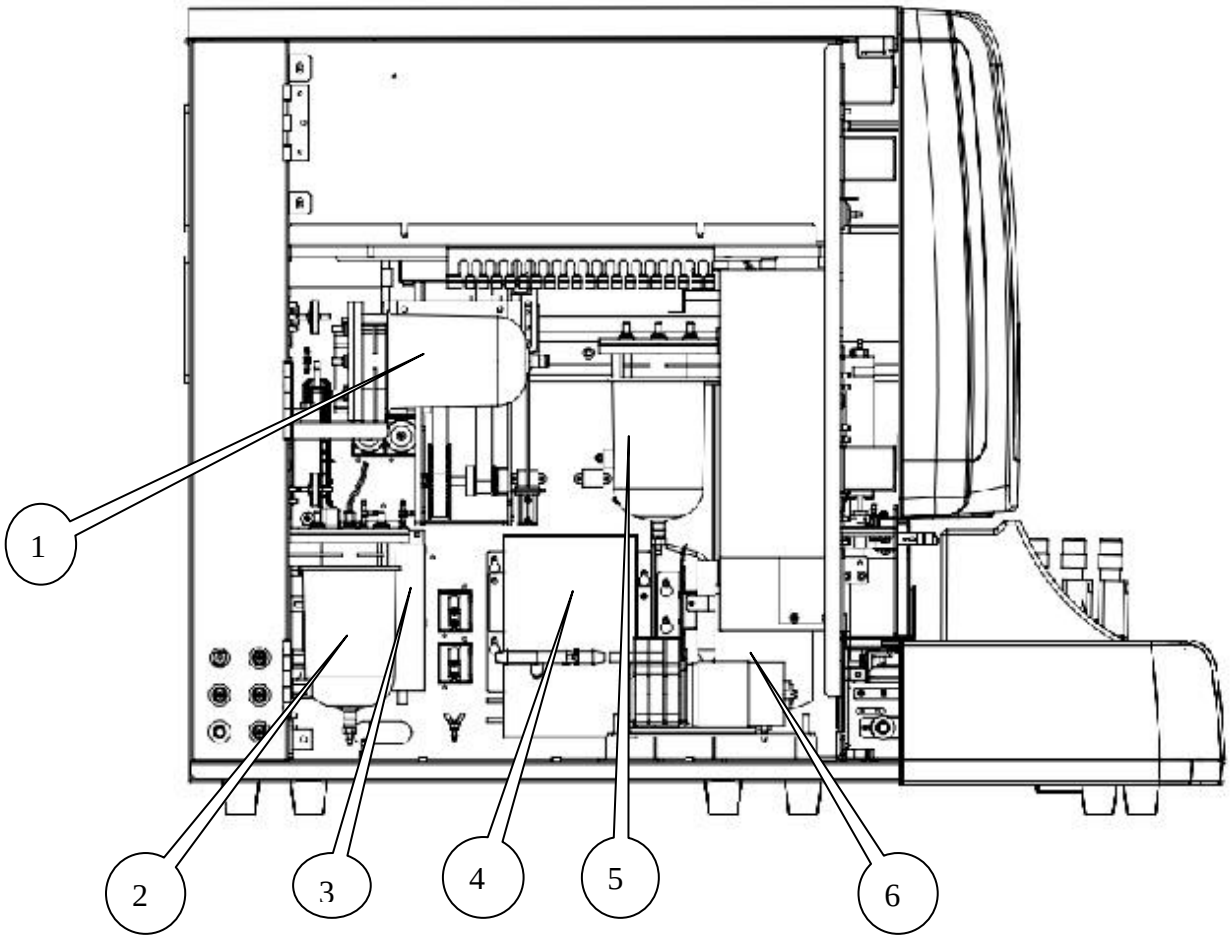


Figure 3-2B Left Side View (Remove the Left side door)

1--- Positive Pressure Tank
2--- Reservoir
3--- LMS Count Board
4--- Counting Chamber of Transducer
5--- Waste Chamber
6--- Mixing Tank

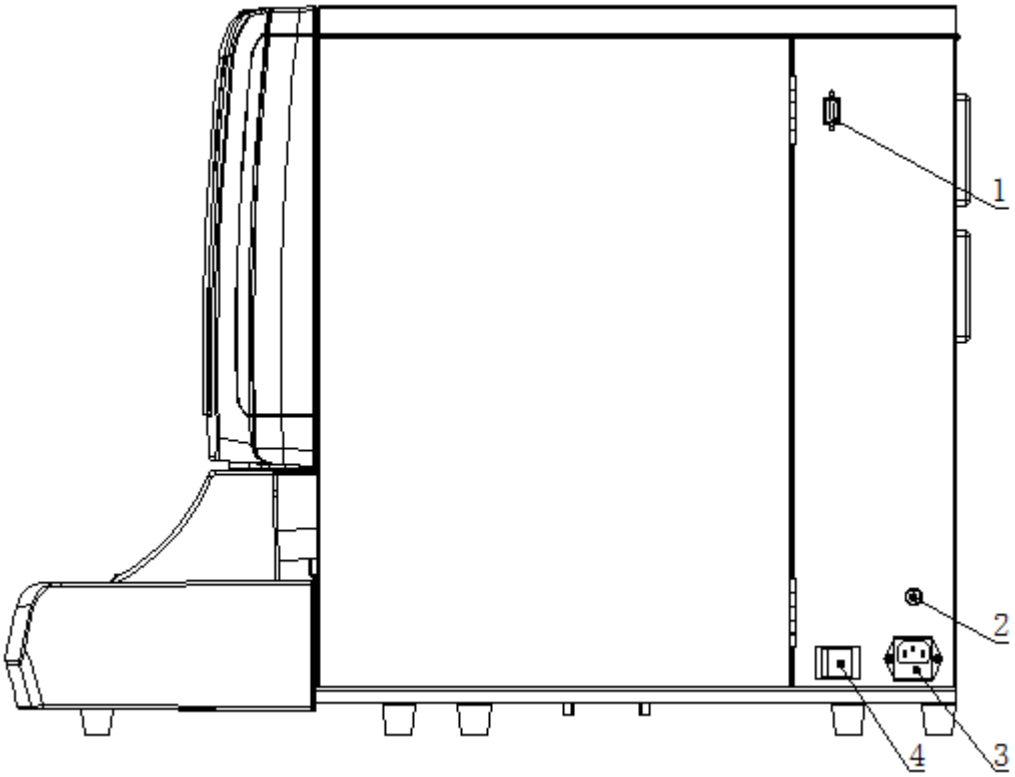


Figure 3-3A Right Side View

1--- COM
2--- Ground Terminal
3--- Power Socket
4--- Power Switch

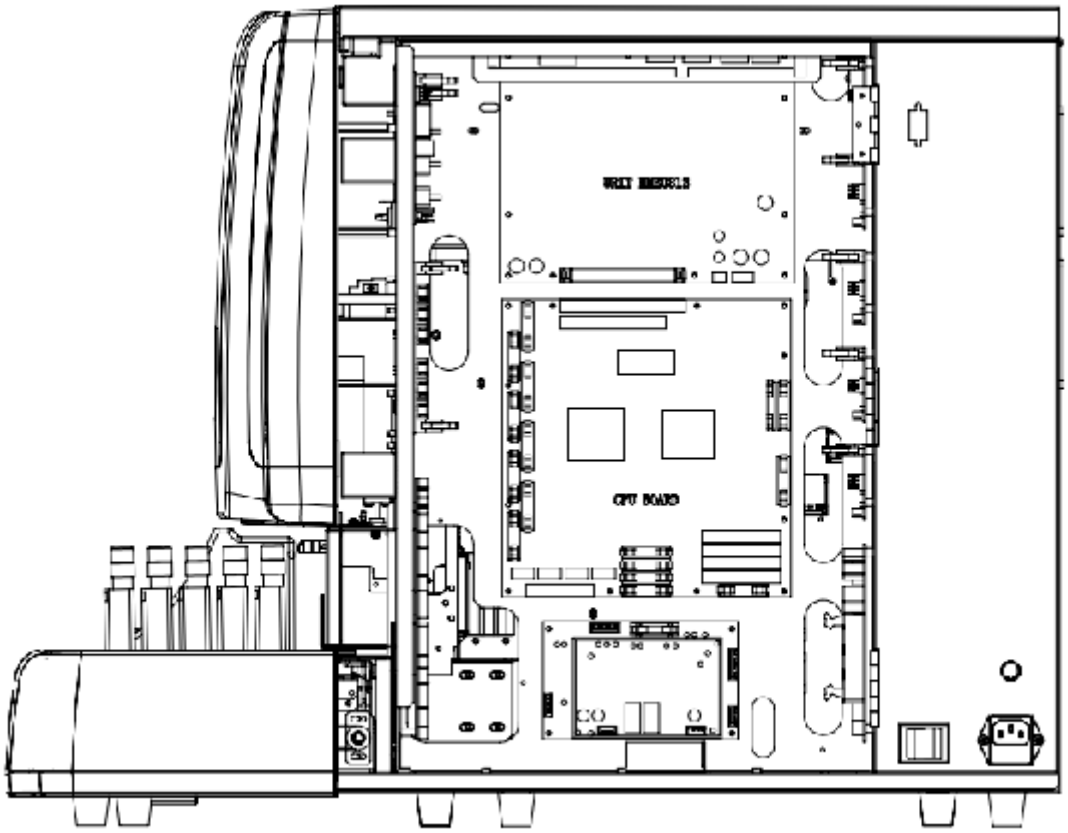


Figure 3-3B Right Side View (Remove the right side door and front housing)

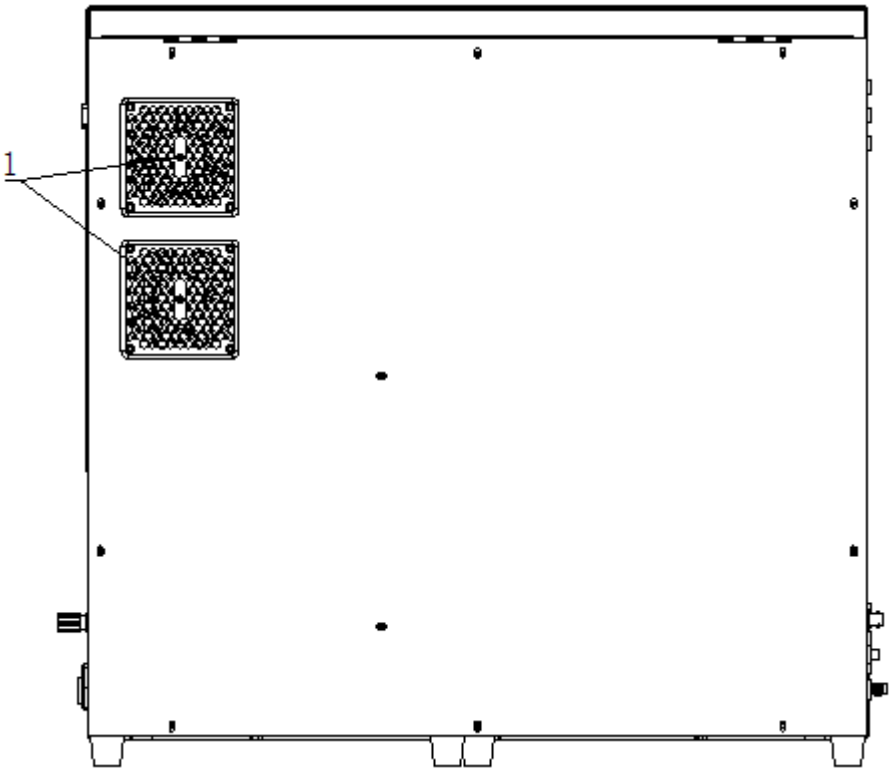


Figure 3-4A Rear View

1--- Cooling Fan

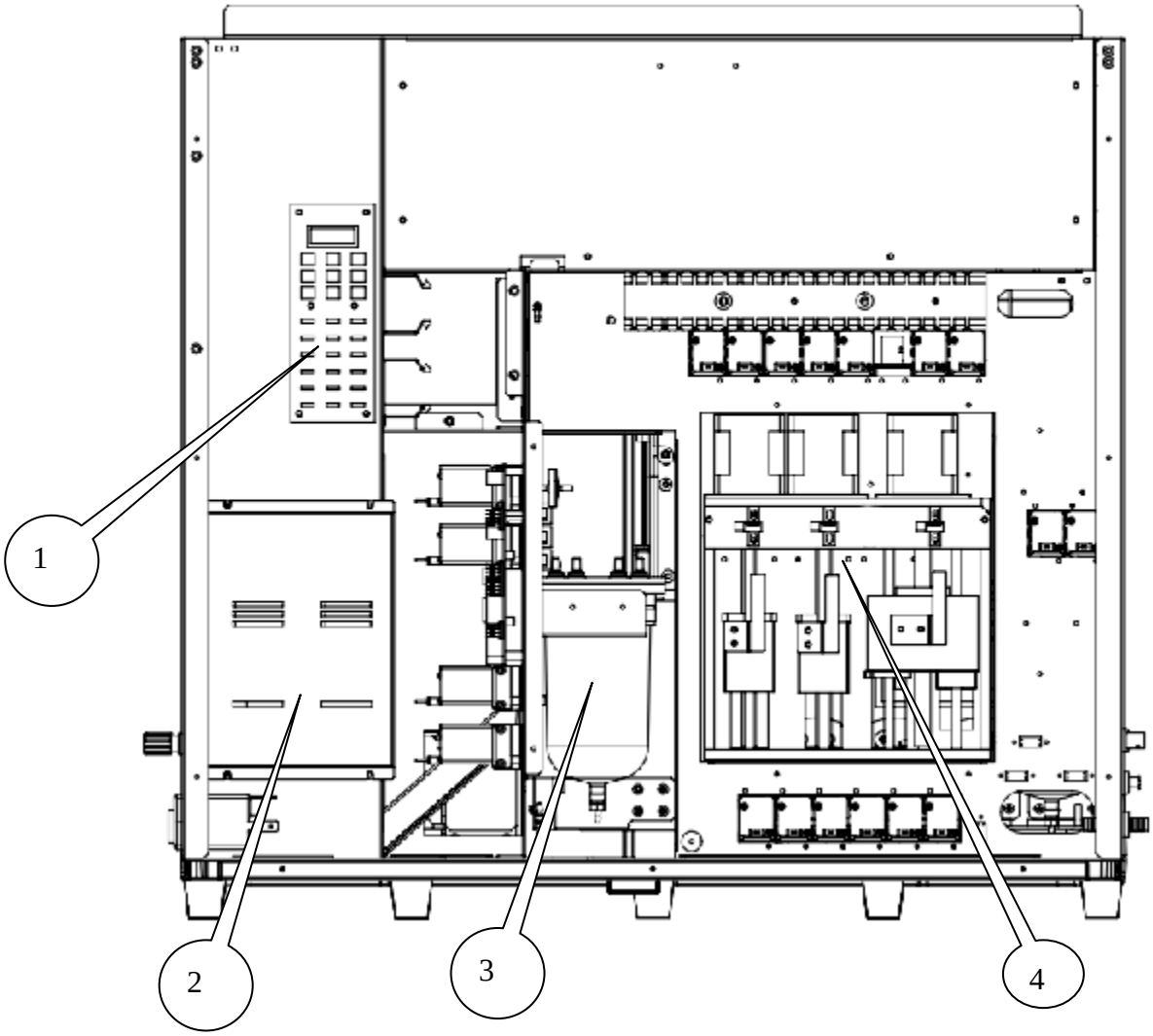


Figure 3-4B Rear View (Remove the back shroud)

1--- P-T
2--- Switching Power Supply
3--- Negative Pressure Tank
4--- Syringe

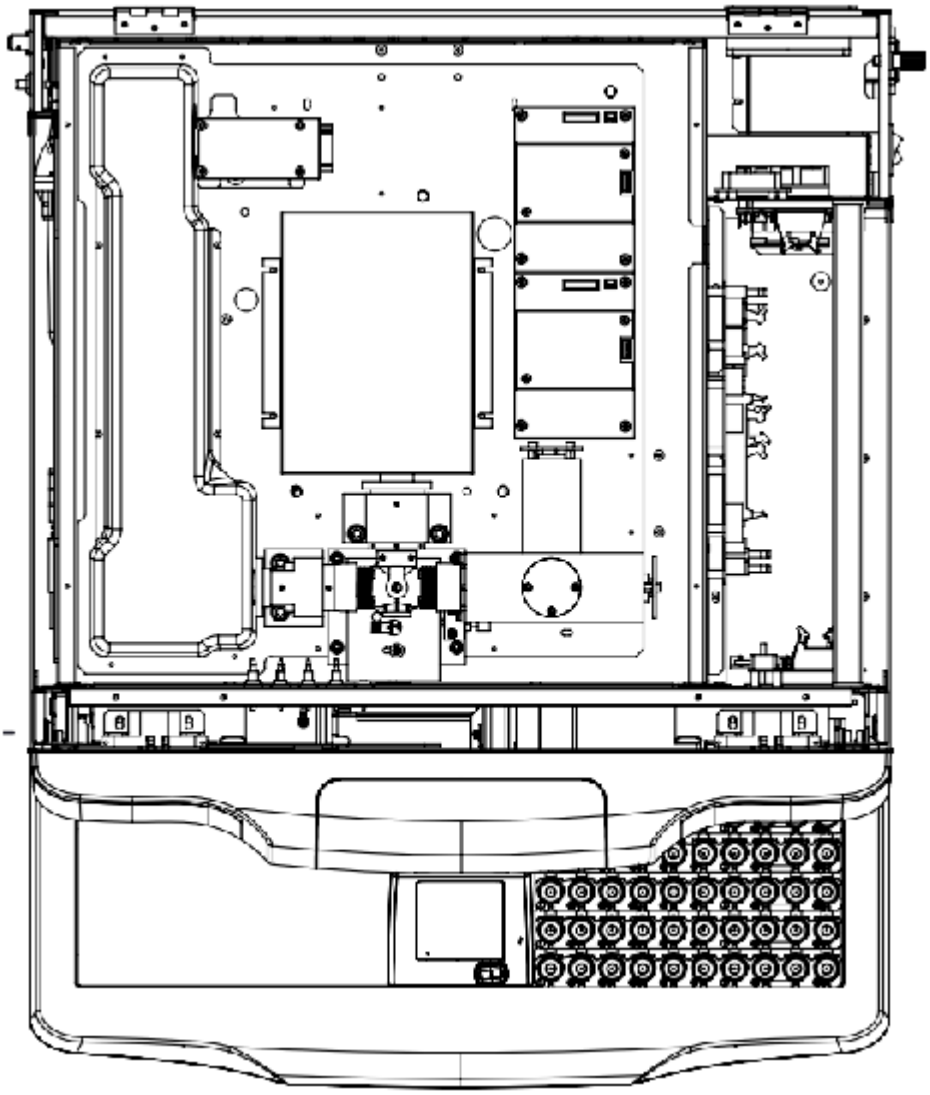


Figure 3-5 Vertical View（Optical Bench）

- Semiconductor Laser is above the analyzer. Do not open the upper cover for your safety, only the authorized personnel authorized by URIT can open it.

3.4 Test Interface

After startup, the analyzer enters “Test” interface automatically.

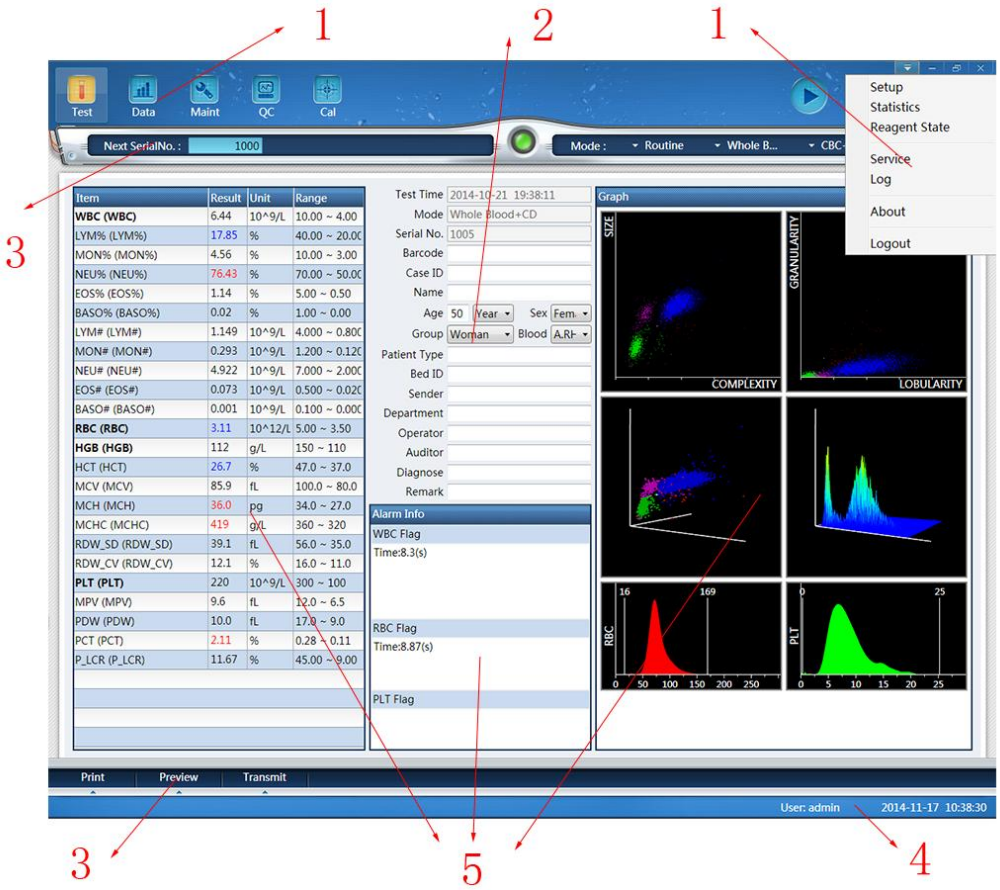


Figure 3-6 Test interface

This interface can be divided into the following areas by functions.

1. Main Menu

Click the button to enter corresponding interface. Please refer to the following table to select the appropriate button.

Table 3-2 Main Menu Button

Button	Function
Test	Counting operations
Data	Query the test results
Maint	Reagents Replacement, analyzer maintenance
QC	Run quality control operation
Cal	Scaling operations for analyzer’s parameters
Test	Start to test and count
Stop	Suspended from multiple sampling counting
Reset	Stop multiple sampling counting

Drain	Drain in diluent mode
Statistics	Workload statistics analysis
Service	Maintain and test
Setup	System parameters setup
Log	Check analyzer operation and fault information
About	Check the analyzer version information
logout	Change user login

2. Data Edit

Name, age, sex, blood type and other details of sample is displayed in this area. Operator can switch input methods by "Ctrl + Shift".

3. Shortcut Key

Table 3-3 Shortcut Key Button

Shortcut Key	Function
Next serial number	Input next ID number
Mode	Blood routine examination, reticulocyte, whole blood and pre-dilution switching operation
Transfer	Transmit test data to other computer systems manually, such as the LIS system
Print	Print the test result
Print Preview	Check the print effect

4. System Time

Display current date and time.

5. Counting Results Display

Display test results, parameter units, reference range, alarms, scatter plot, 3D map and other results information.

3.5 Reagents, Control Materials and Calibrators

For a good test performance, URIT provides special reagent which has been done the factory examination according to the product standard, and it’s all qualified. The measure index of nominal is achieved by using the special reagent. Non-URIT reagents may affect analyzer performance and produce measure error, even resulting the fault to happen. Reagents mentioned in this Manual refer to matching reagents of the analyzer.

NOTE

- Reagents must be stored at room temperature to ensure optimal

performance. All reagents should be protected from direct sunlight, undercooling and overheating during storage.

- The background test should be done after the replacement of diluent, detergent, sheath and detergent to ensure it is within the normal range.
- The reagent inlet tubes have a cap attached that minimizes evaporation and contamination during shipping. The tubes can only insert reagent to right connections. Please close the cap tightly.
- Ensure all reagents to be used in validity period.

3.5.1 Diluent

Diluent which is tasteless transparent isotonic fluid can be used for blood cells counting and classification. It has the following functions.

（1） Dilute whole blood samples.
（2） Keep the shape of cells during test process.
（3） Clean WBC and RBC micro-aperture and tubes.
（4） Provide a conductive environment for counting.

Storage and service life after opening. Keep the diluent under 5℃~35℃. It can be used to the validity period shown on the label after opening. Once opened (connected to the analyzer), the product shelf life is only 60 days.

3.5.2 Sheath

Sheath is used to keep the original ecology of blood cells and bleach RBC to eliminate the scattering of laser.

WBC maintains the cell structure which is closest to its original state. Basophilic granule is soluble in water, so the structure of Basophil has minor changes. RBC osmotic pressure is higher than that of sheath, so RBC is changed by sheath. The hemoglobin of RBC diffuses from the cells, and moisture content of sheath diffuses into cells. Although the cell membrane remains in a good shape, the RBC and sheath have the same refractive index, which makes the RBC invisible under the laser.

Storage and service life after opening. Keep the diluent under 5℃~35℃. It can be used to the validity period shown on the label after opening. Once opened (connected to the analyzer), the product shelf life is only 60 days.

3.5.3 Lyse

Lyse which doesn’t contain azide and cyanide can achieve the following requirements.

（1） Quickly dissolve the RBC and generate less ground substance complex.

（2） Change the WBC cell membrane and make its cytoplasm diffused gradually, meanwhile, the cell membrane surrounds the cell nucleus and contracts, making the WBC become granular.

（3） Convert the HGB to the hemoglobin compounds which is suitable to test in 540nm wavelength.

（4） Cyanide free. Avoid harm to your body and the environment caused by the cyanide .

Storage and service life after opening. Keep the diluent in 5℃~35℃. It can be used to the validity period shown on the label after opening. Once opened (connected to the analyzer), the product shelf life is only 60 days.

3.5.4 Detergent

Detergent contains the active enzyme which can be used to clean the agglomerated protein in the cups and flow system of WBC and RBC. It prevents plugging holes.

Storage and service life after opening. Keep the diluent in 5℃~35℃. Avoid direct sun, or it volatilizes as time goes by. Once opened, the product shelf life is only 60 days.

3.5.5 Probe Detergent

Probe detergent contains the active enzyme which can be used to clean the agglomerated protein. It prevents probe plugging.

CAUTION

Detergent and probe detergent is alkali cleaning agent, so please

（1） prevent skin and eyes from contacting the reagent.

（2） rinse with water if contacting with skin.

（3） rinse with water and seek medical treatment immediately if contacting with eyes.

（4） induce vomiting and seek medical treatment immediately if ingested.

3.5.6 Control Materials and Calibrators

Control and calibrator are for analyzer quality testing and calibration.

Control material which is an industrial production of whole blood is used to check the test results. It is divided into three types, low, normal and high value. Three controls must be run every day to check the operating state and ensure the reliability of the results. Calibrator which is also an industrial production of whole blood is used for calibration. Please refer to the instruction of control and calibrator for use and storage methods.

The "control material" and "calibrator" mentioned in this Manual refers to the special control material and calibrator assigned by URIT. Users can purchase from URIT or agents designated by URIT.

Chapter 4 Installation

4.1 Overview

CAUTION

- Environment requirements
  Temperature:15℃ ~ 35℃, Relative humidity ≤ 85%,

- Place the analyzer on a smooth and big enough platform which is easy to operate. Away from direct sunlight.

- Whenever possible, use a separate AC receptacle. Install stabilized voltage supply or UPS (Uninterruptible Power Supply). Do not share an AC receptacle with centrifuge, room temperature shower (thermostat), refrigerator, air conditioning, ultrasonic cleaning equipment or other equipments, which may interfere with the analyzer.

CAUTION

Installation of the analyzer by an unauthorized or untrained person could result in personal injury which is exclusive of the warranty. Never attempt to install and operate the analyzer without a URIT authorized representative.

This analyzer has been tested strictly before delivery. It is carefully packed before transport to avoid being damaged. Please carefully check the packaging as receiving. If finding any damages, please immediately contact the after-sale service department of URIT or local agent.

4.2 Unpacking and Inspection

Take out the analyzer and accessories from shipping carton, keep the packing material for future transport and storage. Please check

（1） the accessories according to the packing list.

（2） whether it is leakage or soakage.

（3） whether there's mechanical damage.

（4） the bare leads, inserts and accessories.

Please contact URIT Customer Support Center if there's a problem.

4.3 Space Requirements

Considered with heat dissipation, operation, maintenance and reagent changes, please install the analyzer in a place where there is

（1） power supply near.

（2） eight inches of space behind the analyzer.

（3） 100 cm of space above to either side of the analyzer for service access.

（4） sufficient space for placing reagents and waste containers.

4.4 Power Supply Requirements

Check whether the power supply of install site meets the following requirements or not before installation. See Table 4-1 for details.

Table 4-1 Power Supply Requirement

Optimal Voltage	Voltage Range	Frequency
AC 220V	AC 100V～240V	50/60 Hz

WARNING

- Analyzer should be used in the condition of well ground connection, which ensures accuracy of analyzer and operator's safe.
- Frequent voltage fluctuation which leads to low performance and reliability would be dealt with before using, such as the installation of AC manostat (not provided by URIT).
- Frequent power failure seriously decreases the performance and reliability of the analyzer. Proper action such as the installation of Uninterrupted Power Supply (hereinafter referred to as UPS) (not provided by URIT) should be taken before operation.

4.5 Environment Requirements

（1） Temperature:15℃~35℃(Optimum temperature is 25℃)

（2） Relative humidity ≤ 85%

（3） Recommend to install heating and cooling air conditioning

（4） Avoid using the analyzer at extremely high or low temperature.

（5） Away from direct sunlight.

（6） Choose a well-ventilated place.

（7） Away from communication equipment which may interfere the analyzer by producing high frequency electric wave.

WARNING

Taking full account of the electromagnetic compatibility problems, the electromagnetic interference generated by analyzer doesn't disturb itself or devices nearby. If the test result has a large deviation, please check whether the analyzer is placed near a electromagnetic field or a short wave radioactive source (radar, X ray, centrifuge, scanner, cell phone etc.).

4.6 Waste Requirements

As to 20L waste, it is recommended to add the following chemicals into waste containers.

1) 50ml of sodium hydroxide solution (200g / L) to prevent gas forming.
2) 250ml of sodium hypochlorite solution (12% chlorine) to handle the waste biological risk.

WARNING

It is prohibited to pour the waste into the sewer directly. The waste must be processed by biological or chemical methods before pouring into the sewer. Hospitals and laboratories have the obligation to comply with the relevant provisions of environmental protection department of local government.

4.7 System Installation

4.7.1 Computer Installation

Minimum configuration of computer.

CPU	Minimum 1GHZ Pentium Pro or larger
Memory	Minimum 2GB or larger
Hard disk	Minimum 80 GB
Display Screen	No less than 17 inch

CAUTION

Please ensure that the computer equipped is only used for the analyzer. The computer may got infected by virus and system damage or other errors

may caused If installing other software, using removable storage devices such as U disk, playing games or surfing the Internet on the computer.

4.7.2 Tubing Installation

There are five tube-connectors on the left panel, which are DETERGENT, DILUENT, LYSE, SHEATH and WASTE. Each of them is wrapped with a cap to avoid contamination before shipment. Take the cap off for the first time installation. Please store it carefully.

NOTE

- After installation, all tubes should be in a nature relaxed state. Do not forcibly twist or rotate.
- Using tools for tubing installation is prohibitive. Only installing by hand is allowed.
- The reagent bottle cannot be used if it is damage, leakage, exceeding the shelf life or other anomalies. Please contact with local suppliers or after-sale service department of URIT directly.
- In consideration of personal safety and optimal system performance, manufacturer advises to put all reagents on the same base and lower than analyzer position.

LYSE Tubing Installation

Take out the lyse tube with red faucet from the accessories box, and inset it to the LYSE connector on the left panel. Place the other end of the tube into the lyse container and twist the cap tightly.

DILUENT Tubing Installation

Take out the diluent tube with blue faucet from the accessories box, and inset it to the DILUENT connector on the left panel. Place the other end of the tube into the diluent container and twist the cap tightly.

DETERGENT Tubing Installation

Take out the detergent tube with green faucet from the accessories box, and inset it to the DETERGENT connector on the left panel. Place the other end of the tube into the detergent container and twist the cap tightly.

SHEATH Tubing Installation

Take out the sheath tube with yellow faucet from the accessories box, and inset it to the SHEATH connector on the left panel. Place the other end of the tube into the sheath container and twist the cap tightly.

WASTE Tubing Installation

Take out the waste tube with faucet from the accessories box, and inset it to the connector on the left panel. Inset BNC plug to the SENSOR connector on the left panel. Tightly twist the tube’s cap clockwise onto the waste

container. Place the waster container on the level at least 50cm lower than the analyzer.

4.7.3 Printer Installation

Following these steps to install the printer.

（1） Place the printer in an appropriate location adjacent to the analyzer for easy operation.

（2） Take out the printer from package.

（3） Please contact supplier if the printer is damaged.

（4） Check the power supply of printer.

（5） Assembly the printer according to printer instructions.

（6） Connect the power cord to the printer, and connect it to the grounding plug.

（7） Confirm that the printer and computer are properly connected.

（8） Install the ink cartridges and paper according to the instructions, ensure the printer is adjusted to the correct receiving size.

（9） Connect the power cord to a grounded outlet and turn the power on.

4.8 Transport and Storage Requirement

When the analyzer is without using for a long time or before transportation, please run the "Prepare Shipping" procedure. Please refer to *Chapter 10 Maintenance* for details. Operation steps are as follows.

（1） Select " Prepare Shipping " in the "Maint" interface.

（2） Follow the prompts to put the tubes of diluents, detergent, sheath and lyse into the distilled water.

（3） Analyzer starts emptying operation. The progress bar is on the bottom of the screen.

（4） Shut down the analyzer after emptying.

NOTE

- Storage temperature: -20℃ ~ 55℃
- Relative Humidity ≤95%
- Atmospheric pressure: 50kPa-106kPa
- Before delivery, external disinfection is needed.

Chapter 5 Principles of Operation

5.1 Overview

Spincell 5plus, which detects the amount and volume distribution of white blood cells, red blood cells and platelets by the electrical impedance analysis (also known as Coulter principle), tests the content of hemoglobin by colorimetric assay. It also used for is for five part differential of white blood cells by the 4-angle laser scattered method. Three separated channels are used for getting the blood cells counting results respectively.

(1) WBC and five part differential data of sheath flow regulator are detected by laser.

(2) HGB and total amount of WBC is detected by electrical impedance analysis and colorimetric assay in WBC counting chamber.

(3) The data of RBC and PLT is detected by electrical impedance analysis in RBC counting chamber.

The analyzer aspirates, dilutes and mixes the samples and then detects parameters in each counting process.

5.2 Sample Aspiration

Spincell 5plus supports three modes of cell blood counting analysis, the whole blood modes are closed sampling, and the diluent mode is open sampling.

(1) Whole blood automatic (batch) sampling mode

(2) Whole blood single (emergency) sampling mode

(3) Diluent mode

The aspiration volumes

Whole blood automatic (batch) sampling mode	20μL
Whole blood single (emergency) sampling mode	20μL
Diluent mode	20μL

The sample is aspirated into the analyzer by the syringe and then distributed into different measuring channels.

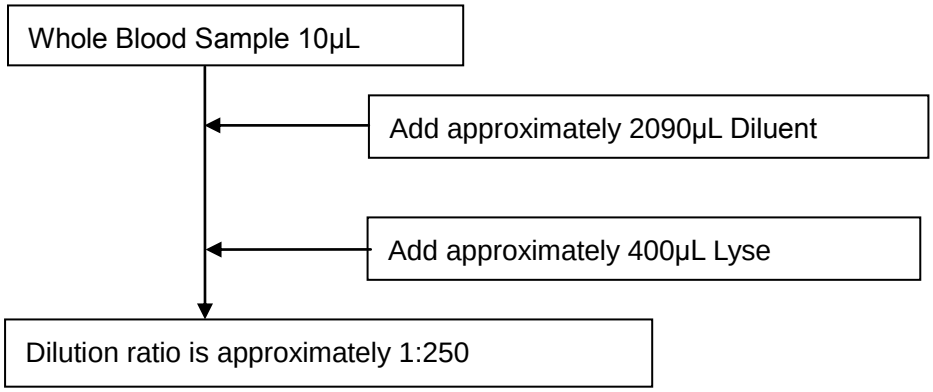
5.3 Sample Dilution

The sample is divided into three parts after being aspirated. These three samples go to the WBC counting chambers, RBC counting chambers and WOC cup respectively, and having effects with different reagents. Then finally getting the results of WBC count/HGB test, WBC/PLT count and WBC five part differential.

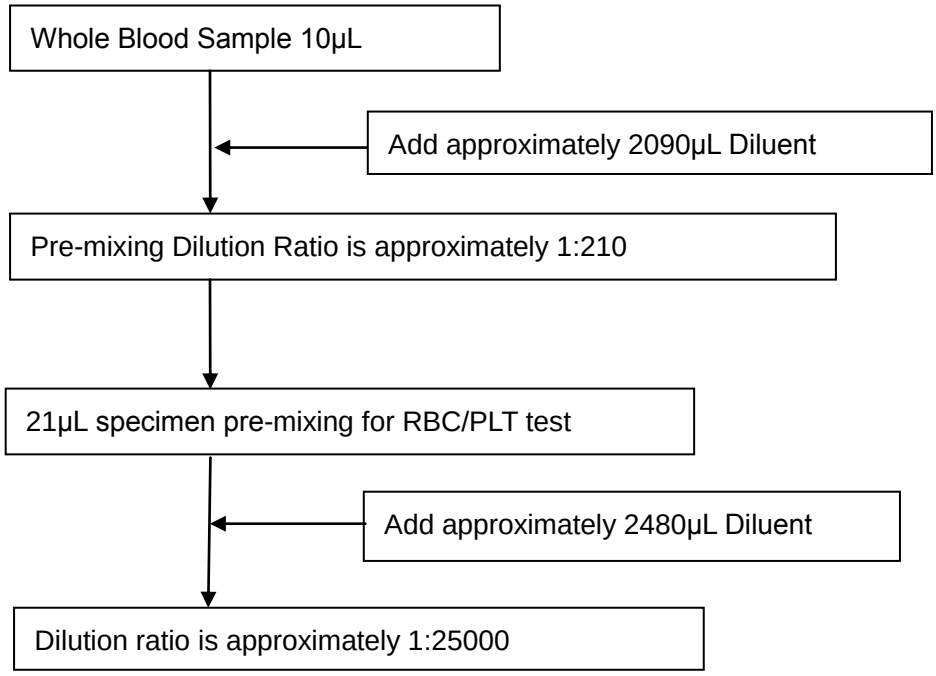
According to the different needs of the operators, the analyzer provides three operating modes which are the whole blood automatic (batch) sampling mode, whole blood single (emergency) sampling mode and diluent mode.

5.3.1 Whole Blood Automatic (Batch) Sampling Mode

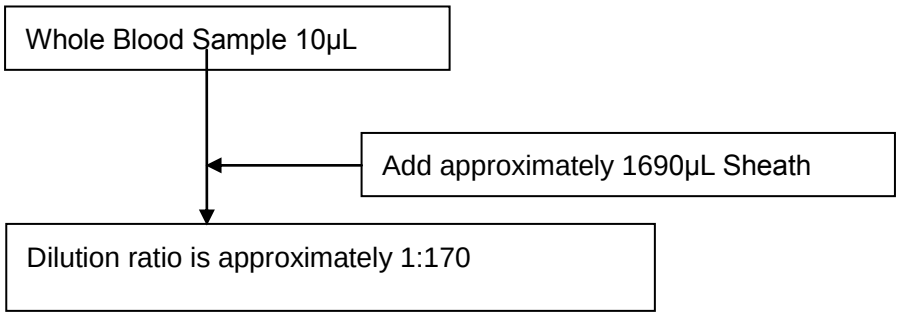
1. WBC / HGB Dilution Process



2. RBC / PLT Dilution Process



3. WBC Differential Dilution Process

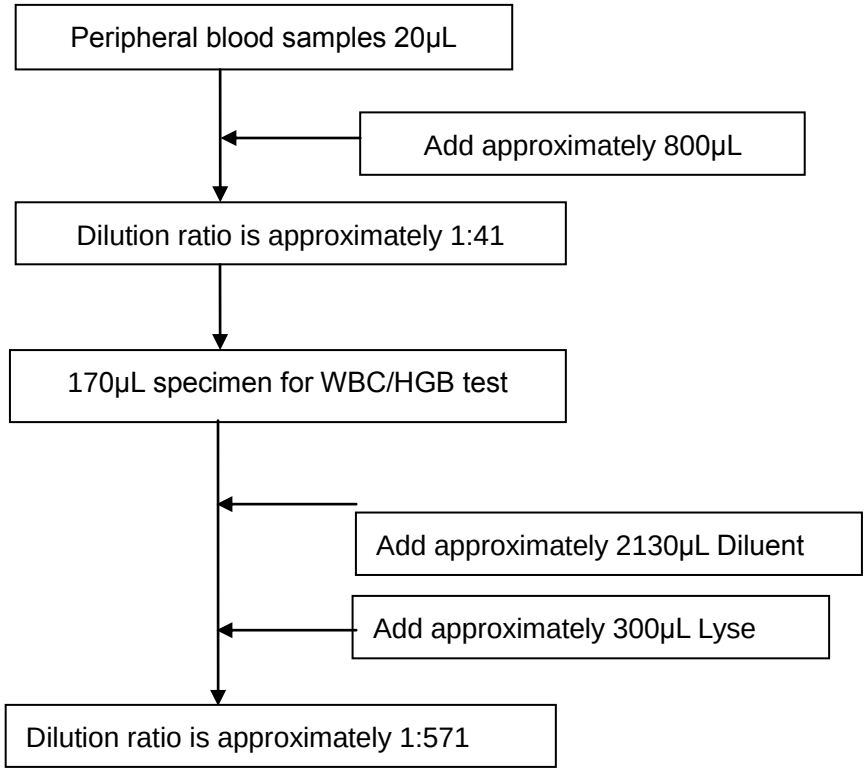


5.3.2 Whole Blood Single (Emergency) Sampling Mode

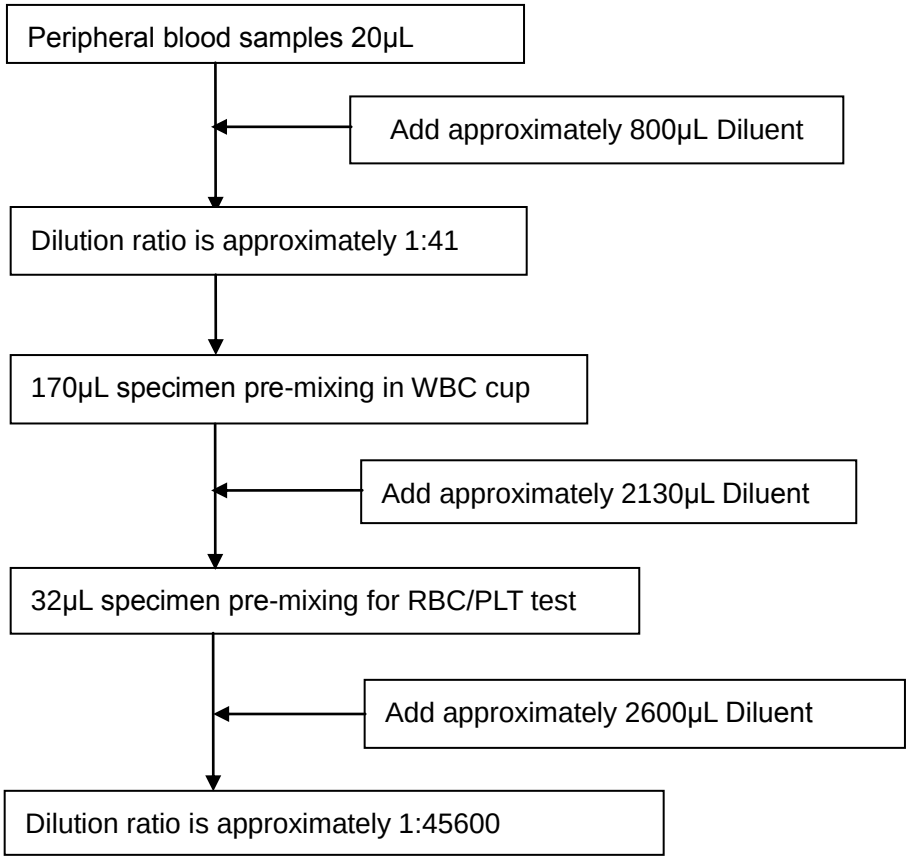
The counting procedure which is the same as that of whole blood automatic (batch) sampling mode stops batch test and makes emergency test in the process of batch test.

5.3.3 Diluent Mode

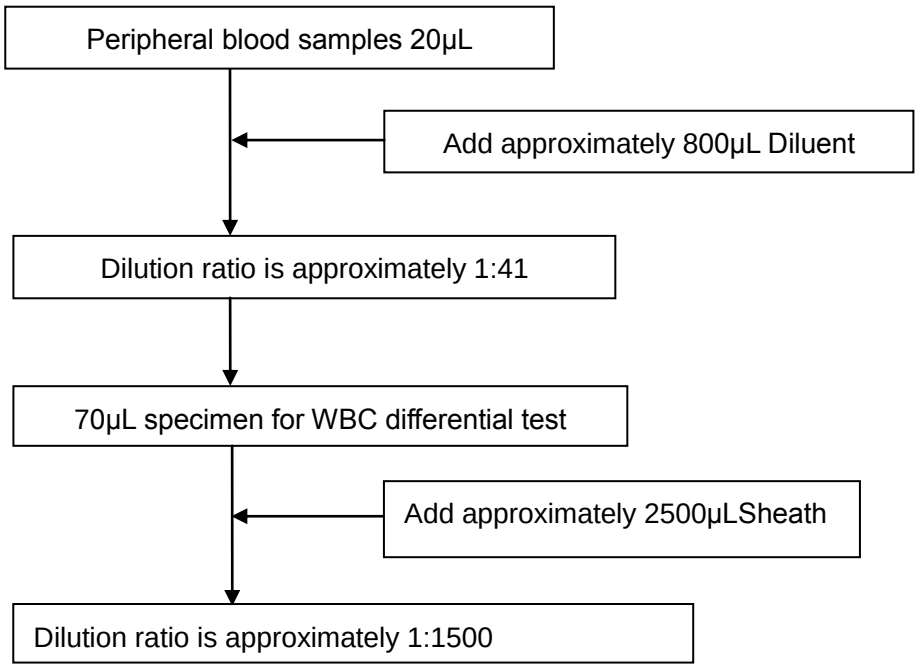
1. WBC / HGB Dilution Process



2. RBC / PLT Dilution Process



3. WBC Differential Dilution Process



5.4 WBC Test Principle

5.4.1 Four-Angle Laser Light Scatter Technology

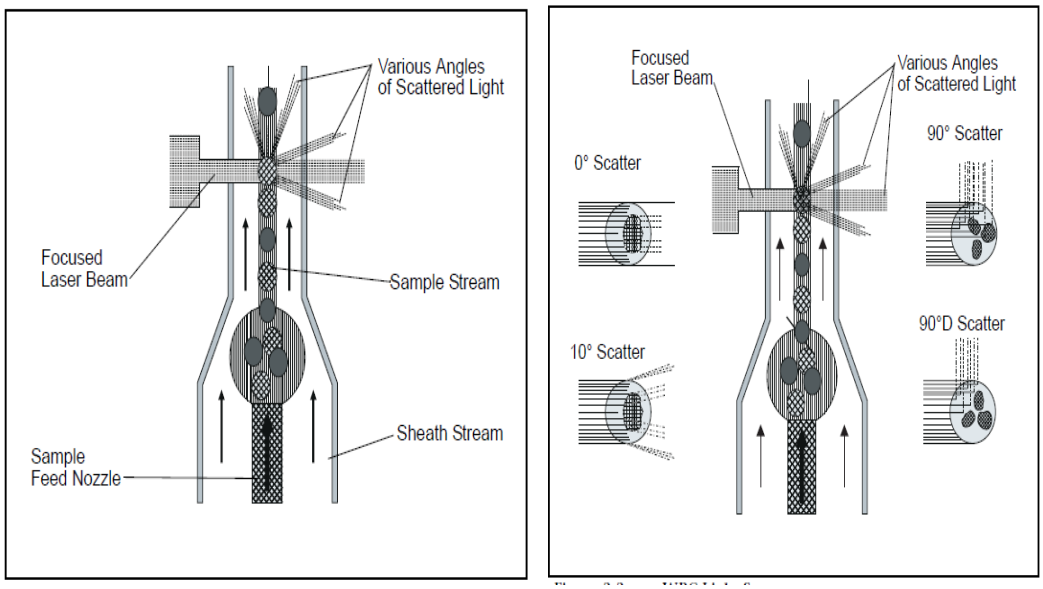


Figure 5-1 Sheath Flow Regulator

The whole blood samples are diluted with an appropriate proportion of sheath. WBC remains its original state. Make cells in a single arrangement flow by FCM (flow cytometry). The scattering density can be measured from four different angles through the laser beam detection zone.

（1） 0^0: Forward Angle Light Scatter (1^0～3^0), roughly measure size of cells,

（2） 10^0: Narrow-Angle Light Scatter (7^0～11^0), which measures cell structure and relative characteristic of complexity.

（3） 90^0 D: Ninety-Degree Depolarized Light Scatter (70^0～110^0), which separates the oxyphil cells from neutrophil cells and other cells certain type of cell granularity .

（4） 90^0: Ninety-Degree Light Scatter (70^0～110^0), which mainly measures the cell component and internal particle.

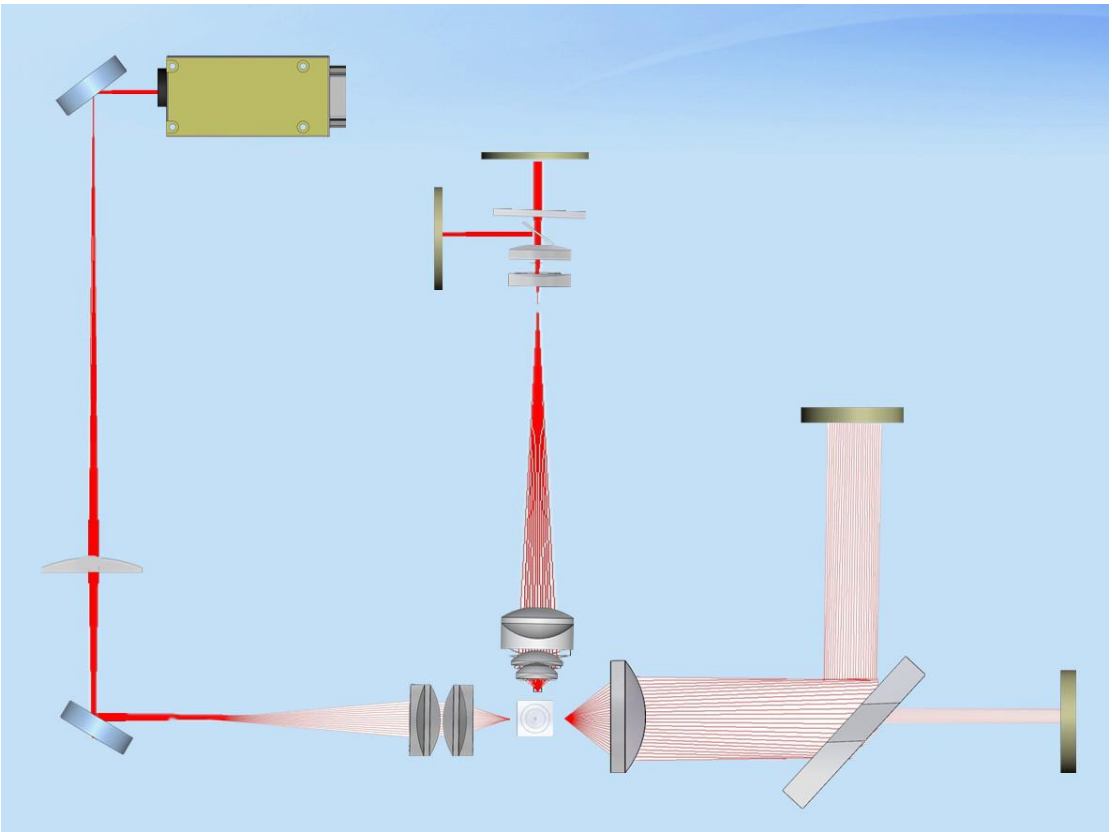


Figure 5-2 Multi-Angle Laser Scatter Optical Bench

The light source shown in the above figure is a vertical direction semiconductor laser with wavelength of 638nm, and the power is 6-8mw. Laser beam goes through a cylindrical lens which can change the shape of beam spot from circle to oval. It is shaped into a spot with a 80um-wide cell through an imaging lens and focus on the WBC in the quartz sheath flow.

The laser beam is small in the horizontal direction, so the cells do not scatter laser much. If the remaining horizontal light reaches the 0° detector, blocker can block it to prevent electronics saturation. The horizontal forward angle light directly scatters to the punch hole through the convergent lens. The light of 0° pass through the hole to the silicon photodiode detective unit of 0°. 0° scattering light reaches to the 10° silicon photodiode detection unit by reflector.

Vertical scattered light is collected by the condenser lens group. After the scattered light which contains cell information passing through the condenser lens group, the vertical scattered light will be divided into two parts by a beam splitter mirror. A part of light directly scatters to the 90° photomultiplier tube. The remaining scattered light will go through the line polarizer, and only the depolarizing scattered light can reach 90°D depolarizing photomultiplier tube.

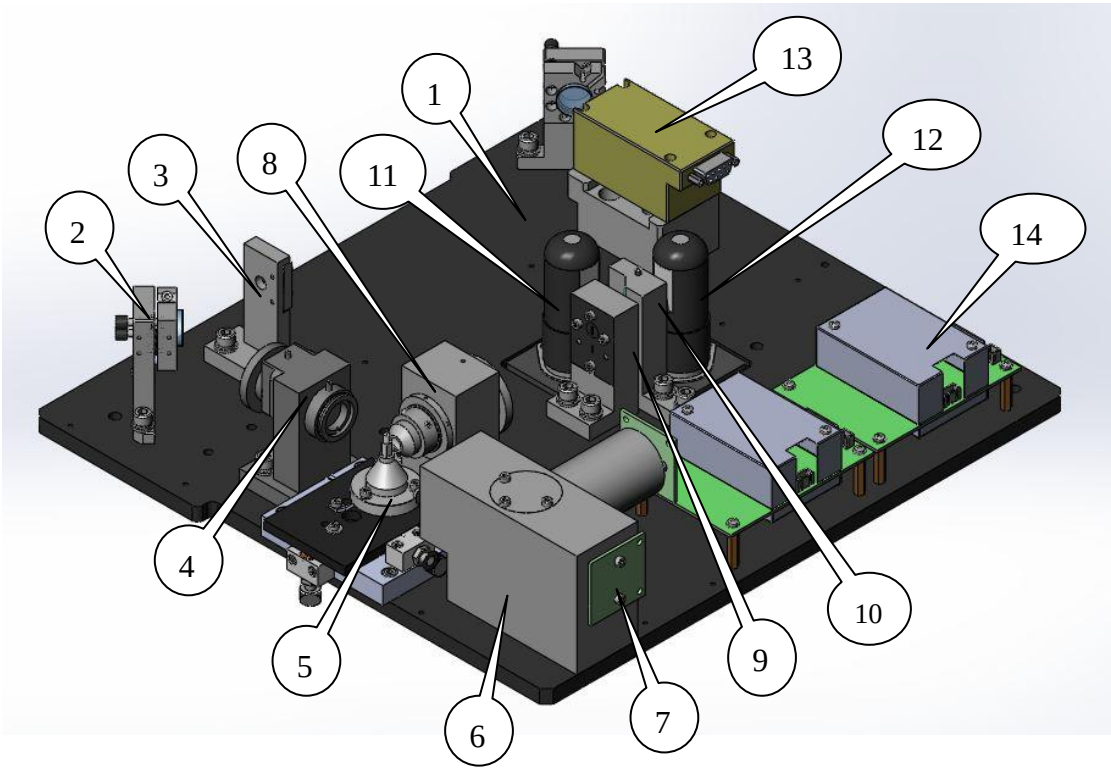


Figure 5-3 Optical Detection System

1—System Work Platform
2—Reflector
3—Cylindrical Mirror
4—Imaging Lens Group and Bracket
5—Sheath Flow Regulator
6—Forward Condenser Group and Bracket
7—PhotoAmp BOARD PCBA
8—Microscope objective components
9—700 Microns Slit and Bracket
10—Spectroscope and polarizer Bracket
11—90° PMT
12—90°D PMT
13—638nm Semiconductor laser
14—High-volage switchboard

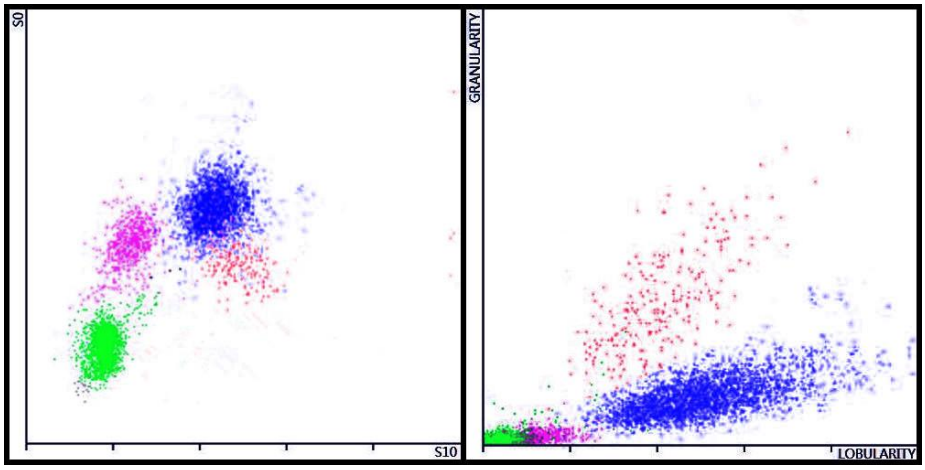


Figure 5-4 Scatter Plot Principle

The gray area in left side figure is the ghost cells. It's the reflection as RBC dissolving into pieces. The green area is the lymphocyte group, the pink area is the monocyte group, the blue area is the neutrophil, the white area is the basophil group, and the red area is the eosinophil group. The blue part in the right scatter plot is the neutrophil group, and the red part is the eosinophil group.

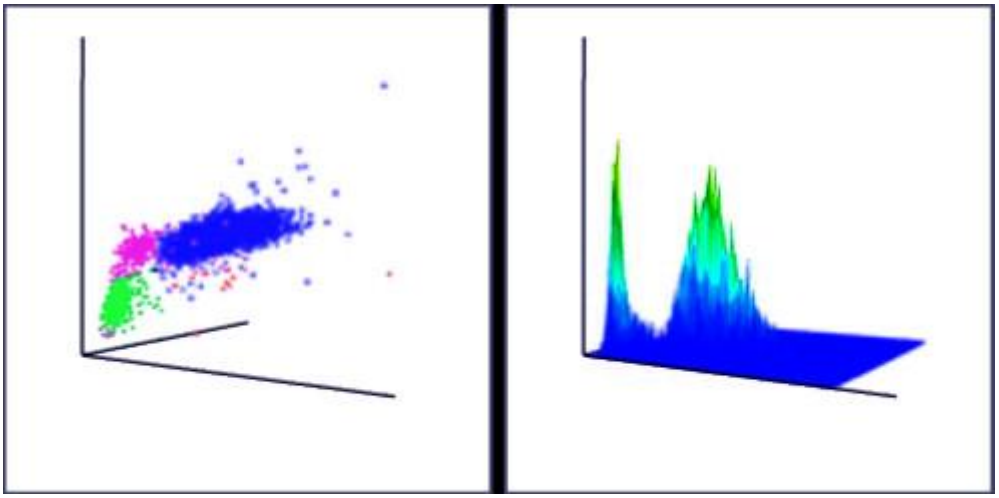


Figure 5-5 Three-dimensional Plot

Figure 5-5 is a three-dimensional plot (3D) of WBC, which can be magnified to see WBC differential and change S0, S10, S90 relative positions according to clinical experience.

5.4.2 WBC Classification

The analyzer divides the WBC into basophil, eosinophil, monocyte, neutrophil and lymphocyte via four-angle scatter analysis as the WBC going through the sheath flow regulator. The default unit of cell amounts is 10^9/L.

- WBC Number

The WOC and WIC is obtained by electrical impedance and laser, and finally gets the total numbers of WBC.

- Lymphocyte Number (Lym#)
- Lymphocyte Percent

  Lym% = Lym#/WBC
- Monocyte Number (Mon#)
- Monocyte Percent

  Mon% = Mon# /WBC
- Neutrophil Number (Neu#)
- Neutrophil Percent

  Neu%=Neu#/WBC
- Eosinophil Number (Eos#)
- Eosinophil Percent

  Eos%=Eos#/WBC
- Basophil Number(Baso#)
- Basophil Percent

  Baso%=Baso#/WBC total amounts

5.5 Test Principle of Hemoglobin Concentration

5.5.1 Colorimetry Principle

After adding lyse into the diluted sample in WBC counting chamber, the RBC dissolves and the hemoglobin is released. The hemoglobin combines with detergent to form hemoglobin mixture which is illuminated by the LED light-emitting diode with a 540nm-wavelength monochromatic light at one end of the WBC counting chamber. Using the optical tube to receive the transmitted light at the other end, amplifying the light intensity signal and convert it to the voltage signal. Compare it with the voltage generated by the transmission light intensity before adding the sample into the colorimetry chamber (only with diluent), the hemoglobin concentration is achieved. Hemoglobin concentration is proportional to the sample absorbance in 540nm wavelength. The process of measurement and calculation is done automatically by the analyzer, relevant results is displayed in the analysis results area.

5.5.2 HGB Parameter

Hemoglobin concentration (HGB) is calculated by the following formula.

$$HGB = K \times Ln\left(\frac{E_B}{E_S}\right);$$

Ln is a natural logarithm.
K is a constant.
E_B is the luminous intensity of light pass through the background.
E_S is the luminous intensity of light pass through the samples.

5.6 RBC/PLT Test Principle

5.6.1 Electrical Impedance Analysis

The electrical impedance is applied to blood cells test and count. Provide constant current source to electrode in conducting liquid (mainly diluent) which makes the circuit form a stable impedance loop (see Figure 5-6). When the cells pass through the pores, the conducting liquid is substituted by cells, the resistance of loop changes and electrical pulses generates. The electrical pulses amplitude is different as different volume of cells passing through the pore, operators determine the amount and volume of cells according to the amount and amplitude of electrical pulses.

As the pulses amount corresponds to the amount of cells passing through the pores, and the pulse amplitude corresponds to the cells volume, the analyzer measures each cell and classifies it according to its volume. The analyzer automatically divides the cells into RBC, WBC, PLT and other groups in accordance with pre-set volume classification procedure.

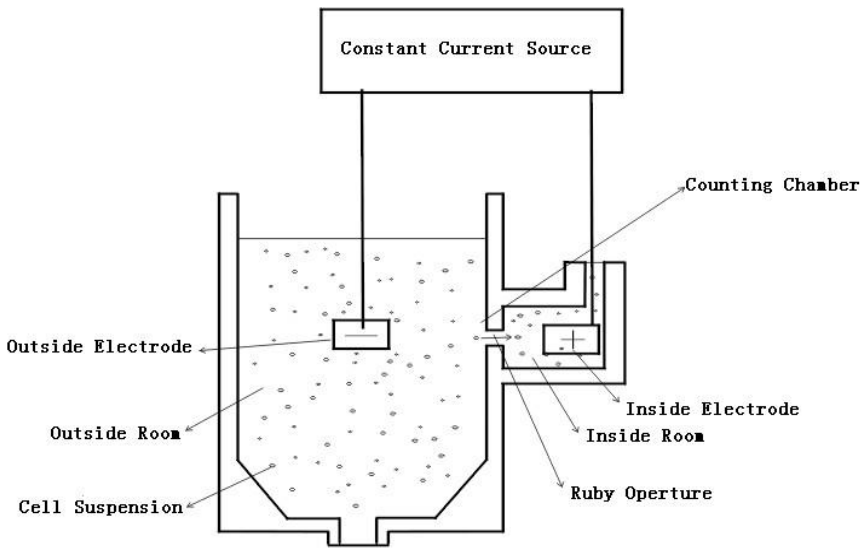


Figure 5-6 Electrical Impedance

5.6.2 Volumetric Metering

The volumetric metering unit controls the sample size passing through the pore during counting to obtain the exact counting results in quantitative samples. The volumetric metering unit includes metering tube and two photoelectric sensors.

As shown in Figure 5-7, empty the metering tube before testing. The liquid level of metering tube declines slowly as the sample passing through the pore. When the liquid level passes through the start detector, one electrical signal generates, and the analyzer starts counting. When the liquid level reaches the stop detector, it also generates an electrical signal, then the counting finishes. If there were bubbles or other abnormal stream in the flow system, "bubble" or "clog" alarm pops up. Please refer to *Chapter 11 Troubleshooting*.

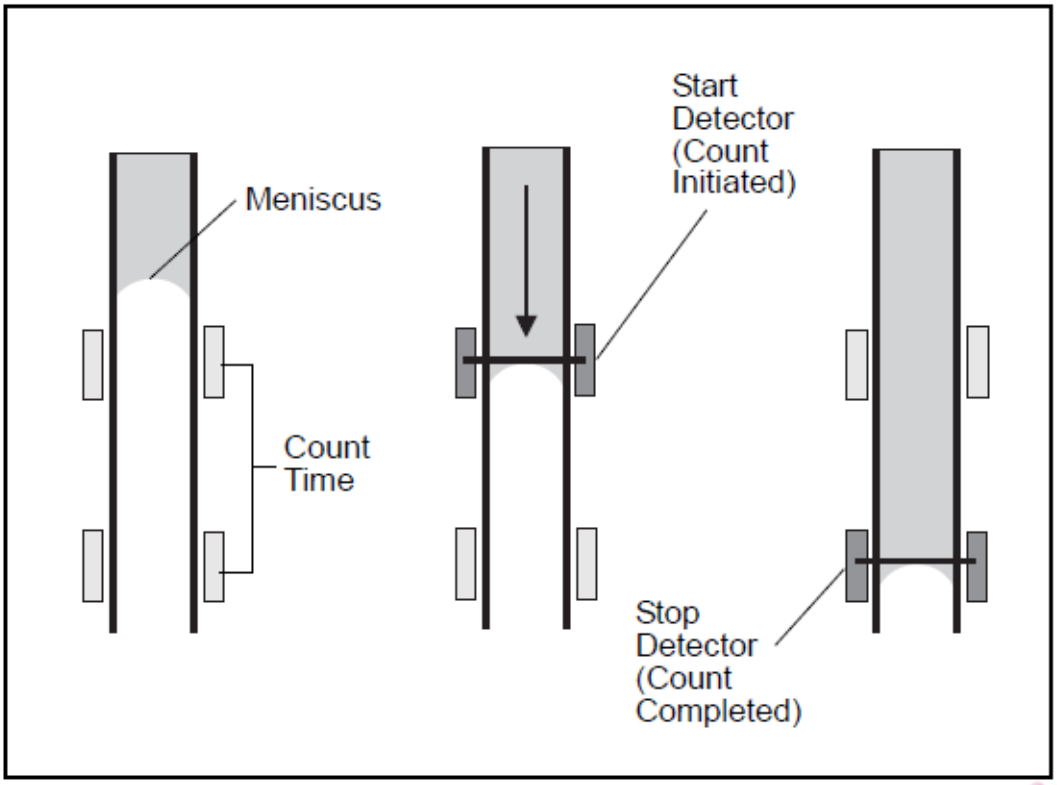


Figure 5-7 Volumetric Metering

5.6.3 RBC Parameters

- RBC Amount

The analyzer directly measures the corresponding electrical pulse amount of RBC to get RBC amount. The unit is 10^12 /L.

$$RBC = n \times 10^{12} / L$$

- Mean Corpuscular Volume

The mean corpuscular volume (MCV) is the average volume of each RBC. The MCV is derived from the RBC size distribution data. The unit is fL.

- Hermatocrit

The hematocrit (HCT) which is the ratio of RBC and plasma is expressed as a percentage of the whole blood volume. HCT is calculated from RBC count and MCV.

$$HCT = \frac{RBC \times MCV}{10}$$

- Mean Corpuscular Hemoglobin

The mean corpuscular hemoglobin (MCH) is the average amount of hemoglobin in the RBC. The unit is pictogram (pg). MCH is calculated from RBC and HGB.

$$MCH = \frac{HGB}{RBC}$$

- Mean Corpuscular Hemoglobin Concentration

The mean corpuscular hemoglobin concentration (MCHC) is the ratio of the hemoglobin weight and the average RBC volume. It is expressed in percent and calculated from HGB and HCT.

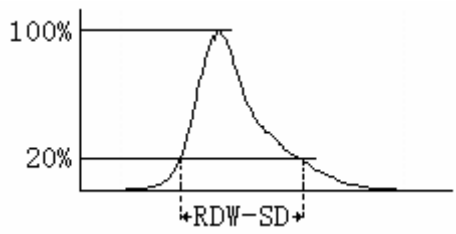
$$MCHC = \frac{HGB}{HCT} \times 100$$

- RBC Distribution Width Coefficient of Variation

The RBC Distribution Width Coefficient of Variation (RDW-CV) is gotten from the RBC histogram and being expressed in percent.

- RBC Distribution Width of Standard Deviation

The RBC Distribution Width of Standard Deviation (RDW-SD) is the width of 20% peak value of RBC distribution histogram .The unit is fL.



- RBC Distribution Width

The RBC Distribution Width (RDW) which is gotten from the RBC histogram is the geometric standard deviation of RBC volume distribution (10 GSD).

5.6.4 PLT Parameters

- Platelet Amount

The analyzer directly measures the corresponding electrical pulses of platelet (PLT) to get amount. The unit is 10^9/L.

$$PLT = n \times 10^9 / L$$

- Mean Platelet Volume

The mean platelet volume (MPV) is calculated by PLT histogram. The unit is fL.

- Platelet Distribution Width

The platelet distribution width (PDW) which is gotten from the PLT histogram is the geometric standard deviation of PLT volume distribution (10 GSD).

- Thrombocytocrit

The thrombocytocrit (PLT) is calculated as follows.

$$PCT = \frac{PLT \times MPV}{10000}$$

Remark. The unit of PLT is 10^9/L. The unit of MPV is fL

5.7 Principles of Reticulocyte Analysis

Reticulocytes are defined by the National Committee for Clinical Laboratory Standards (NCCLS) as transitional red cells, between nucleated red cells and the so-called mature erythrocytes. In contrast to mature RBCs, reticulocytes contain ribosomal RNA. This RNA can be seen with certain supravital, cationic dyes that simultaneously stain and precipitate the polyanion to form a network or reticulum. The Spincell 5plus system reticulocyte method uses the thiazine dye New Methylene Blue N. The reticulocyte assay is performed in the WOC channel of the analyzer. Sample preparation is performed manually by diluting 20 μl of blood into a tube of URIT Reticulocyte Reagent. At room temperature, staining of reticulum is complete within approximately 15 minutes. The stained sample is aspirated in the Open Mode. After the stained sample is aspirated, it is diluted approximately 50-fold with Sheath Reagent. Once diluted with Sheath, the RBCs sphere due to the influence of the nonionic detergent incorporated into the staining solution. Sphering is necessary to eliminate optical orientational noise that would otherwise be introduced into the scatter measurements. The usual lytic action of the Sheath is prevented by electrolytes contained in the staining solution and the lack of the usual incubation period used in this channel during WBC analysis. In addition, the high New Methylene Blue concentration in the staining reagent exerts a stabilizing effect on RBCs.

During data acquisition, 10 degree and 90 degree scatter are collected for up to 300,000 signals. The 0 degree threshold is set high enough to exclude most platelets. Histogram data are used to differentiate reticulocytes, mature RBCs, platelet clumps, and nucleated cells. Reticulocytes have 10 degree scatter that are similar to the scatter for mature RBCs, but differ from them by exhibiting greater 90 degree scatter. Reticulocytes are reported in percent. The analyzer will automatically calculate the reticulocyte Absolute value if an RBC count is entered. The RBC value may be obtained from the Standard Hematology Data Log, or it may be entered by the operator directly on screen.

Immature reticulocytes contain more RNA and absorb more stain than mature reticulocytes, therefore, they exhibit greater 90 degree scatter. On the Spincell 5plus, immature reticulocytes are classified as the population of reticulocytes that exceed a predetermined scatter threshold. Consequently, it is possible to determine the Immature Reticulocyte Fraction (IRF) from the scatter measurements.

The IRF was initially designated as the Reticulocyte Maturation Index (RMI), and defined by NCCLS H44-A as a quantitative expression of the relative maturation of the reticulocytes in the observed reticulum in New Methylene blue-stained preparations. However, these quantitative visual

measurements of reticulocyte maturation have been little used due to the subjectivity and imprecision of the manual analysis. Since Auto reticulocyte methods allow the enumeration of immature reticulocytes as a subfraction of the total reticulocyte population, the preferred nomenclature is Immature Reticulocyte Fraction (IRF). The immature reticulocytes are then reported as a fraction (or percent) of the reticulocytes.

The clinical utility of the IRF is widely recognized as follows.

- Monitor hemopoietic regeneration after bone marrow transplant, hemopoietic stem cell transplantation, or intensive chemotherapy
- Monitor bone marrow toxic insults from drugs (for example, AZT)
- Monitor erythropoietin therapy in renal failure, AIDS, infants, myelodysplastic syndromes, and blood donations
- Classify anemia
- Monitor efficacy of anemia therapy (Fe, B_{12}, Folate)

Chapter 6 Settings

6.1 Overview

Initialization setting of Spincell 5plus has been done before delivery. Setting interface at the first boot is default. To meet the different needs, some parameters can be reset.

6.2 Maintenance

1. Auto Blank

Click “Maintenance” in Setup interface, tick “Auto blank” to make blank test as entering Count interface after each boot. See Figure 6-1.

2. Auto Clean

Click “Maintenance-General” in Setup interface, tick “Auto Clean” and choose “times”. It’s suggest to clean the flow system in every 60 counting. See Figure 6-1.

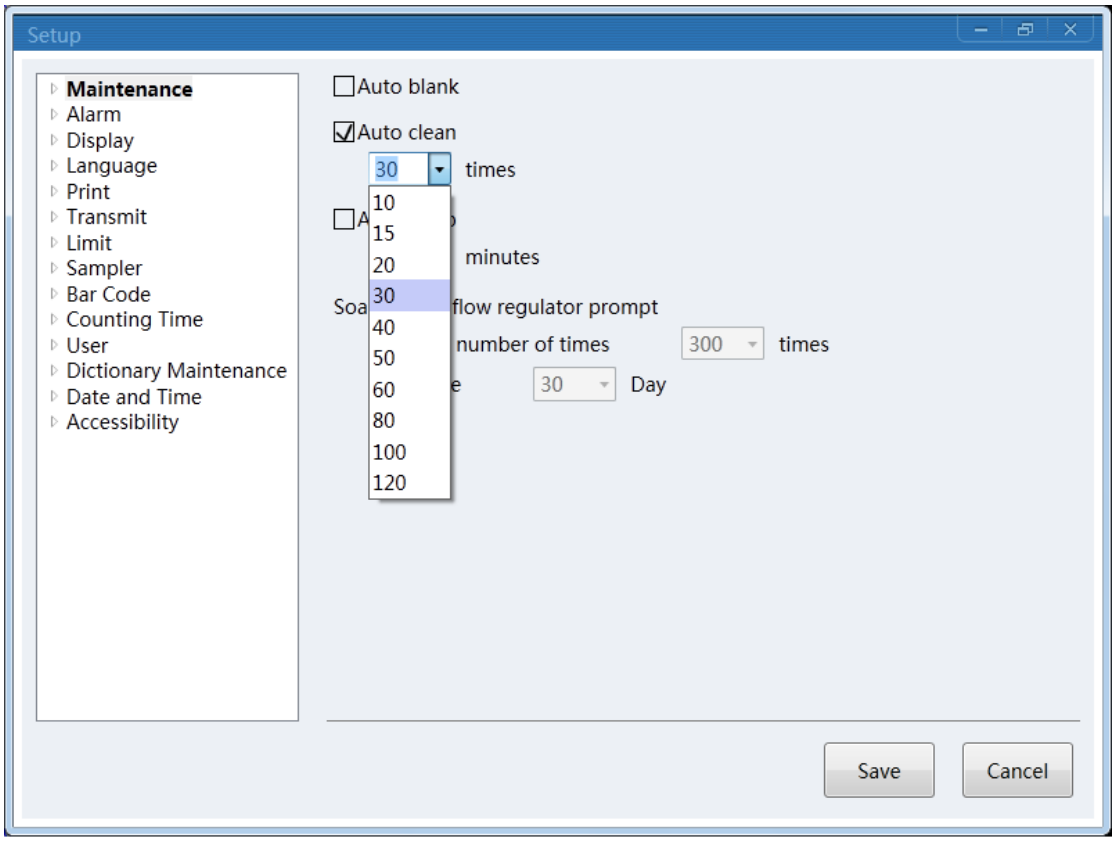


Figure 6-1 Maintenance

6.3 Alarm

Click "Alarm" in Setup interface and choose “Alarm” and “Waste alarm”. It’s suggested to open the tips. See Figure 6-2.

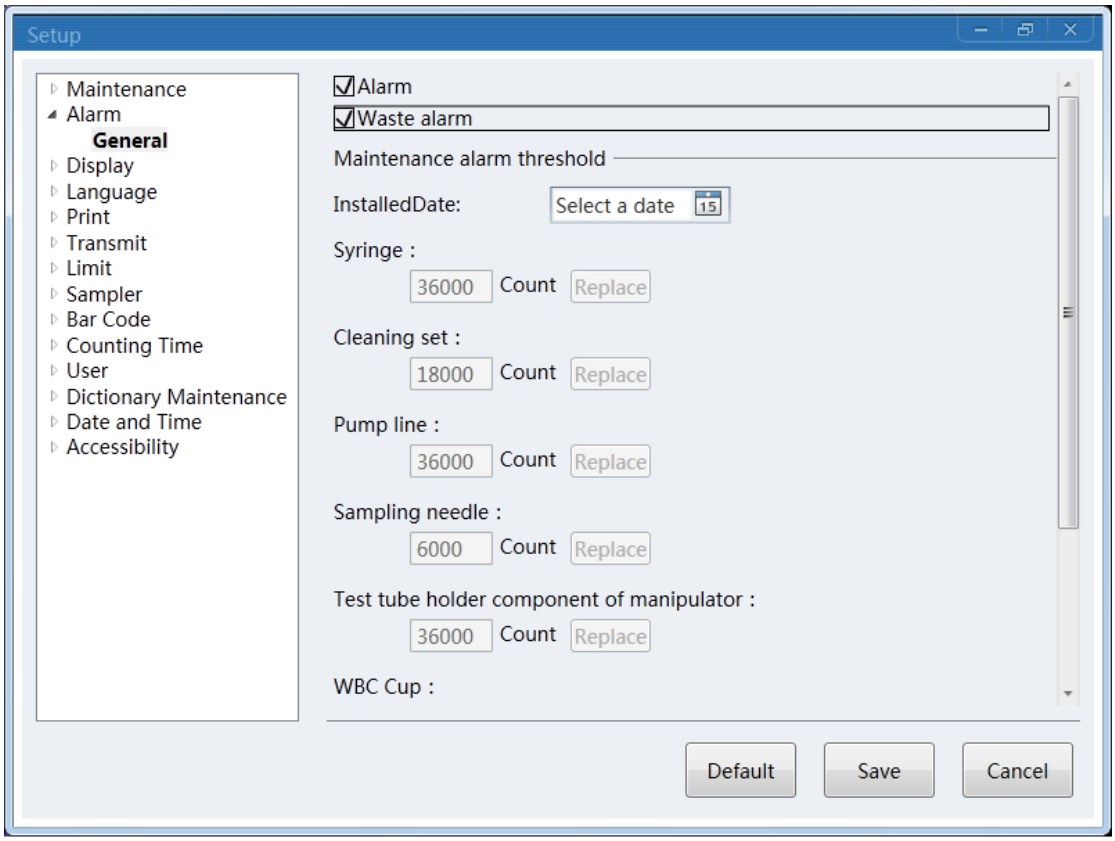


Figure 6-2 Alarm

6.4 Display

1. General

Click "Display" in Setup interface is as shown in Figure 6-3.

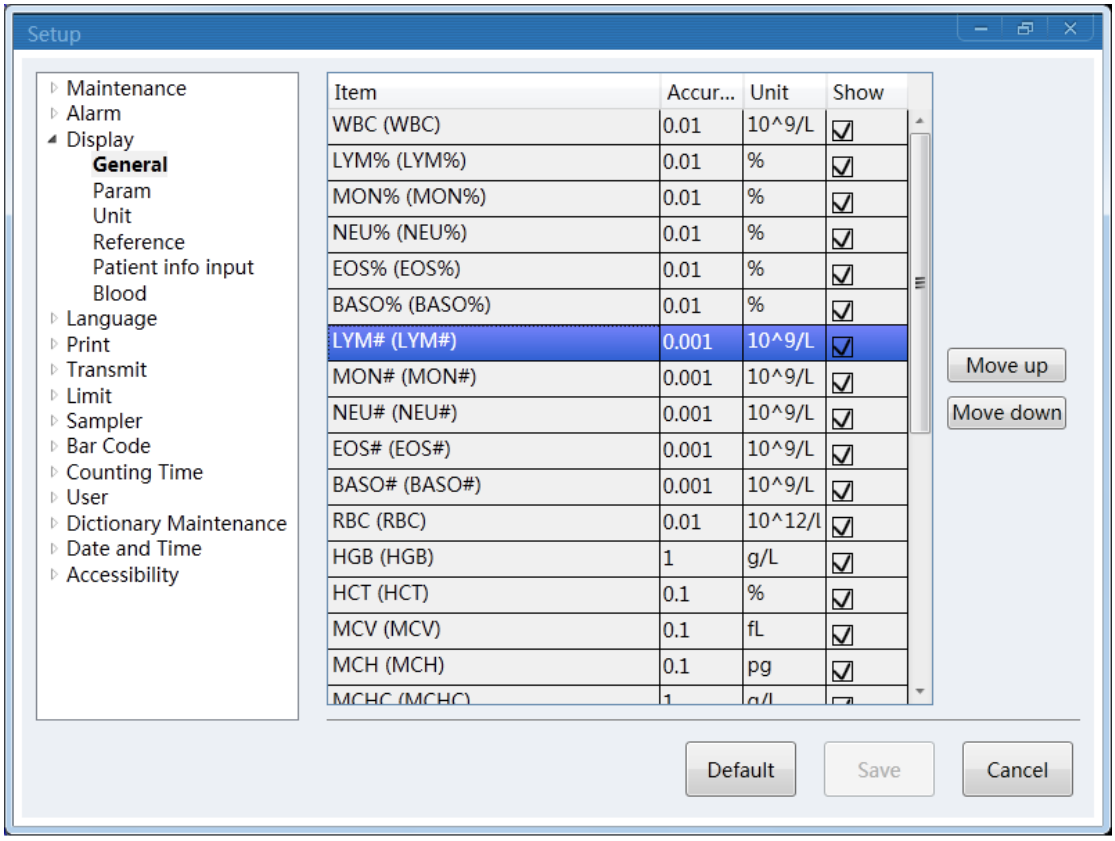


Figure 6-3 General

2. Display Modification

Select different parameters units, parameter language (Chinese and English) and reference value order, printout changes according to your selection.

3. Save and Cancel

Click “Save” to save settings and click “Cancel” to exit the current dialog or not to save settings. (See figure 6-11).

6.5 Print

Operator can choose printer type, print format and auto print in Print interface, and input the corresponding hospital name in “Printer Title”. See Figure 6-4.

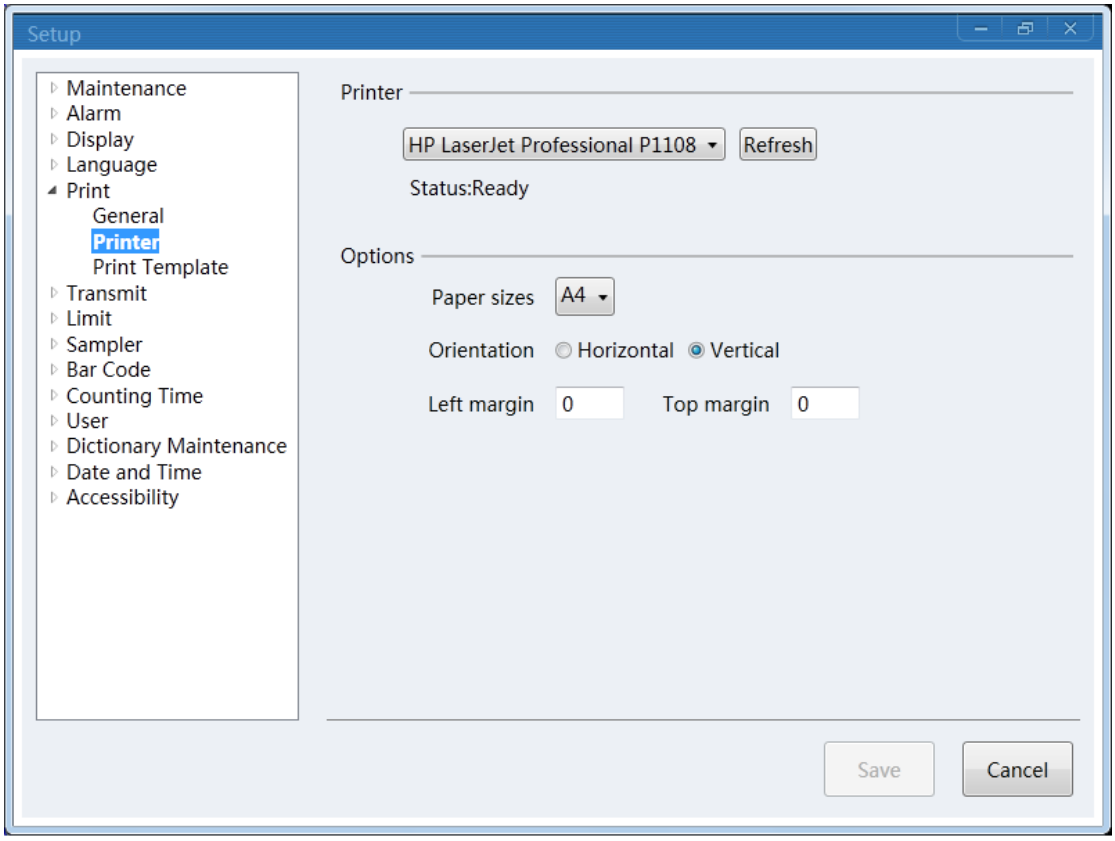


Figure 6-4 Print

6.6 Transmit

Setup of serial port, baud rate, data bit, stop bit and parity is available, which is used for external communication.

1. Transmit

Click " Transmit " in Setup interface is as shown in Figure 6-5.

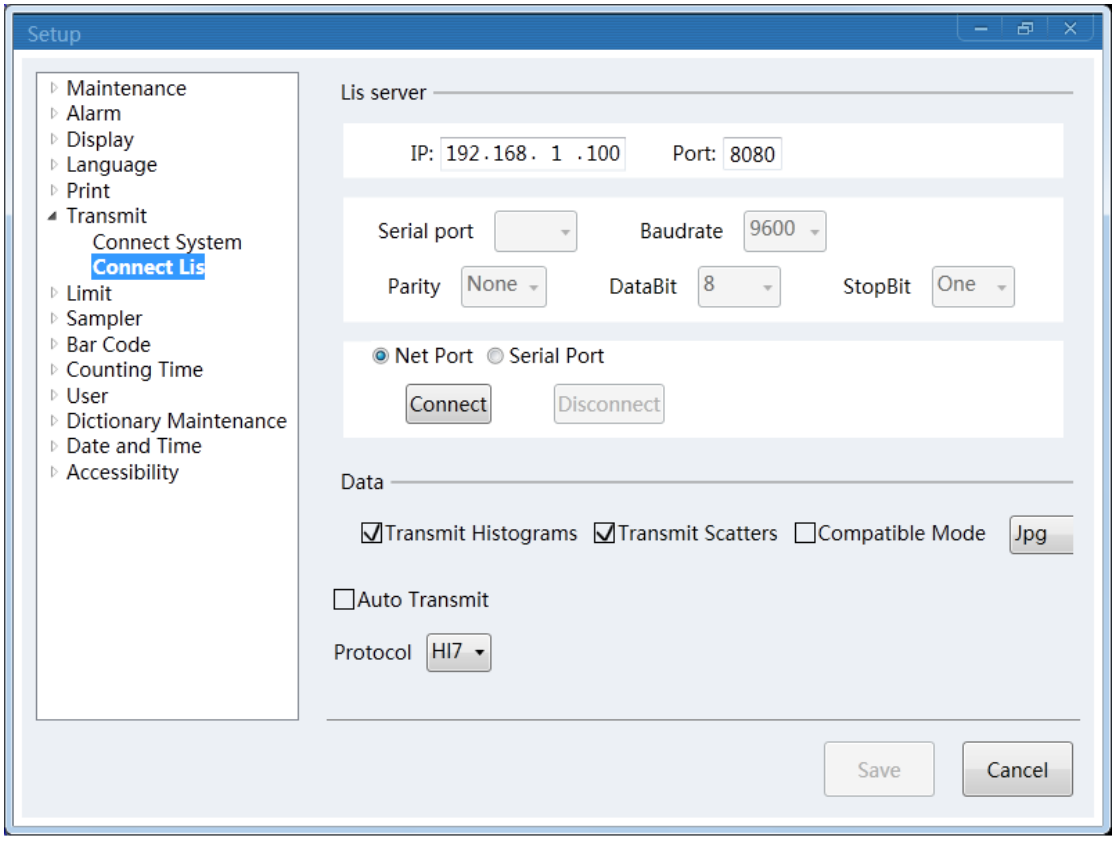


Figure 6-5 Transmit

2. Protocol Modification

Operator sets the serial port, baud rate, data bit, stop bit and parity. When “Auto Transmit” is open, the test results automatically transmit from the communication port after sample test.

NOTE

- Transfer setting is already set before delivery. As a rule, there is no need to reset, or the data transmission will be affected. Necessary modification should be done under the guidance of URIT engineer.
- Do remember save your settings after modification, otherwise your setups would not be saved and not switch to corresponding interface.

6.7 Limit

To monitor abnormal test parameters of blood samples, it is essential for operator to set normal ranges of the parameters according to the needs of laboratory or clinical. Prompts come out if test result exceeds the range. The analyzer provides the upper and lower limit of 28 parameters, test results which exceed the parameter bounds will be marked H (High) or L (Low). H means the results are higher than the upper limit, while L means the results are lower than the lower limit.

CAUTION

Limit change may cause changes in abnormal indication of hematology index. Please confirm the necessity for changing.

1 Limit

Operator setups either parameter limit or use the default.

Default values are different according to the patient group. Parameter limit of "General" group is shown in Figure 6-6, parameter limit of "Custom1" group is shown in Figure 6-7.

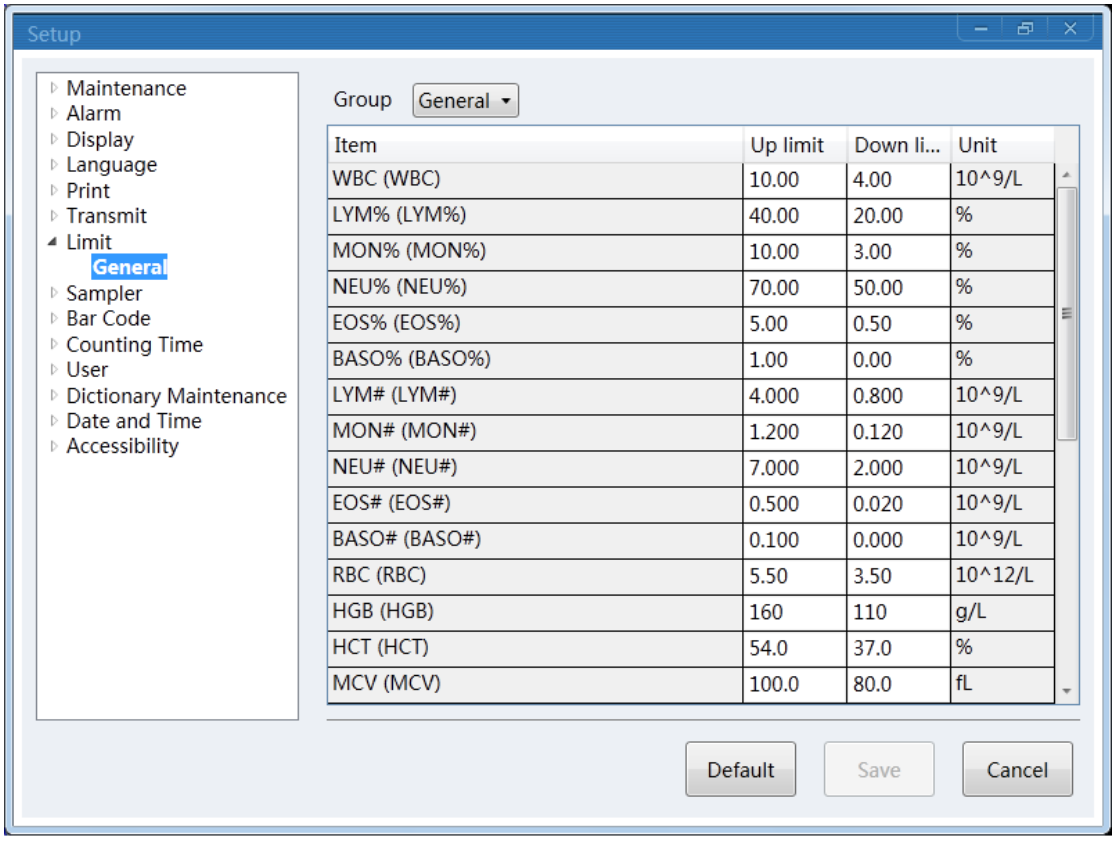


Figure 6-6 Parameter Limit of General

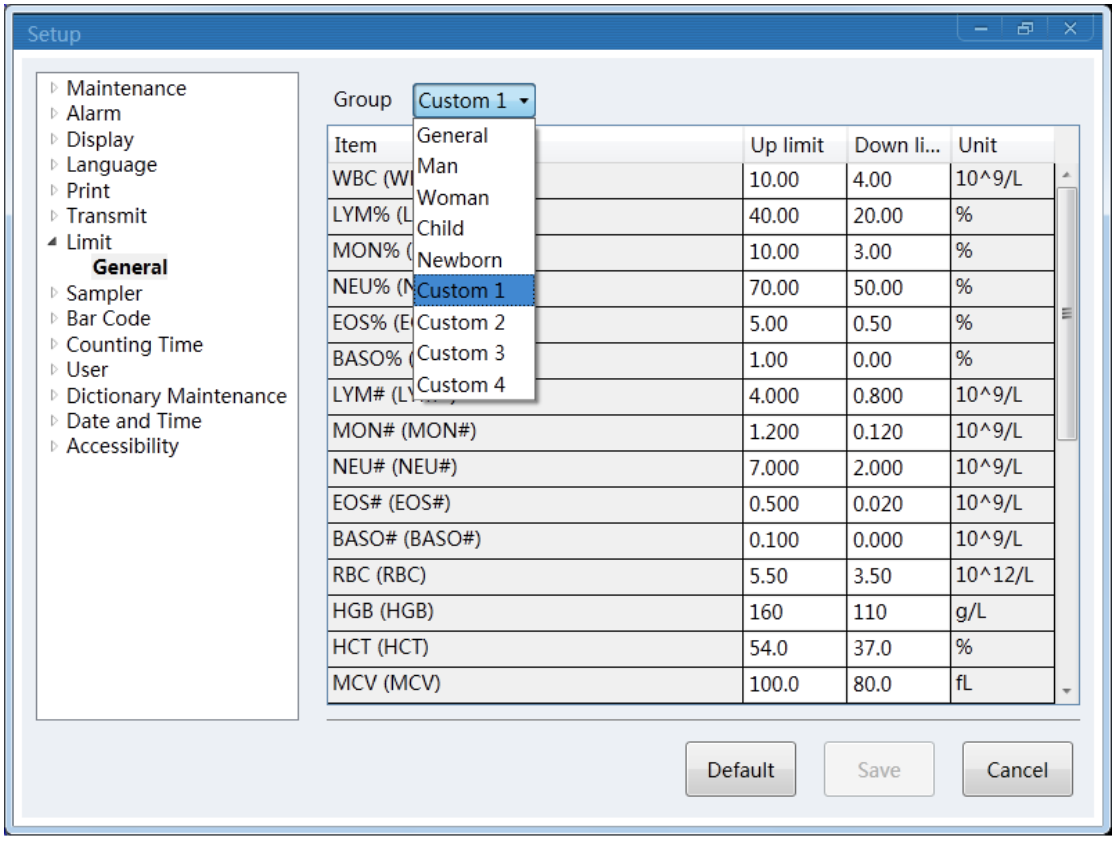


Figure 6-7 Parameter Limit of Custom 1

2 Parameter Limit Modification

Please modify it as follows.

（1） Click “▼” next to the “Group” to choose group needs to be modified.

（2） Select down and upper limit of parameters, move the cursor to edit box, press “Backspace” on the keyboard to delete raw data and input the new down and upper limit.

（3） Click “Save” to save the modification.

6.8 Counting Time

Click "Counting time” in Setup interface to set the upper and lower limit as shown in Figure 6-8.The upper limit of RBC is 15.5 seconds. If the counting time is longer than it, "Clog" alarms. The lower limit of it is 13.5 seconds. If the counting time is less than it, "Bubble" alarms. The upper and lower limit are set before delivery. Please do not modify it so as to avoid false alarm. Contact with the URIT after-sales service if you need to change it.

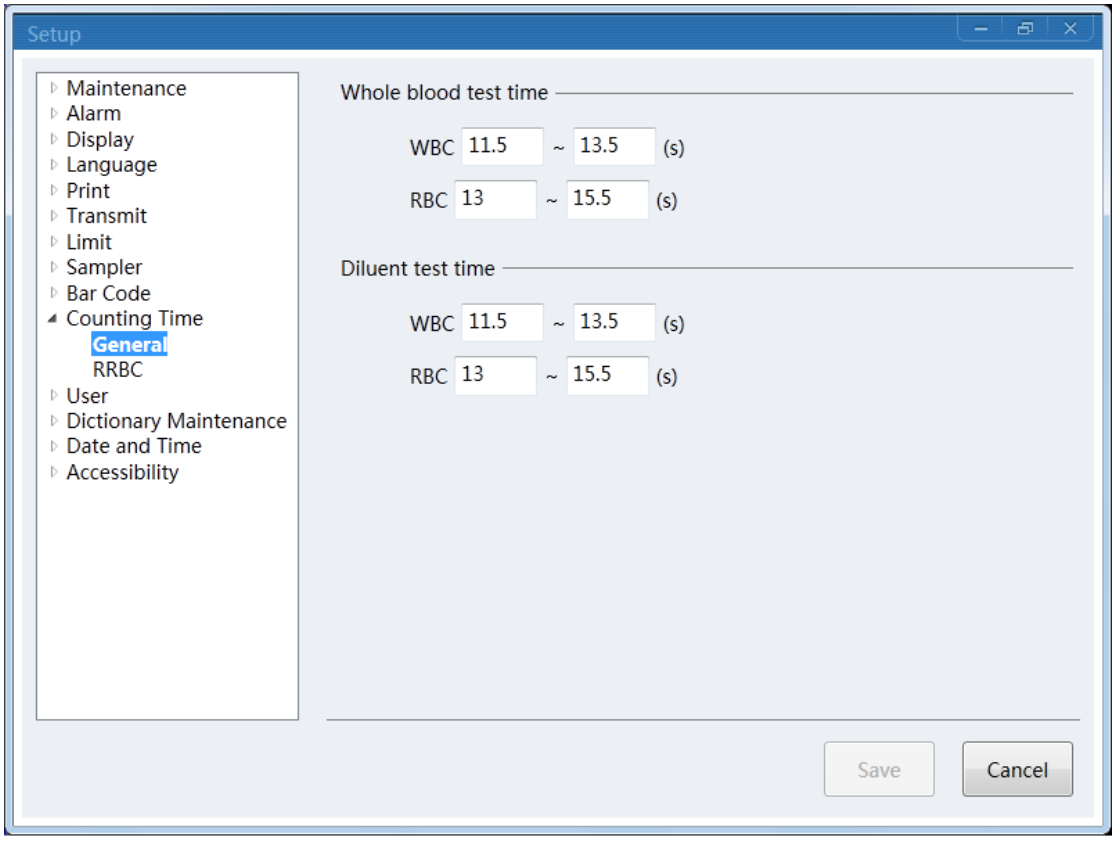


Figure 6-8 Counting Time

6.9 User

Doctors or operators should login the system with identity to operate the routine check, therefore, it is necessary to set doctors' information. Only the administrator can make user setup.

1. General

1.1 Setup

Click "User" in "Setup" interface as shown in Figure 6-9.

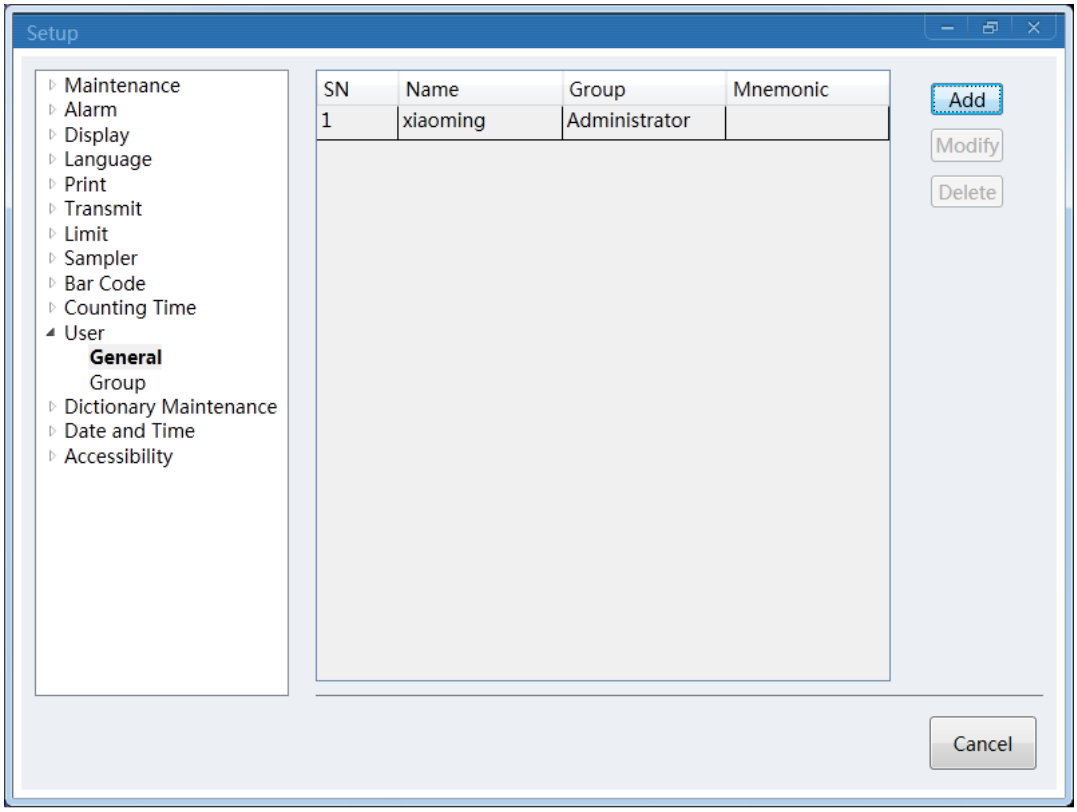


Figure 6-9 User

1.2 Add New User

click “Add” to add the new user’s name, select permissions, set password (default password is null). See Figure 6-10.

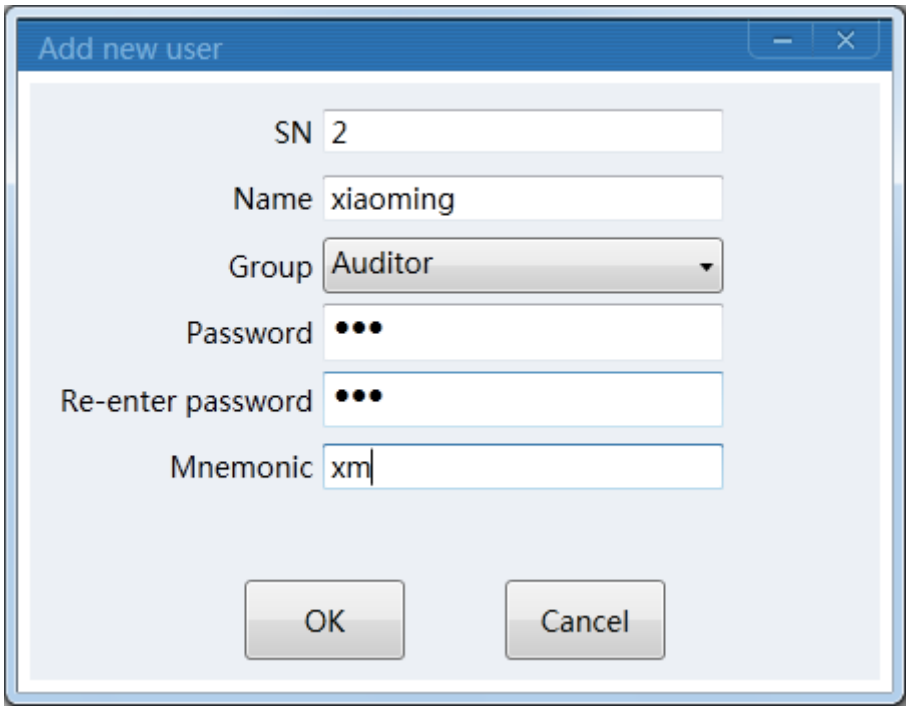


Figure 6-10 Add New User

1.3 Delete User

Select and click “Delete” to delete the user.

Click “OK” or “Cancel” to confirm whether to delete the user or not.

2. Group

In order to guarantee the proper use, it is necessary for the administrator to only give partial permissions to other operators, such as query and count data. Do not give access to delete data.

Click “Group” -- “Add” and check group permissions. See Figure 6-11.

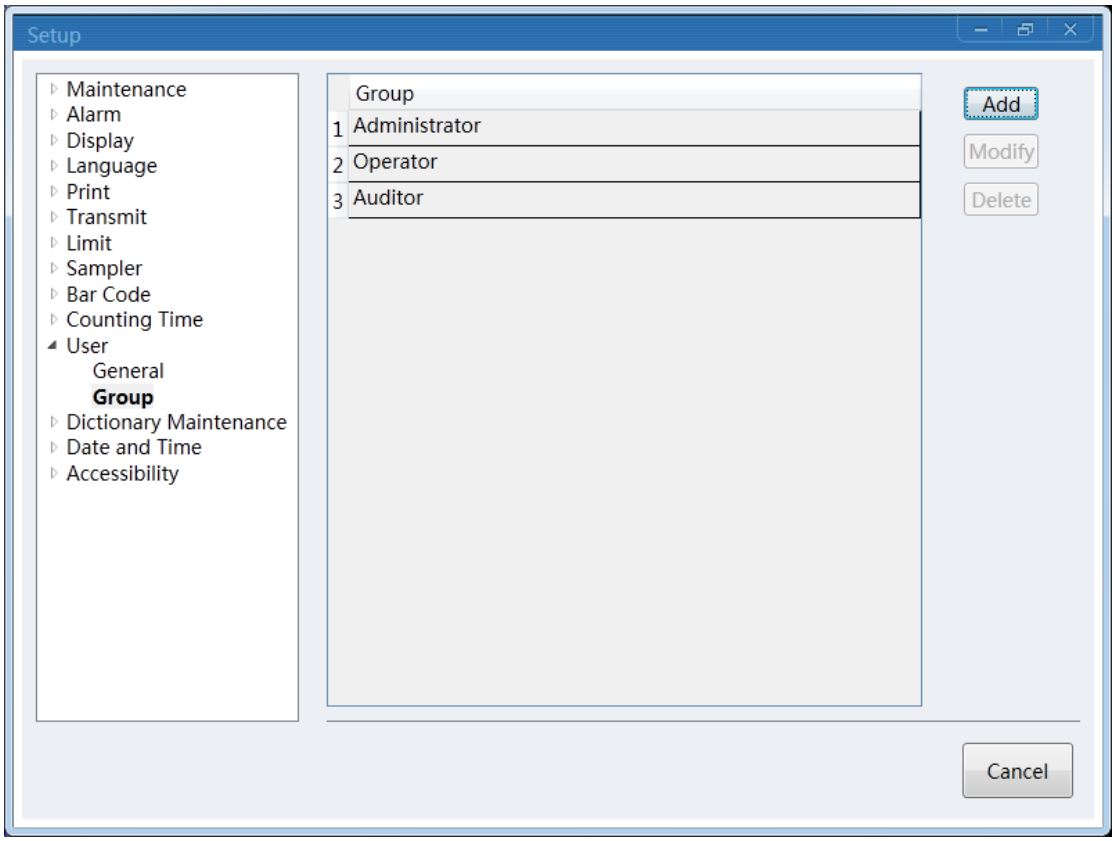


Figure 6-11 Group 1

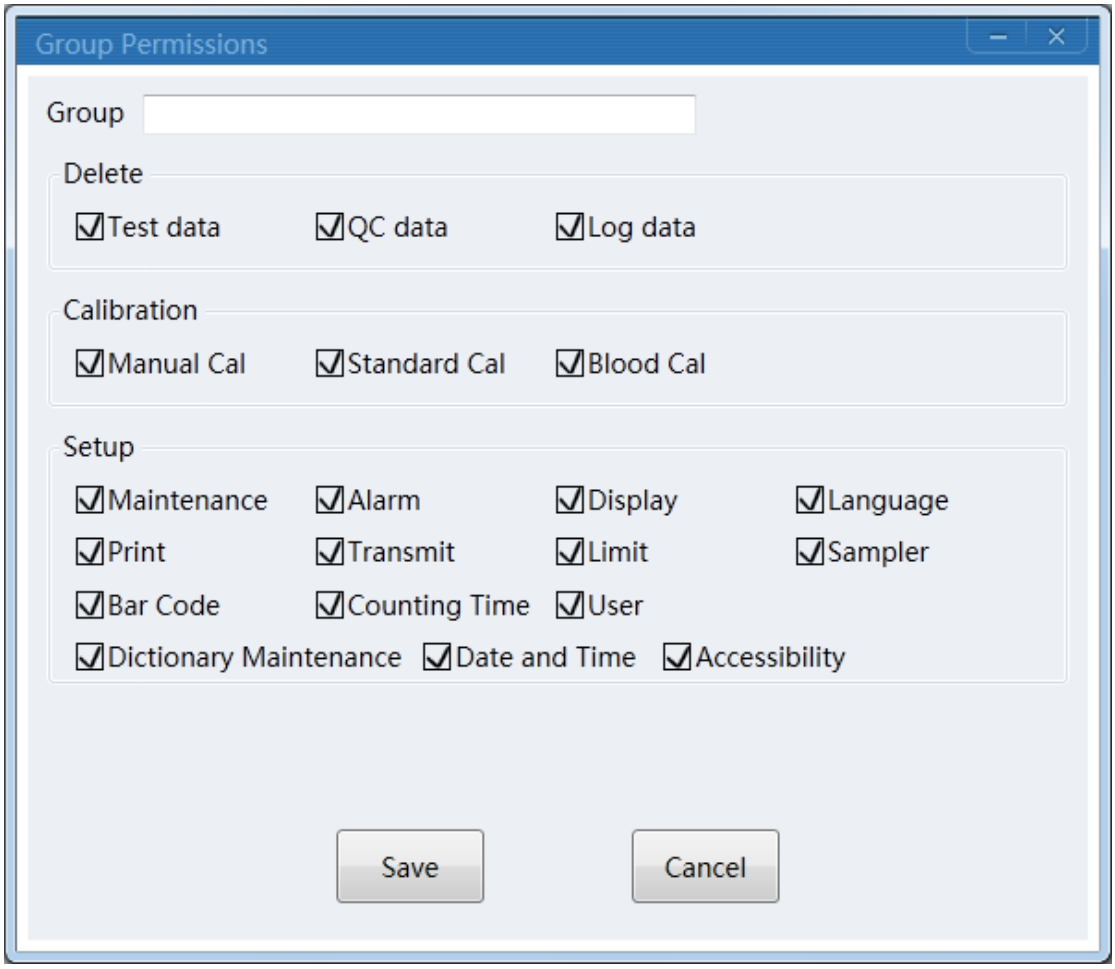


Figure 6-11 Group 2

6.10 Dictionary Maintenance

If it needs to re-type the department and doctor's name as editing patients' information in "Test" and "Query" interface, operators can set up a simple code which operators input and press "Enter" button, the corresponding department or doctor's name displays.

1. Dictionary Maintenance

Click "Dictionary Maintenance" in "Setup" interface. The default interface is shown as Figure 6-12.

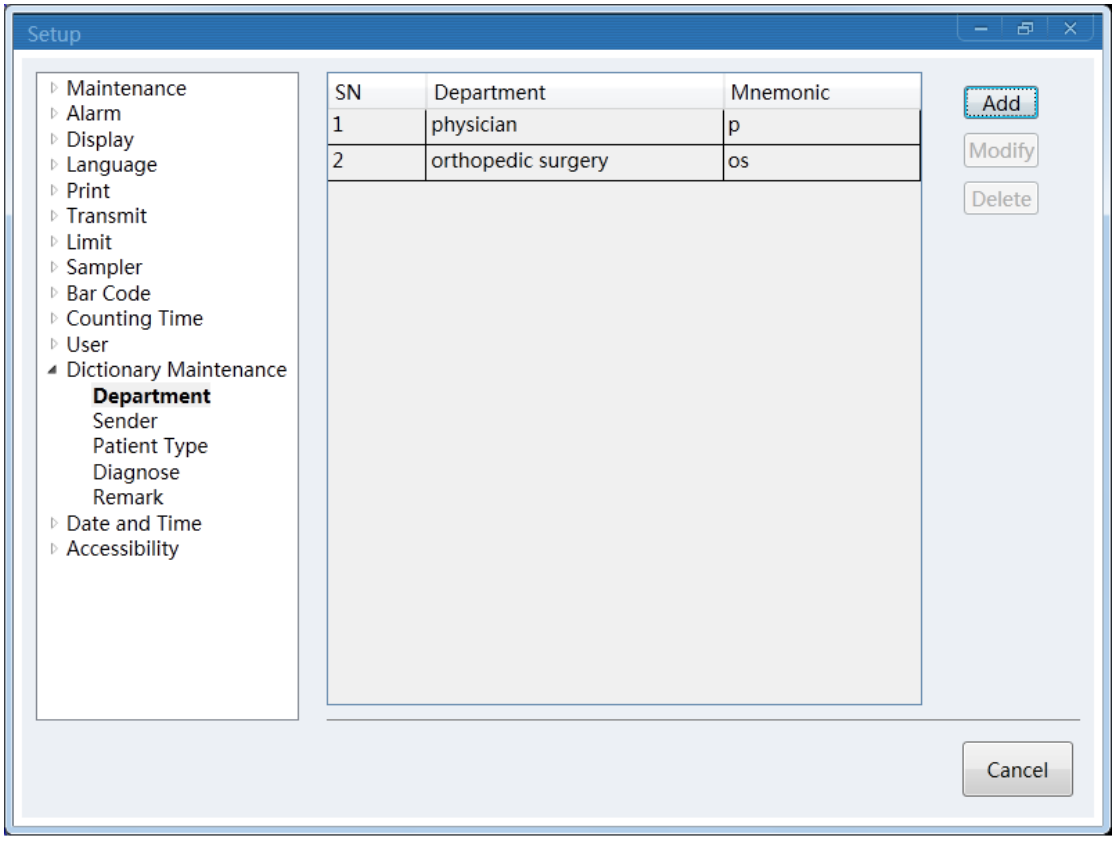


Figure6-12 Department

2. Department

Click "Add" and input department in the name box, such as "internal medicine". Input “1” in “SN”.

Click "Delete" to delete the added department.

Click "Modify" to modify the added department.

3. Sender

Click "Sender" to establish a relationship between SN and sender.

Click "Add" to input doctor's name in “Sender”, such as "LiSi", and input a number, such as “2" in “SN”. "LiSi" comes out as inputting "2" and pressing "Enter".

Click "Delete" to delete the added sender.

Click "Modify" to modify the added sender.

6.11 Date and Time

1. Setup

Click “Date and Time” in “Setup” interface, see Figure 6-13.

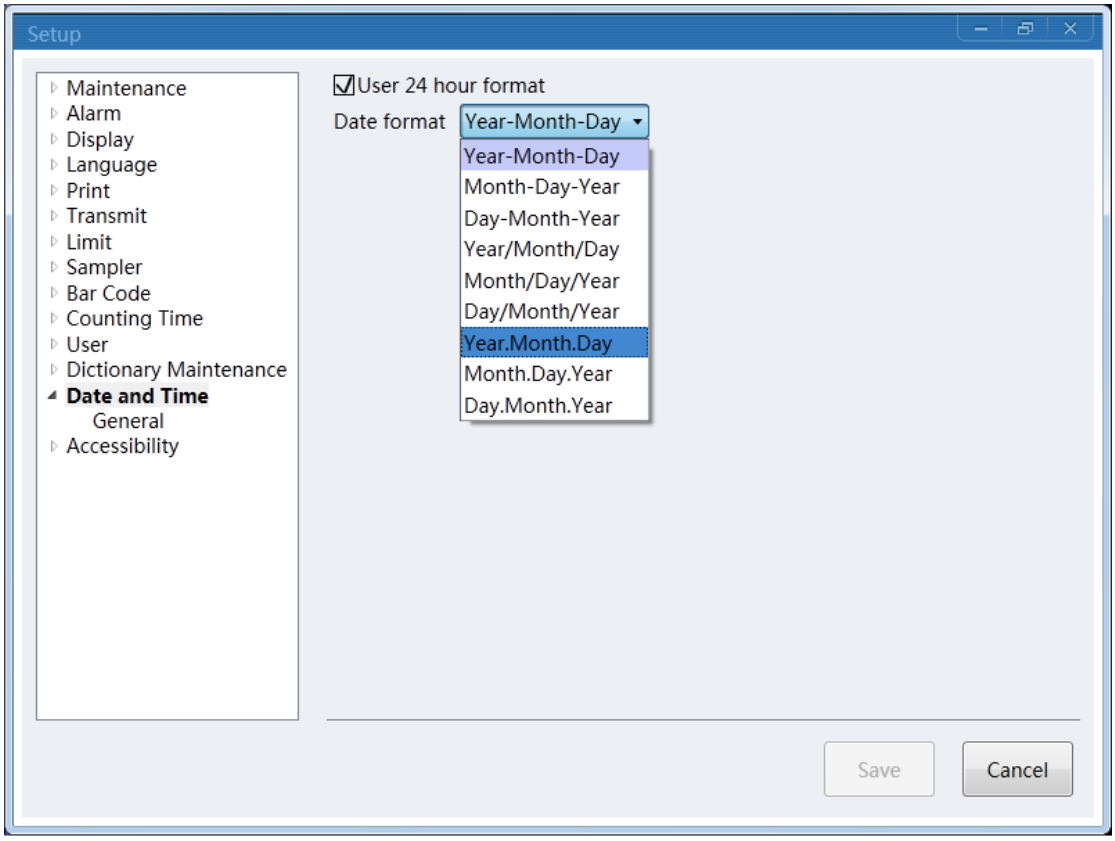


Figure 6-13 Date Setting

2. Date Format

There are nine formats of date, click "▼" to select your desired formats.

3. Use 24-hour Format

Tick "☑" it if using the "24 hour Format".

4. Save and Cancel

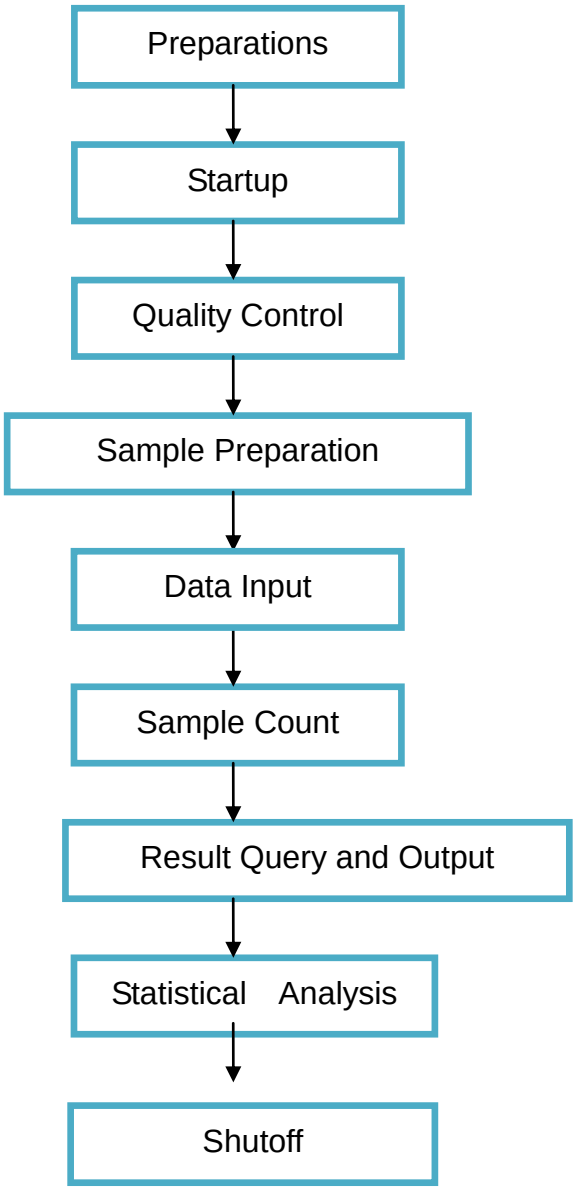
Click "Save" after modification, click "Cancel" to exit.

Chapter 7 Daily Operation

7.1 Overview

This chapter which introduces the whole procedures of daily operation focus on the process of different modes of sample analysis in detail.

Daily Operation Procedures



CAUTION

The analyzer must be operated by medical inspection professionals, trained doctors and technicians.

7.2 Preparations

Check the analyzer as the following steps before startup.

1. Check the Waste Container

The waste should be processed properly and cleaned up before startup every day.

2. Check the Reagents, Tubing and Power

Ensure diluent, detergent, lyse and sheath meets the test requirements.

Ensure the channels of reagents and waste connected well and without bending.

Ensure safety connecting to the power supply.

3. Check the Printer

Ensure printing paper is sufficient and the installation is proper.

Ensure the power is on and the cable has been connected with the analyzer and the computer properly.

4. Check the Mouse and Keyboard

Ensure the mouse and the keyboard has been connected with the computer properly.

CAUTION

All clinical specimens, controls, calibrators and waste has potentially infectious hazard. The operator should comply with the safe operation provisions in laboratory and wear personal protective equipment (lab coats, gloves etc.) when handling these materials.

7.3 Startup

Turn on the power switch on the right panel, the status indicator on the front panel appears orange and turns green after a few seconds. The analyzer automatically checks operation of all components while self-checking and initialization after loading. Then, it rinses the flow system. It takes about 8 minutes to finish this process. The Blood Cell Count interface is shown in Figure 7-1-1 and Figure 7-1-2.

Figure 7-1-1Self-test

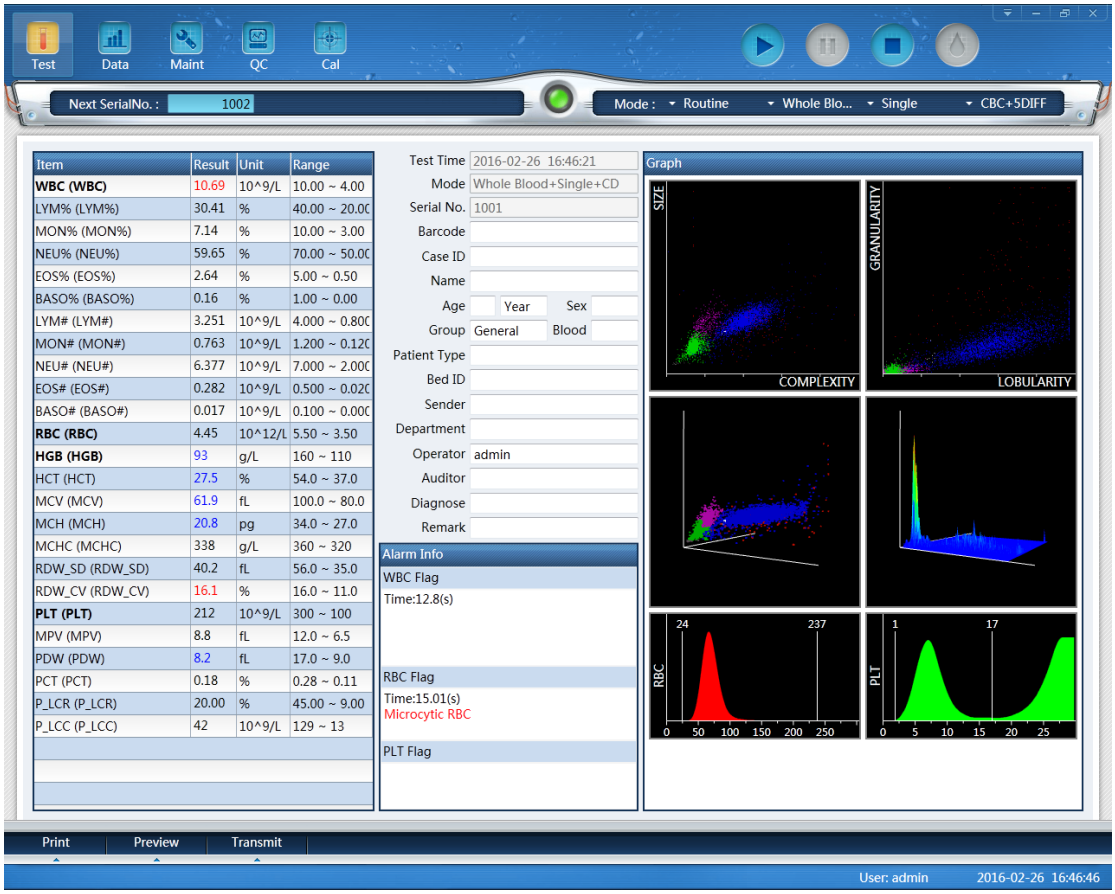


Figure 7-1-2 Test Interface

After startup, blank test should be done before sample test. Operator can set to run it automatically after startup, see *Chapter 6 Settings* for details. The acceptable range of blank test is listed in Table 7-1.

Table 7-1 Range of blank test

Parameters	Acceptable range
WBC	≤0.20x10^9/L
RBC	≤0.02x10^12/L
HGB	≤1g/L
PLT	≤10.0x10^9/L

If the blank test result is out of this range, please repeat the above procedures until it is acceptable. If the result cannot reach the above range requirements after five times testing, please refer to Section *11.4.2 of Chapter 11 Troubleshooting*.

7.4 Quality Control

Quality Control should be performed before daily test for accurate results. Please refer to *Chapter 8 Quality Control*.

7.5 Collection of Blood Samples

WARNING

- Considering all the clinical specimens, control materials and calibrators which may contain human blood or serum has potentially infectious hazards, The operator should comply with the safe operation provisions in laboratory and wear personal protective equipment (lab coats, glasses, gloves etc.) when handling these materials.
- Do not directly contact blood samples, control materials and calibrators. Please follow required procedures to operate it.

CAUTION

- Blood collection and disposal should be performed according to the local and national environmental regulations or laboratory's requirements.
- Ensure the whole procedure of blood collection is clean and contamination-free. All specimens must be properly collected in tubes containing the EDTA (EDTA-$K_2 \cdot 2H_2O$) anticoagulant.
- Do not shake the sample tube violently.
- Venous blood can only be stored for 4 hours at room temperature. If it's not used up in a short period, URIT recommends to keep the blood sample at the temperature between 2℃~8℃.

The indicator in different color means different work status of analyzer. Please see the Table 7-2 for details. If the indicator turns red, please troubleshoot according to prompts.

Table 7-2 Indicator

SN	Color	Work Status
1	Blue	Sampling in Whole Blood Mode
2	Green	Sampling in Diluent Mode
3	Orange	Working
4	Red	Error, alarm

7.5.1 Whole Blood Collection

Collect whole blood sample by vein-puncture and store it in a clean sample tube which is filled with EDTA-K2·2H2O (1.5~2.2mg/mL). The EDTA-K2·2H2O which keeps the configuration of WBC and RBC inhibits PLT aggregation. Gently shake the tube 5~10 times and ensure to mix it well.

The following anticoagulants are commonly used in whole blood collection.

1. Heparin

Lead to cell aggregation and change the cytoplasm color of Romanowsky staining. The concentration of high heparin > 7.5UL/ capillary leads to increase in HCT and MCV.

2. Sodium citrate

The sodium citrate which is a kind of liquid is filled in the tube and diluted to 10/11 of the original. This anticoagulant is used for agglutination, it also can be used when suspected thrombocytopenia from EDTA.

3. ACD and CPDA

ACD and CPDA is the anticoagulant widely used in cell concentration, especially in platelet concentrates. Usually, it's not used for cells count.

4. EDTA

In the salt of EDTA, use EDTA K2（United States and Japan）and EDTA K3（United States and Europe）,sometimes NA2EDTA. And EDTA K2, EDTA K3 which recommend by ISCH in1993 are most widely used in the blood test of the world. But other EDTA salts can also be used. EDTA could lead to Pseudo-thrombocytopenia through Platelet aggregation. (Incidence is about 1/800)

5. Fluoride

Use it before using EDTA. It has been no side effects yet according to the investigation.

7.5.2 Dilutent Sample Preparation

Methods on diluent sample preparation

Method 1

1. Aspirate 800μL diluent from bucket by pipettes.
2. Inject it into a clean disposable plastic tube.
3. Inject 20μL peripheral blood into the tube and mix it well.

Method 2

1. Set the current test mode to "Diluent Mode" in "Test" interface, and move the sample holder of Emergency Sampling to the position of disposable plastic tube.
2. Put a clean disposable plastic tube in the Emergency Sampling.
3. Press "Drain" in the shell or click "Single" in pop-up interface. Click "Drain" in pop-up interface, the analyzer automatically injects 800μL diluent in the plastic tube.
4. Inject 20μL peripheral blood into the test tube and mix it well.

Method 3

1. Set the current test mode to "Diluent Mode" in "Test" interface.
2. Put the disposable plastic tube in the test tube rack which is placed at the

right side of sample loader.

3. Click “Drain” in the interface, and click “Multiply” in pop-up dialog. Input the needed times and click “Drain” as shown in Figure 7-2. The analyzer automatically injects 800μL diluent in each tube.
4. Take out the tubes and inject 20μL peripheral blood into tubes filled with diluent and mix it well.

NOTE

Tubes should be arranged consecutively. The upper limit of “Multiply” is 50.

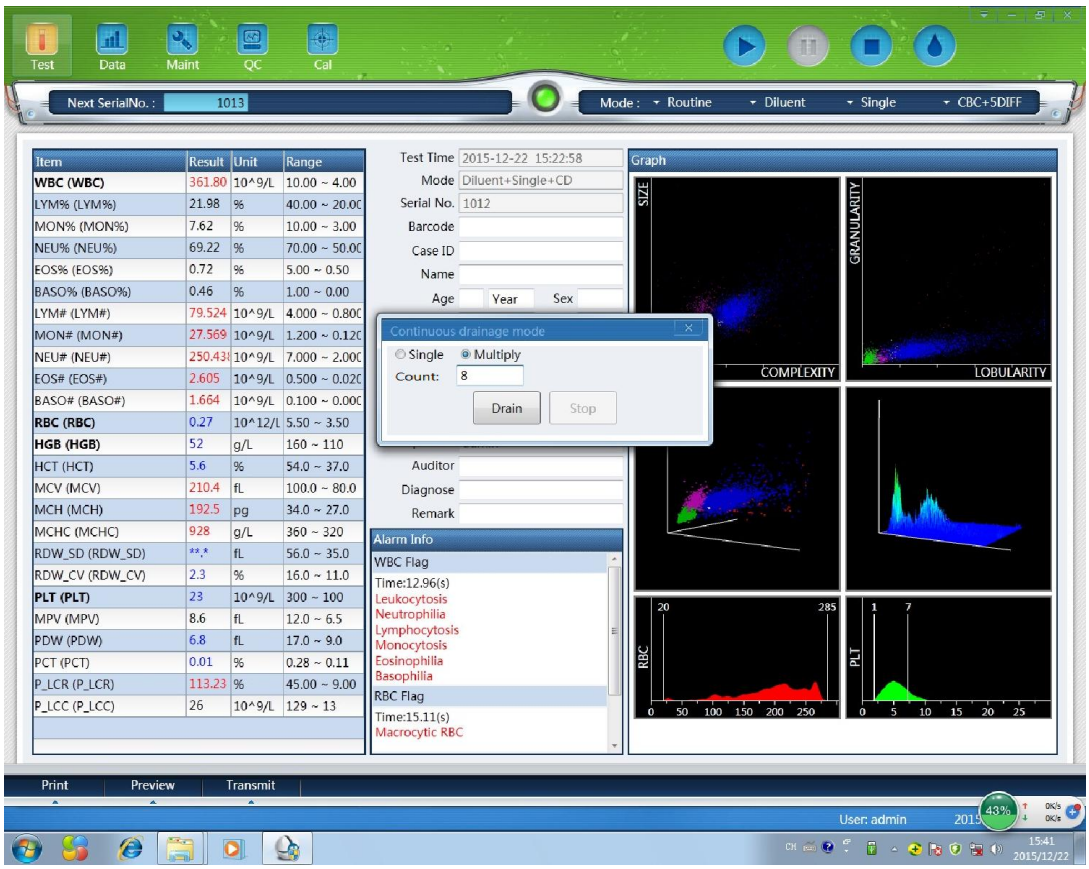


Figure 7-2 Drain

CAUTION

- Avoid dust falling into the prepared diluent, otherwise error may be caused.
- Peripheral blood and diluent after full reaction, should be placed for 3 minutes, and then only after blending again that can do the analyze.
- Ensure that the sample has been analyzed within 30 minutes after dilution, otherwise the analysis results are not reliable.
- The sample placed after a period of time should be blending to anew for analysis.
- Each laboratory should according to their respective sample number, sampling method and the technical level to evaluate the stability of the results under the diluent mode.

7.5.3 Reticulocyte Sample Preparation

1 Add 20 μ L sample into tube filled with RESEARCH-II Stain (4mL), mix it and place at room temperature (15°C ~ 30°C) for 15 to 30 minutes.
2 Precision shall be affected if placing it in the room temperature over 2 hours

CAUTION

Avoid contact with skin and clothing. The ingredient New methylene blue stain skin, clothing and other objects.

7.5.4 Sample Stability

Better to use fresh whole blood for test. ICSH (International Committee for Standardization of Hematology) defined fresh blood as the samples which are processed within 4 hours after collecting. Inject the thoroughly mixed whole blood samples in EDTA-tube and test it within 8 hours, the highest accuracy can be gotten. Test samples within 5 to 20 minutes and over 8 hours, the WBC volume distribution may offset.

7.6 Information Input

Input detailed sample information in “Test” interface. Operator can either input in before sample analysis or input it in data query after counting. See Figure 7-3-1 and Figure 7-3-2.

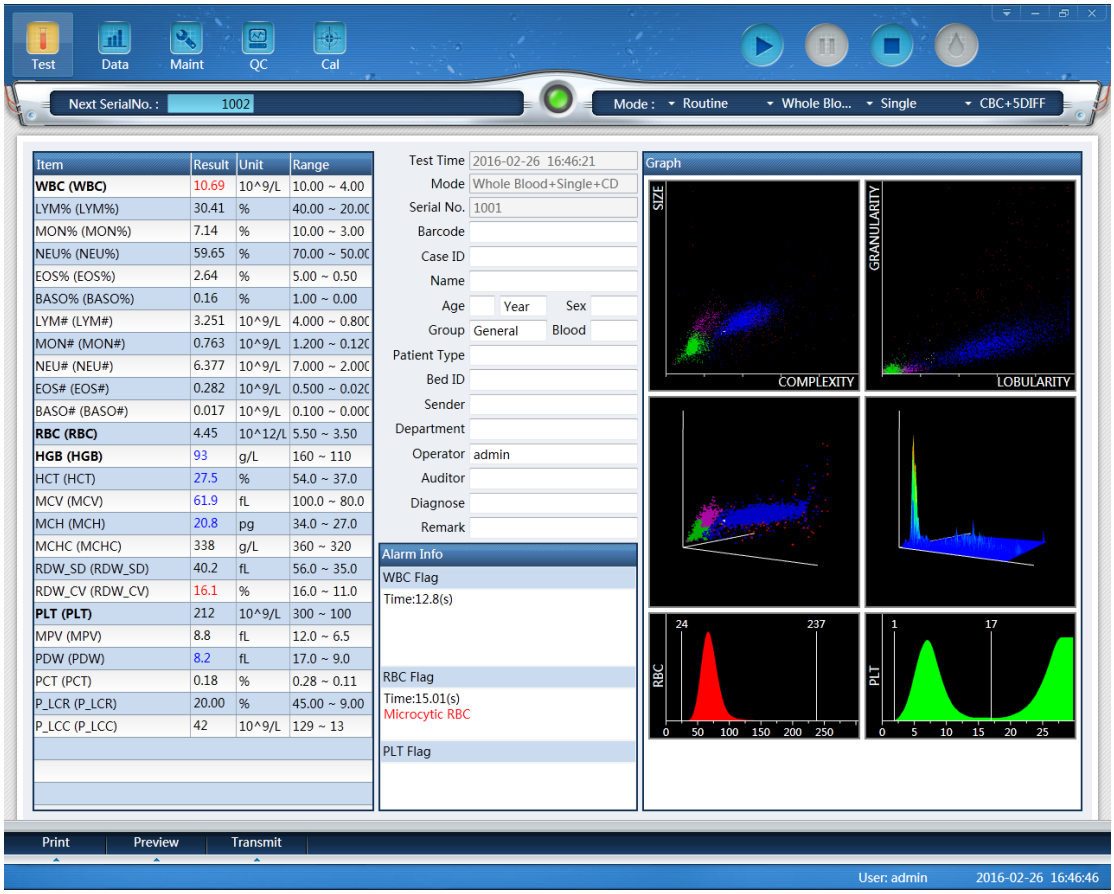


Figure7-3-1 Data Input 1

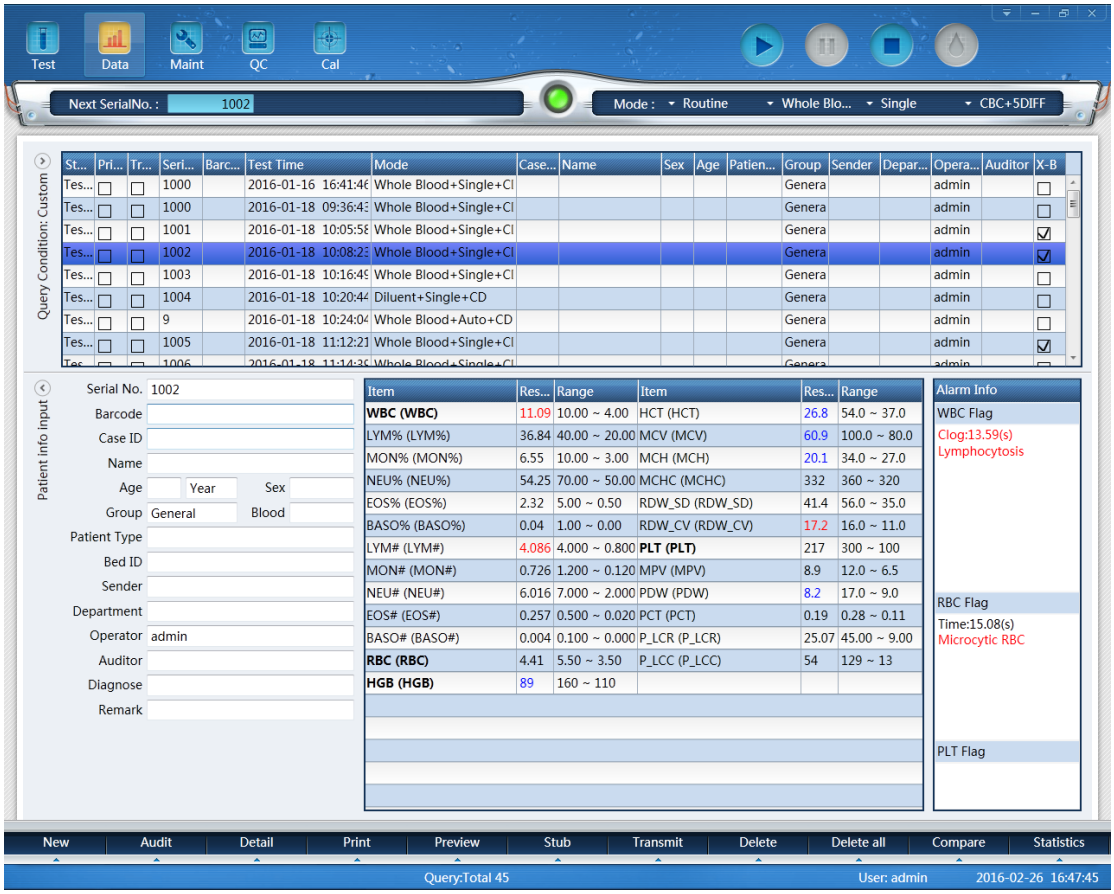


Figure7-3-2 Data Input 2

Press “Ctrl+Shift” on the keyboard to choose input method.

Name: Input Chinese characters, letters and numbers.

Gender: Input corresponding SN of pre-set gender in Dictionary Maintenance, the default is blank**.**

Age: Input corresponding SN of pre-set age in Dictionary Maintenance, the default is blank**.**

Blood Type: Input corresponding SN of pre-set blood type in Dictionary Maintenance, the default is blank**.**

Group: Divided into General, Man, Woman, Child and New-born according to the input age and gender, selected General, Custom 1, Custom 2, Custom3 if needed.

If Auto is selected, the reference values are offered as listed in Table 7-3.

Table 7-3 Group

Reference Value	Age	Gender
General	NO input	Blank, Male, Female
General	≥16 years	Blank
Man	≥16 years	Male
Woman	≥16 years	Female

Child	>1 month and ＜16 years	Blank, Male, Female
New-born	<1 month	Blank, Male, Female

Serial No.: The serial number is in range from 1 to 99999999. If there's no SN input, the analyzer automatically plus 1 on the basis of last SN and take it as the new SN.

Case ID: Input the case number.

Bed ID: Input bed ID.

Department: Input department name or SN.

Operator: Input operator's name or code.

Sender: Input sender's name or code.

Auditor: Input auditor's name or code.

NOTE

The SN 0 is the special one of blank test. Please do not input 0 in sample test.

CAUTION

Each sample has a corresponding identification number. Do not confuse.

7.7 Sample Test

7.7.1 Mode

Click "▽"next to "Whole Blood" in "Test" interface to select the desired operating mode.

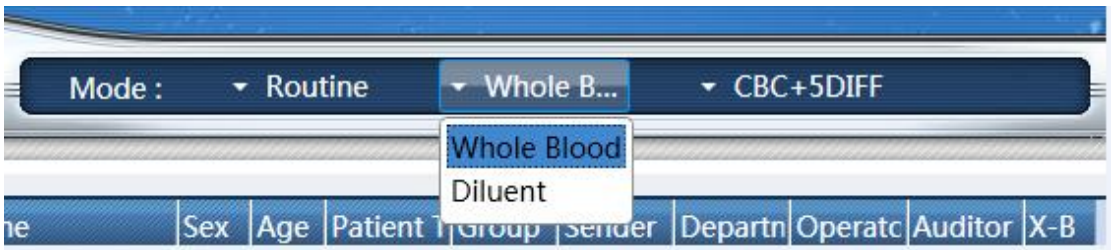


Figure 7-4 Mode

NOTE

- CBC can be chosen both in "Whole Blood" and "Diluent". CBC mode is only available for counting but not classifying the WBC. The counting result includes 18 parameters and the diagrams of RBC and PLT. "CBC+5Diff " counts and classifies the WBC.
- "CBC+5Diff+RRBC" is mainly used to dissolve and count the insoluble RBC. It is suggested to switch the mode to the CBC+5Diff+RRBC and run counting again when RRBC Alarms coming out, which is to eliminate the

interference of WBC. If WBC total number is far less than that of the first counting, it shows that this sample contains insoluble RBC.

7.7.2 Counting and Analysis

WARNING

The probe is sharp, and there might be blood, control materials or calibrators on the probes, which probably have potential infectivity. Do not directly contact the sample probe.

NOTE

- Do not reuse disposable goods.
- Ensure the inputted SN corresponding with the sample.

CAUTION

Do not open the front housing after starting counting.

7.8 Data Query and Output

After each counting, the analyzer automatically saves the counting results in database which stores at least 200,000 results including 34 parameters (2 scatter diagrams, 2 histograms and 2 Three-dimensional plots). Operator could review all of the results, scatter diagrams and histograms that are stored in the database via query and statistics.

7.8.1 Data Query

Click “Data” to enter the query interface. (See Figure 7-5-1)

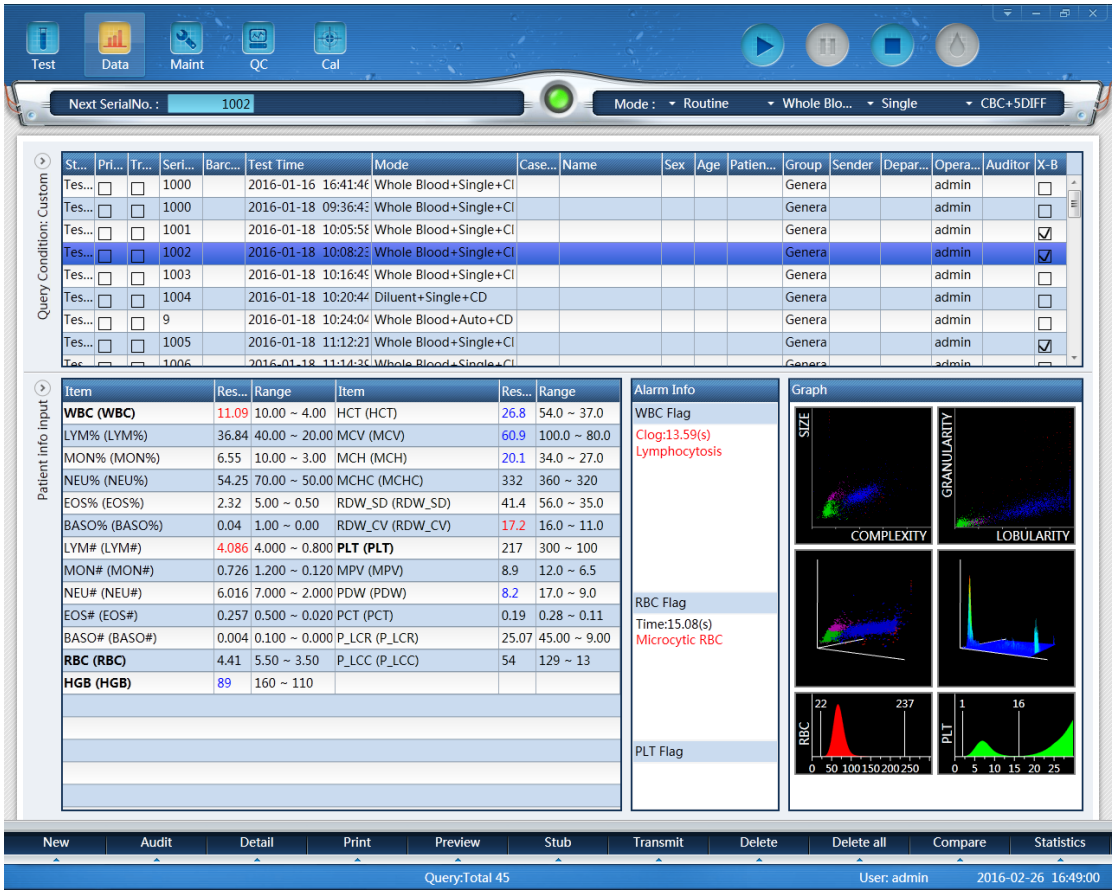


Figure 7-5-1 Data Query

The operator can quickly inquiry the results according to the query condition, such as date, SN, name, gender, age and blood type. Combined Query is available. See Figure 7-5-2.

Figure 7-5-2 Condition Query

7.8.2 Data Selection

Click the selected result which is highlighted. The highlighted sample SN 1001 is shown in Figure 7-6.

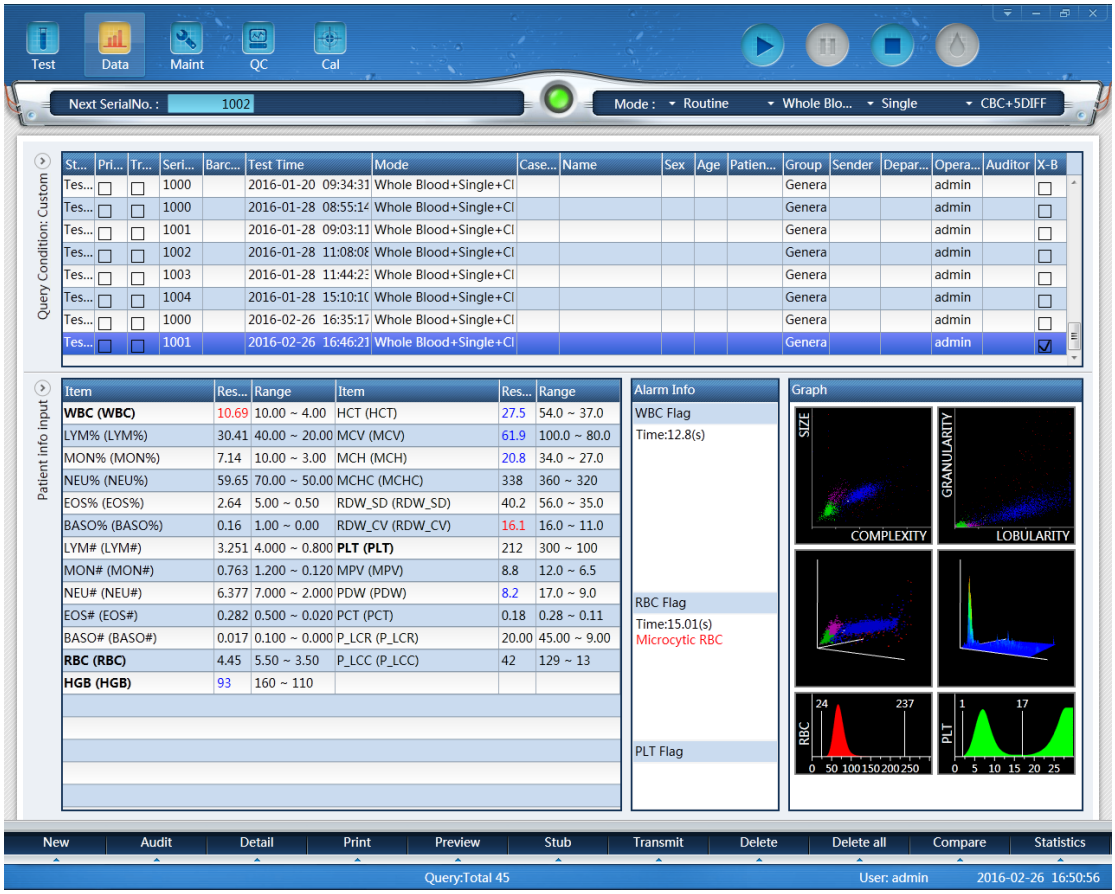


Figure 7-6 Single Result Selection

Select one sample data (such as SN 1001), click “Detail” or double-click the sample data directly, its detailed information comes out as shown in Figure 7-7.

Item	Result	Unit	Range	Hit	Item	Result	Unit	Range	Hit
WBC (WBC)	10.69	10^9/L	10.00 ~ 4.00	H	HCT (HCT)	27.5	%	54.0 ~ 37.0	L
LYM% (LYM%)	30.41	%	40.00 ~ 20.00		MCV (MCV)	61.9	fL	100.0 ~ 80.0	L
MON% (MON%)	7.14	%	10.00 ~ 3.00		MCH (MCH)	20.8	pg	34.0 ~ 27.0	L
NEU% (NEU%)	59.65	%	70.00 ~ 50.00		MCHC (MCHC)	338	g/L	360 ~ 320	
EOS% (EOS%)	2.64	%	5.00 ~ 0.50		RDW_SD (RDW_SD)	40.2	fL	56.0 ~ 35.0	
BASO% (BASO%)	0.16	%	1.00 ~ 0.00		RDW_CV (RDW_CV)	16.1	%	16.0 ~ 11.0	H
LYM# (LYM#)	3.251	10^9/L	4.000 ~ 0.800		**PLT (PLT)**	212	10^9/L	300 ~ 100	
MON# (MON#)	0.763	10^9/L	1.200 ~ 0.120		MPV (MPV)	8.8	fL	12.0 ~ 6.5	
NEU# (NEU#)	6.377	10^9/L	7.000 ~ 2.000		PDW (PDW)	8.2	fL	17.0 ~ 9.0	L
EOS# (EOS#)	0.282	10^9/L	0.500 ~ 0.020		PCT (PCT)	0.18	%	0.28 ~ 0.11	
BASO# (BASO#)	0.017	10^9/L	0.100 ~ 0.000		P_LCR (P_LCR)	20.00	%	45.00 ~ 9.00	
RBC (RBC)	4.45	10^12/L	5.50 ~ 3.50		P_LCC (P_LCC)	42	10^9/L	129 ~ 13	
HGB (HGB)	93	g/L	160 ~ 110	L					

Figure 7-7 Detail

Press and hold the "Ctrl" or "Shift" and click sample data which turns highlight as shown in Figure 7-8.

Figure 7-8 Multiple Data Selection

7.8.3 Data Deletion

After processing plenty of samples, it is necessary to clean up or delete the mass data stored in the analyzer according to the requirement of the operator. Both delete all and delete one are available.

NOTE

Be aware that once the data are deleted, it can NOT be recovered. Please operate with caution.

7.8.4 Precision

Check precision of each parameter of selected sample result, including Mean ($\bar{X}$), Standard Deviation (SD) and Variable Coefficient (CV). The calculation formulas are listed below.

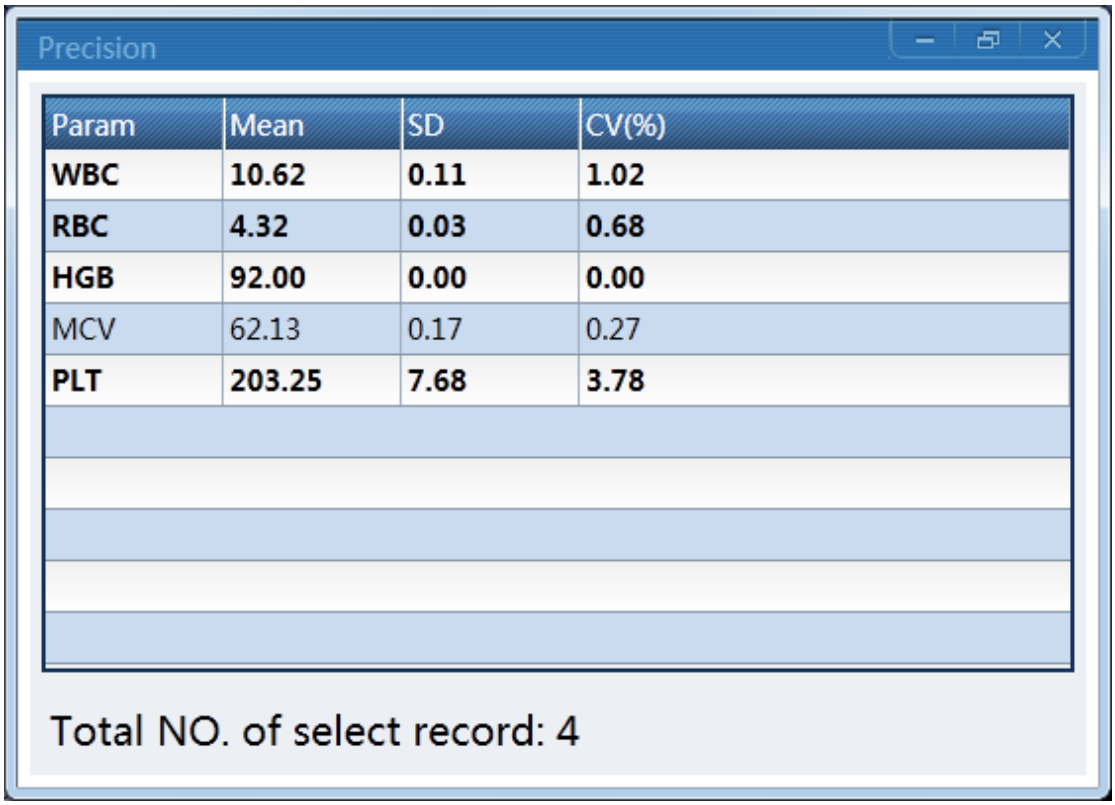
$$\bar{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$SD = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}\left(X_i - \bar{X}\right)^2}$$

$$CV = \frac{SD}{\bar{X}} \times 100\%$$

N is the number of selected samples, Xi is the results of i times for the specified parameters.

Choose the results that need to be calculated CV, right click and select “Precision”. See Figure 7-9.



Param	Mean	SD	CV(%)
WBC	10.62	0.11	1.02
RBC	4.32	0.03	0.68
HGB	92.00	0.00	0.00
MCV	62.13	0.17	0.27
PLT	203.25	7.68	3.78

Figure7-9 Precision

NOTE

- Only 30 index of precision can be calculated.
- "***"means invalid. If the parameter of selected sample is invalid, the precision is invalid too.

7.8.5 Data Comparison

The operator can compare those selected sample data via contrast diagram shown in Figure 7-10. After choosing sample results, click "Compare" to enter data comparison interface and view data comparison.

Compare

Item\SN	1(1020)	2(1021)	3(1022)	4(1023)	5(1024)	6(1025)	7(1026)	8(1027)	9(1028)
WBC (WIC)	**92.91**	**107.49**	**125.04**	**124.21**	**108.92**	**95.31**	**79.54**	**68.63**	**57.06**
WBC (WOC)	**106.27**	**122.10**	**134.66**	**134.74**	**120.45**	**109.03**	**96.01**	**82.60**	**67.98**
LYM% (LYM%)	24.73	27.70	26.92	25.70	25.14	26.42	26.92	27.07	26.50
MON% (MON%)	8.80	6.26	6.13	5.62	7.77	5.92	6.04	5.92	5.42
NEU% (NEU%)	63.57	62.93	64.15	65.94	64.79	65.06	64.50	64.00	65.85
EOS% (EOS%)	2.78	3.06	2.66	2.58	2.22	2.52	2.46	2.95	2.15
BASO% (BASO%)	0.12	0.05	0.14	0.16	0.08	0.08	0.08	0.06	0.08
LYM# (LYM#)	22.977	29.775	33.661	31.922	27.382	25.181	21.412	18.578	15.121
MON# (MON#)	8.176	6.729	7.665	6.981	8.463	5.642	4.804	4.063	3.093
NEU# (NEU#)	59.063	67.643	80.213	81.904	70.569	62.009	51.303	43.923	37.574
EOS# (EOS#)	2.583	3.289	3.326	3.205	2.418	2.402	1.957	2.025	1.227
BASO# (BASO#)	0.111	0.054	0.175	0.199	0.087	0.076	0.064	0.041	0.046
RBC (RBC)	**6.56**	**7.35**	**8.20**	**8.06**	**7.40**	**6.54**	**5.75**	**5.08**	**4.28**
HGB (HGB)	**137**	**151**	**168**	**166**	**153**	**138**	**120**	**105**	**90**
HCT (HCT)	40.4	45.3	50.9	49.6	45.6	40.1	34.9	30.8	25.8
MCV (MCV)	61.7	61.7	62.1	61.6	61.7	61.4	60.8	60.7	60.3
MCH (MCH)	20.8	20.5	20.4	20.5	20.6	21.1	20.8	20.6	21.0
MCHC (MCHC)	339	333	330	334	335	344	343	340	348
RDW (RDW)	17.4	17.5	17.3	16.8	17.5	17.5	17.7	17.7	17.9
RDW_SD (RDW_SD)	57.4	57.4	57.4	56.3	57.4	57.4	56.3	56.3	56.3
RDW_CV (RDW_CV)	17.4	17.5	17.3	16.8	17.5	17.5	17.7	17.7	17.9
PLT (PLT)	**1095**	**1261**	**1390**	**1405**	**1253**	**1100**	**992**	**859**	**696**
MPV (MPV)	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
PDW (PDW)	6.1	6.4	6.4	6.4	6.1	6.4	5.7	5.7	5.4
PCT (PCT)	0.54	0.63	0.69	0.70	0.62	0.55	0.49	0.42	0.34
P_LCR (P_LCR)	12.10	12.63	14.74	12.67	12.12	15.85	12.53	15.75	18.45
P_LCC (P_LCC)	132	159	205	178	152	174	124	135	128
WBC Time(S)	11.59	11.57	11.57	11.58	11.60	11.57	11.58	11.55	11.57
RBC Time(S)	13.68	13.81	13.70	13.67	13.82	13.63	13.75	13.75	13.68

Display graphics

Figure7-10 Data Comparison

7.9 Reticulocyte Analysis

Click "Test" after putting the prepared reticulocyte sample in the emergency sampling position. See Figure 7-11. Input the serial No. and RBC value and click "Test", see Figure 7-12.

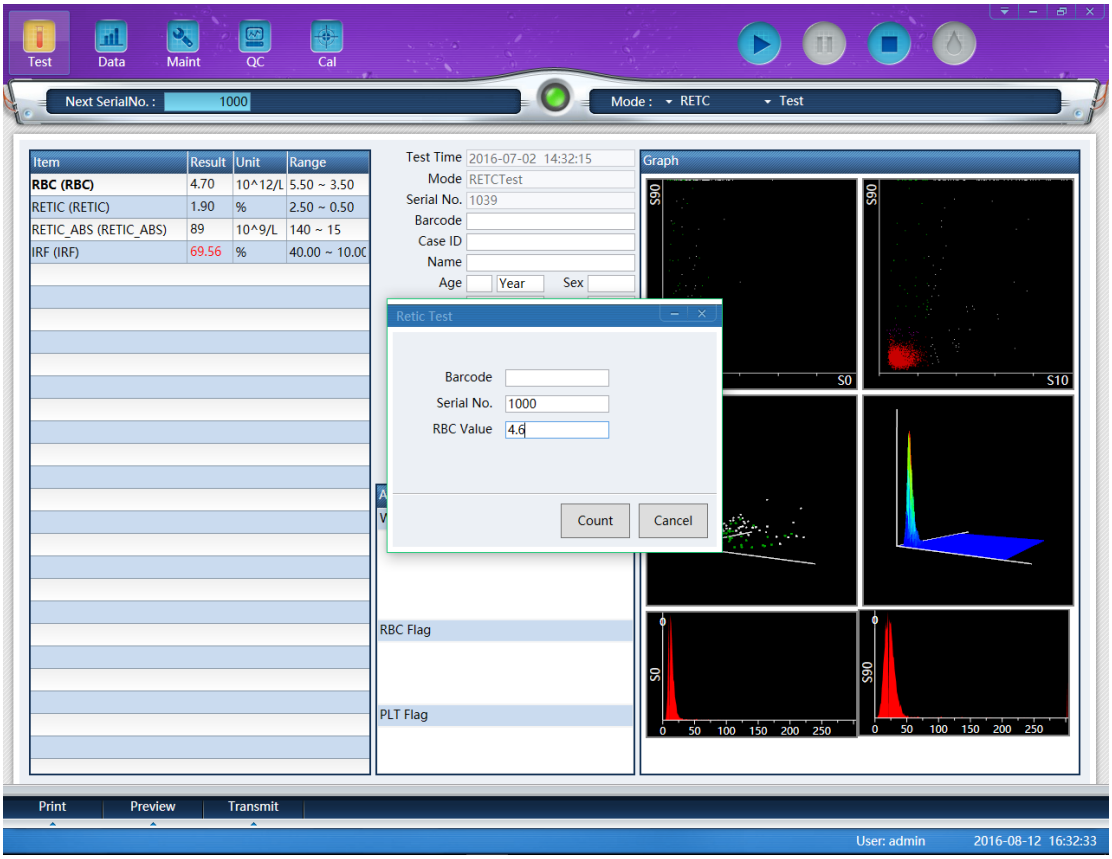


Figure 7-11 Reticulocyte Analysis

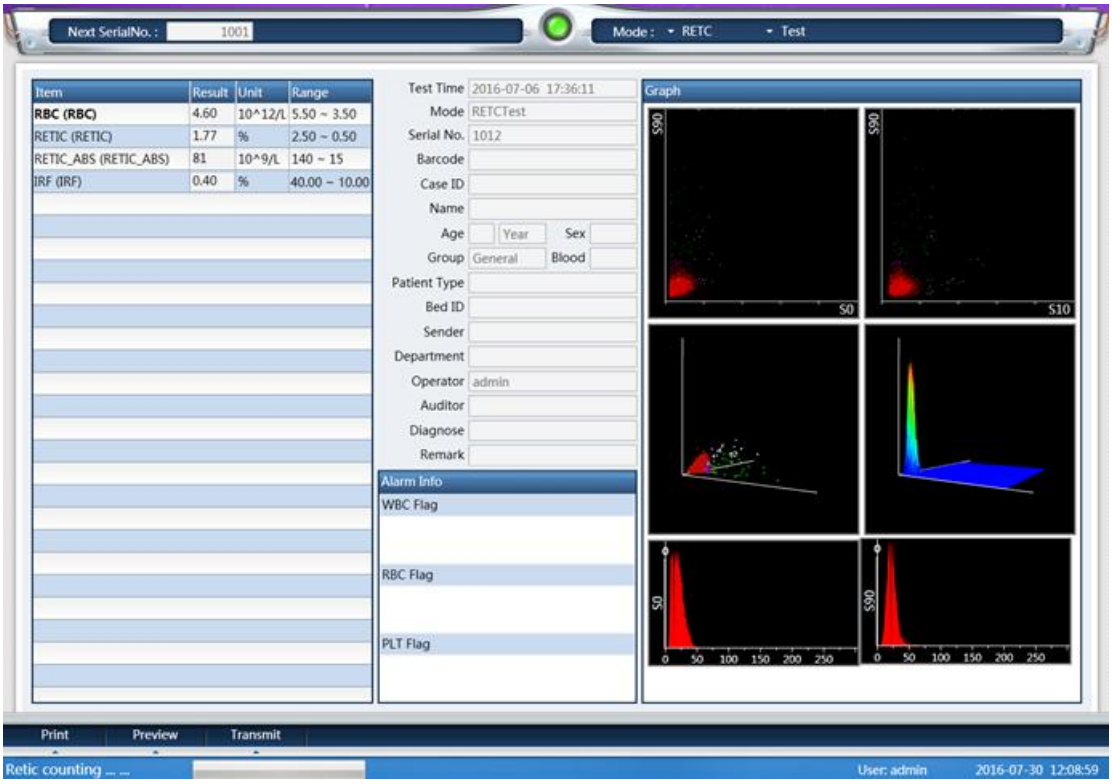


Figure 7-12 Reticulocyte Analysis

7.10 Statistics

Click “Statistics” to enter statistics interface (See Figure 7-13). Operation procedure is as follows.

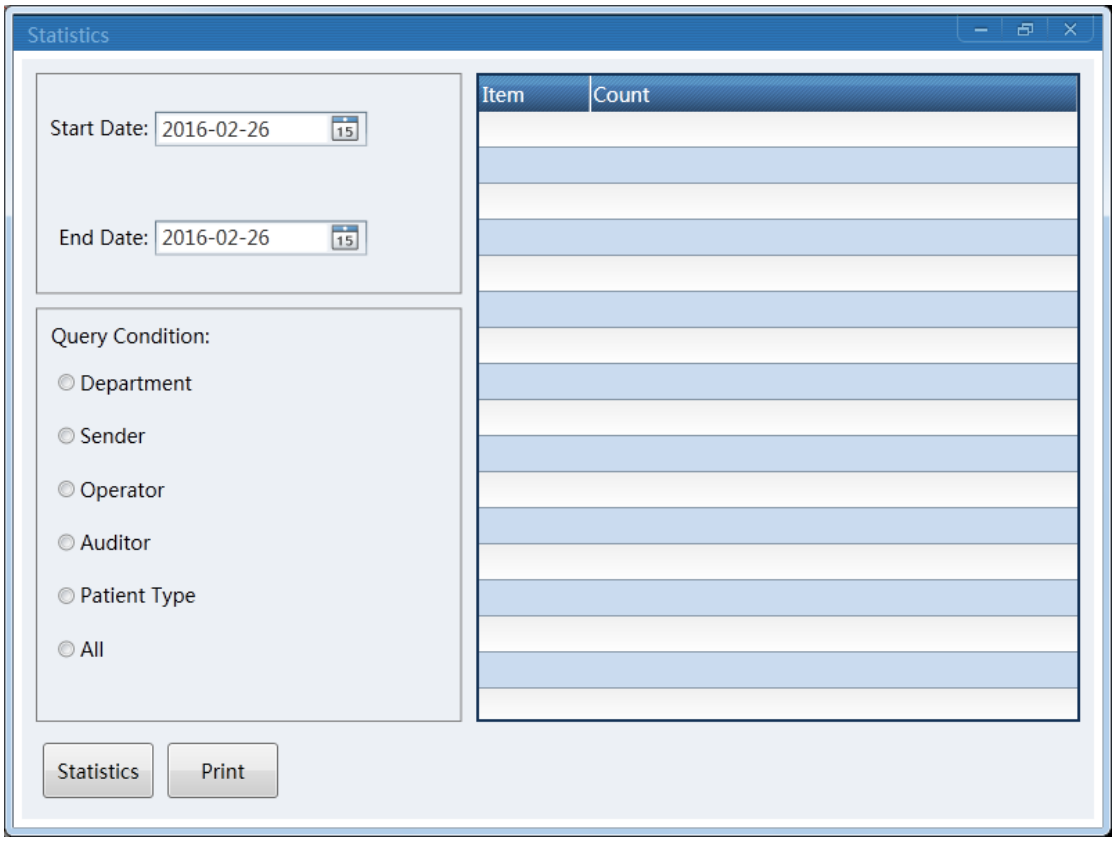


Figure 7-13 Statistics interface

（1） Click to select “Start Date” and “End Date”. See Figure 7-14.

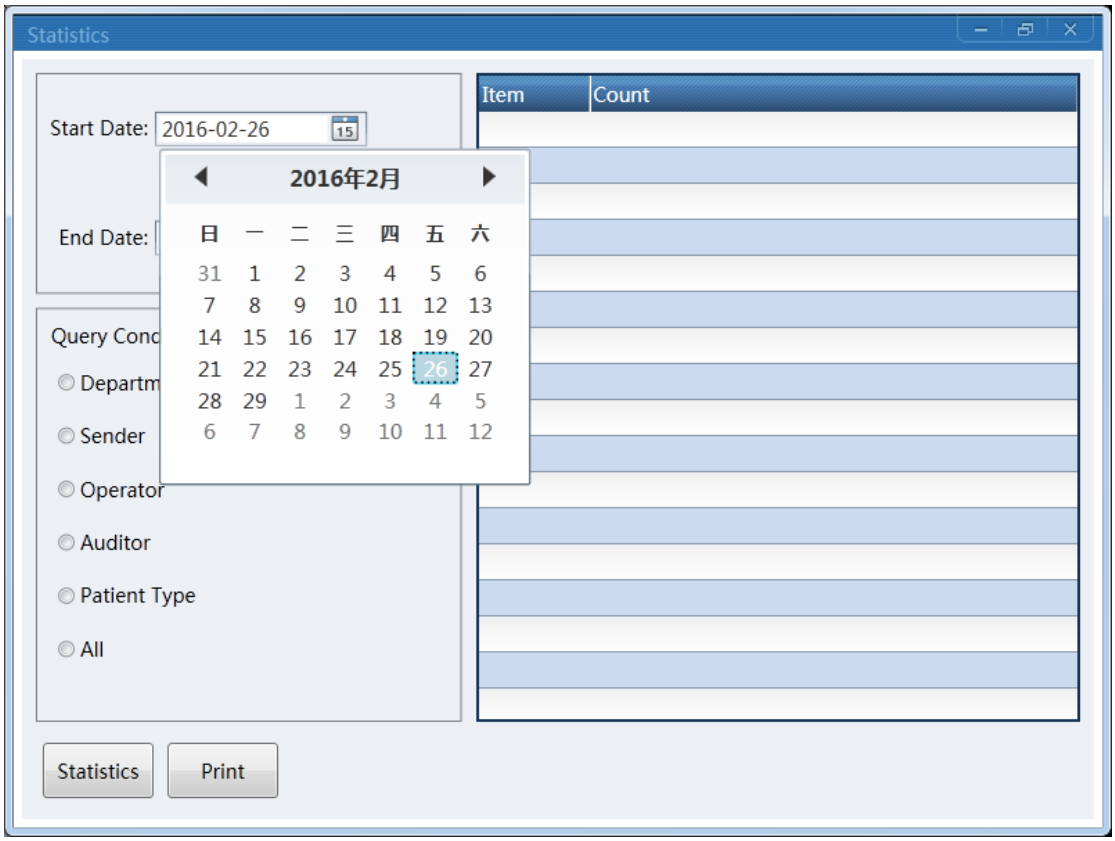


Figure 7-14 Data Selection

（2） Select “Query Condition” such as Department and Sender.

（3） Click “Statistics”, the chosen items and its statistical results are listed in the right list.

（4） Click “Print” to print results.

7.11 Shutoff

After finishing testing all samples, please do the shutoff procedure which is to clean the counting chambers and related channels. If continuously using the analyzer or finishing tests at the end of a day, shutting off procedure should be performed at least once every 24 hours.

Procedures of shutoff

1 Click

2 Confirmation dialog popsup

3 Check whether the procedure of shutoff is finished, the close dialog box is shown or not.

4 Turn off the power of the analyzer and the computer

CAUTION

Data loss and abnormal boot may be caused if the shutoff procedures are not performed.

Chapter 8 Quality Control

8.1 Overview

It' probably leads to unreliable results for a long time use. In order to maintain accurate count and analysis and eliminate system errors, it's necessary to perform quality control (QC).

It's better to use low, normal and high quality control materials to perform QC respectively every day. At least run the normal control in daily use. When using quality control materials of new batch, please use it together with the existing quality control materials for 5 days, twice per day, and the results should be within the range of parameters of the control instruction.

It suggests use URIT quality control materials and run QC in the following conditions.

- After daily start-up procedures completed
- The reagent batch number changed
- After calibration
- After maintenance, or component replacement
- In accordance with the laboratory or clinical QC protocol
- In suspicion of abnormal parameter value

CAUTION

Considering all the clinical specimens, control materials and calibrators that contain human blood or serum as being potentially infectious, wear lab coats, gloves and safety glasses and follow required laboratorial or clinical procedures when handling these materials.

NOTE

Ensure to perform the following procedure before using the control materials which is removed from the refrigerator.

1. Leave it for 15 minutes to reach room temperature (15°C-35°C).
2. Rub the vial for 10 times.
3. And gently mix the vial upside down for a dozen times.
4. Repeat step 2 and 3 for twice or 3 times or for 2 minutes.

8.2 Quality Control Options

This analyzer provides four QC methods, which are L-J QC mode, X-B QC mode, X-R QC mode and X QC mode.

1. L-J QC

L-J QC (Levey-Jennings graph) is a simple and visual QC method with which operator can draw QC value directly on graph after getting the Mean, SD (standard deviation) and CV (coefficient of variation). $\bar{X}$, SD and CV are derived from following formulas.

$$\bar{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$\text{SD}= \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}\left(X_i - \bar{X}\right)^2}$$

$$CV = \frac{SD}{\bar{X}} \times 100\%$$

2. X-R QC

In X-R QC method, X indicates mean value, R indicates range of value. X graph is mainly used to judge that if the mean value falls in required level. R graph is mainly used to judge that if the range of value falls in required level.

3. X QC

X QC is the variation of X-R QC, they have the same basic principle. The difference is that the control dot in X graph indicates the mean value of two values other than one value. On this foundation, it calculates the Mean, SD and CV.

4. X-B QC

X-B QC is a moving average method which is first promoted in 1970s'. It's based on the principle that, RBC count is varied due to the concentration of dilution, human blood pathology and technical factor, but the hemoglobin content in specific unit is hardly interfered by those preceding factors.

According to this characteristic, quality control of the samples is being done by surveying the value of MCV, MCH, and MCHC.

8.3 QC Mode Selection

Click “QC” to enter relevant interface as shown in Figure 8-1.

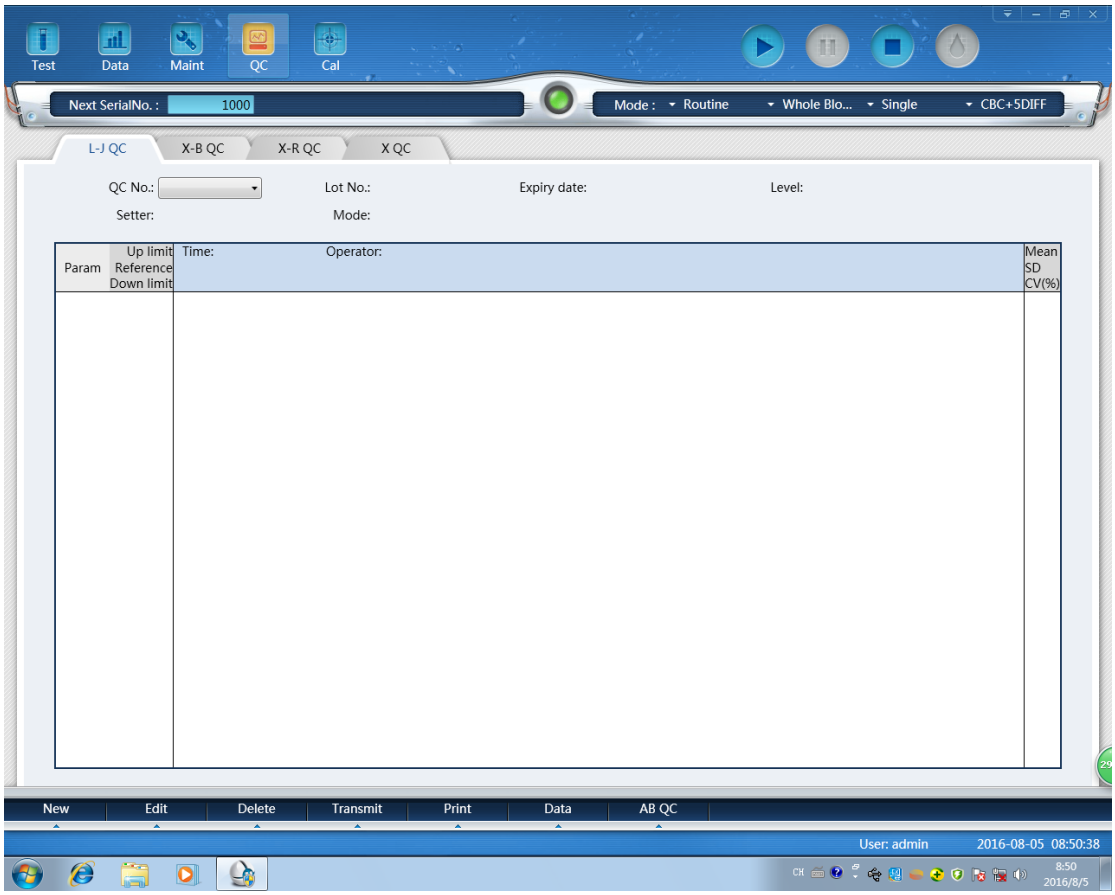


Figure 8-1 QC Mode Selection

There are four QC options, L-J QC, X-B QC, X-R QC and X QC. Select it and click relevant button to enter corresponding interface.

8.4 L-J QC

In L-J QC, the operator could perform QC with 28 test parameters. Considering the different needs, selecting partial parameters for QC is available. 3 QC levels for each of high, normal and low are provided.

8.4.1 L-J QC Edit

Click “L-J QC” to enter corresponding edit interface. Click “New” to enter edit interface in other interface. Input control lot NO., expiry data and level, reference value and SD according to the manual.(See Figure 8-2)

Please note that the SD should not be more than 40% of reference, or,

the new SD cannot be saved in database.

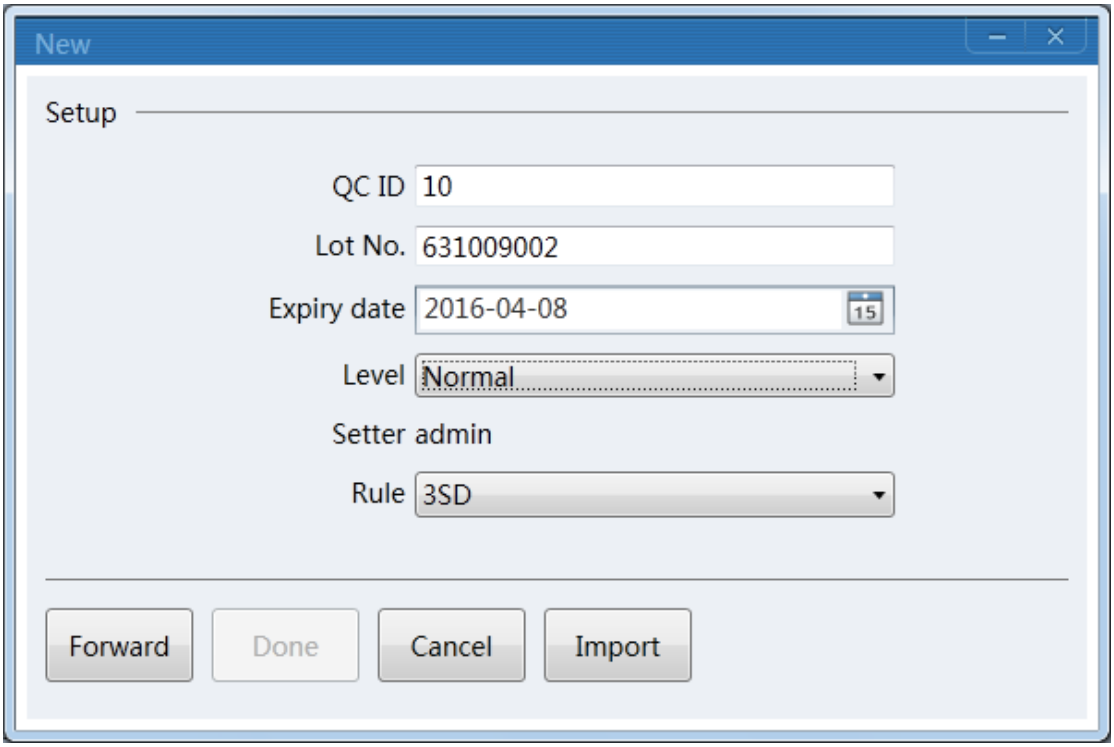


Figure 8-2 L-J QC Edit Interface 1

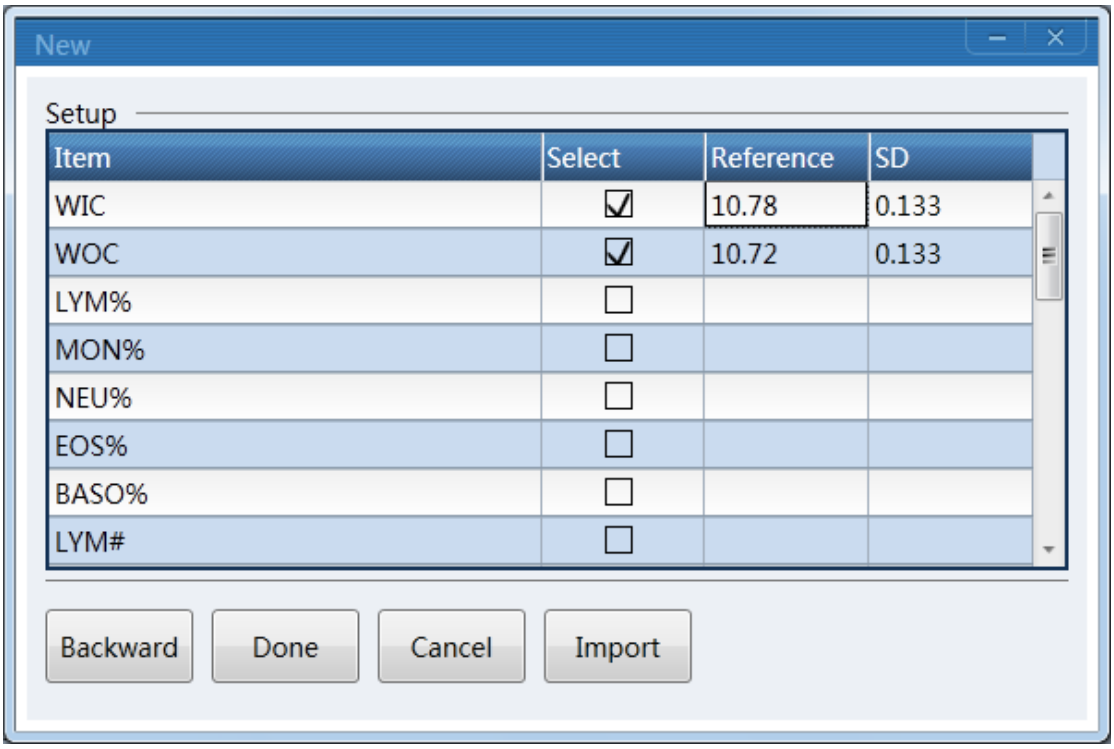


Figure 8-2 L-J QC Edit Interface 2

Click “Done” after editing. Interface shown as Figure 8-3 displays.

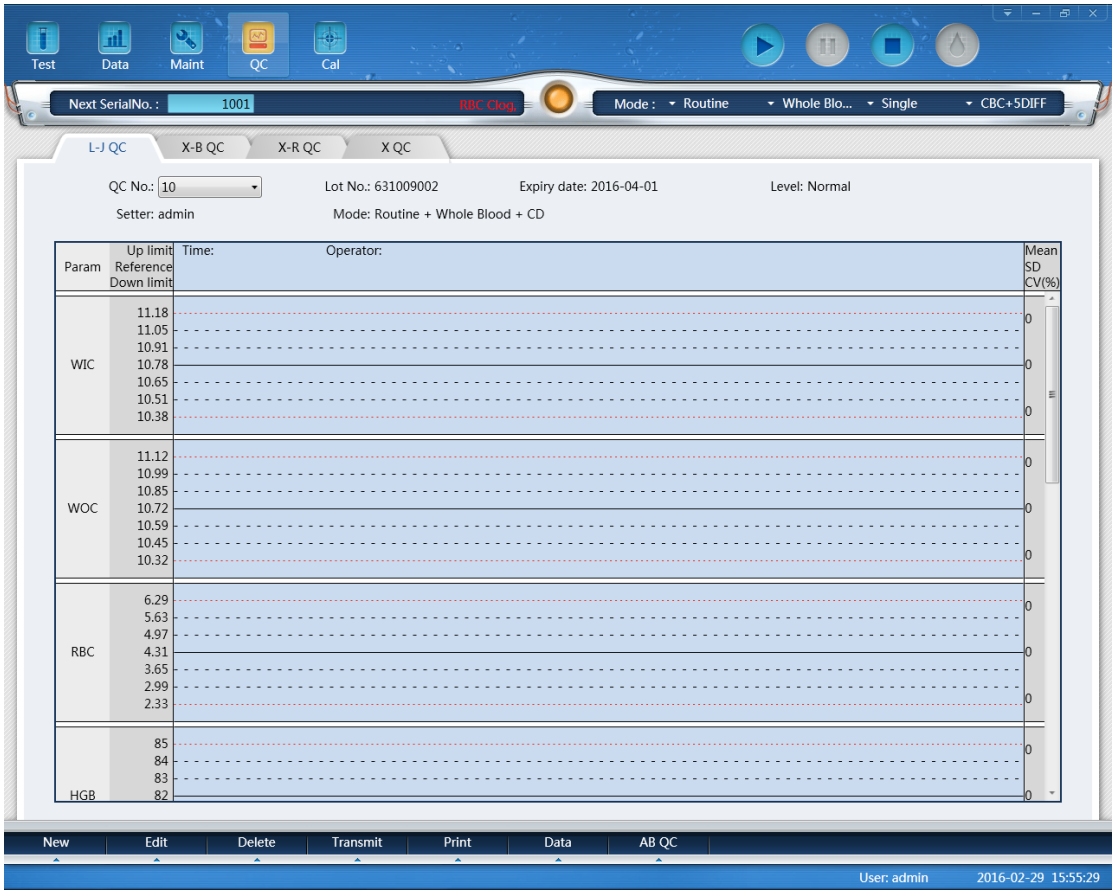


Figure 8-3 Interface

8.4.2 L-J QC Run

Click “Test” in L-J QC interface, see Figure 8-4.

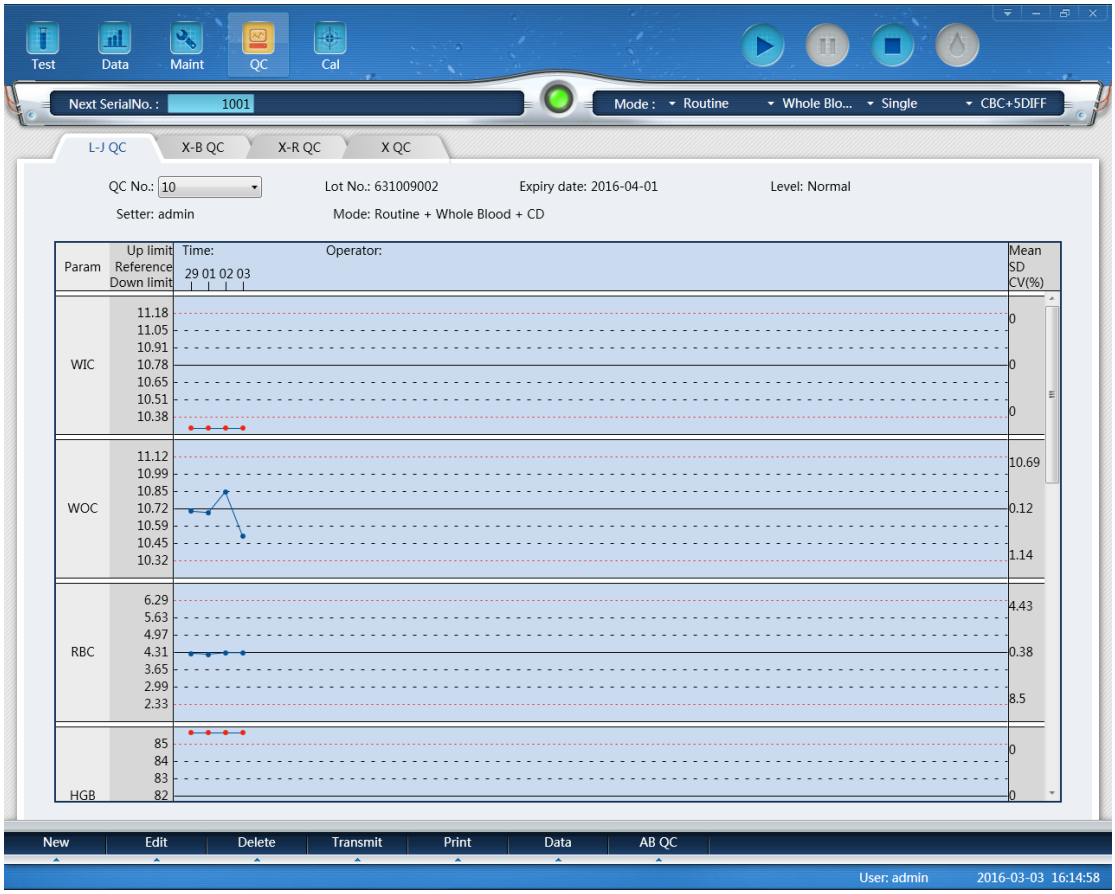
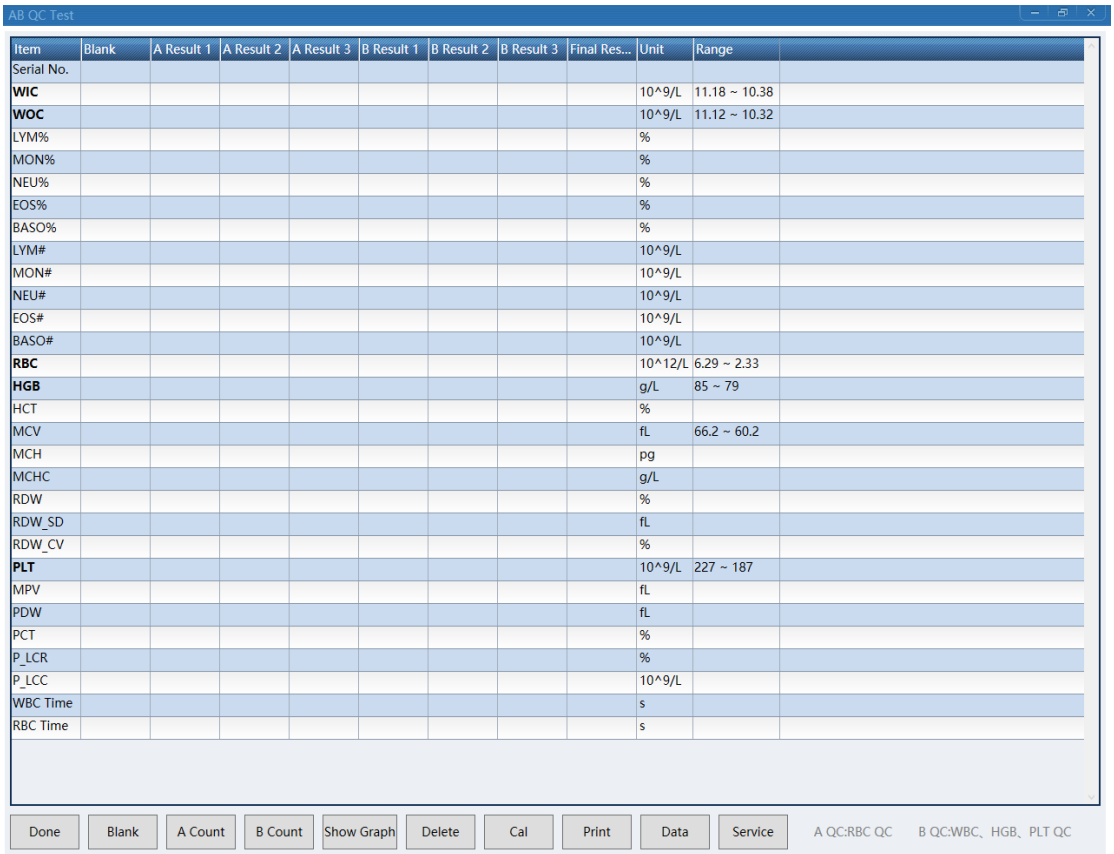


Figure 8-4 L-J QC Run

8.4.3 AB QC Run

Click “AB QC” in L-J QC interface, running the AB QC test. Click “Done” to go back to the QC interface.



Item	Blank	A Result 1	A Result 2	A Result 3	B Result 1	B Result 2	B Result 3	Final Res...	Unit	Range
Serial No.										
WIC									10^9/L	11.18 ~ 10.38
WOC									10^9/L	11.12 ~ 10.32
LYM%									%	
MON%									%	
NEU%									%	
EOS%									%	
BASO%									%	
LYM#									10^9/L	
MON#									10^9/L	
NEU#									10^9/L	
EOS#									10^9/L	
BASO#									10^9/L	
RBC									10^12/L	6.29 ~ 2.33
HGB									g/L	85 ~ 79
HCT									%	
MCV									fL	66.2 ~ 60.2
MCH									pg	
MCHC									g/L	
RDW									%	
RDW_SD									fL	
RDW_CV									%	
PLT									10^9/L	227 ~ 187
MPV									fL	
PDW									fL	
PCT									%	
P_LCR									%	
P_LCC									10^9/L	
WBC Time									s	
RBC Time									s	

Figure 8-5 AB QC Test

8.4.4 L-J QC Graph Analysis

Check whether the analyzer is within control in L-J QC interface, as shown in Figure 8-6.

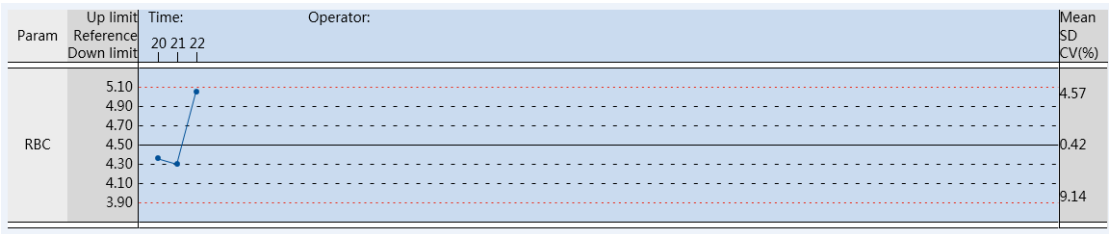
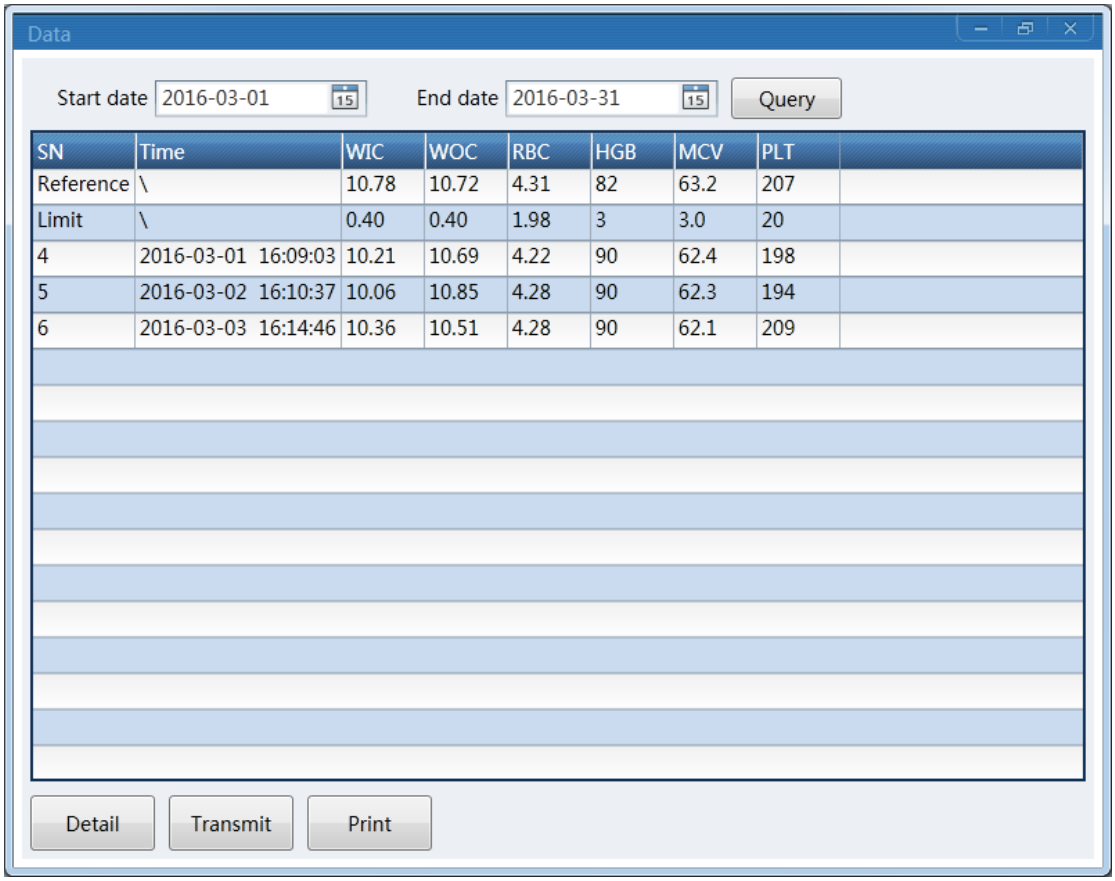


Figure 8-6 L-J QC Graph Analysis

8.4.5 L-J QC Data Query

In the L-J QC interface, click “Data” to enter data query interface as shown in Figure 8-7.



SN	Time	WIC	WOC	RBC	HGB	MCV	PLT
Reference	\	10.78	10.72	4.31	82	63.2	207
Limit	\	0.40	0.40	1.98	3	3.0	20
4	2016-03-01 16:09:03	10.21	10.69	4.22	90	62.4	198
5	2016-03-02 16:10:37	10.06	10.85	4.28	90	62.3	194
6	2016-03-03 16:14:46	10.36	10.51	4.28	90	62.1	209

Figure 8-7 L-J QC Query Interface

8.5 X-B QC

X-B QC is different to others, only three parameters are edited, which are MCV, MCH and MCHC. It is a QC without control materials and a means of monitoring analyzer like controls, but they can't replace each other.

Please run X-B QC when the quantity of samples is more than 100. X-B QC is for the use of random sample, not for classification samples. Observed the trend of QC result in reference range which is made up by reference, upper and lower limit.

8.5.1 X-B QC Edit

Finish the QC editing before QC analysis.

1. In the main interface, click "QC"-"X-B QC" to enter relevant interface.
2. Click "Setup" and input "Reference" and "SD".
3. Input the number of required samples of X-B QC point. The range of selection is 20 to 200, URIT recommends the number is 20.
4. Tick "Open X-B" to use the X-B mode.

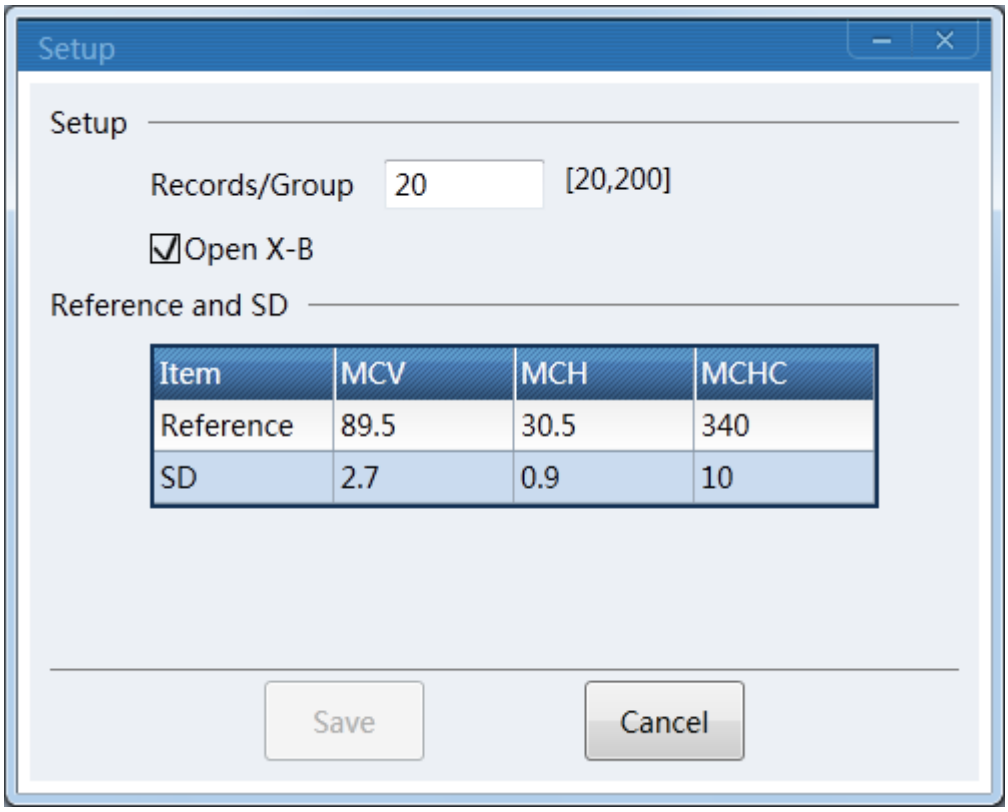


Figure 8-8 X-B QC Setup

8.5.2 X-B QC Run

When finish QC edit, click “Test” to operate quality control. The system automatically operates a QC calculation after analyzing 20~200 samples (according to your setting), and get a QC point that corresponds with each reference of X-B QC and save it in X-B QC graph and X-B QC list.

8.5.3 X-B QC Graph Analysis

Operator can review QC results of three parameters through graphs. After the count of group samples completed, the results of MCV, MCH and MCHC depict a dot on the graph. For example, the “Open X-B” is chosen and “Records/Group” is 20. After the subsequent 20 counts, the system calculates a X-B QC value and a corresponding control dot which displays on the graph.

There are three graphs of MCV, MCH and MCHC. The graphs updates at once after each QC counting. QC results are arranged in graphs according to storage time. The latest is on the left side and its serial number is 1.

QC Graph Instruction

（1） It’s a graph with times of QC count on horizontal axis and results of QC count on vertical axis.

（2） Every parameter graph displays many dots.

（3） The above line of every parameter graph means Reference plus SD.

（4） The below line of every parameter graph means Reference value subtract SD.

If the QC point is between upper and lower limit of the corresponding graph, it means that it's under control range, If not, the QC point is not under control range.(see Figure 8-8)

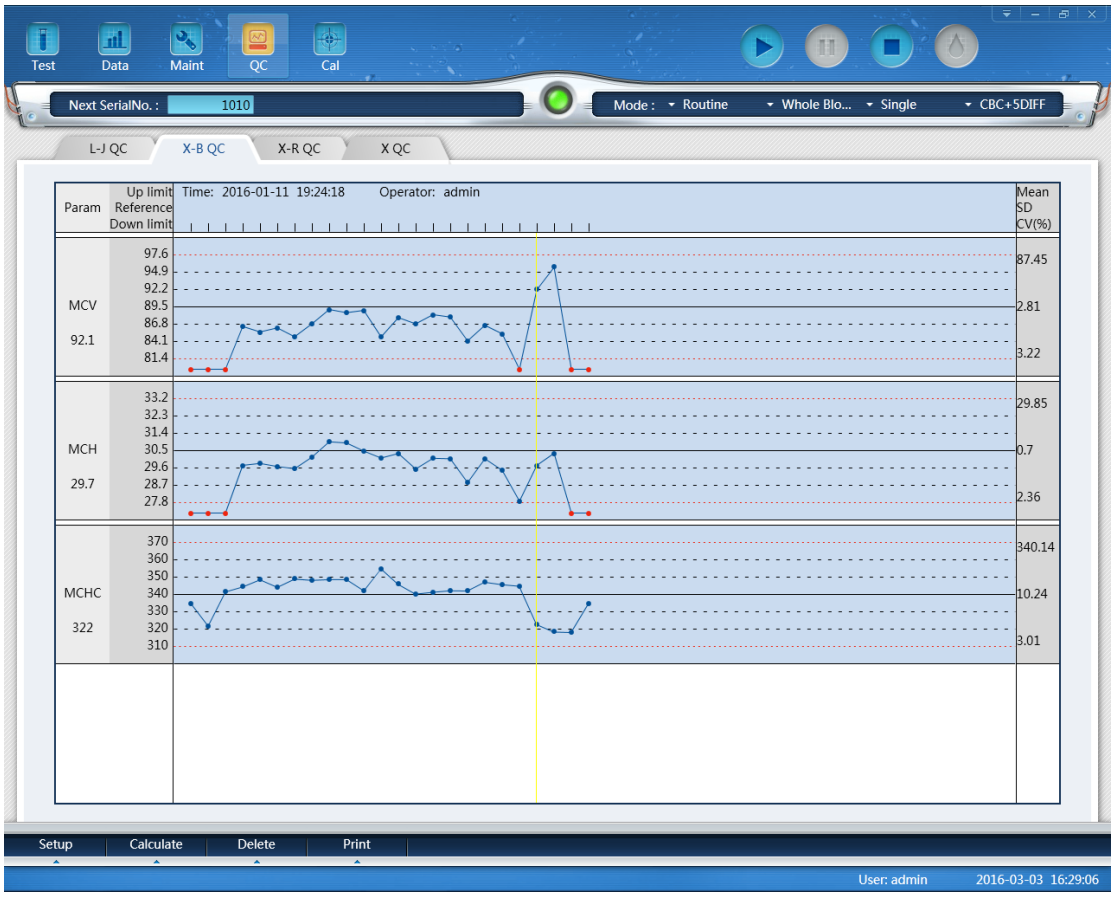


Figure 8-9 X-B QC Graph

8.6 X-R QC

X-R QC which has the control material is one of the methods of QC. If running a blank count, the system alarms that QC count result is invalid.

8.6.1 X-R QC Edit

Before QC analysis, operator should finish QC Edit as follows.

1. Click "QC" in main interface, then click "X-R QC"-"New" to enter X-R QC Edit/Run interface. (See Figure 8-10).

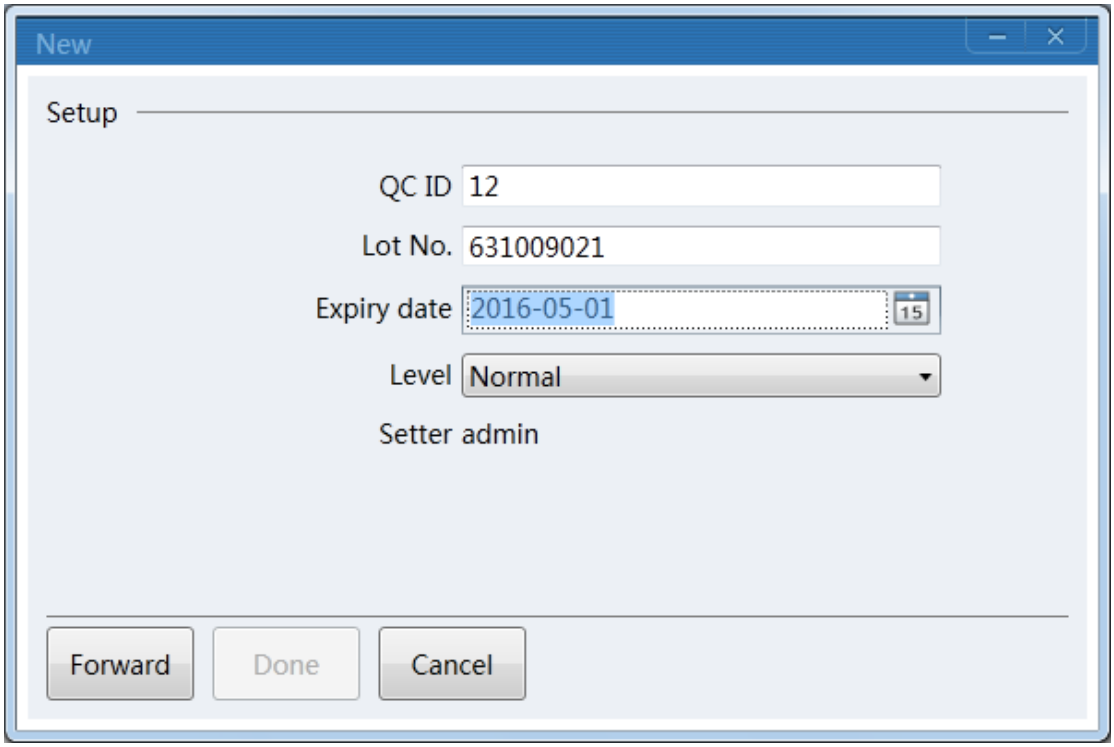


Figure 8-10 QC Edit/Run 1

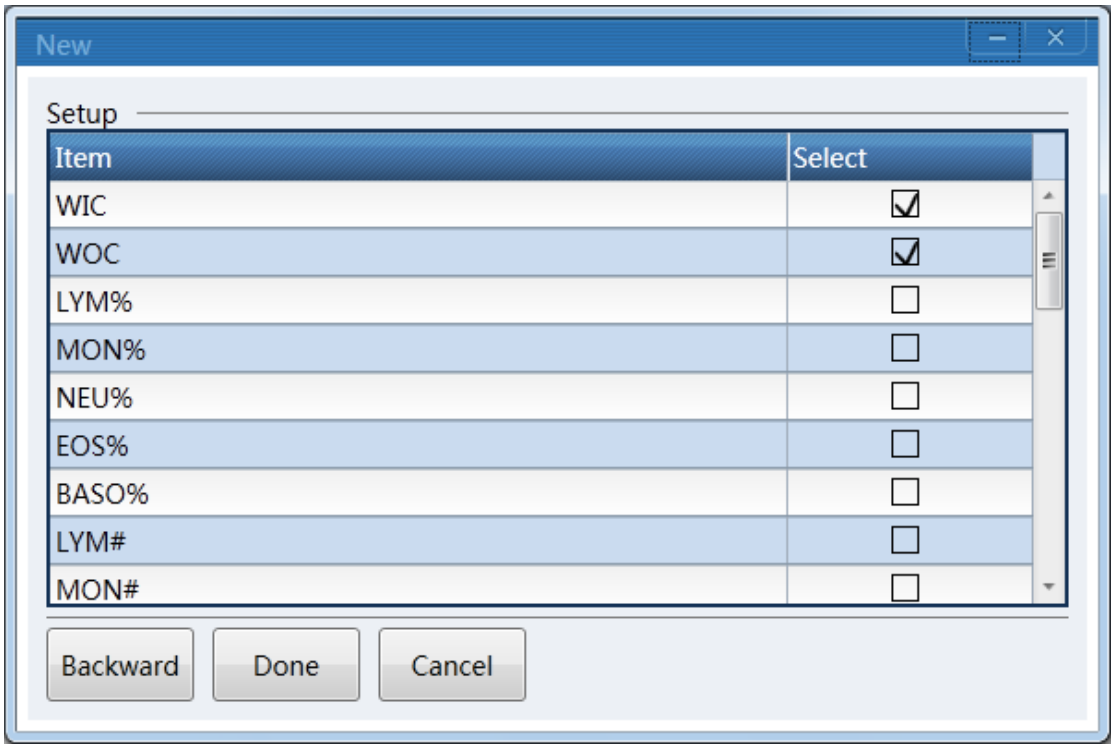


Figure 8-10 QC Edit/Run 2

2. Select corresponding levels (Low, Normal and High).
3. Input “Lot No.”, and select “Expiry date” according to Operation Manual.

8.6.2 X-R QC Run

When finishing QC Edit, click “Test” to start QC analysis.

In QC interface, system displays twice control results and automatically calculates twice mean and range after finishing the second QC count.

8.6.3 X-R QC Graph Analysis

X-R QC is similar to X QC. Operator can review QC results of 28 parameters through QC graphs. Click “X-R QC” to enter graph analysis interface. (See Figure 8-11).

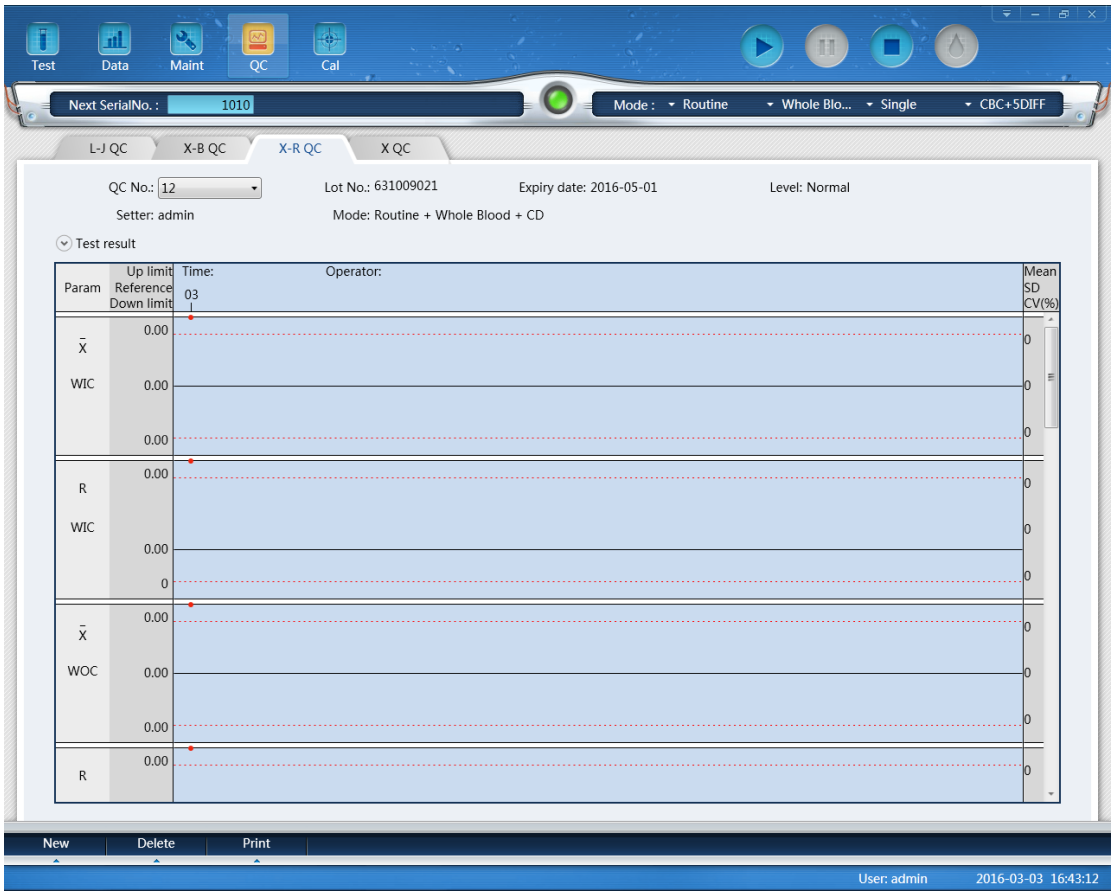


Figure 8-11 X-R QC graphs

The difference between X-R QC and X QC is that each dot at X-R QC Graph indicates mean value or range of two QC results. The system cannot display low, normal and high control graphs simultaneously in one interface, please select Level to change.

In X-R QC interface, there are X graph and R graph. X graph displays the mean value dot while the R graph displays the range dot.

If operator selects “Low” and do QC test twice, the dot is within X graph corresponding with low level. It also fits for the dots of other groups—the dot correspond with range is within corresponding R graph.

QC results are arranged in QC graph according to storage time, the latest is on the left side and its serial number is 1.

X graph Instruction

（1） Graph abscissa indicates QC run times, ordinate indicates QC result.
（2） Every parameter graph can display at most many dots.
（3） Every parameter graph's center line indicates X (overall mean value of QC results).
（4） Above line of every parameter graph means X upper limit＝X＋A×R.
（5） Below line of every parameter graph means X lower limit＝X－A×R.
（6） The 3 values on the left side of parameter graph mean
a) upper limit —— X upper limit＝X＋A×R
b) middle line —— X
c) lower limit —— X lower limit＝X－A×R

R graph Instruction

（1） It's a graph with QC times on horizontal axis and QC results on vertical axis.
（2） Every parameter graph display many dots.
（3） Every parameter graph's center line indicates R (mean value of QC result range).
（4） Above line of every parameter graph means R upper limit＝B×R.
（5） Below line of every parameter graph means R lower limit＝C×R.
（6） The 3 values on the left side of parameter graph mean
a) upper limit —— R upper limit＝B×R
b) middle line —— R
c) lower limit —— R lower limit＝C×R

If the control dot falls in the area between above and below lines, it means the dot is under control range. If not, the dot is not under control range.

8.6.4 X-R QC Data Query

When finish QC count, operator can review QC result of 28 parameters through QC graphs. See Figure 8-12.

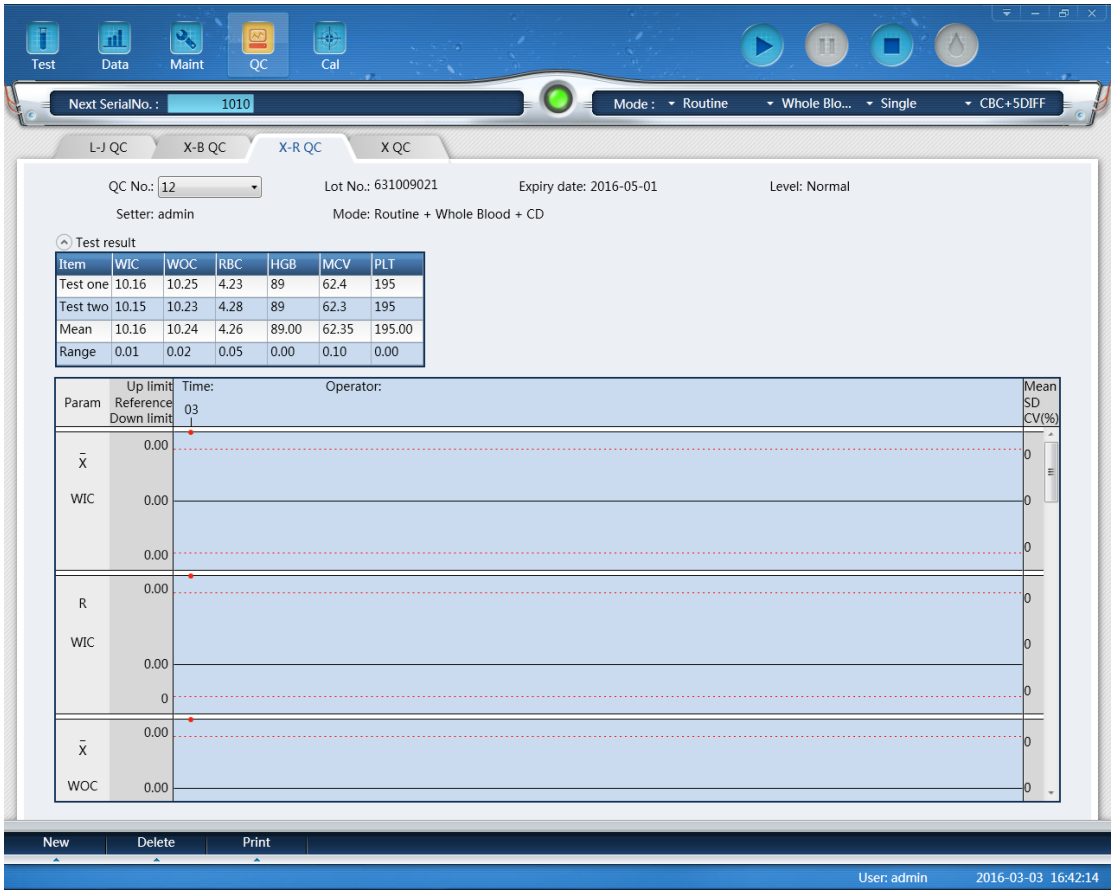


Figure 8-12 X-R QC Query Interface

The difference between X QC and L-J QC Query is that X QC results include mean value and range, and the total mean and average range is shown in QC recalling table.

The QC data would update after running two new controls.

8.7 X QC

X QC which has the control material is one of the methods of QC. The analyzer aspirates control material to operate QC. The operator could perform QC to 28 parameters. Considering the different needs, it is available to do the QC to some parameter. 3 QC documents of high, normal and low are provided for saving.

8.7.1 X QC Edit

Before QC analysis, operator should finish QC Edit as the follows.

1. Click “New” in “X QC”, see Figure 8-13.

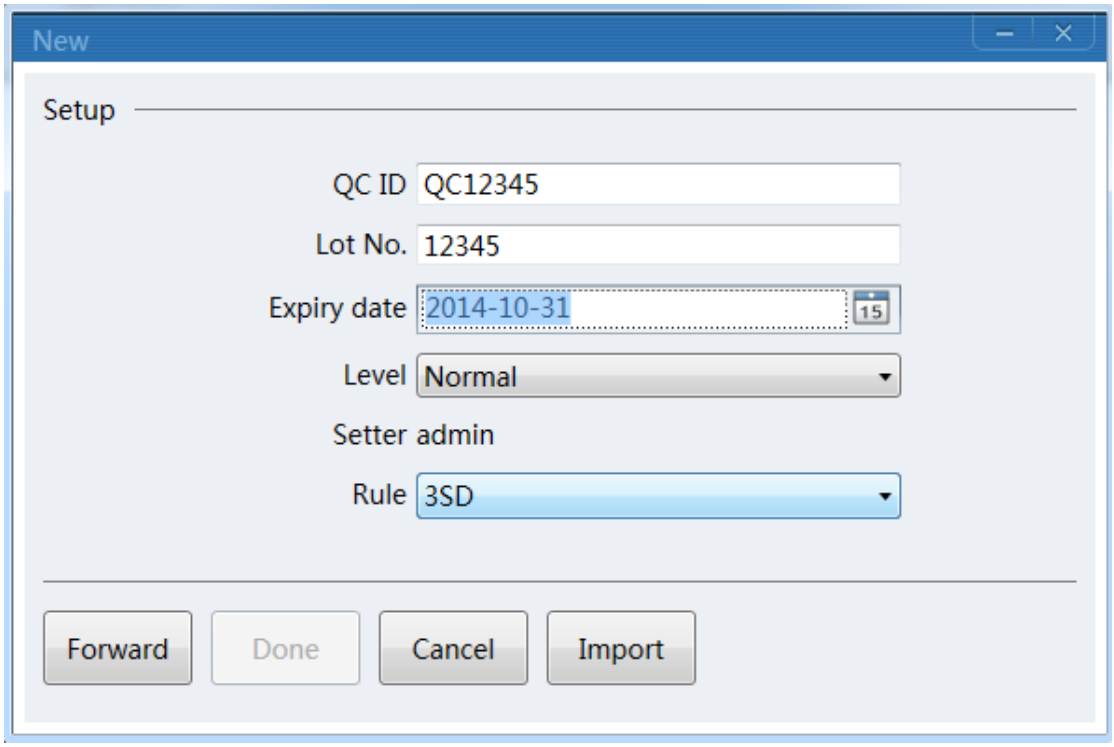


Figure 8-13 X QC Edit Interface 1

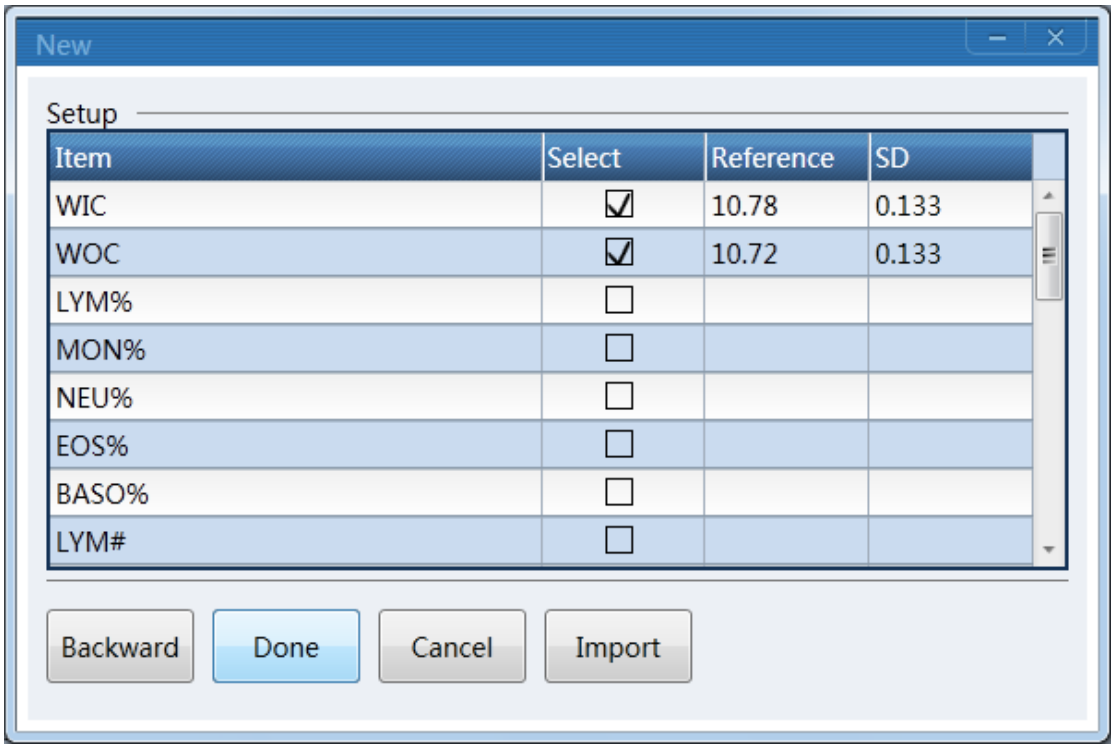


Figure 8-13 X QC Edit Interface 2

2. Select corresponding level (Low, Normal and High).
3. Input “Lot No.”, and select “Expiry date” according to Operation Manual.
4. Input “Reference” and “SD” according to Operation Manual.

After QC Edit, click “Done” to save your edit, click “Cancel” to cancel your edit.

8.7.2 X QC Run

System automatically enter X QC interface after editing. (See Figure 8-14)

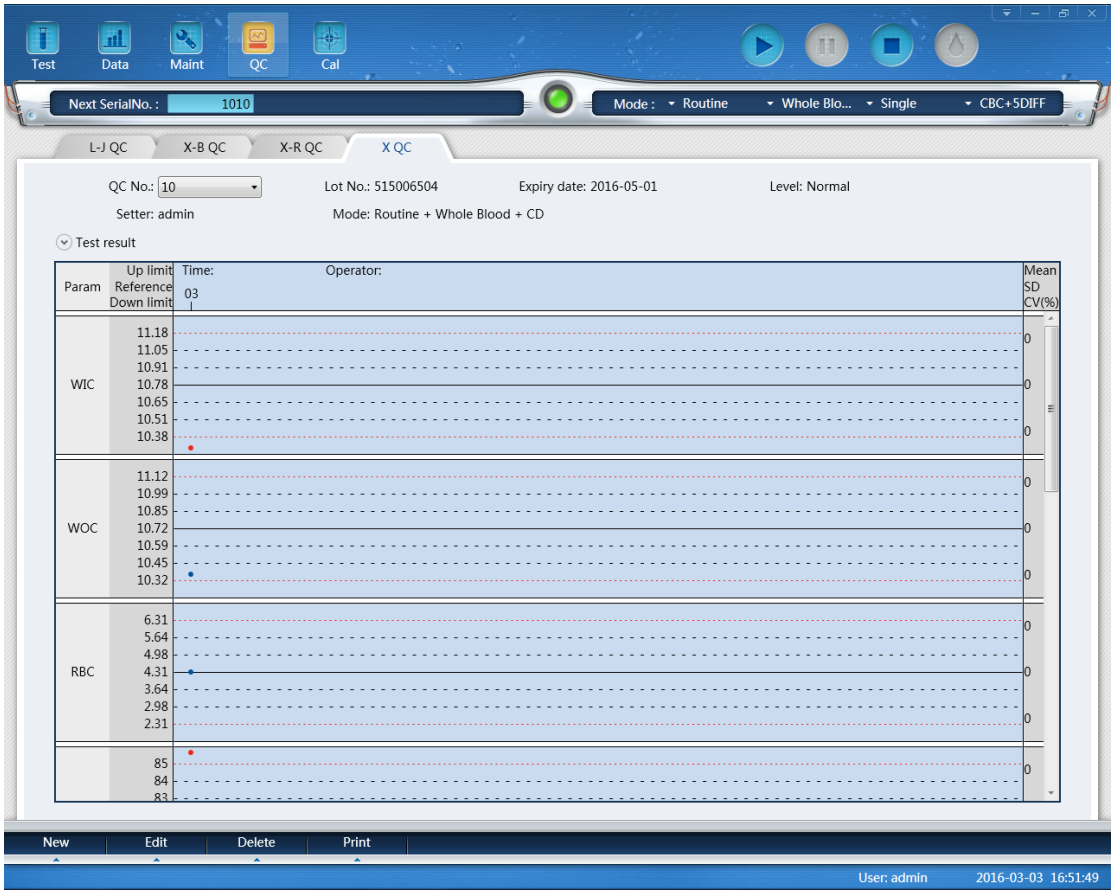


Figure 8-14 X QC

In QC interface, system displays two control results, and calculates the mean value automatically after finishing the second QC count. The column of mean value show the mean value, the column of reference range show reference range that user input in the QC Edit.

In the QC Run interface, place the prepared control in Emerge place, the analyzer automatically aspirates the control materials to start analysis. If the reference value of current group is empty, the system alarms and cannot run the QC count. Back to QC edit interface, input QC reference value and SD for running QC count.

If running a blank QC, the system alarms QC result is invalid.

8.7.3 X QC Graph Analysis

After QC Run, operator can review QC results of 28 parameters through QC Graph. See Figure 8-15.

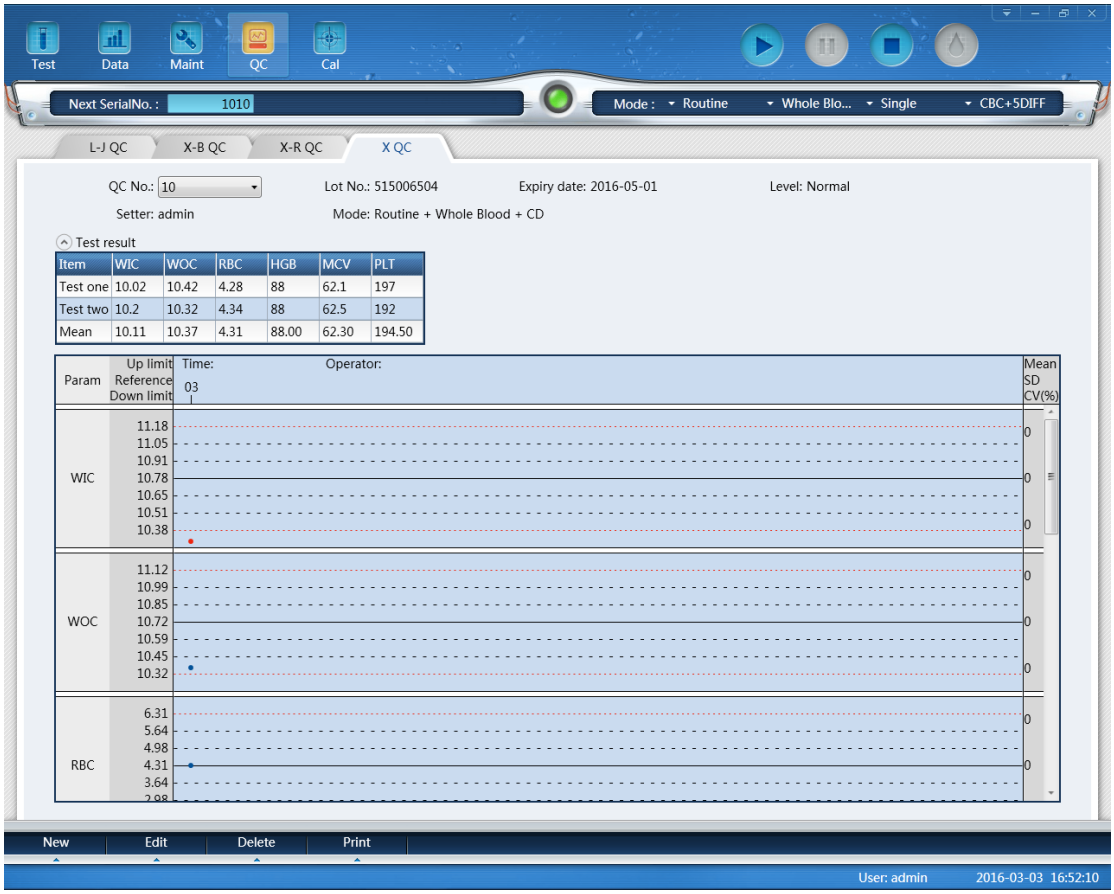


Figure 8-15 X QC Analysis

The dot on the X QC Graph indicates mean value of two QC results. There are low, normal and high graphs. If select “Low” to run a control sample, the control dot presents in low graph. Other selections present in corresponding graph.

QC results are arranged in graphs according to storage time. The latest is on the left side and its serial number is 1.

QC graph Instruction

（1） It’s a graph with QC times on horizontal axis and QC results on vertical axis.

（2） Every parameter graph displays at most 31 dots.

（3） Above line of every parameter graph means Reference plus SD.

（4） Below line of every parameter graph means Reference subtract SD.

（5） The 3 values on the left side of parameter graph mean.

a) upper limit ——Reference + SD

b) middle line ——Reference

c) lower limit ——Reference - SD

If the control dot falls in the area between above and below lines, it means the dot is under control range. If not, the dot is not under control range.

Chapter 9 Calibration

9.1 Overview

Analyzer is detected and calibrated before delivery. For some reasons the result may be a little out of the range. Calibration is to insure the accuracy of results. Calibration is a process to standardize the analyzer by its deviation of value and parameter, calibration factor.

The analyzer provides three calibration modes, which are “Standard Cal”, “Blood Cal” and “Manual Cal”.

CAUTION

- Only calibrators recommended by URIT can be used to accomplish the calibration.
- Follow the use instruction to store and use calibrator.
- Check if the container is broken or cracked before using the calibrator.
- Make sure the calibrators are brought to room temperature and well mixed slowly before use.
- Make sure the calibrators are within the expiry date.
- Make sure there’s no fault tips and precision meets requirements.
- Never apply to the laboratory or clinic use unless all the parameters are accurately calibrated.

NOTE

- Slowly remove a vial of blood calibrator from refrigerator, and warm to room temperature by rubbing.
- Ensure the contents of a vial are completely suspended by mixing it upside down for 30 times at least.

9.2 Calibration Frequency

To ensure precision and obtain reliable test results, the parameters(WBC，RBC，PLT，HGB and MCV) should be calibrated in the following situations.

（1） Working environment changes greatly.
（2） One or multiple parameters' test results are moving.
（3） Any major component that affect the measurement is replaced.
（4） For long time no use.
（5） Requirement of the laboratory or the clinic.
（6） The reagent has been replaced.
（7） The analyzer presents deviation when running quality control.

MCV and HCT are relative parameters to each other, thus one can be obtained from given value of the other. Only MCV can be calibrated by the analyzer. Usually the manufacturer gives the value for MCV and HCT at the same time.

WARNING

Considering all the clinic specimens, control materials and calibrators that contain human blood or serum as being potentially infectious, wear lab coats, gloves and safety glasses, and follow require laboratory or clinic procedures when handling these materials.

9.3 Preparation

Before calibration, inspect the analyzer as the following requirements.

（1）Ensure the reagents are in the shelf life, adequate and uncontaminated.

（2） Run a blank test and make sure the results are accordance with the following ranges.

Table 9-1 Blank Range

Parameter	Range
WBC	≤0.20x10^9/L
RBC	≤0.02x10^12/L
HGB	≤1g/L
PLT	≤10.0x10^9/L

（3） Make sure there's no errors.

（4） Verify the accuracy of precision. Run continuous counting with mid-value control material or human blood for 11 times, take the results from the second to eleventh, check the precision in "Data" interface. Make sure the

CVs are accordance with Table 9-2 CV.

Table 9-2 CV

Parameter	CV	Range
WBC	≤2.0%	4.0×10^9/L ~ 15.0×10^9/L
RBC	≤1.5%	3.00×10^12/L ~ 6.00×10^12/L
HGB	≤1.5%	100 g/L ~ 180g/L
HCT	≤2.0%	35% ~ 50%
MCV	≤1.0%	70fL ~ 120fL
PLT	≤5.0%	100×10^9/L ~ 149×10^9/L
	≤4.0%	150×10^9/L ~ 500×10^9/L

（5） Running high control materials in “Test” for three times and then run low control materials three times immediately. The carryover is calculated by the following formula and result is confirmed to Table 9-3.

$$Carryover(\%) = \frac{low_1 - low_3}{High_3 - low_3} \times 100\%$$

Table 9-3 Carryover

Parameter	Result
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.5%
PLT	≤1.0%

9.4 Calibration Modes

9.4.1 Standard Calibration

Select “Standard Cal” mode in “Cal” interface as Figure 9-1.

Please calibrate according to the following procedures.

（1） Input “Batch number”, and select “Validity” according to Operation Manual.

（2） Select the parameter needed.

（3） Input “Reference” according to Operation Manual, those reference values of parameters which does not need to be calibrated is blank.

（4） Press “Test” to start calibration. The analyzer could automatically calculate the mean value of 11 tests at most. URIT recommend testing 3 to 5 times at least.

（5） The new calibration coefficient is calculated according to the reference value of calibrators and mean.

（6） Click “Print” to print the new calibration coefficient.

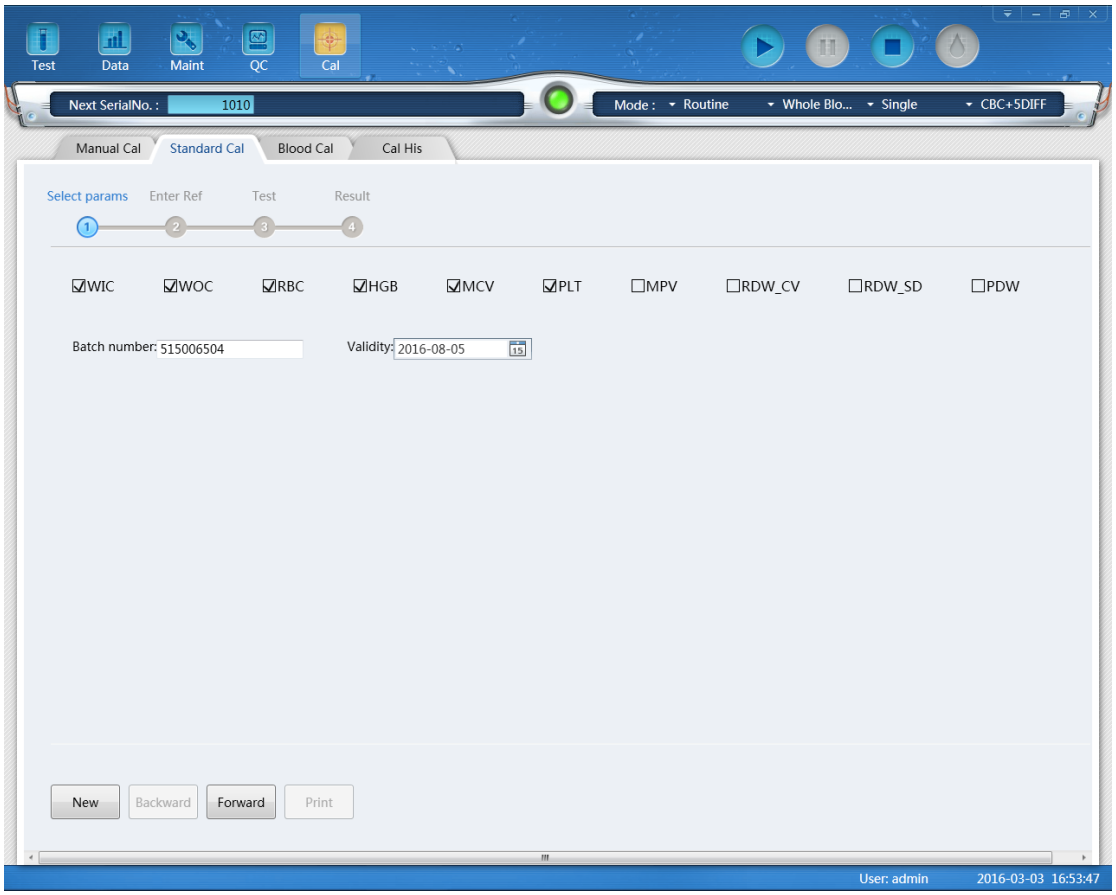


Figure 9-1 Standard Cal 1

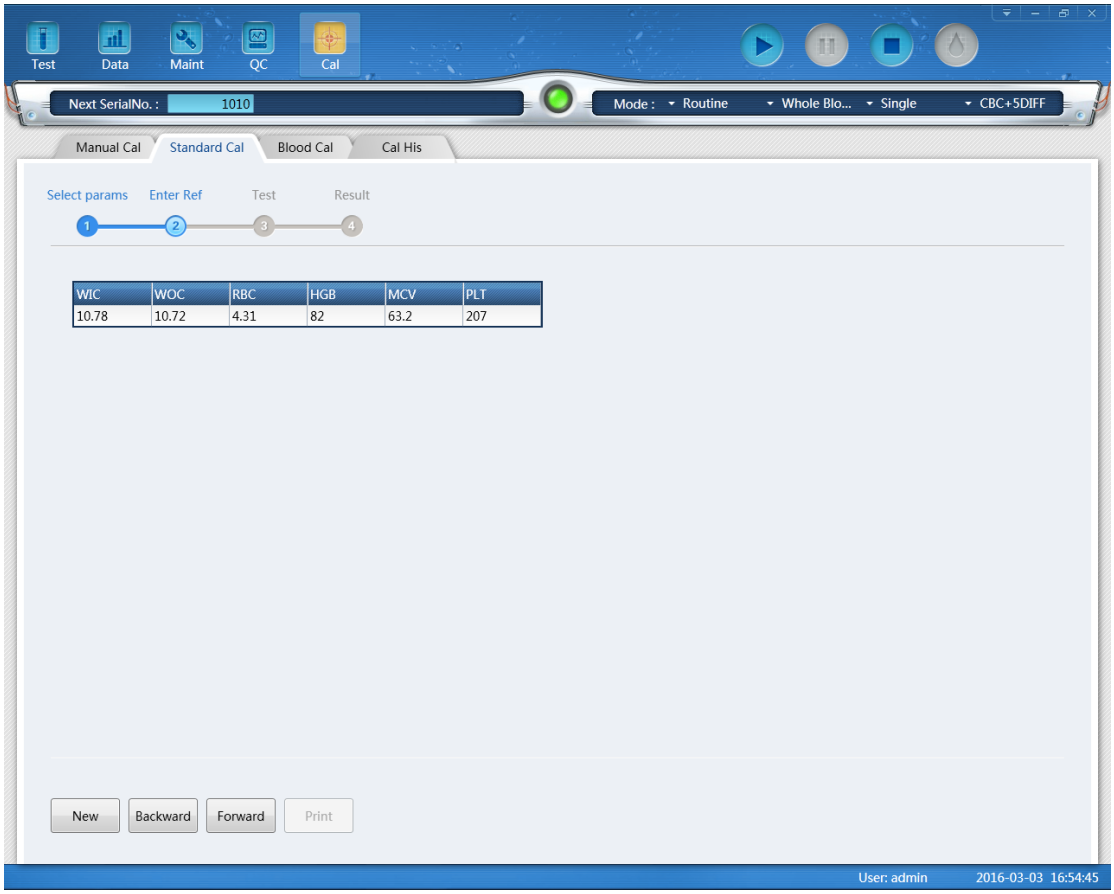


Figure 9-1 Standard Cal 2

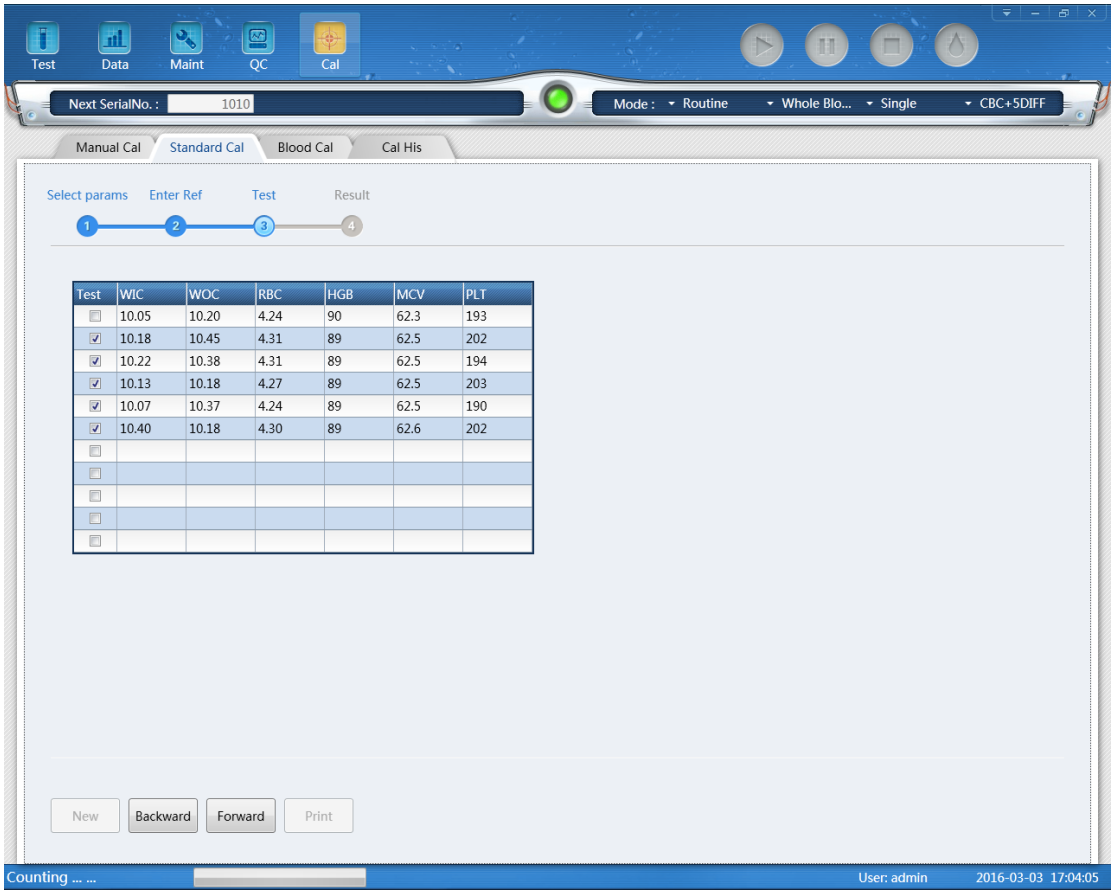


Figure 9-1 Standard Cal 3

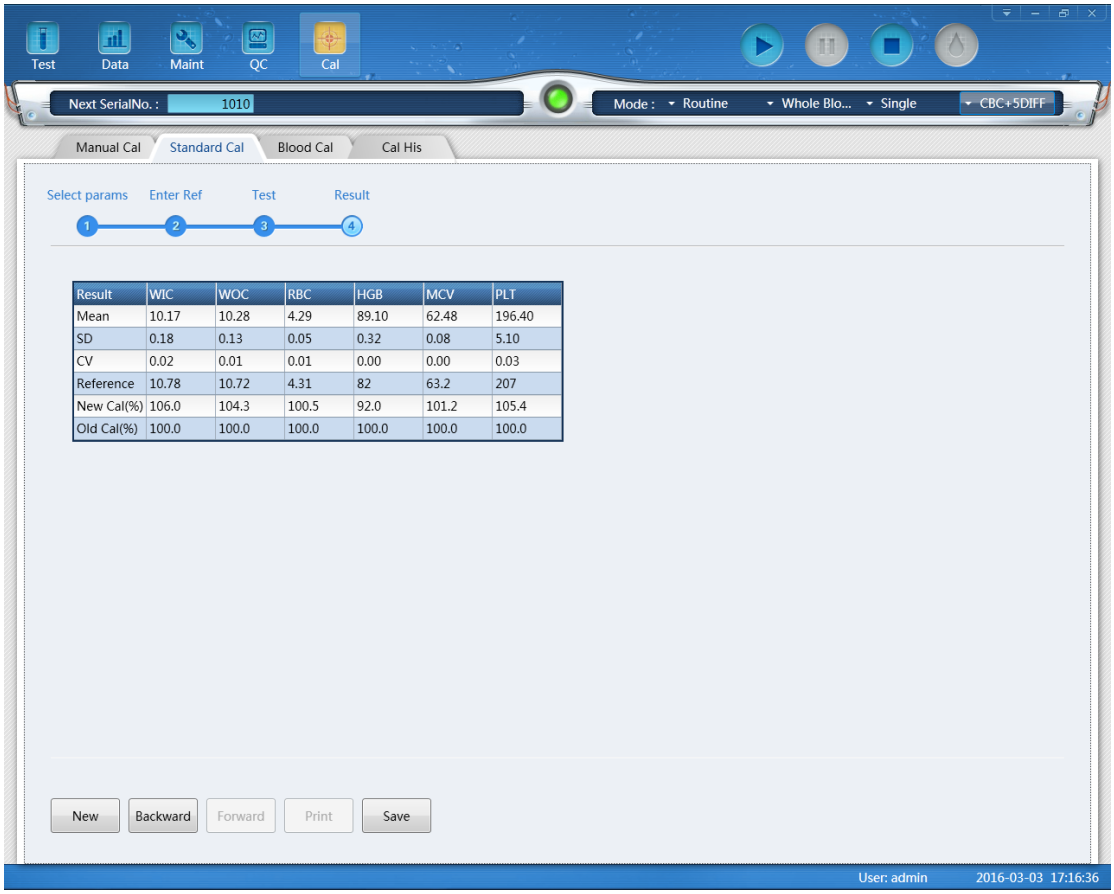


Figure 9-1 Standard Cal 4

NOTE

- WIC refers to get WBC results by electrical impedance analysis, and the WOC refers to get WBC results by photo-electric technique.
- The analyzer can calibrate a certain or all parameters of WIC, WOC, RBC, HGB, MCV, MPV, RDW_CV, RDW_SD, PLT and PDW.

7. Verification of Calibration coefficient

After calibration, URIT recommends to follow the following steps to verify the calibration coefficients.

(1) Test the calibrators at least three times, and check whether the results are within the allowed range.

(2) Test level “High”, “Normal” and “Low”, and each of it should be tested for three times at least. Check whether the results are within the allowed range.

(3) Analyze at least three normal whole blood samples, each of it should be tested for three times at least. Check whether the results are within the allowed range.

8. The calculation principle of new calibration value

- Mean value=(value1+value2+value3+value4)/times
- New calibration value=(reference value/mean value)×former calibration value
- If the new calibration value<70%, consider it equals to 70%, if the new calibration value>130%, consider it equals to 130%

For example, the PLT reference value of the calibrator is 220, current calibration value is 103% and mean value is 230, thus the new calibration value is New calibration value =103%×220/230=98.52%

NOTE

The calibration coefficient is allowed in the range of 70%~130%, if the test values exceed the limit, the critical value in the limit range should be selected as the new coefficient for calibration. And in that case, operator should find out reasons and calibrate again.

9.4.2 Blood Calibration

Click “Blood Cal” in “Cal” interface. See Figure 9-2.

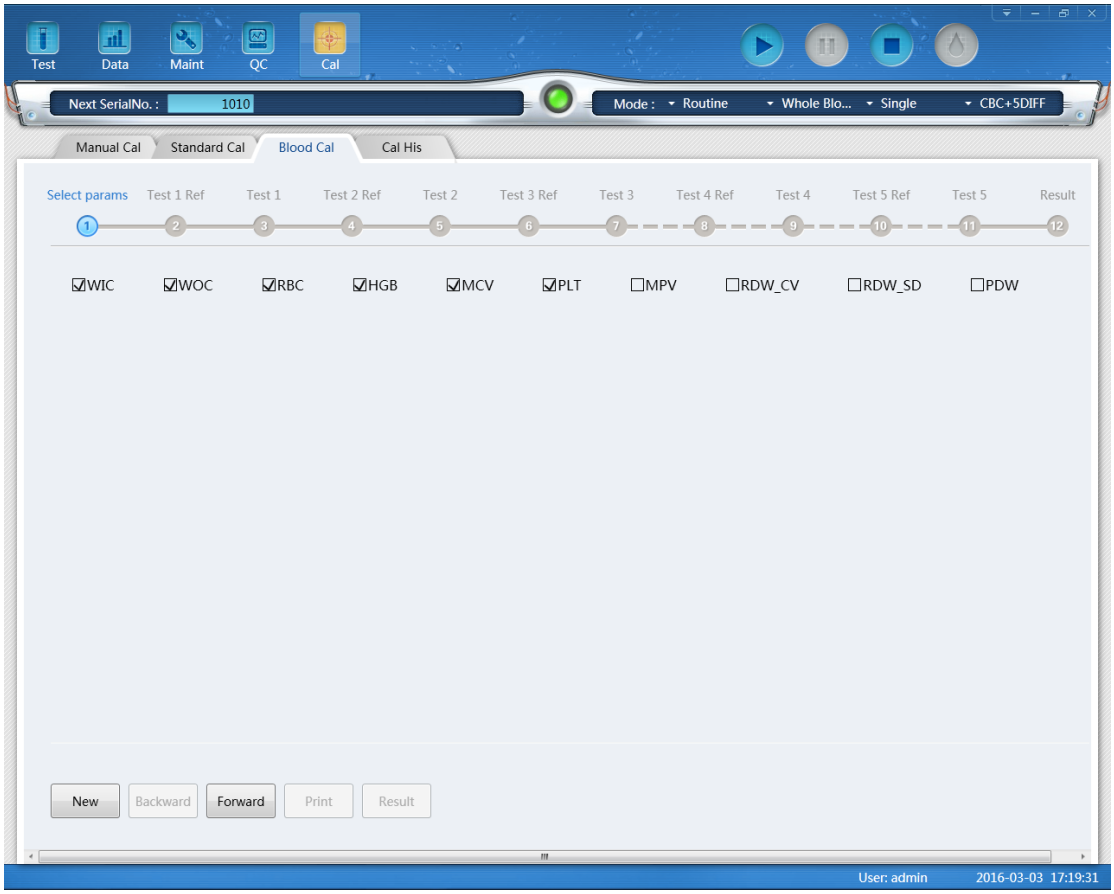


Figure 9-2 Blood Cal 1

Please calibrate as follows.

(1) Select the desired parameters and current sample SN.

(2) Prepare 3 to 5 whole blood samples according to the *Chapter 7 Daily Operation*.
(3) Test each of the prepared samples at least three times to get the mean and take the mean value as the reference value, or test and calculate according to the reference method, take the results as the reference value.
(4) Press “Test” to start calibration, the analyzer could automatically calculate the mean value of 11 tests at most. URIT recommends testing 3 to 5 times at least.
(5) Repeat steps 4 until obtaining more than three calibration coefficients. The system automatically calculates the mean value of each calibration coefficient.
(6) Click “Save” to save the new calibration coefficient.
(7) Click “Print” to print the new calibration coefficient.

NOTE

WIC refers to get WBC results by electrical impedance analysis, and the WOC refers to get WBC results by optical method.

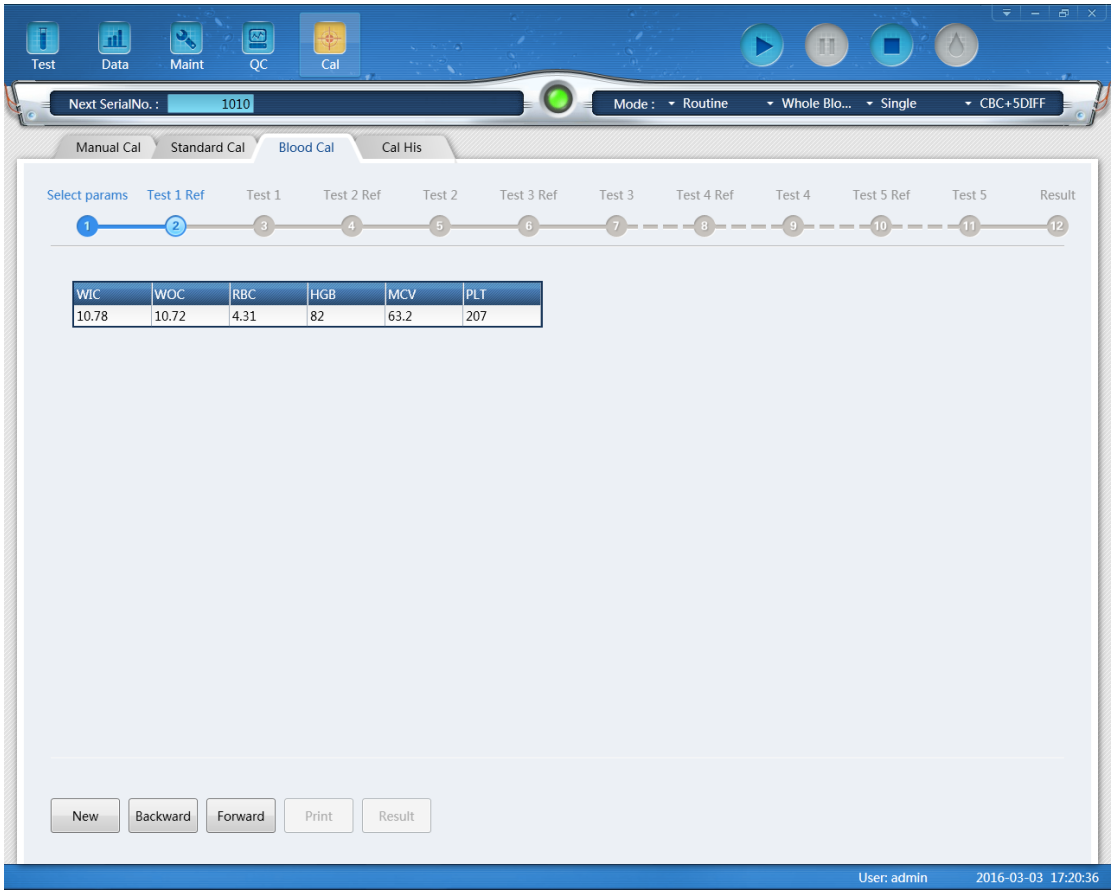


Figure 9-2 Blood Cal 2

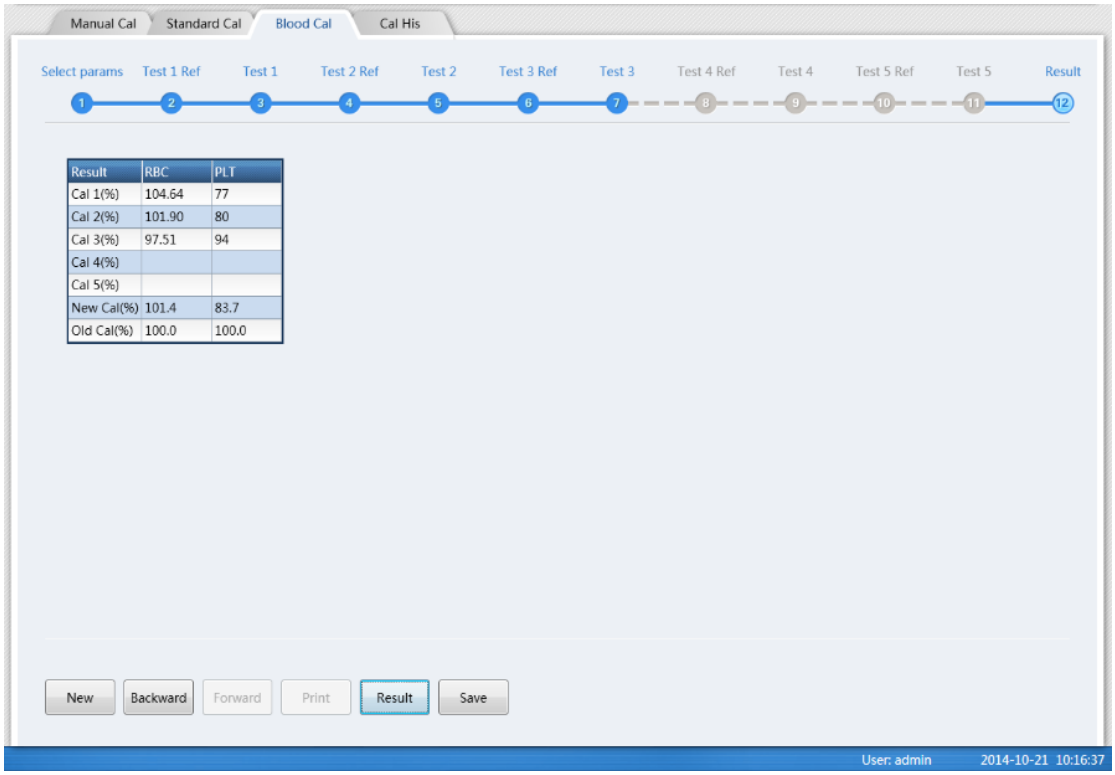


Figure 9-2 Blood Cal 3

(8) Verification of Calibration coefficient

After calibration, URIT recommends to follow the following steps to validate the calibration coefficients.

a) Test the calibrators three times at least, and check whether the results are within the allowed range.
b) Test level “High”, “Normal” and “Low”, and each control should be tested for three times at least. Check whether the results are within the allowed range.
c) Analyze three fresh blood samples, three times for each at least. And check whether the results are within the allowed range.

9.4.3 Manual Calibration

Please calibrate according to the following procedures.

1. Setup the count mode as whole blood single sampling and do more than three times calibrator testing to obtain mean.
2. Click “Cal” in main interface, and click “Manual Cal” in “Cal” interface. See Figure 9-3.

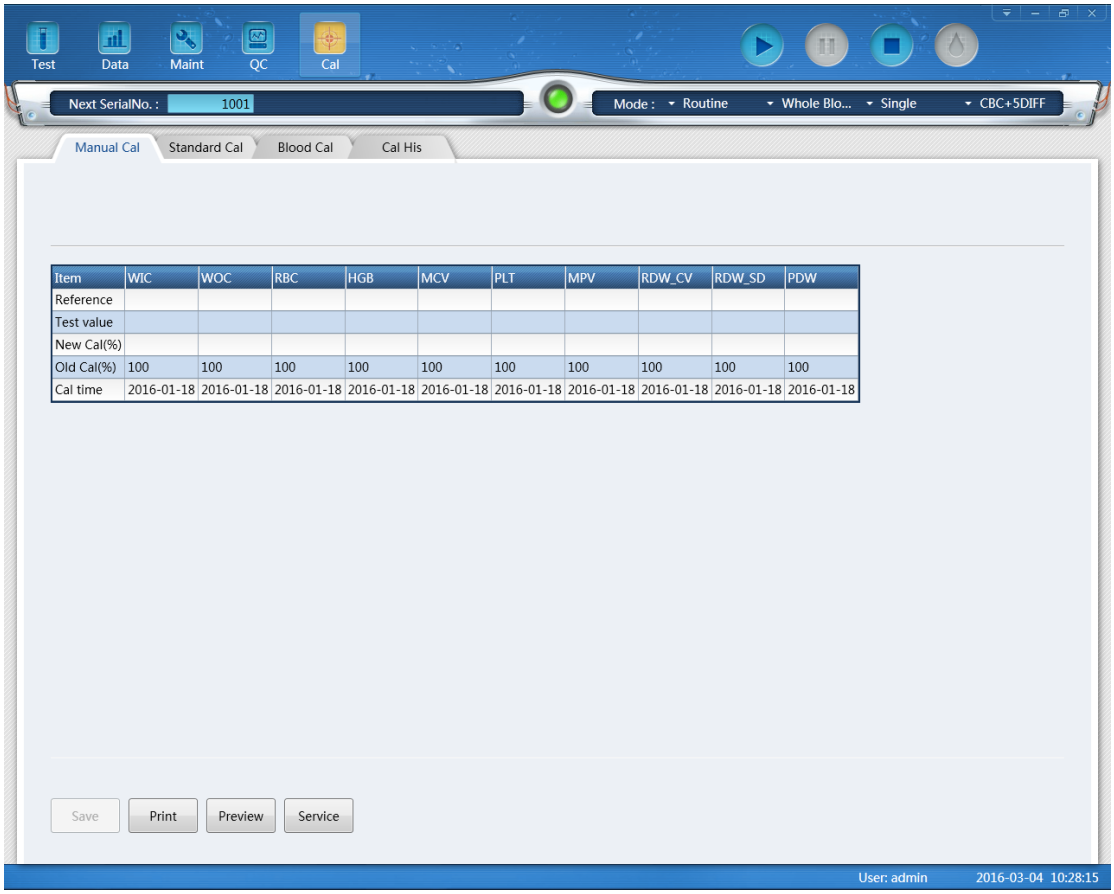
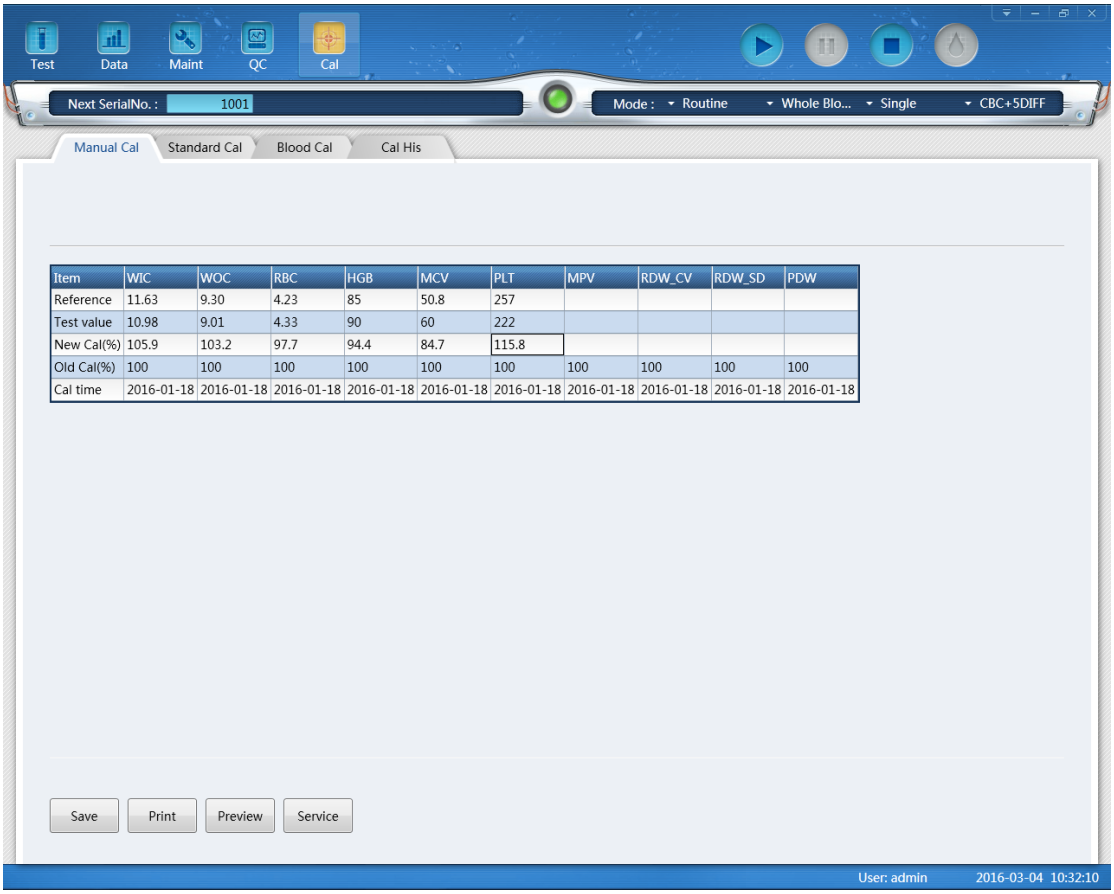


Figure 9-3 Manual Cal 1

NOTE

- WIC refers to get WBC results by electrical impedance analysis, and the WOC refers to get WBC results by optical method.
- The analyzer can calibrate a certain or all parameters of WIC, WOC, RBC, HGB, MCV, MPV, RDW_CV, RDW_SD, PLT and PDW.

3. Input the reference value and mean value of desired parameters of calibrator, and click “Cal”, the system automatically calculates the new calibration coefficient.(See Figure 9-4)



Item	WIC	WOC	RBC	HGB	MCV	PLT	MPV	RDW_CV	RDW_SD	PDW
Reference	11.63	9.30	4.23	85	50.8	257				
Test value	10.98	9.01	4.33	90	60	222				
New Cal(%)	105.9	103.2	97.7	94.4	84.7	115.8				
Old Cal(%)	100	100	100	100	100	100	100	100	100	100
Cal time	2016-01-18	2016-01-18	2016-01-18	2016-01-18	2016-01-18	2016-01-18	2016-01-18	2016-01-18	2016-01-18	2016-01-18

Figure 9-4 New Calibration Coefficient Calculating

4. Click “Save” to save the new setting.
5. Verification of Calibration coefficient

After calibration, URIT recommends to verify the calibration coefficients according to the following steps.

（1） Test the calibrators three times at least, and check whether the results are within the allowed range.

（2） Test level “High”, “Normal” and “Low”, and each of it should be tested at least three times. Check whether the results are within the allowed range.

（3） Analyze three normal fresh blood samples, three times for each at least. And check whether the results are within the allowed range

Chapter 10 Maintenance and Care

10.1 Overview

Routine care and regular maintenance are essential to keep the best status and precision, and to minimize system problems and extend its life. Procedures and instruction for preventive maintenance are discussed in this chapter. More information is available at URIT Customer Support Centre.

Preventive maintenance should be performed daily, weekly and monthly. Routine maintenance is also included in this Chapter according to actual requirement.

WARNING

Considering all components' surface may be potentially infectious, safety protective measures should be taken to avoid infection, electric shock or burn. Wear gloves when some cleaning do or maintenance works. Clean hands with disinfectant after work.

10.2 Routine Maintenance

10.2.1 Daily Maintenance

1. Auto Clean

The analyzer is designed with auto clean program. Run the auto clean after continuously working on more than 60 sample testing. And blank test is performed automatically after startup. See Figure 10-1.

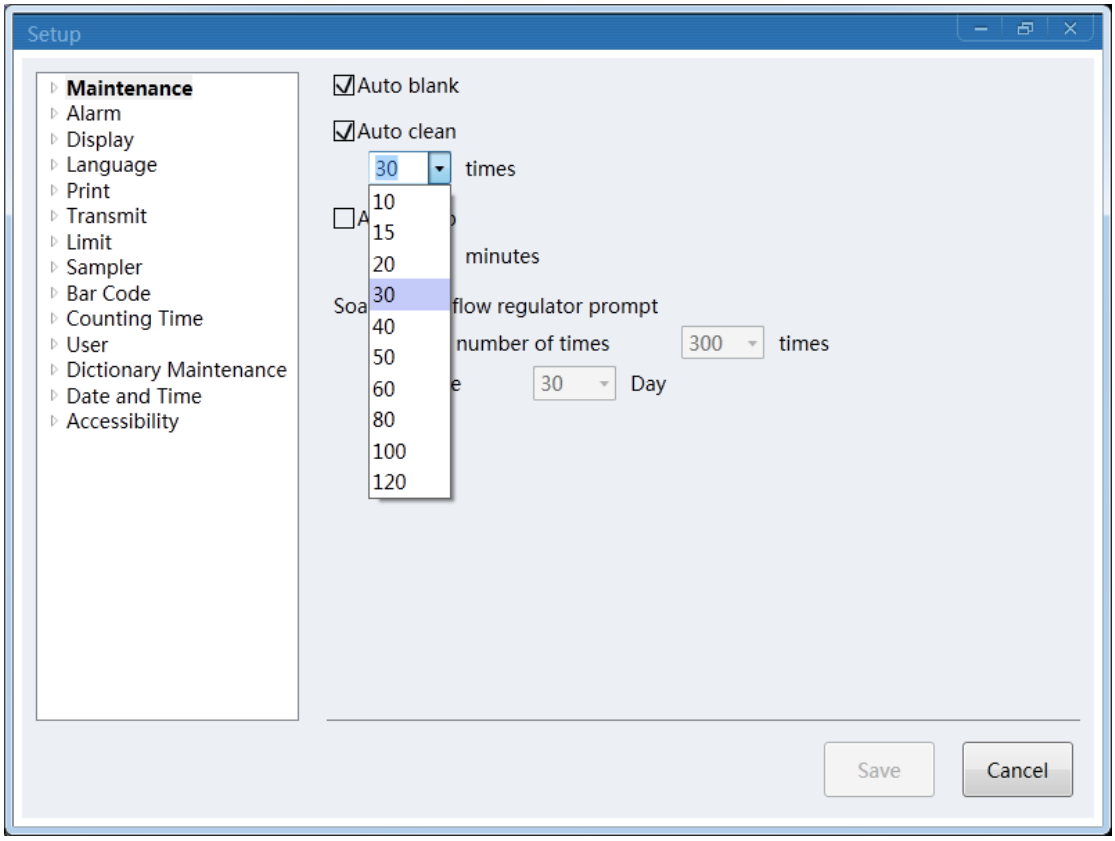


Figure 10-1 Setup

2. Shutoff

To get correct results, it's necessary to clean counting chambers and rinse the flow system to prevent measurement errors caused by residues. Shutoff program should be performed when the analyzer tests more than 500 specimens or finish one day work. If continuously using the analyzer, shutdown program should be performed once at least every 24 hours. Please refer to *7.11 of chapter 7 Daily Operation* for details.

10.2.2 Weekly Maintenance

1. Surface Maintenance

Clear the smudge on the surface, especially the blood on the aspiration probe, which prevents protein deposition and mildewing. Wipe the surrounding

area of probe and the probe with cleaning cloths soaked by neutral detergent.

CAUTION

Never use corrosive acids, alkali or volatile organic solvent (such as acetone, aether and chloroforms) to wipe the outside of the analyzer, but only use neutral detergent.

2. Clean Aspiration Probe

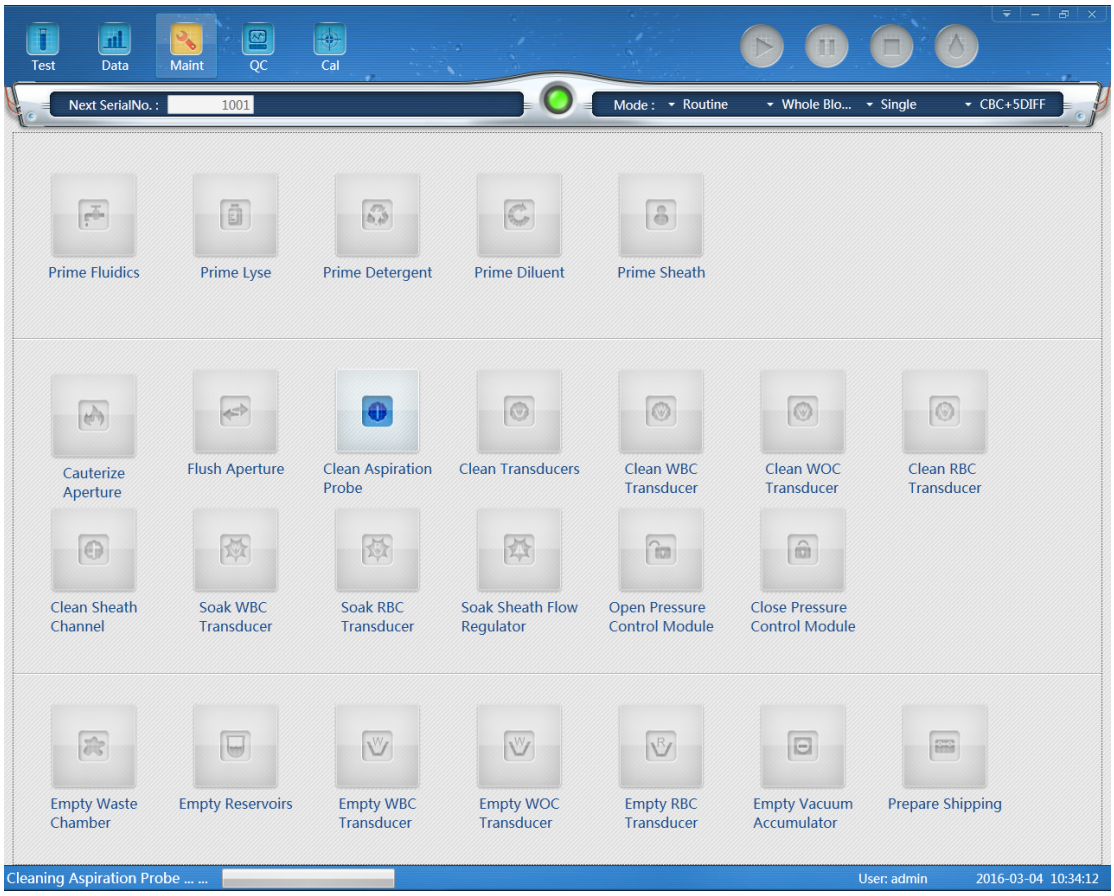


Figure 10-2 Clean Aspiration Probe

Click “Maint” to enter the maintenance interface. Click “Clean Aspiration Probe” to clean the probe. Regular cleaning ensures the accuracy and precision of performance and prevents block caused by reagent and blood residue. If the probe was blocked, please removed and cleaned it. Please refer to Maintenance Manual for details or contact with URIT Customer Support Centre for help.

10.2.3 Monthly Maintenance

1. Check and Clean Reagent Syringes

The reagent syringes need to be cleaned regularly, which prevents reagent deposition, leakage and improper operation. Syringes should be cleaned one by one and ensure to put it in correct position.

Materials Requirements

（1） A large container filled with approximately 500 mL of deionized water
（2） Clean and soft cloth
（3） Small containers used to refill the clean syringes
（4） Personal protective facilities

Clean Procedures

（1） Empty the flow system
（2） Open the left door to find the syringe
（3） Pull the syringe out from the pluggable bracket
（4） Aspirate the deionized water into the syringe till full. Pull the piston until it is removed from the syringe tube.
（5） Rinse the syringe piston and tube thoroughly with deinoized water. Replace the seal ring if it gets worn.
（6） Carefully reinsert the piston into the wet syringe tube
（7） When the syringe has been reinstalled, observe and run several times of blank count. The piston should move smoothly up and down and the syringe should not leak.

CAUTION

Do not push or pull on the piston when the syringe is dry, it might be damaged. Avoid touching the piston because oil from the fingers may make it move erratically.

2. Maintenance of Mechanical Parts

It mainly aims at mechanism maintenance, including lubricating electricity axis, X, Y rail of sampling etc.

10.3 Maintenance Programs

Click “Maint” in main interface, see Figure 10-3.

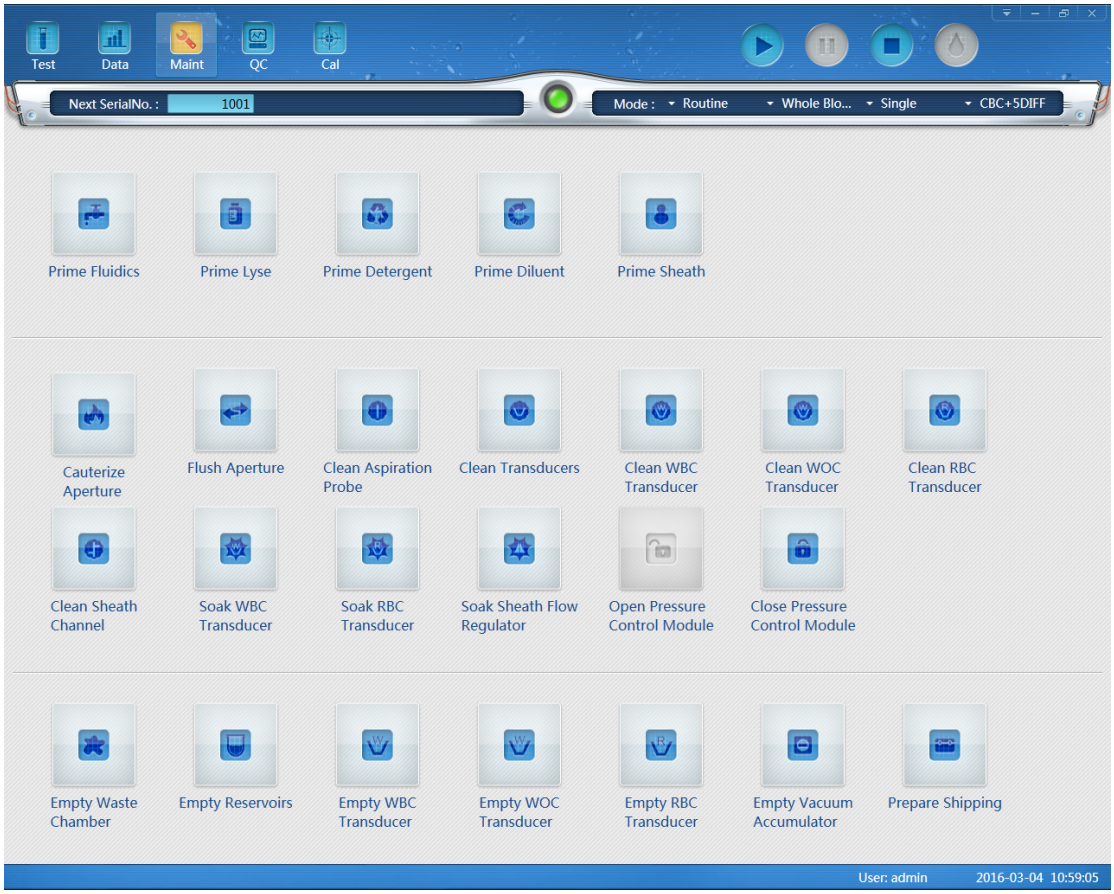


Figure 10-3 Maintenance Interface

The analyzer offers the following three kinds of maintenance operations on flow system.

- Prime-aspirate all or depart of reagents to the corresponding tube to replace the reagent.
- Clean-clean counting chamber, aspiration probe, sheath flow regulator, etc.
- Drain-empty counting chamber, waste chamber, vacuum accumulator or all tubing.

10.3.1 Prime Fluidics

Prime all reagents into tubing for cleaning. Please operate it in following conditions.

- In first time use
- Replace all reagents
- Analyzer failure

Operation Procedures

1. Click “Prime Fluidics” in “Maint”
2. Prime Lyse, Prime Detergent, Prime Diluent and Prime Sheath starts. The progress bar is at the bottom of screen. See Figure 10-4.

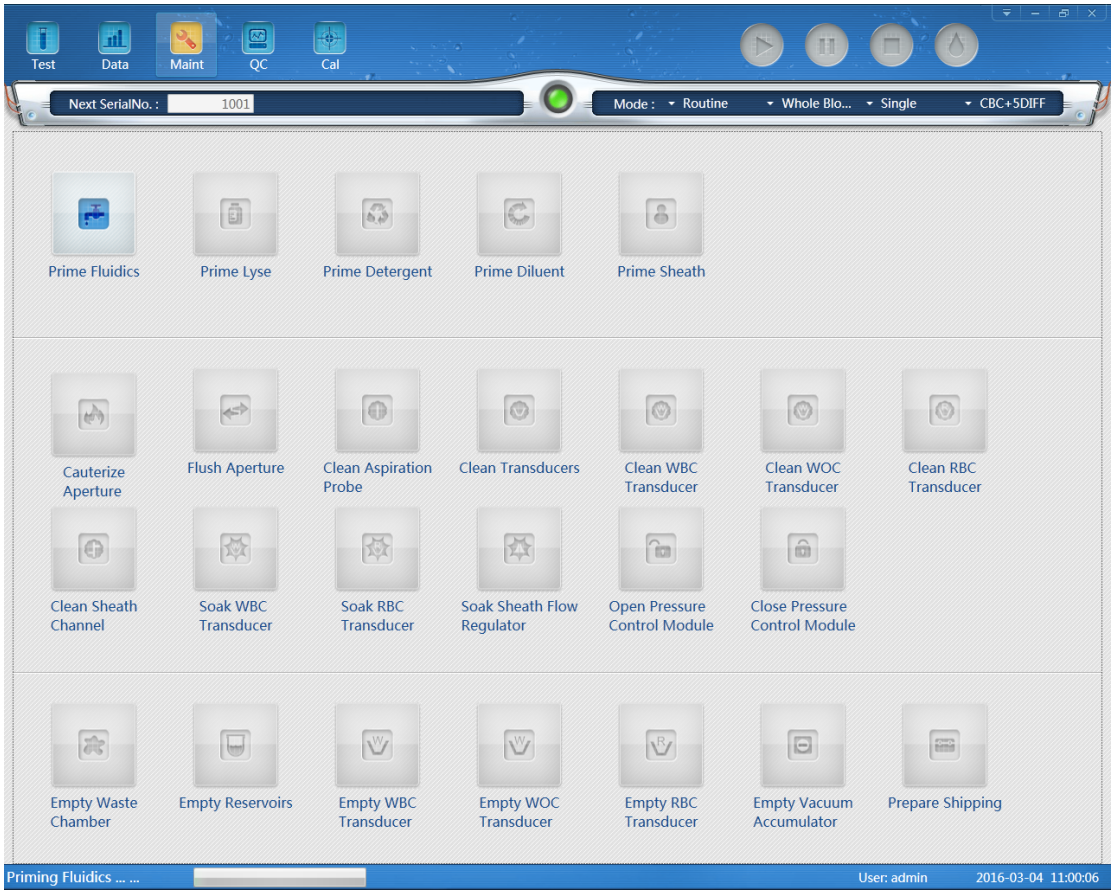


Figure 10-4 Prime Fluidics

WARNING

Samples, control materials, calibrators and waste may contain human blood or serum. Considering the existence of potentially infectious, please wear lab coats, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials.

NOTE

- Keep the reagent still for a certain time to ensure it stable.
- After replace the diluent, detergent or sheath, perform blank count to ensure the blank values are in the acceptable range.

10.3.2 Prime Lyse

Please operate it in following conditions.

- There are bubbles in lyse tubing and prompt that there's no lyse.
- Lyse in tubing is contaminated.
- Replace a bottle of lyse.

Operation Procedures

（1） Click "Prime Lyse" in "Maint" interface.

（2） The analyzer starts to execute it. The progress bar is at the bottom of screen.

10.3.3 Prime Diluent

Please operate it in following conditions.

- ◆ There are bubbles in tubing.
- ◆ Diluent in tubing is contaminated.
- ◆ Replace diluent.

Operation Procedures

（1） Click “Prime Diluent” in “Maint” interface.

（2） The analyzer starts to execute it. The progress bar is at the bottom of screen.

10.3.4 Prime Detergent

Please operate it in following conditions.

- ◆ Three are bubbles in tubing l.
- ◆ Detergent in tubing is contaminated.
- ◆ Replace detergent.

Operation Procedures

（1） Click “Prime Detergent” in “Maint” interface.

（2） The analyzer starts to execute it. The progress bar is at the bottom of screen.

10.3.5 Prime Sheath

Please operate it in following conditions.

- ◆ Three are bubbles in the sheath flow regulator.
- ◆ Detergent in tubing is contaminated.
- ◆ Replace sheath.

Operation Procedures

（1） Click “Prime Sheath” in “Maint” interface.

（2） The analyzer starts to execute it. The progress bar is at the bottom of screen.

10.3.6 Cauterize Aperture

Cauterize both sides of the aperture with a high voltage to clear protein, dust and other impurities, which prevents to block the aperture. Steps are as follows.

（1） Click “Cauterize Aperture” in the “Maint” interface.

（2） The analyzer starts to cauterize the aperture. The progress bar is at the bottom of screen. See Figure 10-5.

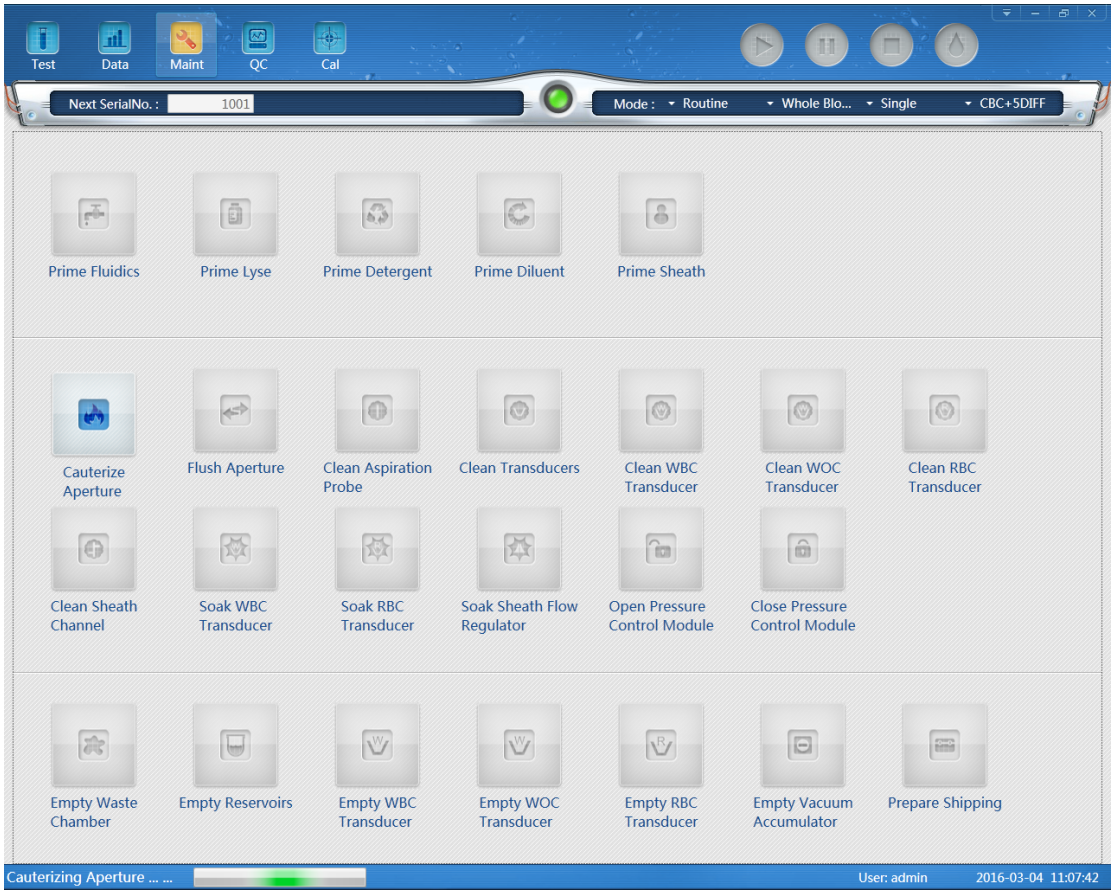


Figure 10-5 Cauterize Aperture

10.3.7 Flush Aperture

Together with “Cauterize Aperture”, “Flush Aperture” prevents and eliminates blockage. The procedures are as follows.

1. Select Flush Aperture in the “Maint” interface.
2. The analyzer start to perform the function and display the process bar at the bottom of the screen.

10.3.8 Clean Transducers

WARNING

Samples, control materials, calibrators and waste may contain human blood or serum. Considering the existence of potentially infectious, please wear lab coats, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials.

“Clean Transducers” function is to rinse sample cup with diluent and scour it. The procedures are as follows.

（1） Click “Clean Transducers” in the “Maint” interface.

（2） The analyzer starts to perform the function. The progress bar is at the

bottom of screen.

If blockage is severe, select “Soak WBC Transducer” or “Soak RBC Transducer”, steps are as below.

（1） Prepare a tube filled with probe detergent (4ml).

（2） Put this tube in the Emergency and push it in sampling position.

（3） Click “Soak WBC Transducer” or “Soak RBC Transducer” in “Maint” interface.

（4） The analyzer starts to perform the function.

CAUTION

Consider the probe detergent is corrosive, operator should wear lab coats, gloves, and follow required laboratory or clinical procedures.

10.3.9 Prepare Shipping

Perform this function before shipping or unused for a long time. The procedures are as follows.

（1） Take out the diluent inlet tubing connecting with the “DELUENT” on the rear panel from container, and put it into deionized water.

（2） Take out the lyse inlet tubing connecting with the “LYSE” on the rear panel from container, and put it into deionized water.

（3） Take out the detergent inlet tubing connecting with the “DETERGENT” on the rear panel from the container, and put it into deionized water.

（4） Take out the sheath inlet tubing connecting with the “SHEATH” on the rear panel from container, and put it into deionized water.

（5） Keep the remaining reagents in their containers and store them according to instructions. Operator should establish and confirm to the effective storage measures to prevent reagent from deteriorated, misusage or misdrinking. The reagent should be away from temperature extremes.

（6） Click “Prepare Shipping” in “Maint” interface.

（7） The analyzer start to perform the function and display the process bar at the bottom of the screen. See Figure 10-6

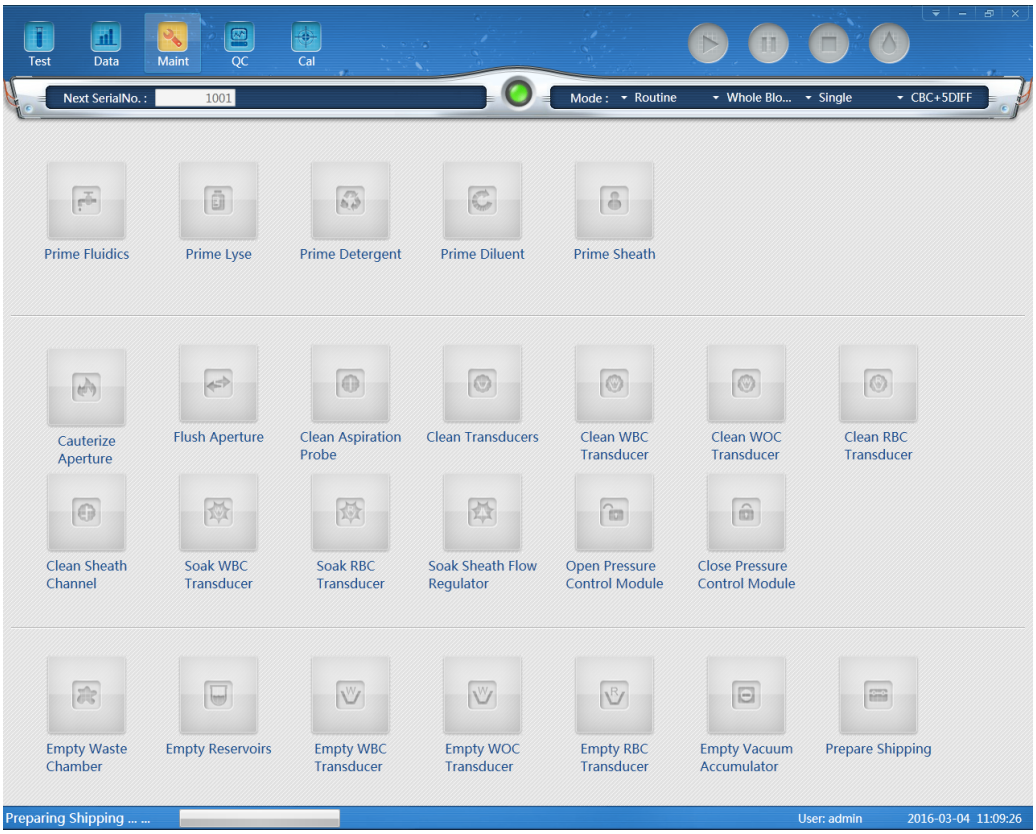


Figure 10-6 Prepare Shipping

10.3.10 Other Maintenances

Clean Aspiration Probe--------scour the inner wall of aspiration probe with diluent.

Clean Sheath Channel--------clean sheath flow regulator.

Clean WBC Transducer---------clean WBC sample cup in impedance channel.

Clean RBC Transducer--------clean RBC sample cup in impedance channel.

Clean WOC Transducer---------clean WOC cup in optical channel.

Soak Sheath Flow Regulator--------soak and clean the inner wall of it.

Open Pressure Control Module------- provide positive and negative pressure to positive pressure chamber and negative press chamber respectively.

Close Pressure Control Module--------release pressure in press chamber and negative press chamber.

Empty Waste Chamber---------discharge the waste which temporarily stores in waste chamber.

Empty Reservoirs---------discharge the diluent which temporarily stores in waste chamber.

Empty WBC Transducer----------empty the diluent remained in the WBC cup.

Empty WOC Transducer----------empty sheath remained in WOC cup.

Empty RBC Transducer----------empty the diluent remained in the RBC cup.

Empty Vacuum Accumulator----------empty the waste temporarily stored in negative pressure chamber.

Chapter 11 Troubleshooting

11.1 Overview

This chapter gives instructions for identifying and troubleshooting. If the malfunction is not solved by this guidance, or if more detail information is needed, please contact URIT Customer Support Centre.

NOTE

This manual which is not the maintenance manual, only provides measure as there being a malfunction alarm.

WARNING

Considering the analyzer handling the materials that contain human blood or serum as being potentially infectious, please follow the established bio-safety procedure when maintain or troubleshoot the analyzer.

11.2 Guidance

Troubleshooting Guidance is used to assist operator in identifying and resolving analyzer problems. Instruction is also given for obtaining technical assistance immediately from URIT Customer Support Centre. The first step in the process is to understand normal analyzer operation and preventive Maintenance. Good experience of the analyzer is essential for identifying and resolving operational problems.

Please follow these three steps to do troubleshooting.

(1) Problem confirmation

(2) Problem classification

(3) Troubleshooting

Step1 Problem Confirmation

Confirm what is wrong, and know what it should be in normal circumstance. Only right confirmation makes right troubleshooting.

Step2 Problem Classification

Generally divided problems into three categories.

(1) Hardware-related failures

(2) Software-related failures

(3) Failures of sample analysis measurement

Hardware and software problems can only be corrected by a URIT authorized engineer. The operator can correct sample measurement problems with assistance from URIT engineers.

Step3 Troubleshooting

Engineers take appropriate action to deal with the problem. If operator can deal with it by himself or with URIT engineer’s assistance, This increases the efficiency of troubleshooting.

11.3 Technical Assistance

Please contact with URIT Customer Support Centre for technical assistance. Before that, please provide the following information to Customer Support Specialists.

(1) The analyzer model

(2) Serial number and version number

(3) Description of the problem and surroundings, including status and operation

(4) The lot number of the reagents (lyse, diluent, detergent etc.)

(5) Related data and report of the problem

Common faults and disposals are given in this Chapter. The operator can identify the cause according to the warning information and operate according to Troubleshooting Guidance.

11.4 Troubleshooting

Common faults and corrective actions are listed as follows. If the problems cannot be dealt with, and if technical assistance is needed, please contact with URIT Customer Support Centre.

11.4.1 Faults Related to Reagents

Fault	Probable Cause	Corrective Action
Lyse empty	Lyse is run out or lyse inlet tubing is blocked.	● Check that if the lyse is run out. ● Perform “Maint”→“Prime Lyse”. ● If fault still occurs, please contact with URIT.
Diluent empty	Diluent is run out.	● Check that if diulent is run out. ● Perform “Maint”→Prime Diluent. ● If fault still occurs, please contact with URIT.
Detergent empty	Detergent is run out.	● Check that if the detergent is run out. ● Perform “Maint”→“Prime Detergent”. ● If the fault still occurs, please contact with URIT.
Sheath empty	Sheath is run out	● Check that if the sheath is run out. ● Perform “Maint”→“Prime Sheath” ● If the fault still occurs, please contact with URIT.
Waste full	Waste container is full or waste sensor is in fault.	● Check that if the waste container is full. ● Check that if the sensor is wet or short circuit. ● If the fault still occurs, please contact with URIT.

11.4.2 Faults Related to Test Value

Fault	Probable Cause	Corrective Action
High blank value	Reagents are contaminated or overdue, Reagent tubing contaminated.	● Check that if the reagents are contaminated or overdue. ● Perform “Maint”→ “Prime All” to rinse the flow system. ● If the fault still occurs, perform “Maint”→ “Clean Transducers”. Run a blank test again to check if the fault disappeared. ● If the fault still occurs, please contact with URIT.
HGB inaccuracy	HGB blank voltage hopping.	● Press “Ctrl+F2” to open Debug Window to check the HGB_AMP_SET results ● If the HGB_AMP_SET is out of range, contact with the URIT to modify the value.
WBC clog or RBC clog	aperture clogged WBC counting time incorrect solenoid valve problem	● Perform “Cauterize Aperture” or “Flush Aperture” in “Maint” interface. Then run a blank counting to check the count time. ● If fault still occurs, inject probe detergent with the syringe into WBC/RBC cup to soak the aperture. ● If fault still occurs, please contact with URIT.
WBC bubble or RBC bubble	Diluent or detergent run out or deficient. Reagent tubing loose leads to leakage.	● Check that the diluent or detergent if run out. ● Check the reagent tubing connection, prevent leakage. ● Perform “Prime Fluidics” in “Maint” interface. ● If the fault still occurs, please contact with URIT.

11.4.3 Fault Related to Hardware

Fault	Probable Cause	Corrective Action
No response when startup	● The power wire is not connection well with the power socket. ● The fuse may be burnout.	● Check the power wire connection. ● Check whether the fuse has been burned out. ● If the fault still occurs, turn off the power, and contact with URIT.
Moto sounds abnormally	● Moto connecting wire loose. ● Travel Optocoupler problem. ● Moto problem. ● Moto drive circuit problem.	Turn off the power, and contact with URIT.
Printer no response	● Connecting wire problem. ● Printer problem	● Check the power wire and connecting wire of the printer. If the printer still doesn't work, please re-plug wires and restart the computer and printer. ● If the fault still occurs, connect the printer to another normal computer separately and install the driver to test the printer if it is normal. ● If the fault still occurs, please contact with URIT.

Appendix A Specifications

A.1 Technical Specifications

A.1.1 Parameters

Abbreviation	Full Name	Unit
WBC	White Blood Cell Count	10^9/L
LYM%	Lymphocyte Percent	%
MON%	Monocyte Percent	%
NEU%	Neutrophile Percent	%
EOS%	Eosinophile Percent	%
BASO%	Basophil Percent	%
LYM#	Lymphocyte Count	10^9/L
MON#	Monocyte Count	10^9/L
NEU#	Neutrophile Granulocyte Count	10^9/L
EOS#	Eosinophile Granulocyte Count	10^9/L
BASO#	Basophil Granulocyte Count	10^9/L
RBC	Red Blood Cell Count	10^12/L
HGB	Hemoglobin	g/L
HCT	Hematocrit (relative volume of erythrocytes)	%
MCV	Mean Corpuscular Volume	fL
MCH	Mean Corpuscular Hemoglobin	pg
MCHC	Mean Corpuscular Hemoglobin Concentration	g/L
RDW_CV	Red Blood Cell Distribution Width repeat precision	%
RDW_SD	Red Blood Cell Distribution Width STDEV	fL
PLT	Platelet Count	10^9/L
MPV	Mean Platelet Volume	fL
PDW	Platelet Distribution Width	fL
PCT	Plateletcrit	%
P_LCC	Large Platelet Count	10^9/L
P_LCR	Large Platelet Percent	%
RETIC	Reticulocyte	%
RETIC_ABS	Reticulocyte absolute number	10^9/L
IRF	Immature Reticulocyte Fraction	%

A.1.2 Test Speed

Whole Blood Automatic (Batch) Sampling Mode Not less than 60 / hour

Whole Blood Single (Emergency) Sampling Mode Not less than 60 / hour

A.1.3 QC Modes

L-J QC, X-B QC, X-R QC and X QC.

A.1.4 Reagents

Diluent, lyse, detergent and sheath. Please refer to *A.4 Reagent Specification* for details.

A.1.5 Calibration Modes

Standard Cal

Blood Cal

Manual Cal

A.1.6 Parameters Measurement and Calculation

(1) WBC classification using four angle laser scattering flow cytometry.
(2) Colorimetric method for the determination of HGB without cyanide.
(3) Electrical impedance method for determining the quantity of WBC, RBC and PLT.
(4) MCV，HCT，RDW，MPV，PDW，MCH，MCHC and PCT are obtained directly by calculating the stored data.

A.1.7 Input & output Devices

(1) Outer computer
(2) Outer printer (optional)
(3) Handheld barcode scanner (optional)
(4) Auto sample bar code reading device (optional)

CAUTION

Computer, printer and other external devices must be passed CCC(C&E) Compulsory Certification. It may cause the system work improperly and personal injury by using substandard external devices.

A.2 Physical Specifications

A.2.1 Power Requirements

Optimum work Voltage	Work Voltage range	Frequency
AC 220V	AC 100V～240V	50/60 Hz

A.2.2 Environment Requirements

(1) Temperature 15°C~35°C
(2) Relative Humidity ≤85％
(3) Barometric Pressure 60kPa~106kPa

A.2.3 Storage and Transport Environment

(1) Temperature -20°C~55°C
(2) Relative Humidity ≤95%
(3) Barometric Pressure 50kPa~106kPa

A.2.4 Size and Weight

(1) Length approximately 580mm
(2) Height approximately 550mm
(3) Width approximately 705mm
(4) Weight approximately 73kg

A.2.5 Waste

Dispose the waste according to the national or local regulations.

A.2.6 Minimum Sample Volume

Whole blood sampling mode 20μL
Diluent Sampling Mode 20μL

A.2.7 Dilution Ratio

(1) WBC approximately 1:250
(2) RBC/PLT approximately 1:25000

A.2.8 Diameter

(1) WBC 100μm
(2) RBC/PLT 68μm

A.2.9 HGB measurement

(1) Measure HGB in WBC/HGB cup
(2) The illuminant is led, and the wavelength is 540nm.

A.3 Performance Index

A.3.1 Precision

Parameters	Precision Range	Acceptable Limits（CV）
WBC	4.0 x10^9 /L ~15.0x10^9 /L	≤2.0%
RBC	3.00 x10^12 /L ~6.00x10^12 /L	≤1.5%
HGB	100 g/L ~180 g/L	≤1.5%
PLT	100 x10^9 /L ~149x10^9 /L	≤5.0%
	150x10^9 /L ~500x10^9 /L	≤4.0%
HCT /	35%~50%	≤2.0%
MCV	70 fL ~120 fL	≤1.0%

A.3.2 Linearity

Parameters	Linearity Range	Acceptable Limits
WBC	0 x10^9 /L ~10.0x10^9/L	≤±0.3 x10^9 /L
	10.1 x10^9 /L ~99.9x10^9 /L	≤±5%
RBC	0.10 x 10^12/L ~1.00x10^12 /L	≤±0.05 x10^12 /L
	1.01 x10^12/L ~7.00x10^12 /L	≤±5%
HGB	0 g/L ~70 g/L	≤±2 g/L
	71 g/L ~300 g/L	≤±2%
PLT	0x10^9 /L ~100x10^9 /L	≤±10 x10^9/L
	101 x10^9 /L ~999x10^9/L	≤±10%

A.3.3 Accuracy of WBC Classification

The WBC classification accuracy shall meet the requirements of *Section 5.5.2 of YY/T 0653-2008.*

A.3.4 Carryover

Parameters	Measurement Results
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.5%
PLT	≤1.0%

A.3.5 Blank Count

Parameters	Measured Value Range
WBC	≤0.20x10^9 /L
RBC	≤0.02x10^12 /L
HGB	≤1g /L
PLT	≤10.0x10^9 /L

A.3.6 Comparability

Parameters	Acceptable Range (%)
WBC	≤±5.0%
RBC	≤±2.0%
HGB	≤±2.0%
HCT /MCV	≤±3.0%
PLT	≤±7.0%

A.3.7 Display Range of Main Parameters

Parameters	Display Range
WBC	0～200.0 x 10^9/L
RBC	0～18.00 x 10^12/L
HGB	0～300g/L
HCT	0%～80%
PLT	0～2000 x 10^9/L

A.4 Reagent Specifications

Name	Specification
Diluent	20L
Detergent	20L
Sheath	10L/20L
lyse	500mL/1L

CAUTION

Do not pour the remaining reagent in it when replace a new reagent, or it may lead to cross contamination of the reagents.

A.5 Reagent Consumption

Operation	Diluent	Detergent	Sheath	Lyse
Startup	162mL	65mL	29mL	11.5mL
Test	32mL	27mL	10mL	0.5mL
Prime (Clean)	162mL	65mL	27mL	11.5Ml
shutdown	52mL	19mL	25mL	0mL

A.6 Alarm Information

Alarm		Interpretation	Measures
WBC Flag	WBC？	WBC? Indicates a suspect WBC results 1.WBC is over the linear range 2.there's differences in clinical in WIC and WOC value. Besides, The algorithm cannot determine the exact value of WBC	If the NRBC and (or) RRBC displays together with WBC?, please retest the sample in CBC+5DIff+RRBC mode to removal of interfering substances caused by the RBC. If the mark is still there, please check whether there's NRBC in the stained smears, it may affect WIC count. Check the LYM value, and check WBC value via conversion method according to your laboratory procedures.
	NRBC	NRBC. Nucleated red blood cells The following conditions may cause NRBC alarm. WIC count>WOC count, there's NRBC or not.	Check whether there's NRBC in the stained smears, and operate according to your laboratory procedures. If the NRBC exists, please quantitate according to your laboratory procedures. There's no need to correct the WBC count. If the WBC ？ appears together with NRBC, please retest the sample in CBC+5DIff+RRBC mode to removal of interfering substances caused by the RBC.
	RRBC	RRBC：Refractory red blood cells The following conditions may cause RRBC alarm. WOC count >WIC count, there's RRBC or not.	Retest the sample in CBC+5DIff+RRBC mode to removal of interfering substances caused by the RBC. (The CBC+5DIff+RRBC mode reduces generated marks numbers, but false positives tape mark will be significantly increased.) Please operate according to the WBC description box. If WBC? appears, please check the stained smears to ensure the interference cause. Check WBC value via

			conversion method according to your laboratory procedures.
	DFLT（NLMEB）	DFLT：Leukocyte categories abnormal (NLMEB：N＝NEU, L＝LYM, M ＝ MON, E=EOS, B＝BASO) The following conditions may cause DFLT alarm. ● There is no detection of a low trough used to distinguish between the two cell populations areas. 2. The number of cells in a specific subgroup is abnormally low. Such as WBC increase & decrease, neutrophil increase & decrease, lymphocytes increase & decrease, eosinophils increase & decrease, basophils increase & decrease	Check the stained smears and test subgroup classification values via description box.
RBC Flag		The following conditions may cause RBC Flag alarm. Bubble, plugging holes, test time tips, Anisocytosis, small cell erythrocytes, large cell erythrocytes, RBC increase and low color	Check the stained smears, whether there's abnormal RBC value or PLT morphology. Please operate according to your laboratory procedures.
PLT Flag		The following conditions may cause PLT Flag alarm. PLT increase & decrease	Please operate according to your laboratory procedures. Check the stained smears, whether there's abnormal PLT morphology or PLT aggregation, and check the PLT count.

Appendix B External communication protocol

A. Communication Protocol

Information is transferred by the following methods.

<SB>information<EB><CR>

<SB> is Start Block Character needs 1byte corresponds to ASCII <VT> hexadecimal 0x0B

<EB> is End Block Character needs 1byte corresponds to ASCII <FS> Hexadecimal 0x1C

<CR> is Carriage Return needs 1byte corresponds to ASCII <CR> hexadecimal 0x0D

Information is the data that we want to transfer. Please refer to the following for details.

B. Information Grammar

1. Delimiter

| --- Fields Delimiter

^ ---Component Delimiter

& ---Subcomponent Delimiter

~ ---Repeat Delimiter

\ --- Escape Character

2. Data Type

CX extended composite id which check digit

CE code element

CM composite

CQ composite quantity with units

DR date time range

DT data

DLN driver’s license number

EI entity identifier

HD hierarchic designator

FN family name

FT formatter text

IS coded value for user-defined tables

ID coded values for HL7 tables

JCC job code

NM numeric

PT processing type

PL person location

ST string

SI sequence ID
TS time stamp
TQ timing quantity
TX text data
XAD extended address
XCN extended composite ID number and name
XON extended composite name and ID number for organizations
XPN extended person name
XTN extended telecommunications number
VID version identifier

3. Field Meaning

3.1. There is a message header at the beginning of each message. It is MSH field.

The meaning of MSH is shown as below

No.	Field	Data Type	Length	Explanation
1	Field mark	ST	1	Separator
2	Encoding chars	ST	4	Separator listing
3	Sending Application	EI	180	Sending end applications
4	Sending Facility	EI	180	Sending end facility
5	Receiving Application	EI	180	Receiving end applications
6	Receiving Facility	EI	180	Receiving end facility
7	Date Time Message	TS	26	Current message event, system time
8	Security	ST	40	Security
9	Message Type	CM	7	Message Type
10	Message Control ID	ST	20	Message control ID is used to distinguish different messages. See the table below.
11	Processing ID	PT	3	Dispose of ID P Product
12	Version ID	VID	60	HL7 version is 2.3.1
13	Application Acknowledgment Type	IS	1	Set null
14				Retain
15				Retain
16				Retain
17				Retain
18	Encoder	ST		Encoding is UNICODE

MSH-10	Description
0001	Analyzer transmits results automatically.
1001	LIS responses, analyzer transmits results automatically.

Example. MSH|^~\&|URIT|Spincell 5plus|LIS|PC|20100930100436||ORU^R01|0001|P|2.3.1|1|||||UNICODE

3.2. PID--- Definition of patients' data field

No.	Field	Data Type	Length	Explanation
1	Set ID PID	SI	4	Identify different fields, fill with 1 generally.
2	Patient ID	EI	20	Patient ID., hospital No., set null
3	Patient Identifier List	CX	20	Indicate batch number when QC
4	Alternate Patient ID	CX	20	Bed No.
5	Patient Name	XPN	48	Name
6	Mother’s Maiden Name	XPN	48	Mother’s Maiden Name, set null
7	Date/Time of Birth	TS	26	Birthday； Indicate validity when QC
8	Sex	IS	1	Male or female
9	Patient Alias	XPN	48	Retain patient alias
10	Race	CE	80	Retain race
11	Patient Address	XAD	106	Retain patient address
12	County Code	IS	4	Retain county code
13	Phone Number	XTN	40	Retain phone No.
13	Phone Number Bus	XTN	40	Retain office phone No.
14	Primary Language	CE	60	Retain mother tongue
15	Marital Status	CE	80	Retain Marital Status
16	Religion	CE	80	Retain religion
…	The rest part is not needed to be filled.			

Example. PID|1|1010051|A1123145|15|Mary||19811011|M

3.3. PV1---Definition of patient visiting record field

No.	Field	Data Type	Length	Explanation
1	Set ID PV1	SI	4	Identify different fields, fill with 1 generally.
2	Patient Class	IS	1	Patient category
3	Assigned Patient Location	PL	80	Be used to indicate patient department

Example. PV1|1Clinic| Surgery |

3.4. OBR--- Definition of Doctor's Advice

No	Field	Data Type	Length	Explanation
1	Set ID OBR	SI	4	Identify different fields, fill with 1 generally.
2	Placer Order Number	EI	22	Serial number
3	Assigned Patient Location	EI	22	Sample number
4	Universal Service ID	CE	200	Universal service ID
5	Priority	ID	2	Priority set null
6	Requested Date Time	TS	26	Application time
7	Observation Date Time	TS	26	Inspection starting time, set null
8	Observation Date Time end	TS	26	Inspection end time
9	Collection Volume	CQ	20	Specimen collection capacity, set null
10	Collector Identifier	XCN	60	Sender name
11	SPE Action Code	ID	1	Sample handling code, set null
12	Danger Code	CE	60	Danger code alarm
13	Relevant Clinical Info	ST	200	"Diagnosis" ^ "Remark", each length should not be more than 100 bytes
14	SPE Received Date Time	TS	26	Sample receiving time
15	SPE Source	CM	300	Sample classification, blood, urine etc.
16	Ordering Provider	XCN	120	Inspector name
17	Order Callback Phone Number	XTN	40	Callback phone, set null
18	Placer Field1	ST	60	Sender field 1, Inspection department

19	Placer Field2	ST	60	Set null
20	Filler Field1	ST	60	Operator field 1, set null
…	The rest part is not needed to be filled.			Set null
28	Result Copies to	XCN	60	Verifier

Example：
OBR|1|1010051|000001|URIT^Spincell 5plus||20101010093000||20101010093500||sender|||diagnosis^remark||BLD|Inspector||||||||||verifier|

3.5. OBX

No	Field	Data Type	Length	Explanation
1	Set ID OBX	SI	4	Identify different fields, fill with 1 generally.
2	Value Type	ID	3	NM means figure type, ST means value type
3	Observation Identifier	CE	590	Observe identifier name
4	Observation Sub ID	ST	20	Observe sub-id project name
5	Observation value	ST	65535	Check result
6	Units	CE	90	Unit
7	References Range	ST	90	Reference range is from small to big, QC means reference value and deviation.
8	Abnormal Flags	ID	5	H,L and N indicate high, low and normal value respectively.
9	Probability	ID	5	Probability, set null
10	Nature of Abnormal Test	ID	2	C indicates WBC and RBC clog, B indicates bubble, when normal, set null
11	Observe Status	ID	1	Observe results, take F for final result.
12	Date Last Observe	TS	26	The time for observing normal value, set null
13	User Defined Access Checks	ST	20	Original results

Example. OBX|1|NM|WBC||8.21|10^9/L|4.00-10.00|L|||F||

3.6. MSA

No	Field	Data Type	Length	Explanation
1	Acknowledgment Code	ID	2	Confirmation code. AA is for receiving, AE for error and AR for refusing.
2	Message Control ID	ST	20	
3	Text Message	ST	80	Message
4	Expected Sequence Number	NM	15	
5	Delayed Acknowledgment Type	ID	1	
6	Error Condition	CE	100	Error condition

MMSA-6 is used to indicate different errors, see the table below.

MSA-1	MSA-6	MSA-3	False Description
AA	0	Message accepted	Receive successfully
AE	101	Segment sequence error	The fields order in message is not correct, or the necessary fields are lost.
	102	Required field missing	Necessary fields of a paragraph are lost.
	103	Data type error	Data type of fields is false. For example, digital is changed into character.
	104	Key not found	Key identifier is not found
	105	Resend	Resend data
AR	201	Unsupported message type	Unsupported message type
	202	Unsupported event code	Unsupported event code
	203	Unsupported processing id	Unsupported processing ID
	204	Unsupported version id	Unsupported version ID
	205	Unknown key identifier	Unknown key identifier，For example, transmit an inexistent patient information.

	206	Duplicate key identifier	Duplicate key identifier
	207	Application record locked	Affairs in application storage level can't be carried out. For example, database is locked
	208	Application internal error	Other errors in unknown application.
	209	Application unready	Application is not ready

3.7. ERR

No	Field	Data Type	Length	Explanation
1	Error Code and Location	CM	80	Code and position error

ERR-1

Assembly 1	Assembly 2	Assembly 3	Explanation
001	Record already exist	Test tube No.	The test tube record has already existed.
002	Lis Recieved Faild	Test tube No.	Lis receiving error, resending data is required.
003	Read REQ error	Test tube No.	Fail to read request form.
004	Read BarCode Errer	Test tube rack No.	Analyzer fails to read test tube number.

3.8. QRD

No	Field	Data Type	Length	Explanation
1	Query Date/Time	TS	26	Query time
2	Query Format Code	ID	1	D （display format）
3	Query Priority	ID	1	I（Immediate）
4	Query ID	ST	10	Distinguish different queries ,accumulate with query times. The initial value is 1.
5	Deferred Response Type	ID	1	Set null
6	Deferred Response Date/Time	TS	26	Set null
7	Quantity Limited Request	CQ	10	RD（Records）
8	Who Subject Filter	XCN	60	Take as a test tube code \

				sample number.
9	What Subject Filter	CE	60	OTH
10	What Department Data Code	CE	60	Set null
11	What Data Code Value Qual.	CM	20	Set null
12	Query Results Level	ID	1	

3.9. QRF

No	Field	Data Type	Length	Explanation
1	Where Subject Filter	ST	20	Take Spincell 5plus
2	When Data Start Date/Time	TS	26	Application time
3	When Data End Date/Time	TS	26	Deadline
4	What User Qualifier	ST	60	Set null
5	Other QRY Subject Filter	ST	60	Set null
6	Which Date/Time Qualifier	ID	12	RCT(Specimen receipt date/time, receipt of specimen in filling ancillary (Lab))
7	Which Date/Time Status Qualifier	ID	12	ANY(Any status)
8	Date/Time Selection Qualifier	ID	12	ALL(All values within the range)
9	When Quantity/Timing Qualifier	TQ	60	Set null

3.10. QSP

No	Field	Data Type	Length	Explanation
1	Set ID - DSP	4	SI	
2	Display Level	SI	4	
3	Data Line	TX	300	Content queried
4	Logical Break Point	ST	4	
5	Result ID	TX	20	

Use QSP-1 to distinguish different queried information in QSP fields.

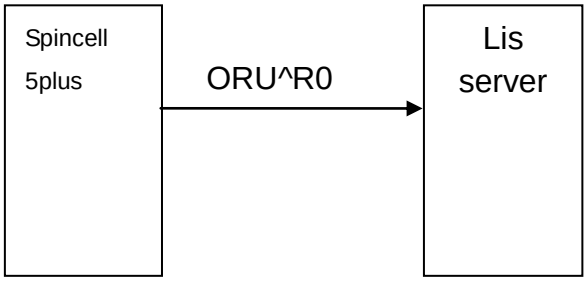
Set ID – DSP	Message
1	Test Tube Number
2	Serial Number
3	Name

4	Sex
5	Birthday
6	Blood Type
7	Group
8	Patient Number
9	Bed Number
10	Patient Type
11	Department
12	Sender
13	Inspector
14	Verifier
15	BLDV is for venous blood, BLDC is for peripheral blood.
16	Clinical diagnosis
17	Remark
18	Sampling time, sending time
19	inspection time

Example
DSP|1||Mary||<CR>

4. Communication process

4.1. Analyzer transmits test results to lis server



<SB>
MSH
PID
PV1
OBR
OBX
OBX
……
<EB><CR>

OBX fields can be repeated. Transmitted test results include patient information, 24 parameters, 2 histograms and 2 scatter plots. The 2 histograms and 2 scatter plots are BMP format and transmitted with base64 code,

For example：
Analyzer transmits test results to lis server
<SB>
MSH|^~\&|URIT|Spincell
5plus|LIS|PC|20110627144458||ORU^R01|0001|P|2.3.1|||||UNICODE<CR>
PID|1|||||||<CR>
PV1|1|||<CR>
OBR|1||BAR101010101|URIT^Spincell
5plus||||01110621143134|||||^||||||||||||||<CR>
OBX|1|NM|WBC||110.0|10^9/L|40.0-100.0|H|||F||||||<CR>
OBX|2|NM|LYM||35.57|%|20.00-40.00||||F||||||<CR>
OBX|3|NM|MON||5.84|%|3.00-8.00||||F||||||<CR>
OBX|4|NM|NEU||57.37|%|50.00-70.00||||F||||||<CR>
OBX|5|NM|EOS||1.14|%|0.50-5.00||||F||||||<CR>
OBX|6|NM|BASO||0.08|%|0.00-1.00||||F||||||<CR>
OBX|7|NM|LYM#||284.5|10^9/L|80.0-400.0||||F||||||<CR>
OBX|8|NM|MON#||46.7|10^9/L|10.0-80.0||||F||||||<CR>
OBX|9|NM|NEU#||458.9|10^9/L|200.0-700.0||||F||||||<CR>
OBX|10|NM|EOS#||9.1|10^9/L|0.0-50.0||||F||||||<CR>
OBX|11|NM|BASO#||0.6|10^9/L|0.0-10.0||||F||||||<CR>
OBX|12|NM|RBC||4.49|10^12/L|3.50-5.50||||F||||||<CR>
OBX|13|NM|HGB||0|g/L|0-1079738368|L|||F||||||<CR>
OBX|14|NM|HCT||26.4|%|37.0-50.0|L|||F||||||<CR>
OBX|15|NM|MCV||59.0|fL|80.0-100.0|L|||F||||||<CR>
OBX|16|NM|MCH||24.0|pg|27.0-31.0|L|||F||||||<CR>
OBX|17|NM|MCHC||0|g/L|0-1081344000|H|||F||||||<CR>
OBX|18|NM|RDW_CV||16.1|%|11.5-14.5|H|||F|||||<CR>
OBX|19|NM|RDW_SD||45.0|fL|35.0-56.0||||F|||||<CR>
OBX|20|NM|PLT||0|10^9/L|0-1079574528|H|||F||||||<CR>
OBX|21|NM|MPV||12.3|fL|7.0-11.0|H|||F||||||<CR>
OBX|22|NM|PDW||14.7|fL|15.0-17.0|L|||F||||||<CR>
OBX|23|NM|PCT||0.41|%|0.10-0.28|H|||F||||||<CR>
OBX|24|NM|P_LCR||1.37|%|0.50-1.80||||F||||||<CR>
OBX|25NM|RBCHistogram^LeftLine||1|||||F|||||<CR>
OBX|26|NM|RBCHistogram^RightLine||118|||||F|||||<CR>
OBX|27|ED|RBCHistogram||Spincell
5plus^Histogram^512Byte^HEX^000000000000000000000000000000000000
00000102030406080a0d0101010202030404050607080 90a0b0c0c0d0d0c0c
0c0b0a0a09080807070606060505050404040403030303020202020101010101
01010f0d0c0a09080707060505050404040303030202020201010101010000
00000000000000000000000000000000000000000000000000000000000000000

0000000000000000000000000000000000000000000000000000000000000000
0000000000000000000000000000000000000000000000000000000000000000
0000000000000000000000000000000000000000000000000000000000000000
0000000000000000000000000000000000000000|||||F|||||<CR>
OBX|28|NM|PLTHistogram^LeftLine||8|||||F|||||<CR>
OBX|29|NM|PLTHistogram^RightLine||127|||||F|||||<CR>
OBX|30|ED|PLTHistogram||Spincell
5plus^Histogram^256Byte^HEX^000000000505060101020304050506070809
0a0b0b0b0b0b0b0a0a0a0b0b0b0b0c0c0b0b0a0a09080706060505050606
060606050505040403030303020202020202020202020202020202020202
020101010101010102020202020303030302020202010101010101020202
020202020202020202020303030303030303|||||F|||||<CR>
OBX|31|ED|S0_S10DIFFScattergram||Spincell
5plus^Image^BMP^Base64^Qk32IgMAAA……<CR>
OBX|32|ED|S90_S90DDIFFScattergram||Spincell
5plus^Image^BMP^Base64^Qk32IgMAAA……<CR>
<EB><CR>

Appendix C License for Manufacturing

Measuring Analyzers

Appendix D Toxic and Hazardous Substances or Elements

Parts		Toxic and Hazardous Substances or Elements					
		Plumbum（Pb）	Mercury（Hg）	Cadmium（Cd）	Chromium VI（Cr(VI)）	Polybromi-nated Biphanyls(PBB)	Polybrominate-d Diphenyl Ethers（PBDE）
Host	Shell	○	○	○	○	○	○
	Printed circuit board Assembly	×	○	○	○	○	○
	Sheet metal Parts	○	○	○	×	○	○
	Plastic Parts	○	○	○	○	○	○
	Machining parts	○	○	○	○	○	○
	Hardware	○	○	○	○	○	○
	Flow System Parts	○	○	○	○	○	○
	Cable	○	○	○	○	○	○
Accessories		○	○	○	○	○	○
Packaging Materials		○	○	○	○	○	○

○：The content of toxic or hazardous substance in the homogeneous materials of the parts above is in the acceptable range of SJ/T11363-2006.
×：The content of toxic or hazardous substance is exceed the acceptable range of SJ/T11363-2006 in at least one kind of homogeneous material of the parts above.
(The circuit board used lead solder in machining process and sonme parts of the board contain plumb；And some sheetmetal parts use chromium VI for surface ）
Memo：Printed circuit board Assembly is consist of printed circuit board, capacitance, connector and other parts. Lithium cell is detachable and recyclable part.

Appendix E Daily Operation Procedures

1. Startup and Run

(1) Make sure the power wire is properly connected, None reagent tubes is bending or detached, Check if the waste container is full.

(2) Turn on the power of computer and analyzer,

(3) The analyzer starts to performing initialized self-checking program automatically and rinse the flow system, then goes to main Interface. It's takes about 8 minutes.

(4) Perform a background count and QC control to ensure the analyzer operates normally.

(5) Whole Blood Auto Sampling mode for analyzing a group of specimens and Whole Blood Single Sampling mode for an emergency specimen.

(6) Query, output and print the data.

(7) Necessary maintenance should be operated according to the situation.

2. Shutoff Procedures

(1) Click Exit in the main interface to shutoff,

(2) The analyzer automatically rinse the flow system,

(3) Turn off the power switches off the analyzer and computer when display "Thank you for using, please turn off the power" display on the screen.

3. Daily Maintenance (perform it before shutoff

(1) The analyzer automatically performs daily maintenance with the time set according to the quantity of the test samples.

(2) If ruby aperture is clogged, perform "Cauterize Aperture", "Flush Aperture" "Soak WBC" and "Soak RBC" procedures in the MAINT interface.

(3) When continuously use the analyzer, shutoff procedure should be performed at least once every 24 hours.

4. Weekly Maintenance

(1) The surface maintenance of the analyzer.

(2) Clean the aspiration probe.

(3) Clean the groove of auto sampling and sample frame.

5. Monthly Maintenance

(1) Check and clean the reagent syringes.

(2) Mechanical parts maintenance.

6. Other Maintenances

If the ruby aperture is block aging severely, put the tube filled with probe detergent in emergency and perform “Soak WBC” or “Soak RBC”. select Empty WBC/RBC Cup, the analyzer will automatically empty the liquid in both sides of the aperture. And remove the ruby aperture, brush it with probe detergent or enzyme, then wash it with distilled the probe detergent is injected automatically into the cup soaking counting hole. Please do the blank count after soaking to check it is still clogged or not.

Appendix F Key Components

SN	Key components	Specifications
1	Power Supply	INPUT:AC 100V-240V OUTPUT:DC +5V/+12V/+24V
2	Wire	10A 250V
3	Outlet filter	120/250VAC 3A 50/60Hz
4	Fuse	T3.15AL 250V