5-Part-Diff Auto Hematology Analyzer

Spincell 5compact

Operation Manual

SPINREACT,S.A.U

Copyright and Declaration

Welcome to use our automated hematology analyzer. It will bring you new experience and convenience.

Declaration

All contents in this manual were strictly compiled according to related laws and regulations in local, as well as the specific condition of automated hematology analyzer, covering all the updated information before printing. Supplier 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.

All the information included is protected by copyright. No part of this document may be reproduced, stored or transmitted in any form or by any means unless written authorization by supplier.

All instructions must be followed strictly in operation. In no event should supplier 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

The manual for automated hematology analyzer, defines the rights and obligations between the supplier and the customers about the responsibility for quality warranty and after-sale service, also the related agreements on commencement and termination.

Supplier warrants the sold by the supplier 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 analyzer must comply

with the provisions of this manual.

3. Only the engineers who authorized by supplier can do the Maintenance and repair, and only the spare parts which approve by supplier 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 conditions.

6. The reagents comply with the provisions of the user manual.

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

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

a) Failure due to abuse the analyzer or neglect the Maintenance.

b) Use reagents and accessories other than manufactured or recommended by supplier.

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

d) Replace accessories not specified by supplier, or after Maintenance or repair by a service agent not approved or authorized by supplier.

e) Components are been dismounted, stretched or readjusted.

f) Operators not been trained.

Auto Hematology Analyzer hereinafter referred to as "analyzer".

 **CAUTION**

THE ANALYZER IS FOR PROFESSIONAL AND PRESCRIPTION USE ONLY.

Technical service and troubleshooting are provided by supplier Customer Support Center. Professional technician and sale representative will be sent to

offer you timely service when necessary.

SPINREACT,S.A.U

Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (Girona) España

Tel: +34 972 69 08 00

Fax: +34 972 69 00 99

Web: http://www.spinreact.com

Email: spinreact@spinreact.com

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Content

Chapter 1 Introduction

1.1 Overview

Welcome to read the Operation Manual of Spincell 5compact 5-Part-Diff Automated Hematology Analyzer. This manual includes instructions of analyzer operation and maintenance, as well as matters needing attention. To keep good performance, you must operate and maintain this instrument according to the manual.

Spincell 5compact 5-Part-Diff Automated Hematology Analyzer is an in vitro diagnostic medical device. It can analyze and output 34 parameters, 2 scatter diagrams and 2 histograms. It uses Multi-angle laser light scattering flow cytometry to detect, use colorimetry to measure HGB, uses coulter theory to measure WBC, RBC and PLT count.

NOTE

- Read this manual carefully before operating, especially the safety information. Please keep this manual properly for future reference.
- Misoperation will lead to misdiagnosing and delay of illness caused by inaccurate test results, or damage to operators and instrument, if it isn't used according to this manual.
- 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 accuracy of instrument.
- Please follow the manual strictly when operating this instrument. Any operations to simplify or optimize the inspection program may affect the accuracy of the test results.
- There are no reticulocyte parameters in specific instruments.Therefore there are only 31 parameters in these instruments.

1.2 Scope of Application

This manual applies to medical examiners, trained doctors, nurses and labors. Untrained personnel may not operate the analyzer. Read this manual to learn about Spincell 5compact's hardware and software, to set the system parameters and to perform daily operations, system maintenance and troubleshooting.

1.3 Hazard Sign

This manual uses the following warning conventions.

Symbol	
 **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 which, if non-compliance with procedures or engineering controls, may result laser damage to eyes.
	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

- analyzer complies with the requirements of Emission and Immunity of GB / T 18268.26-2010.
- According to the GB4824 A class equipment calculation and testing, the analyzer may cause radio interference in family environment. Please take protective measures.
- Please make electromagnetic environmental assessment before using it.

NOTE

- Please read this manual before the instrument is used, maintained and moved.
- Please strictly follow this manual to operate.
- Operating this analyzer in dry environment, especially with man-made materials (artificial fabrics, carpets, etc.), may cause static electricity and wrong conclusion.
- Do not use this instrument near strong radiation sources, otherwise it may be interfered.

1.4 Guidance

Operator can find the needed information according to the following table.

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 Service
Troubleshooting	Chapter 11 Troubleshooting
Detailed Specification	Appendix A
Communications Protocol	Appendix B

Name and content of poisonous and harmful substances or elements	Appendix C
Daily operation procedures	Appendix D
Key components	Appendix E
List of Accessories	Appendix F

1.5 Technical Parameters

Item	**Content**	**Explanation**
Measured Parameter	34 parameters ,2 scatter diagrams and 2 histograms	Scatter diagram, histogram
Operation	Open type sampling mode	Only need 20μL blood sample for test
Language	English	Upgrade software by U disk or online
Display Setting	Equipped with 10.4 inch color LCD monitors.	Data management and networking are convenient.
Data Storage	≥ 200,000 test results (with graphics)	
Speed	60 samples/ h	
Output Mode	External printer. Histogram can be chosen to be printed. Different warning signs prompt probable abnormalities of specimen.	Reference range can be printed out in English and Chinese report format.

Sample volume	Whole Blood Sampling Mode≤ 20 μL	Anticoagulation with EDTA-K2/EDTA-K3 in whole blood.
	Diluent Sampling Mode ≤20 μL	
Reagents	Diluent, Lyse, Detergent and Sheath	
Sample Probe Rinsing	Use the automatic washing device to flush the inside and outside wall of sample aspiration probe.	Avoid samples cross contamination and operators contact the samples.
Blood Separation	Precision stepper motor aspirates samples.	High precision and hard-wearing.
Unit Selection	Two units for WBC, RBC, HGB, PLT and other items.	Meet the parameters unit requests for different countries and places.
HGB Measurement	Measure HGB by cyanide-free spectrocolorimetry colorimetry. LED light source, 540nm wavelength colorimetry.	Environmental regents can avoid affecting operators' health, and be good for environmental protection. If use the toxic reagents, you need to purchase specialist processing equipment, which will increase costs.
RETIC Test	Test RETIC percentage by multi-laser scattering method.	
QC and Calibration	Calibration modes include standard, blood and manual calibration. QC modes includes L-J, X, X-R and X-B QC.	
Structure	Adopt separately	Enhance accuracy and Maintain

	removable syringe structure.	easily
Maintenance	Automatic monitoring function prompts operators 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.	Parameters can be adjusted according to different geographical groups, and the analyzer will automatically identify and match the best reference.
Flush	High-voltage cautery, soaking with probe detergent, flushing and intelligent auto rinsing.	
Security	Have a good electrical security with the flow electricity isolation system.	
Host Size	L490mm×W332mm×H459mm	
Power	250VA	
Fuse	250V/3.15AH	
weight	About 35kg	

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

- 5-Part-Diff Automated Hematology Analyzer is for blood cell count, WBC five part differential and hemoglobin concentration measurement in clinical laboratory.
- Only the reagents and detergents mentioned in this manual is allowed to use. 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 the functions of the analyzer will lose due to accidental mechanical damage and undesirable environment.
- The analyzer must be operated in accordance with the methods mentioned in this manual strictly.
- Keep long hair, fingers and clothes away from rotating parts.
- Turn off the power switch and unplug the power cord immediately if the analyzer gives off odor or smoke, otherwise it will cause fire, electric shock or injury. If this happens, please contact the our after-sale service department.
- Do not spill the samples or reagent and do not let other things to fall into

the instrument, otherwise it will cause short circuit. If this happens, turn off the power switch and unplug the power cord immediately, then contact the after-sale service department.

- Do not touch the circuit, especially a wet hand, which may cause electric shock.
- The analyzer must be connected to a power outlet with correct voltage, and grounding at the same time.
- Avoid damaging the power cord. Do not put any device upon the power cord. 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 instrument shall generate alternative electric field and magnetic field.
- The analyzer may not function properly due to the strong electromagnetic interference.
- It may cause data conversion errors and incorrect results due to strong electromagnetic interference and poor grounding.

2.5 Installation

- The analyzer must be installed in dry and dust-free place. Avoid placing in the place where is wet and with poor ventilation or in the dirty air with salt and sulfur. Since the 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 the analyzer to the place with large temperature difference and direct sunlight.

- Avoid vibration. The analyzer should be put into the box with foam to prevent damage during storage and transport. Improper package may lead to abnormal operation of the instrument.
- Installation site must be well ventilated.
- This analyzer does not produce ionizing radiation, but other equipment which produces X-ray and γ -ray may cause test results errors.
- The equipment should not be installed in the place where stores chemicals and generates gas.
- The frequency and voltage required should be consistent with those in the instruction and have the ability to allow current. The analyzer should be equipped with precision power supply or UPS.
- The equipment is about 35kg, so falling may cause injury during carrying.
- Wrong reagent or incorrect operation may cause wrong results.

2.6 Infection Prevention

- All the components and surface of the analyzer have potential infectivity. The sample probe should keep an appropriate distance from the surrounding objects in order to facilitate running.
- Wear protective clothing and rubber gloves during operation, maintenance, service or repair. Wash hands with disinfectant after work.
- Do not contact the waste and its components with free hands.
- If accidentally contact infectious material or surface, cleaning the skin with water immediately, and then sterilize 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 material 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 the reagent, rinse it with plenty of water immediately.
- If eye contacts the reagent, rinse it with plenty of water and seek medical advice immediately.
- It’s necessary to establish a set of emergency measures in laboratory.
- 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 let the reagents spill. If it happens, wipe away with a cloth.
- If you swallow reagents accidentally, please seek the medical attention immediately.
- Diluent is a kind of good conductor, if it’s spilled 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 detergent 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 instrument.

2.8 Maintenance

- As a precision electro-optical instrument, maintenance is necessary for normal operation. The test data may have small deviations without regular cleaning. In rare cases, 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 operation manual.
- Do the daily, weekly, monthly Maintenance in accordance with the operation manual .
- If the analyzer is not used for a long time, empty and rinse fluid system 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. It's a kind of class 3B laser product, at wavelength of 531-533nm, and the maximum power 11mW. Its visible laser 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 supplier can open it.

2.10 Consumables

The disposal of residual reagents, detergent 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 instrument work improperly.

2.11 Security Sign

	Caution. Refer to the accompanying document		Caution. Electric shock
	Caution. Hot surface		Biohazard
	Protective earthing		Power on
	Power off		In vitro diagnostic medical device
	Environmental protection lifetime		Keep away from heat and radioactive source
	Serial number		Manufacturer
	Recovery		May cause personal injury
	Refer to the operating manual		Put it up
	To be protected from rain		Do not roll
	Handle with Care		Stacking layers limit

2.12 Operators

- This medical analyzer must be operated by well-trained personnel exclusively. Misoperation will lead to misdiagnosing and delay of illness caused by inaccurate test results, or damage to operators and instrument, if it is used by untrained personnel. To avoid these risks, it's necessary to emphasize and make operators understand them.
- Failed to operate in accordance with instruction leads 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 resulted from unauthorized technicians and nonstandard maintenance.
- Invalid hardware/software affects the accuracy of test results. Operator needs to contact the after-sale service personnel as soon as possible.

WARNING

- Sample probe is sharp. It keeps moving when instrument is running, so please don't approach to it if you don't operate instrument.Please operate instrument in right way, and avoid pricking hands.

Chapter 3 System and Function

3.1 Overview

5-Part-Diff Automated Hematology Analyzer is an in vitro diagnostic medical device. It is used for blood cell count, WBC five part differential and hemoglobin concentration measurement in clinical tests. This analyzer provides necessary reference for clinical diagnosis.

The analyzer provides a fast count. All operations (including sampling, measurement and results output) are full automatic. The analyzer automatically starts testing after aspirating samples. Graphics data and results can be displayed in the LCD screen about 60 seconds later. The results can be printed or transmitted to the LIS system.

The biggest feature of the analyzer is that only 20μL blood sample is needed for the test.

3.2 Parameter

The analyzer automatically analyzes and arranges the samples data and shows the blood cell and white blood cell 5 part differential count respectively. Also, it gives the three-dimensional plot and scatter diagram of WBC and histogram of RBC and PLT, and generates the following 34 test parameters in Table 3-1, two histograms 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 value	10^12/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_LCR	Large Platelet Percent	%
P_LCC	Large Platelet Count	10^9/L

ALY%	Abnormal Lymphocyte Percent	%
ALY#	Abnormal Lymphocyte Count	10^9/L
LIC%	Large Immature Cell Percent	%
LIC#	Large Immature Cell Count	10^9/L
NRBC%	Nucleated Red Blood Cell Percent	%
NRBC#	Nucleated Red Blood Cell Count	10^9/L

Remark: PCT PDW ALY% ALY# LIC% LIC# NRBC% and NRBC# are the inferred parameters. They are provided for researching only.

3.3 Structure

WARNING

- The analyzer needs several people work together to move since it is 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 analysis part, information management part, result output part and an external printer (optional).

The analysis part is mainly composed of laser parts, sampling unit, A/D and the central control panel, the WBC measurement unit, RBC/PLT measurement unit, fluid system, and display screen.

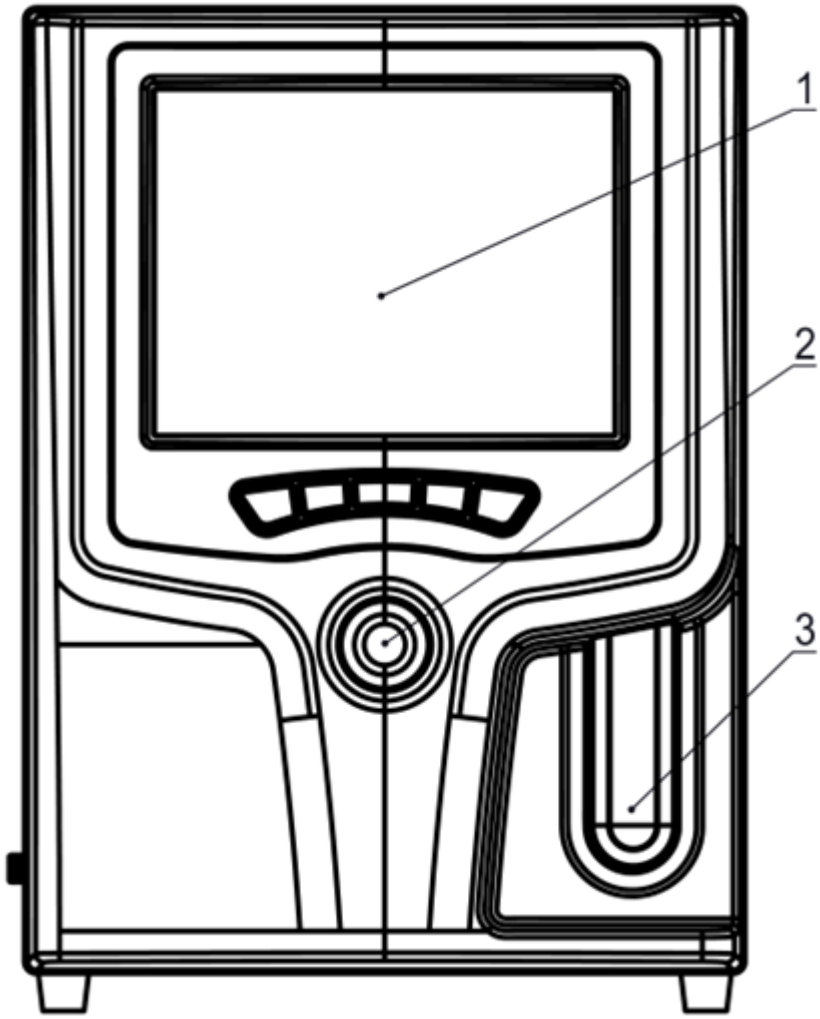

Figure 3-1A Front View

1--- Screen

2--- Working Status Indicator

3--- Counting Button

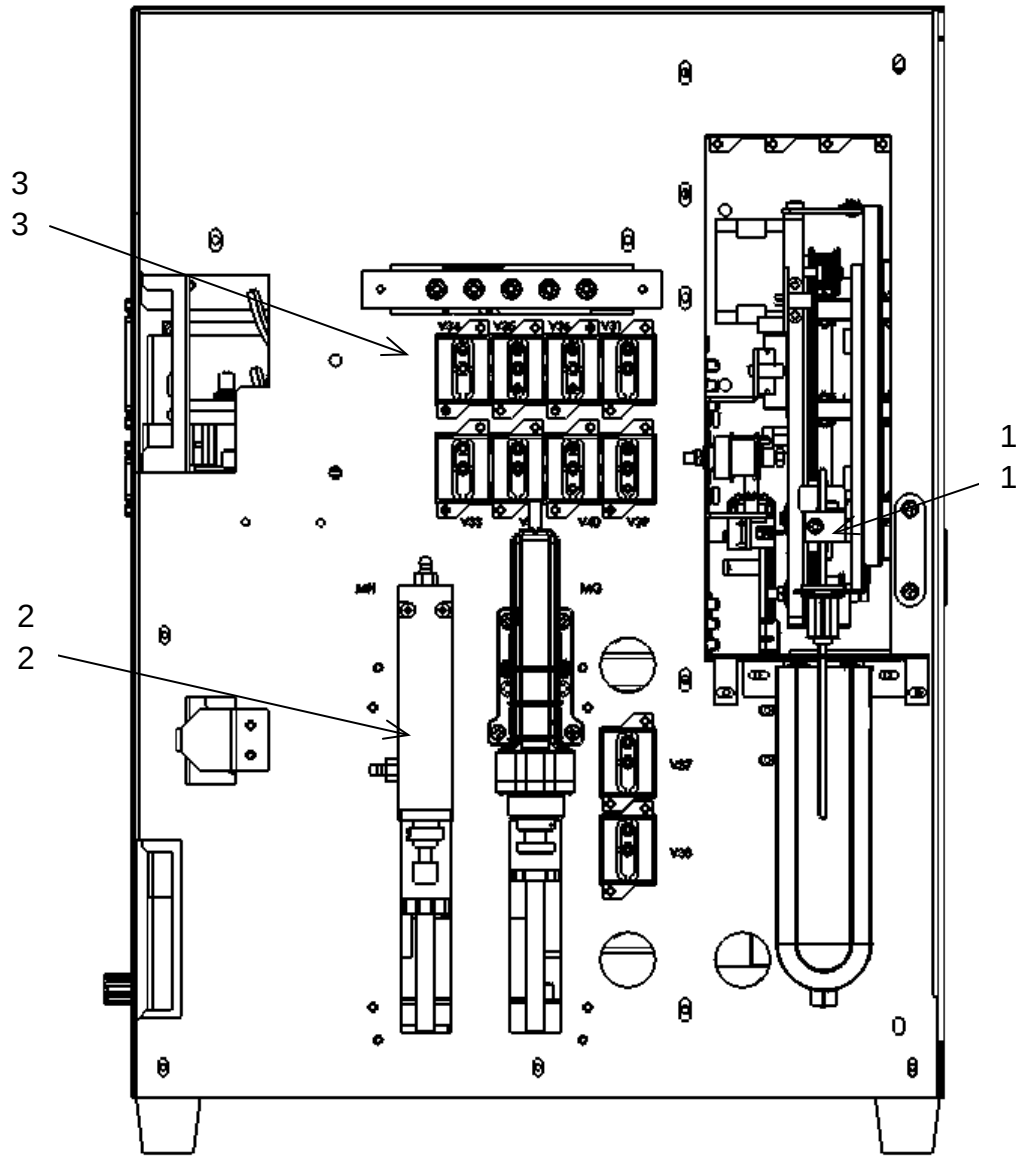

Figure 3-1B Front View (Remove the front housing)

1--- Sampling Unit

2--- Syringe Mechanism

3--- Solenoid Valve

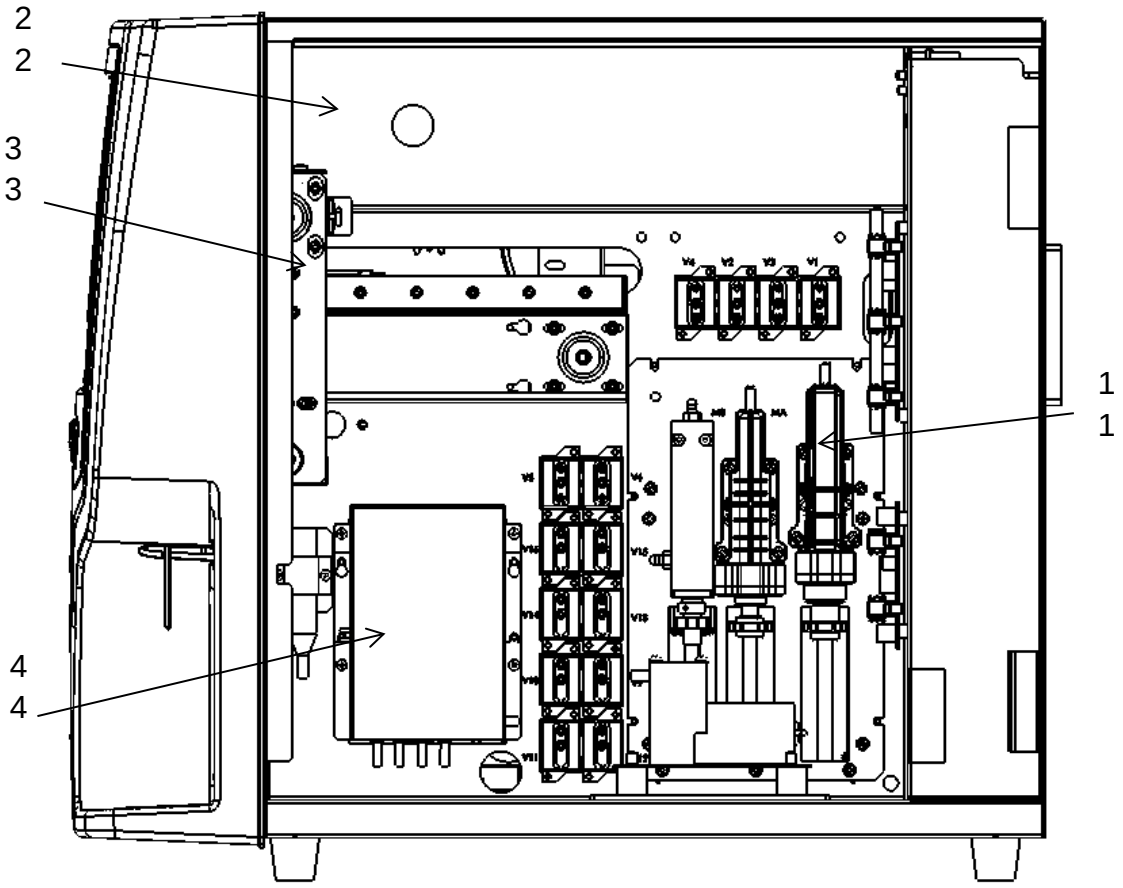

Figure 3-2 Right Side View (Remove the right side door)

1--- Syringes Module 2--- Optical Module

3--- Sampling Unit 4--- Transducer

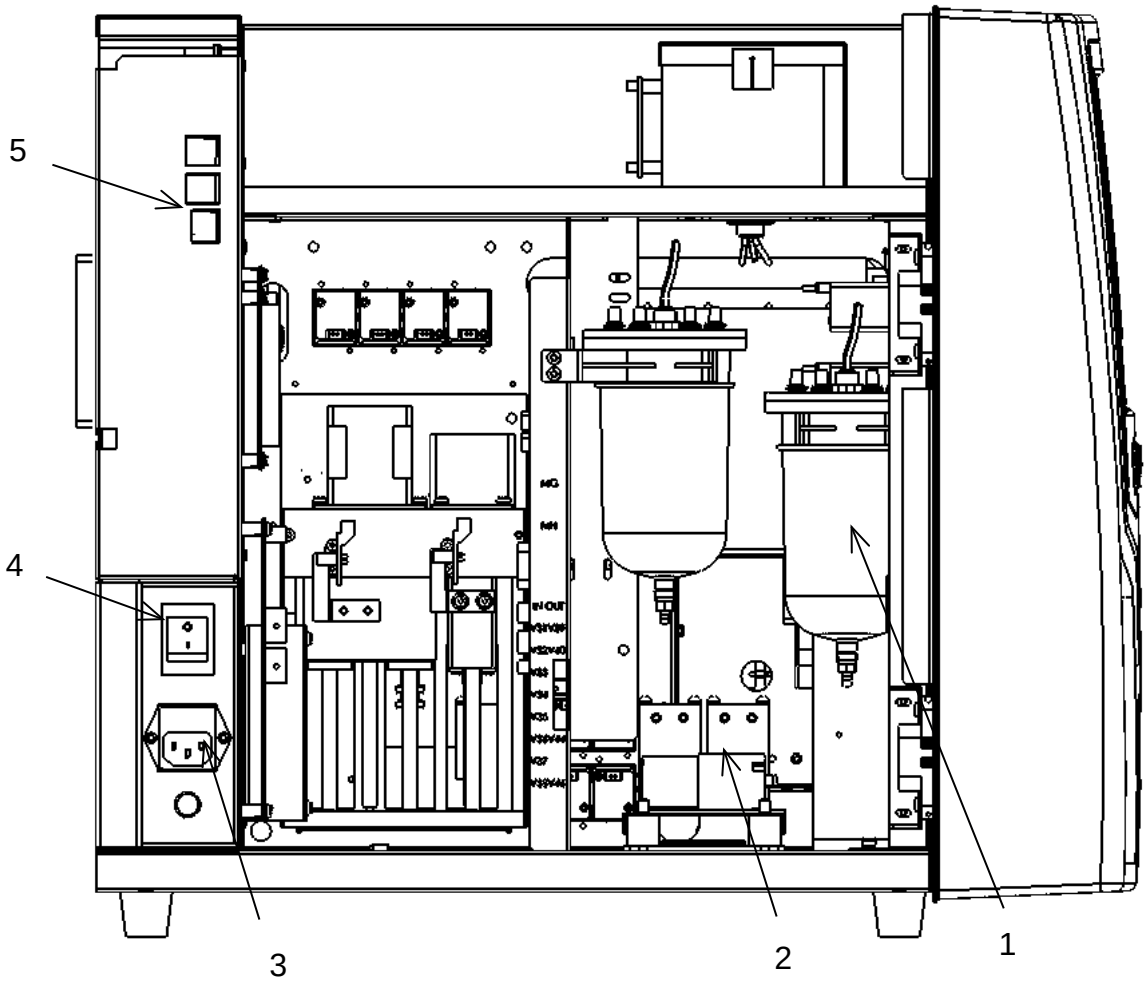

Figure 3-3 Left Side View (Remove the Left side door)

1--- Liquid pot 2--- Pump

3--- Power Socket 4--- Power Switch

5--- USB and Internet Interface

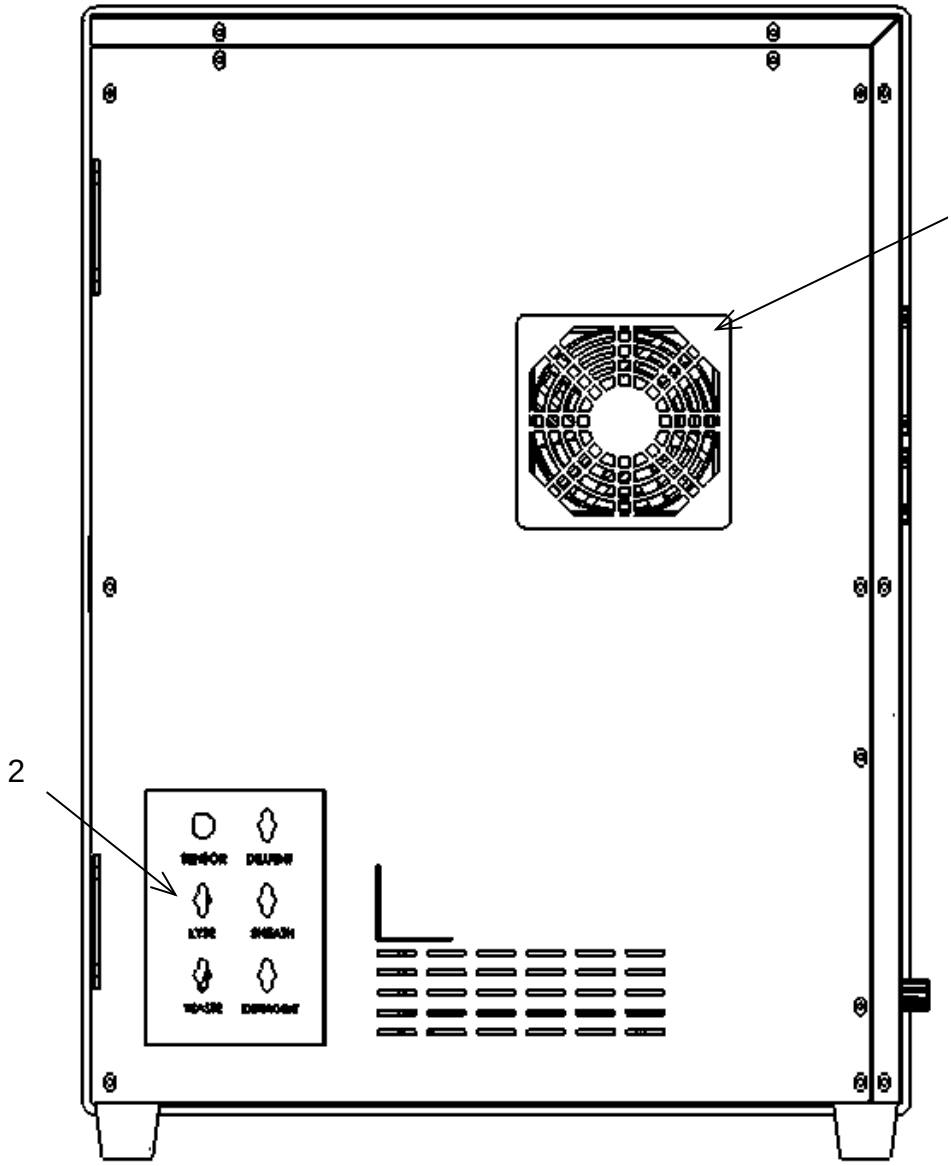

Figure 3-4 Rear View

1---Cooling Fan 2---Liquid interfaces

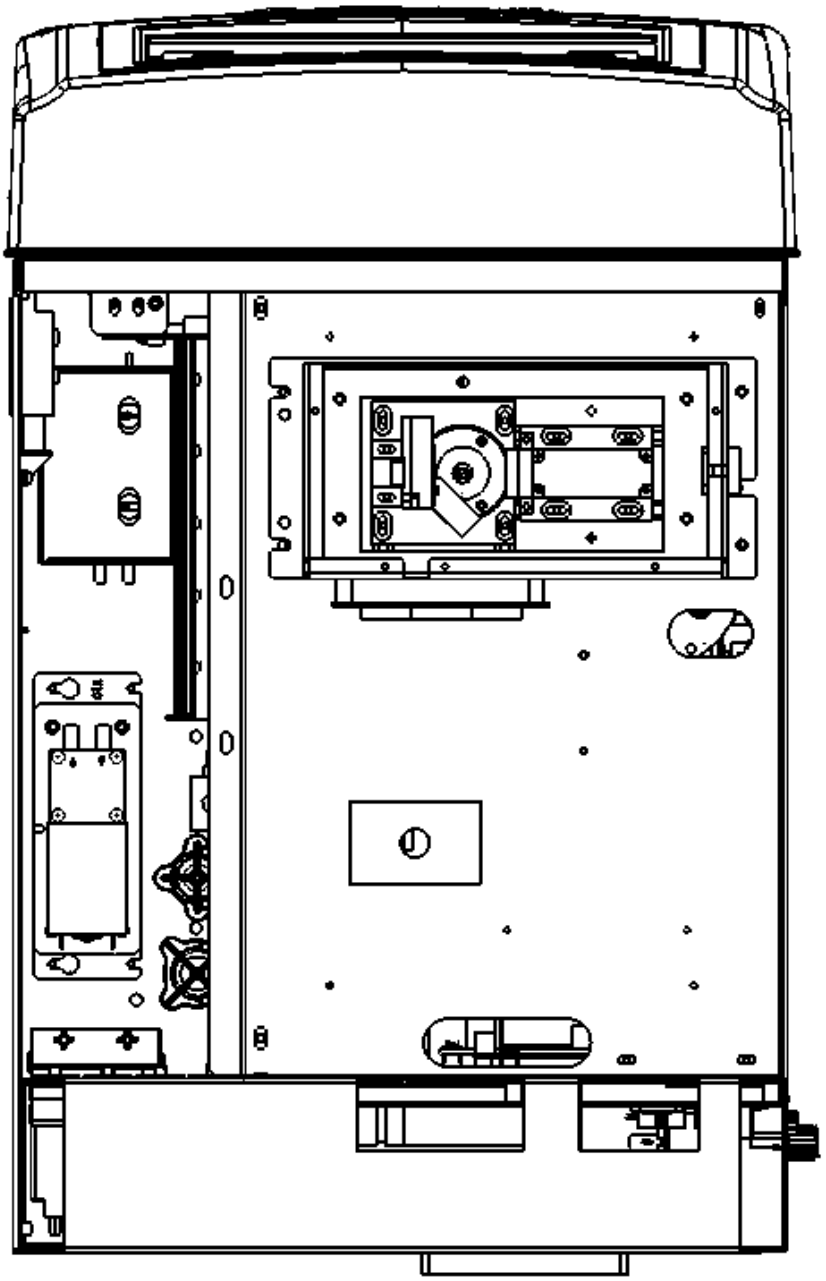

Figure 3-5　Vertical View（Optical Bench）

WARNING

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

3.4 Boot interface

Turn on the power switch on the left side, the analyzer program starts and enter self-checking interface. See Figure 3-6.

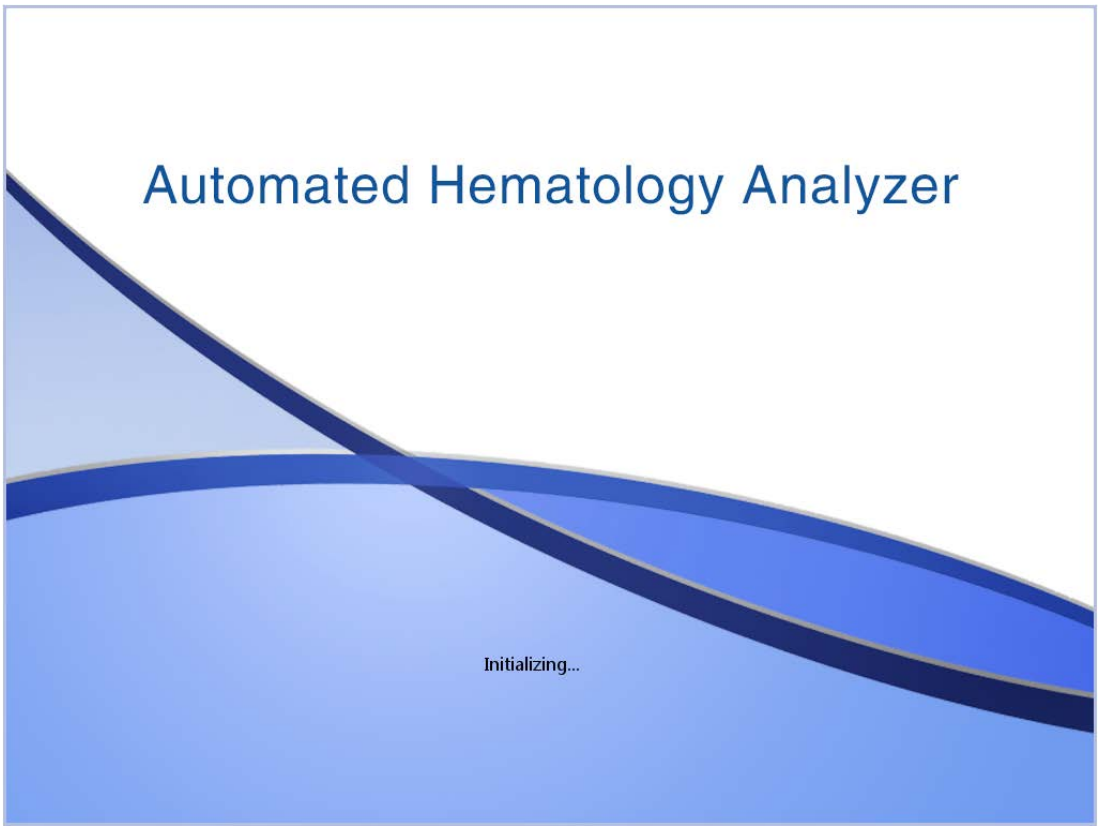

Figure 3-6 Initialization

Login interface pops up after initializing. The default username and password are “admin”. Click “Login” to enter test interface, click “Shut down” to turn it off. See Figure 3-7.

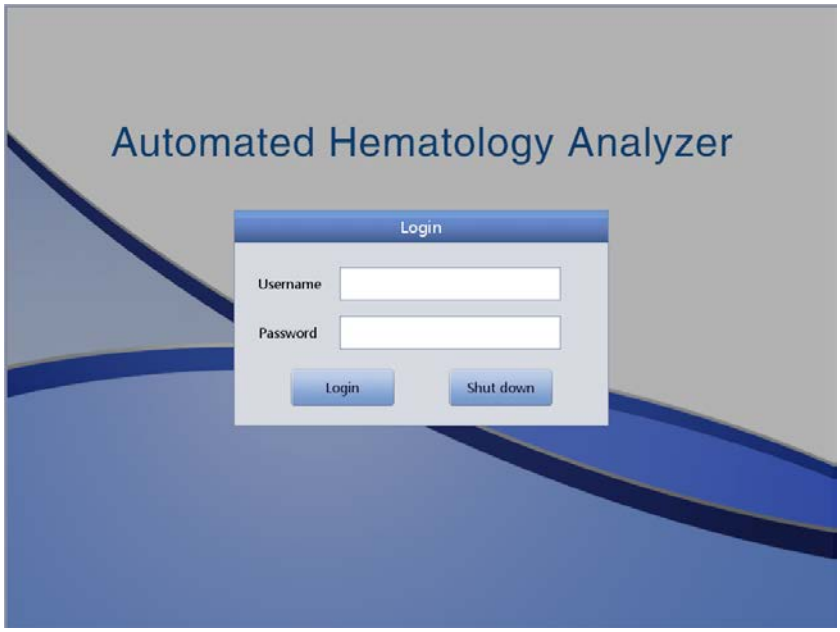

Figure 3-7 Login Interface

3.5 Test Interface

After startup, the analyzer enters test interface. See Figure 3-8.

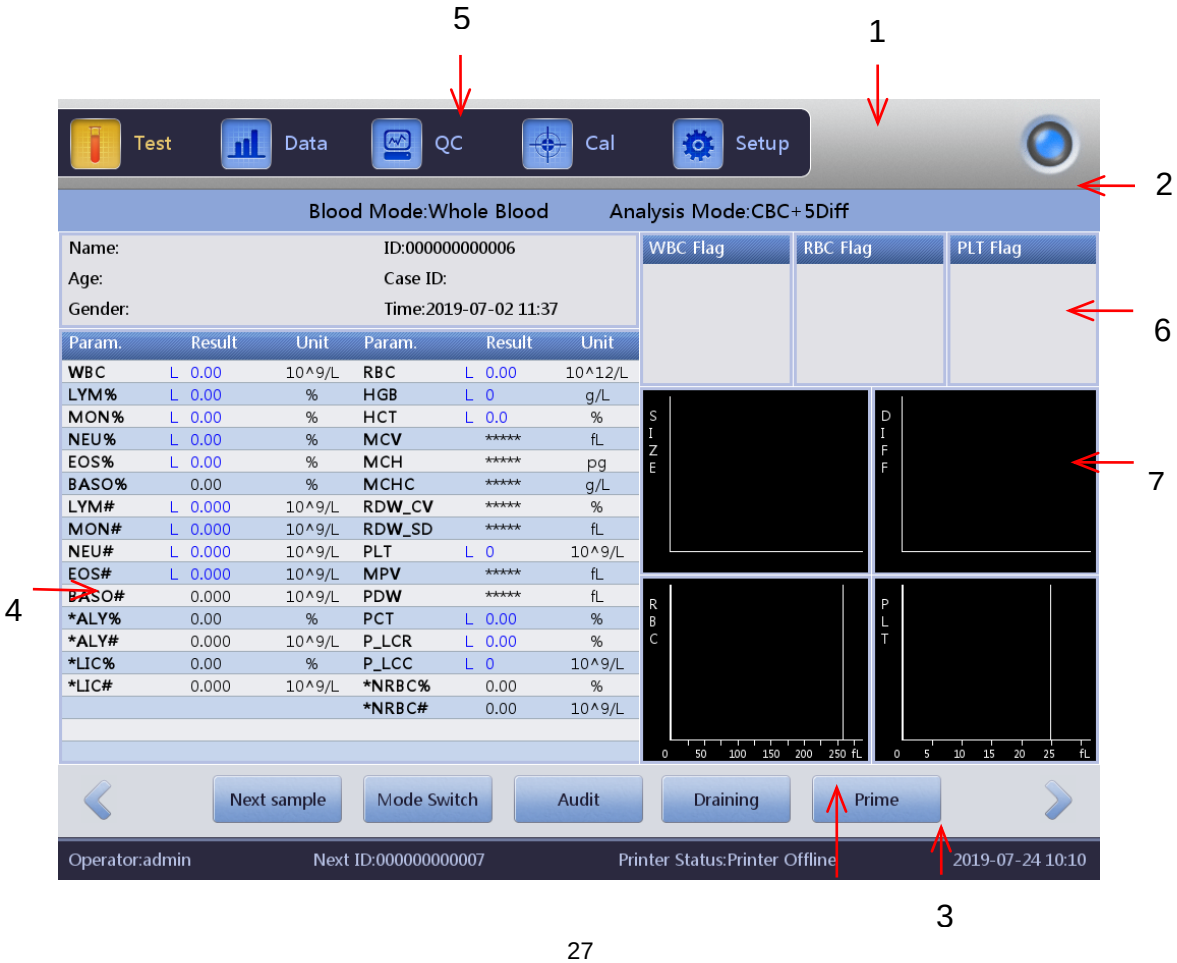

Figure 3-8 Test Interface

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

（1） **Information prompt area**

Display the anomalies that occur while using it.

（2）**Analysis modes area**

Select and indicate the system running state.

（3）**System status area**

Display the current time, date, operator, next ID and printer status.

（4）**Parameter information area**

Display each parameter results.

（5）**Function buttons area**

Display function buttons. There are three sets of function buttons.

The first set:

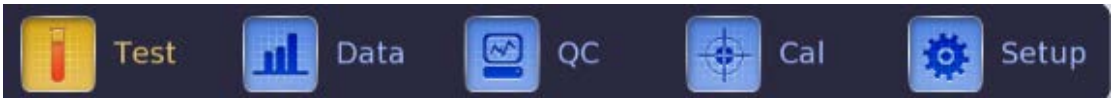


Figure 3-9A Function Button 1

Test: display test interface.

Data: enter data storage interface, query sample results.

QC：Enter the QC interface to run quality control operation.

Cal：Enter the calibration interface to run calibration operation.

Setup：Enter the setup interface to set system parameters.

The second set:

Figure 3-9B Function Button 2

Next sample: Create a new sample ID and edit it.

Mode switch: Switch the counting mode to ‘Rout. Blood’, ‘Retic. test’ or ‘Retic. Back. ’. Switch the blood mode to whole blood sampling mode or diluent mode, switch the analysis mode to CBC, CBC+5DIFF or CBC+5DIFF+RRBC.

Audit: audit the sample.

Draining: draining approximately 500 ul of diluent. It can only be used in diluent mode.

Prime: cleaning fluid system.

The third set:

Figure 3-9C Function Button 3

Click  and  to see the above figure.

Pre.record: to see the last record.

Next record: to see the next record. If the current record is the last one, it shows gray.

Audit: audit the sample.

Edit result: modify sample results.

Print: print the sample results.

Transmit: transmit sample data.

（6） Prompt area of abnormal results

Display abnormal results.

（7）Graphic display area

Display the scatter diagram and histogram.

3.6 Reagents, Control Materials and Calibrators

The reagent is configured specifically for the analyzer flow system in order to provide optimal system performance. Each analyzer is checked at the factory using the specified reagents and all performance claims were generated using these reagents. Thus non-analyzer reagents may affect analyzer performance, or result in serious mistakes, even accidents. Reagents mentioned in this Manual refer to the assorted 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 blank test should be done after the replacement of diluent, detergent, sheath or lyse 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.

3.6.1 Diluent

Diluent is a kind of tasteless transparent isotonic solution which is 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 to obtain accurate count and size.

(3) Clean WBC and RBC micro-aperture and fluid system.

(4) Provide a conductive environment for testing.

Validity period: Keep diluent under 5℃~35℃ after opening. Use it within validity period labeled in operation manual.

Once opened (connected to the analyzer), the product shelf life is only 60 days.

3.6.2 Sheath

Sheath is used to keep the original ecology of blood cells and bleach RBC to eliminate the scattering of laser. WBC maintains the closest cell structure to its original state. Basophil structure occur minor changes for the water-soluble property of basophilic granule. RBC osmotic pressure is higher than 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 good, the RBC and sheath have the same refractive index, and it showed under the laser virtually.

Validity period: Keep sheath under 5℃~35℃ after opening. Use it within validity period labeled in operation manual.

Once opened (connected to the analyzer), the product shelf life is only 60 days.

3.6.3 Lyse

Lyse is a kind of new reagent without azide and cyanide. It meets the following test requirements.

(1) Dissolve RBC instantly with minimum ground substance complex.

(2) Transform the membrane of the WBC to diffuse the cytoplasm. At the same time, the membrane will shrink around the nucleus. As a result, WBC is present in granular shape.

(3) Transform the hemoglobin to the hemo-compound which is suitable for the measurement in the condition of 540nm wavelength.

(4) Avoid the serious pollution to human body and environment that caused by cyanide.

Validity period: Keep lyse under 5℃~35℃ after opening. Use it within validity period labeled in operation manual.

Once opened (connected to the analyzer), the product shelf life is only 60 days.

3.6.4 Detergent

Detergent contains active protease which can eliminate protein aggregation so as to clean WBC cup and RBC cup and fluid system, and prevent clogging.

Validity period: Keep detergent under 5℃~35℃ after opening. Use it within validity period labeled in operation manual.

Once opened (connected to the analyzer), the product shelf life is only 60 days.

3.6.5 Probe Detergent

The probe detergent contains potent oxide that can clear protein so as to solve the problems of WBC and RBC cups clogging.

WARNING

- Detergent and probe detergent is alkali cleaning agent.

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

  (2) Once contact with skin, rinse with water.

(3) Once contact with eyes, rinse with water and seek medical treatment immediately.

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

3.6.6 Control Material and Calibrator

Control material and calibrator are for analyzer quality testing and calibration.

Control material is an industrial production of whole blood. It is a hematology reference control used in monitoring determinations of blood cell values on hematology analyzers.There are three kinds of control materials: low, normal and high value. These three kinds must be run every day to ensure the reliability of the results. Calibrator is also an industrial production of whole blood. It is used for calibration. Please refer to the instruction of control material and calibrator for use and storage methods.

The control material and calibrator mentioned in this manual refer to the special control material and calibrator assigned by supplier. Users can purchase from supplier or agents designated by supplier.

.

Chapter 4 Installation

4.1 Overview

CAUTION

- Environment Requirements
- Temperature: 15℃~ 35℃
- Relative humidity: 30%~85%
- Place the analyzer on a smooth and big enough platform which is easy to operate. Away from direct sunlight.
- Try to use a separate AC outlet, and install stabilized voltage supply or UPS (Uninterruptible Power Supply). Do not share an AC outlet with centrifuges, room temperature shower (thermostat), refrigerators, air conditioners or ultrasonic cleaning equipment or other equipment which may interfere with the analyzer.

WARNING

- Installed and unpacked the analyzer by an unauthorized or untrained person could result in personal injury and instrument damage. Never attempt to install and unpack the analyzer without a supplier authorized representative.

This analyzer has been tested strictly before delivery. It has been carefully packed before transporting in order to avoid damage. Check the package carefully to see whether there is a physical damage when arrive. If damaged, please immediately contact our after-sale service department or local agent.

4.2 Unpacking and Inspection

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

(1) Count accessories according to the packing list.

(2) Check if there is leakage or soakage.

(3) Check if there is mechanical damage.

(4) Check all exposed lead, inserts and accessories.

Please contact our after-sale service department or local agent if any problem occurs.

4.3 Space Requirements

In order to ensure the proper space for operation, maintenance and replacement of reagents, the host installation needs to meet the following requirements.

(1) Near the power supply.

(2) Eight inches of space behind the analyzer must be left for air flow.

(3) 50 cm of space at least to either side of the analyzer for service access.

(4) Sufficient space is required beneath for placing reagents, waste containers.

4.4 Power Supply Requirements

Be sure that the system is located at the desired site before attempting any connections. 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 for ensuring accuracy of analyzer and safety of operator.
- A fluctuated voltage would impair performance and reliability of the analyzer. Proper action such as the installation of AC manostat (not provided by supplier) should be taken before operation.
- Frequent power failure shall seriously decrease the performance and reliability of the analyzer. Proper action such as the installation of UPS (not provided by supplier) should be taken before operation.

4.5 Environment Requirements

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

(2) Relative humidity: 30% ~ 85%

(3) It's recommended to install air conditioner.

(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.

(8)Electromagnetic compatibility design for class A of group1, electromagnetic environment assessment should be carried out before use.

WARNING

- The analyzer takes full account of the electromagnetic compatibility problems. The electromagnetic interference generated by analyzer does not disturb itself and devices nearby. If the test result has a large deviation,

please check whether the analyzer is placed near an electromagnetic field or a short wave radioactive source (radar, X ray, centrifuge, scanner, cell phone etc.

4.6 Waste Requirements

For every 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

- To prevent environmental pollution, the waste is prohibited to pour 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 Tubing Installation

There are five liquid interfaces on the rear panel, which are DETERGENT, DILUENT, LYSE, SHEATH and WASTE. Each of them is wrapped with a cap to avoid contamination by the supplier before delivery. Uncover and set the caps aside carefully for further use on initial installation.

NOTE

- After installation, all tubes should be in a nature relaxed state and without distortion.
- Using tools for tubing installation is prohibitive. Only installing by hand is allowed.
- The reagent cannot be used if the container is damaged or leaked, or if it exceeds the shelf life. Please contact local suppliers or after-sale service department directly.
- To ensure safety and take optimal system performance into account, manufacturers recommend that all reagents should be placed on the same base and lower than analyzer.

---

1. LYSE Tubing Installation

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

2. DILUENT Tubing Installation

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

3. DETERGENT Tubing Installation

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

4. SHEATH Tubing Installation

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

5. WASTE Tubing Installation

Take out the waste outlet tube with faucet from the accessories box, and inset it to the interface on the rear panel. Inset BNC plug to the SENSOR interface 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.

4.7.2 Printer Installation

Please install the printer according to the following steps.

1. Place the printer near to the analyzer so as to operate easily and put other reference manuals.
2. Take out the printer from the package.
3. Check the printer. If it’s damaged, please contact supplier.
4. Check that the printer power is off.
5. Assembly the printer according to printer manual.
6. Connect the power cord to the printer and 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 receiver size.

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

4.8 Transport and Storage Requirement

Before storage for a long time or transportation, please run the "Prepare Shipping" procedure. Please refer to *Chapter 10 Service* for details. Operating steps are as follows.

1. Select "Prepare Shipping" in "Maint" interface.
2. Follow the prompts to unplug the relevant tube connectors.
3. Analyzer starts to empty tubes.
4. Shut down the analyzer after emptying.
5. Keep all reagents' tubes well.

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 5compact uses electrical impedance method (also known as Coulter principle) to detect RBC and PLT count and volume distribution, colorimetry to measure HGB concentration, multi-angle laser light scattering method to do WBC five part differential. Three separated channels are used for getting the blood cells counting results respectively.

(1) Five part differential data are detected by laser in sheath flow regulator.
(2) HGB is measured by colorimetry in WBC/HGB cup.
(3) The data of RBC and PLT is detected by electrical impedance analysis in RBC cup.
The analyzer aspirates, dilutes and mixes the samples and then detects parameters in each counting process.

5.2 Sample Aspiration

Analyzer supports two modes of blood cell counting analysis.

1. Whole blood sampling mode

2. Diluent sampling mode

The sample volumes:

Whole blood sampling: 20μL

Diluent sampling: 20 μL

The whole blood sample is aspirated into the analyzer by the precision stepper motor and distributed into different measuring channels.

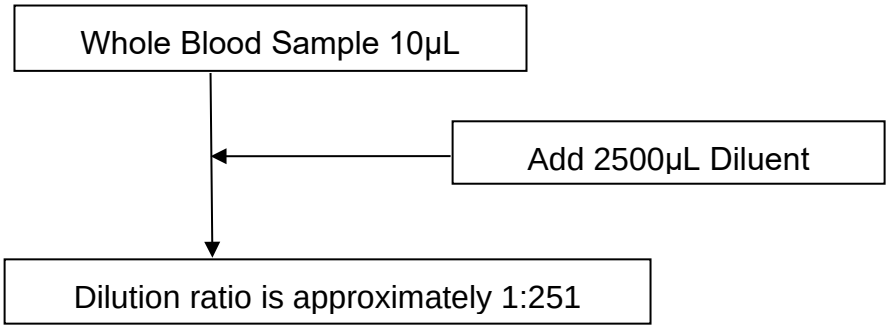
5.3 Sample Dilution

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 react with different reagents. Finally results of

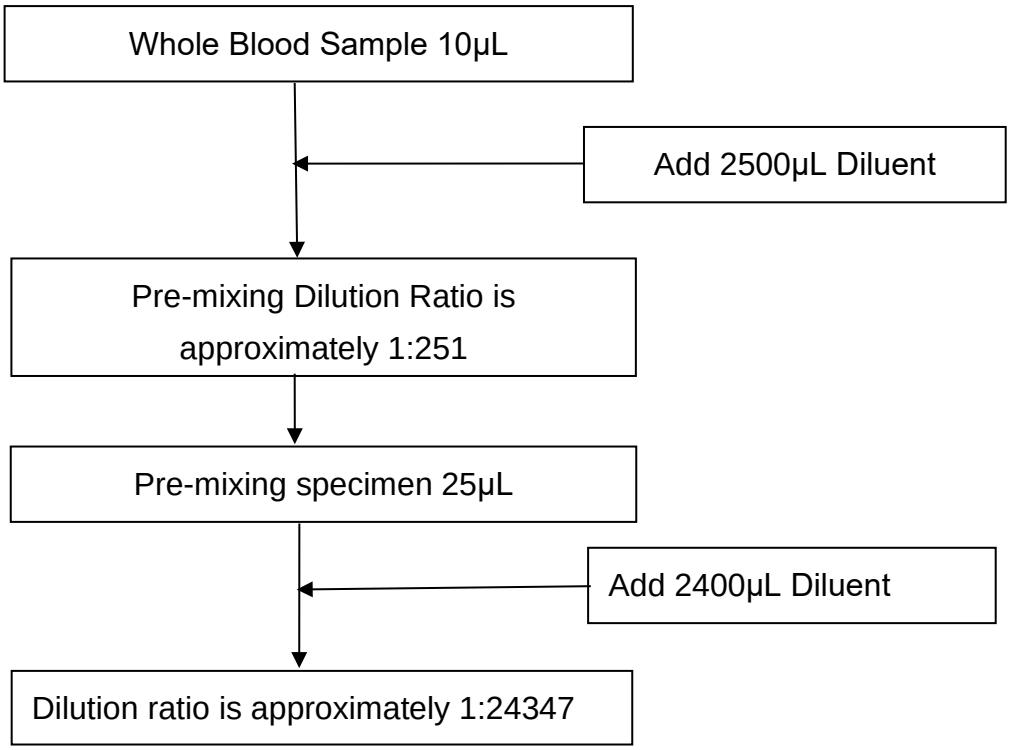
WBC count/HGB measurement, WBC/PLT count and WBC five part differential are obtained.

5.3.1 Whole Blood Sampling & 5Diff

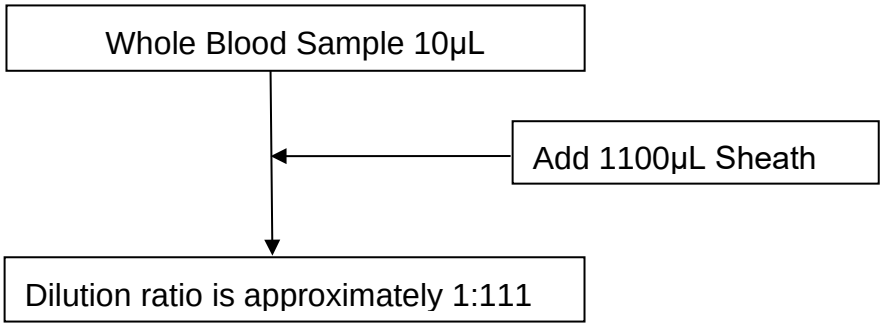
（1）WBC / HGB Dilution Process



（2）RBC / PLT Dilution Process

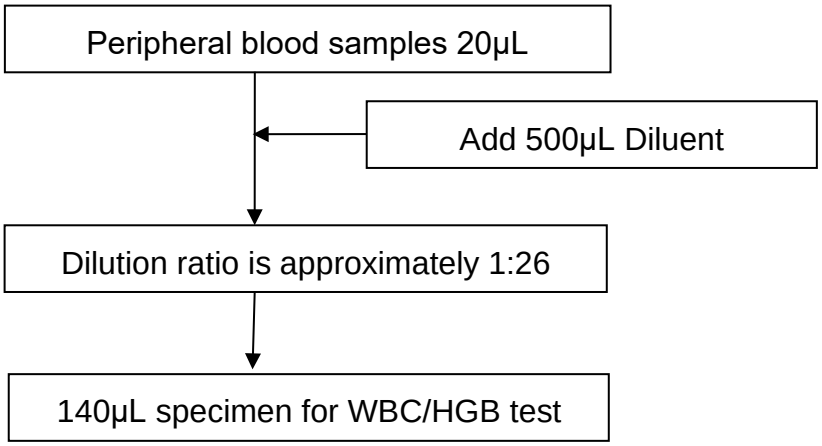


（3）WBC Differential Dilution Process

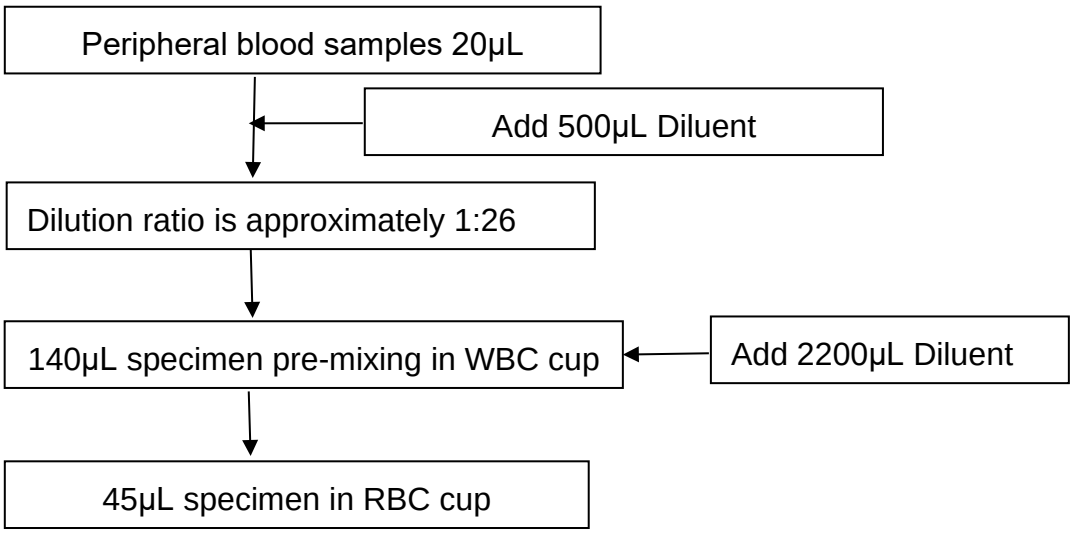


5.3.2 Pre-diluent CBC & 5Diff

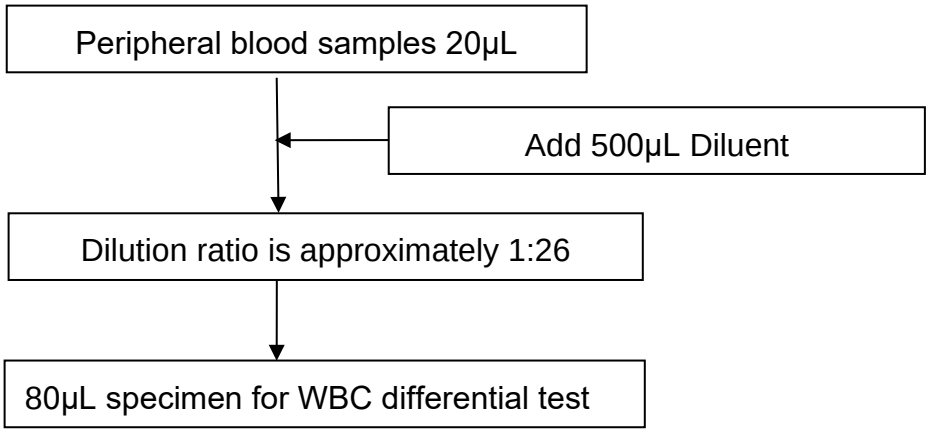
（1）WBC / HGB Dilution Process



（2）RBC / PLT Dilution Process



（3）WBC Differential Dilution Process



5.4 WBC Test Principle

5.4.1 Multi-Angle Laser Light Scattering Technology

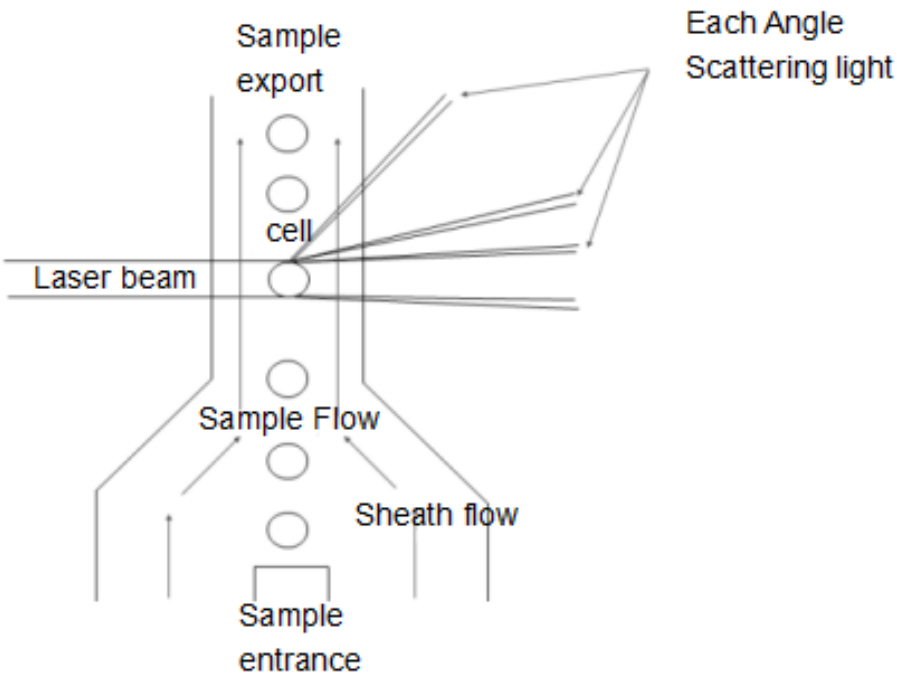


Figure 5-1 Sheath Flow Regulator

The whole blood samples are diluted in an appropriate proportion with sheath, and white blood cell remains its original state approximately. Using flow cytometry to make the cells in a single arrangement flow. The scattering density can be measured through the laser beam detection zone. Scattered light intensity of different types of cells from every angles is different due to the differences of cell size, cell membrane and cell internal structure. Scattered light signals received by photodetector at each angle are converted into pulse signals with different amplitudes. By analyzing the pulse signals of different angles, we can get the scatter diagram which represents the cell volume and related information. WBC are classified by the distribution of the pulse signals and the scatter diagram.

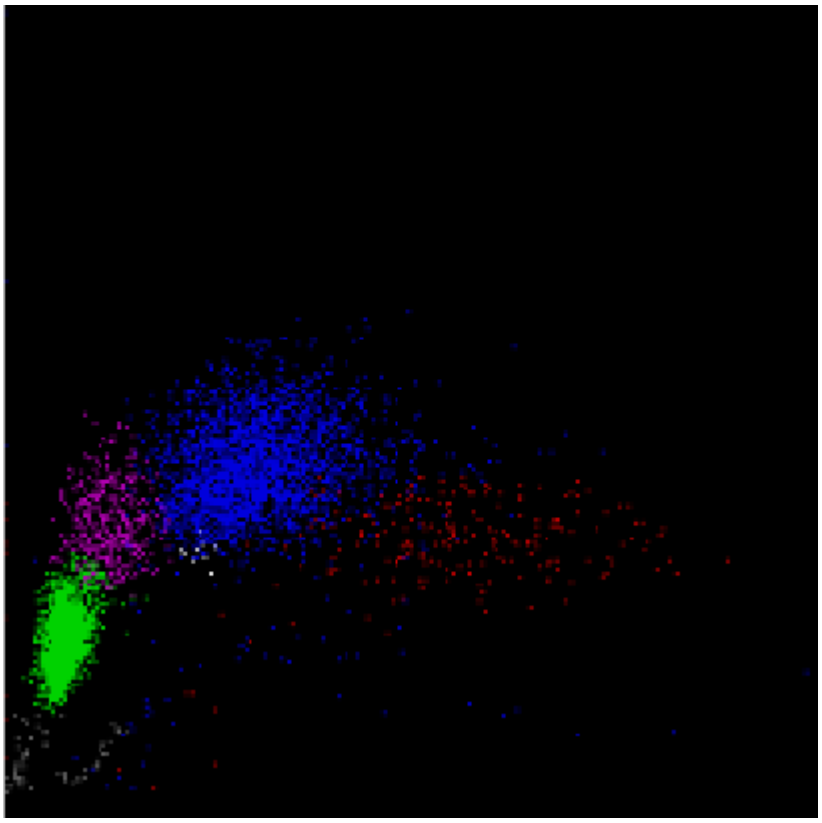


Figure 5-2 Scatter Diagram

The gray area is the ghost cells. It reflects that RBC dissolve into pieces on the scatter diagram; green is lymphocyte group; pink is monocyte group; blue is neutrophil; white is basophil group; red is eosinophil group.

5.4.2 WBC Differential

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

- White Blood Cell Number

Get the value of WOC and WIC simultaneously by laser and electrical impedance methods

- 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

5.5 Test Principle of Hemoglobin Concentration

5.5.1 Colorimetry Principle

Adding lyse into the diluted sample in WBC cup, RBC dissolves and hemoglobin is released. The hemoglobin combines with lyse to form hemoglobin complex which is illuminated by the LED light-emitting diode with a 540nm-wavelength monochromatic light at one end of the WBC cup. The transmitted light at the other end is received by the optical tube, and the light intensity signal is converted into voltage signal after amplifying. 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 obtained. Hemoglobin concentration is proportional to the sample absorbance in 540nm wavelength. The process of measurement and

calculation is done automatically by the analyzer, and relevant results is displayed in the analysis results area.

5.5.2 HGB Parameter

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

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

5.6 RBC /PLT Test Principle

5.6.1 Electrical Impedance Principle

The analyzer uses the traditional electrical impedance for the blood cells measurement and count. As shown in Figure 5-4, conductive liquid (mainly diluent) provides constant current source for electrode to help the circuit form a stable impedance loop. When cells pass through the pores, the conductive liquid is substituted by cells, and the resistance of loop changes to produce electrical pulses. As different volumes of cells passing through the pore, different electrical pulses amplitude is generated. The number and size of cells are determined according to the number and amplitude of electrical pulses.

The number of pulses corresponds to the number of cells pass through the pores, and the pulse amplitude corresponds to the volume of the cells, so the analyzer can count and classify the cells according to size of the cells. The analyzer automatically divides the cells into RBC, WBC, PLT and other groups in accordance with pre-set volume classification procedure.

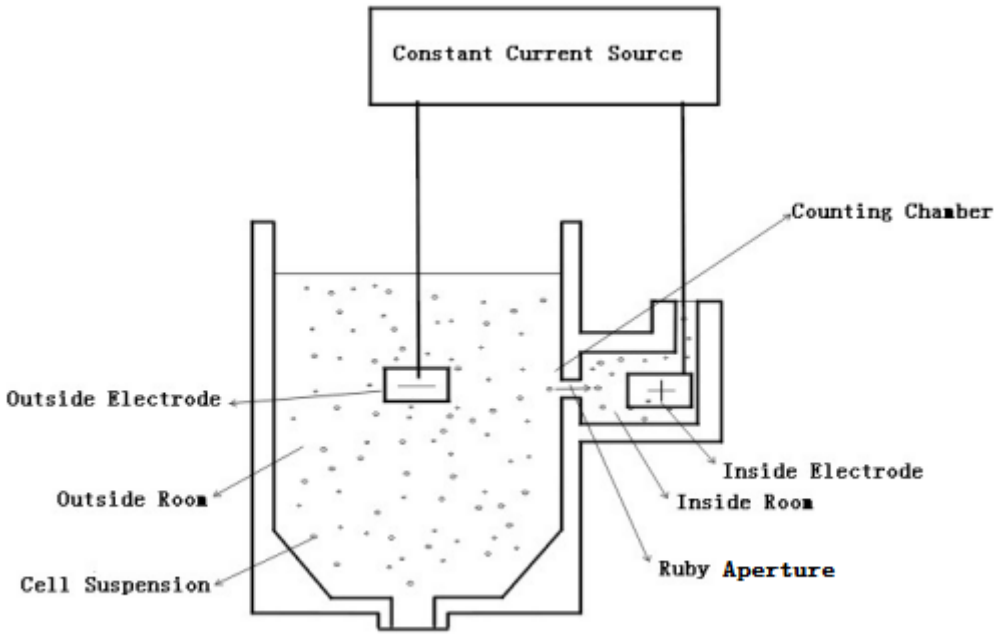


Figure 5-4 Electrical Impedance

5.6.2 Volume Measuring

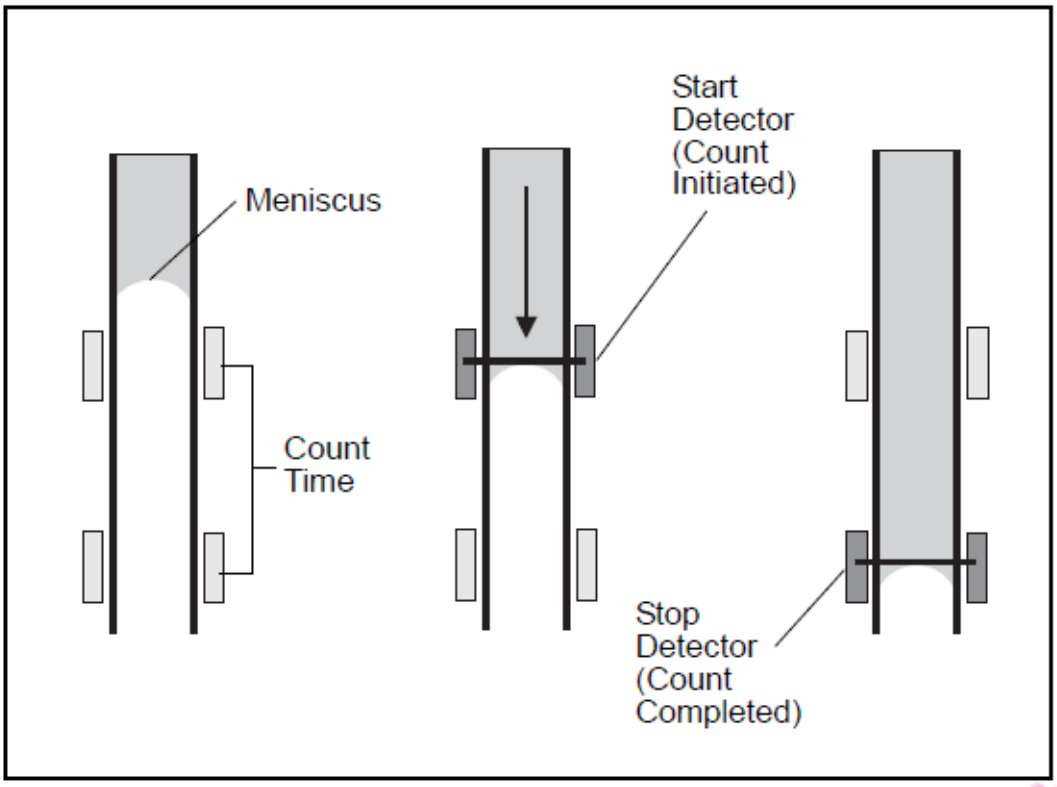


Figure 5-5 Volume Metering

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

As shown in Figure 5-5, 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 fluid system, "bubble" or "clog" alarm pops up. Please refer to *Chapter 11 Troubleshooting*.

5.6.3 RBC Parameters

- RBC Number

The analyzer gets the number of red blood cell (RBC) by measuring the corresponding electrical pulse numbers of RBC directly. The unit is 10^12/L.

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

- MCV

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

- HCT

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

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

- MCH

The mean corpuscular hemoglobin (MCH) is the average amount of hemoglobin in the red blood cell and is expressed in unit of pg. MCH is calculated from the RBC and the HGB as follows.

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

- MCHC

The mean corpuscular hemoglobin concentration (MCHC) is the ratio of the weight of hemoglobin to the volume of the average red blood cell. It is expressed in percent and calculated from the HGB and the HCT as follows.

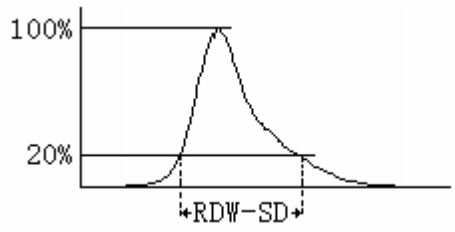
$$MCHC = \frac{HGB}{HCT} \times 100$$

- RDW-CV

The RDW-CV is derived from the RBC histogram and is expressed as percent.

- RDW-SD

The RDW-SD is the width of 20% peak value of red blood cell distribution histogram .The unit is fL.



- RBC Distribution Width

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

5.6.4 PLT Parameters

- PLT Number

The analyzer gets the number of platelet (PLT) by measuring the corresponding electrical pulses of RBC directly. The unit is 10^9/L.

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

- MPV

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

- PDW

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

- PCT

The PLT is calculated as follows. The unit of PLT is 10^9/L. The unit of MPV is fL.

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

`

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. The RNA can be considered as a kind of in vitro cationic dyes which simultaneously stain and precipitate the polyanion

to form a net or reticulum.

5.7.1 RBC Development Process

The development process of RBC system in skeleton is : multipotential stem cells→monopotential stem cells→prorubricyte→polychromatic erythroblast→metarubricyte→reticulocyte→mature erythrocyte. So reticulocyte is a immature red blood cell which has taken off cell nucleus, and it's a phase of RBC development process.

5.7.2 Characteristics of Reticulocyte

1.It contains ribosome（RNA）-- a kind of alkaline matter containing dotted or net structure.

2.After reticulocyte is vital stained by brilliant crystal blue, the dotted or net structure will be stained blue.

3.The reticulocyte in blood circulation takes about 24-48 hours to mature.

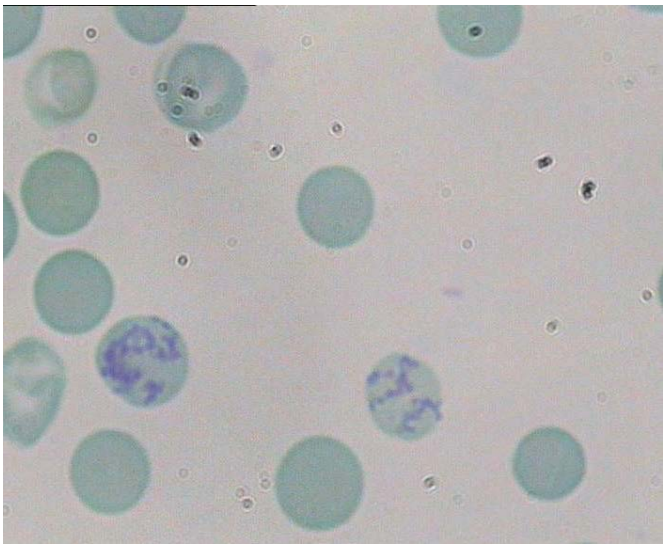


Figure 5-6 Dyed Reticulocytes

5.7.3 Testing Principle of Reticulocyte

Reticulocytes contain alkaline matter RNA which have dotted or net structures, but mature RBC hasn't. For this reason, we can distinguish mature RBC and reticulocyte, as Figure 5-6.

Stain samples firstly:

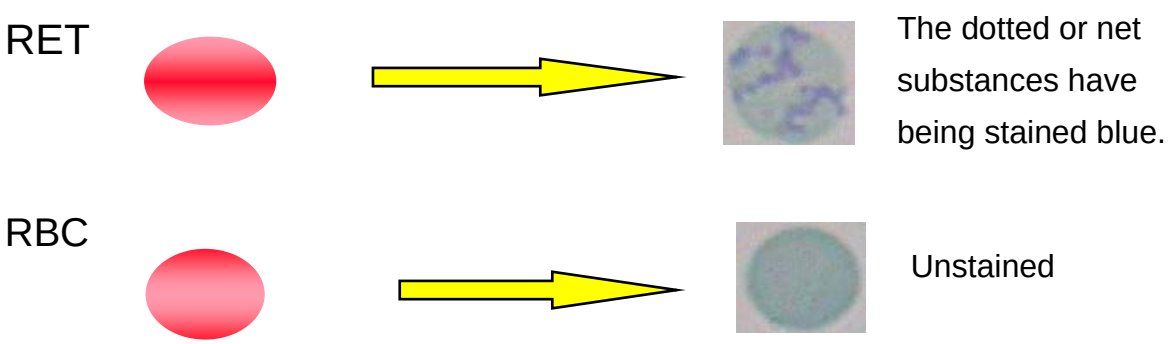


Figure 5-7 Staining

Illuminated with polarized light, the stained dotted or net substances will strengthen scatted light on wide-angle direction:

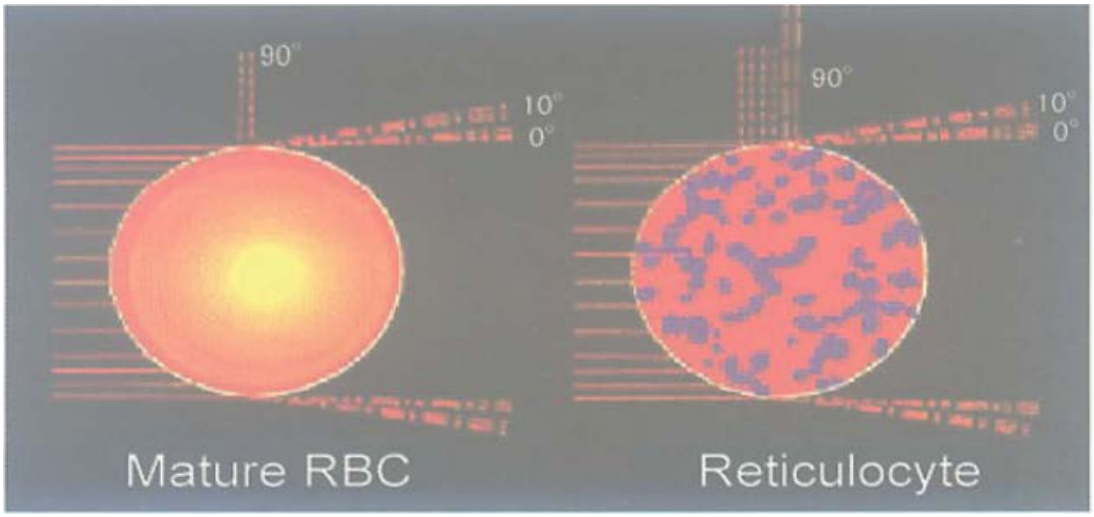


Figure 5-8 Cells scatting of light

RBC and reticulocyte have the same laser scattering characteristics at 0 and 10 degrees. But Illuminated with polarized light at 90 degrees, reticulocytes have different light scattering characteristics, so they can be distinguished. When optical signal transforms to electrical signal, it can be distinguished in scatter diagram visually.

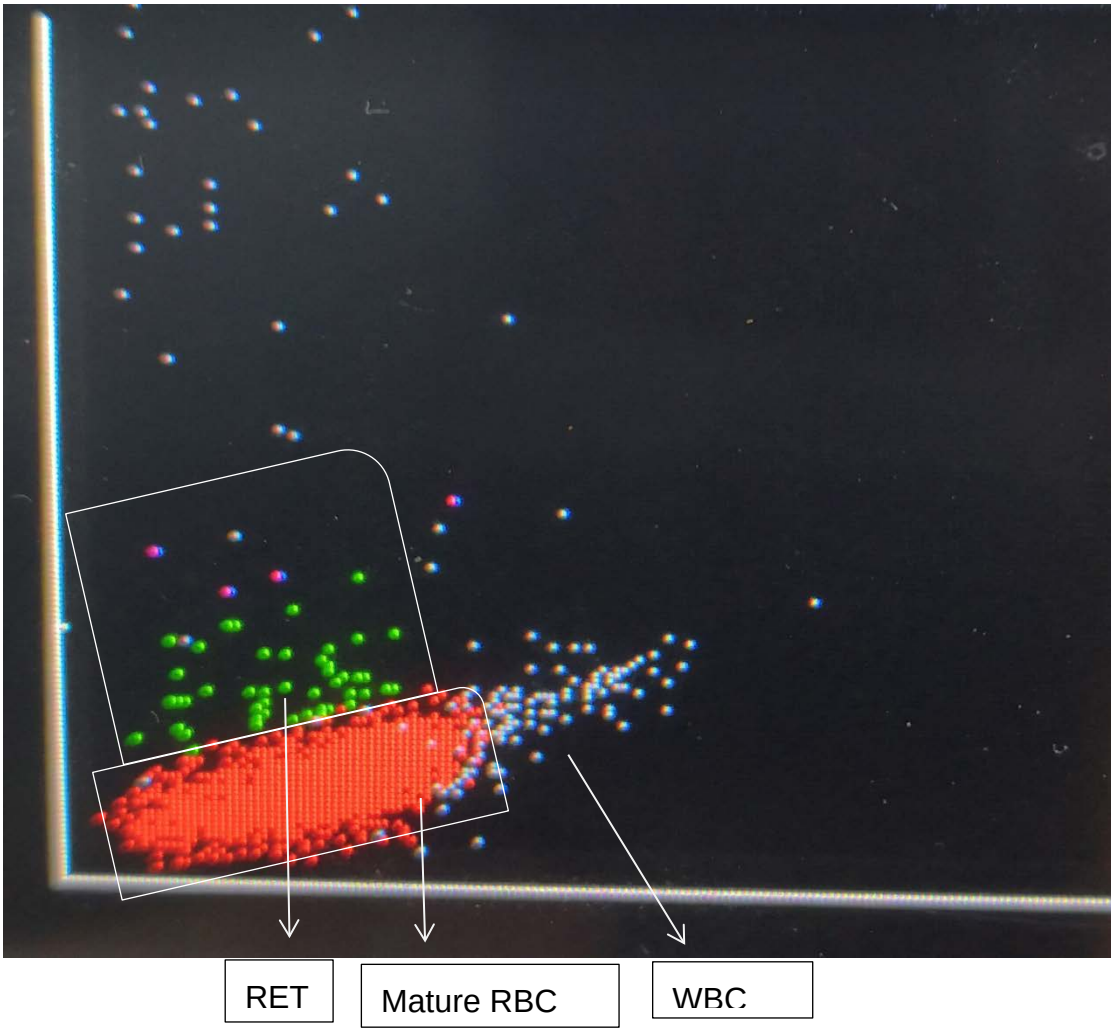


Figure 5-9 RETIC scatter diagram

5.7.4 RETIC_ABS

RETIC_ABS is the concentration of RETIC. It equals to the ratio of RETIC to RBC multiplies by RBC concentration:

$$RETIC\_ABS = RET \times RBC$$

5.7.5 IRF

IRF has more RNA than mature reticulocytes and absorb more stain. So their wide-angle scattering light signal is larger. IRF is classified as reticulocyte population which exceeds preconcerted scattering threshold, as the purple part in Figure 5-8.

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 automated 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.

$$IRF = (IRFpo\text{int}s / RETICpo\text{int}s) \times 100\%$$

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

1) Monitor hemopoietic regeneration after bone marrow transplant, hemopoietic stem cell transplantation, or intensive chemotherapy

2) Monitor bone marrow toxic insults from drugs (for example, AZT)

3) Monitor erythropoietin therapy in renal failure, AIDS, infants, myelodysplastic syndromes and blood donations

4) Classify anemia

5) Monitor efficacy of anemia therapy (Fe, B12 and Folate)

NOTE

- There is no reticulocyte test mode in specific machines.

Chapter 6 Settings

6.1 Overview

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

6.2 Settings

Click “Setup” to enter setting interface, see Figure 6-1.

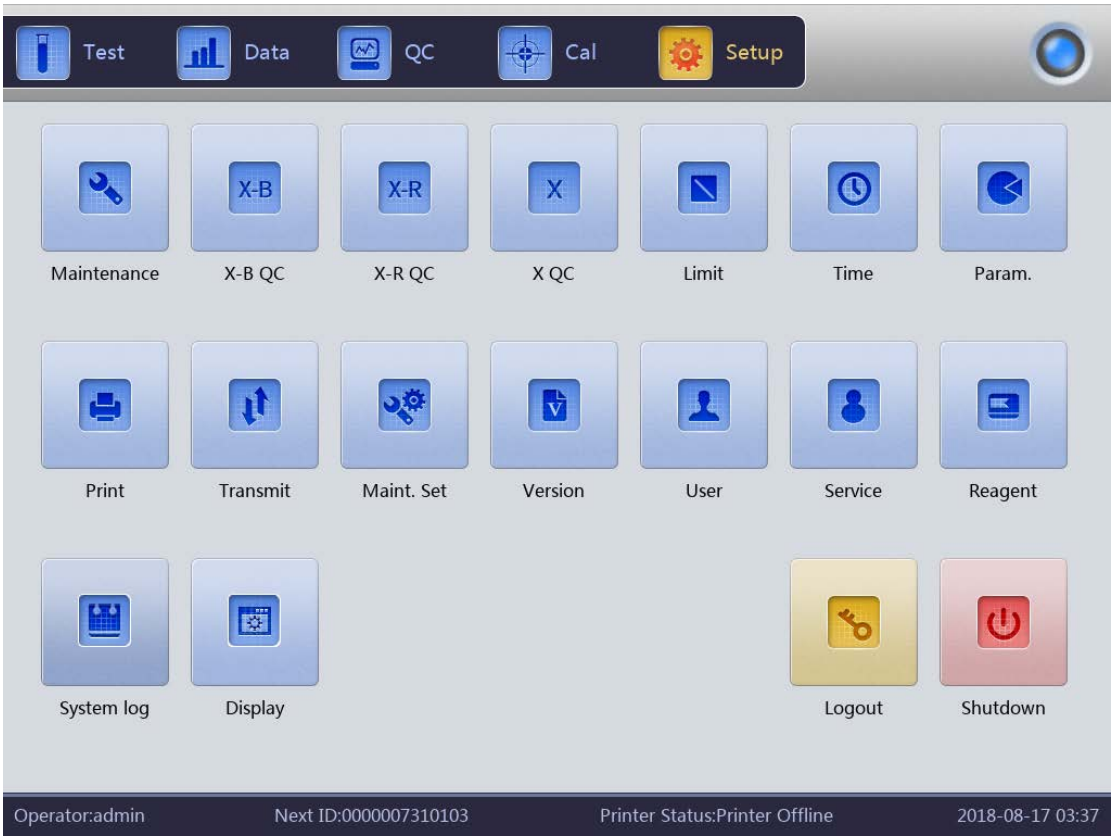


Figure 6-1 Setup Interface

6.3 System Maintenance

Click “Maintenance” to enter maintenance interface, see Figure 6-2.

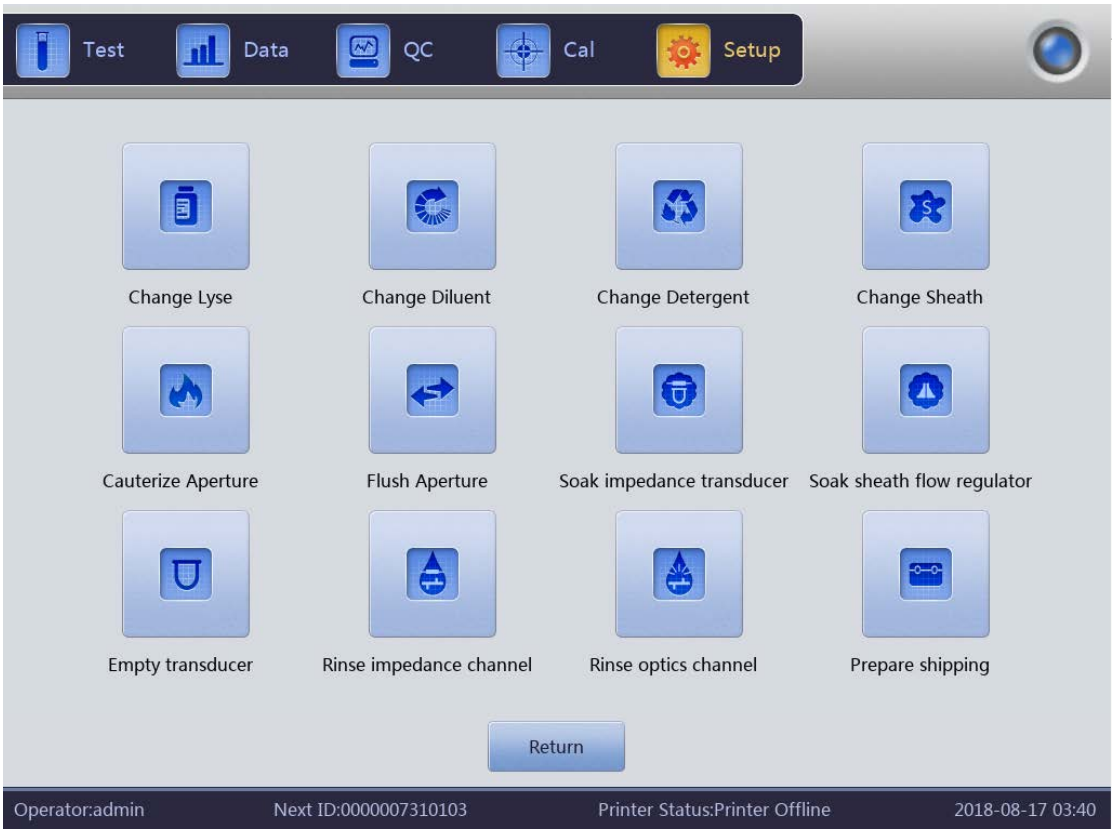


Figure 6-2 Maintenance

Change lyse: click it to prime lyse automatically after replacement.

Change diluent: click it to prime diluent automatically after replacement.

Change detergent: click it to prime detergent automatically after replacement.

Change sheath: click it to prime sheath automatically after replacement.

Cauterize aperture: click this button to eliminate clogging.

Flush aperture: click this button to eliminate clogging.

Soak impedance transducer: click this button as it clogging or getting high blank test result.

Soak sheath flow regulator: click this button to clean inner wall of sheath flow regulator.

Empty transducer：click this button to empty the transducer.

Rinse impedance channel: click it to clean the impedance channels.

Rinse optics channel: click it to clean the optical channels.

Prepare shipping: perform this function before shipping or unused for a long time to empty fluid in the tubing.

6.4 X-B QC

Click “X-B QC” to enter QC interface. Please refer to *Chapter 7* for details.

6.5 X-R QC

Click “X-R QC” to enter QC interface. Please refer to *Chapter 7* for details.

6.6 X QC

Click “X QC” to enter QC interface. Please refer to *Chapter 7* for details.

6.7 Limit

Click “Limit” to enter the interface. See Figure 6-3.

Param.	Lower	Upper	Param.	Lower	Upper
WBC	3.50	10.00	HGB	110	175
LYM%	20.00	40.00	HCT	35.0	54.0
MON%	3.00	10.00	MCV	80.0	100.0
NEU%	50.00	70.00	MCH	26.0	34.0
EOS%	0.50	5.00	MCHC	315	360
BASO%	0.00	1.00	RDW_CV	11.0	16.0
LYM#	0.800	4.000	RDW_SD	35.0	56.0
MON#	0.120	1.200	PLT	100	350
NEU#	2.000	8.000	MPV	6.5	12.0
EOS#	0.020	0.500	PDW	9.0	17.0
BASO#	0.000	0.100	PCT	0.10	0.28
RBC	3.50	6.00	P_LCR	11.00	45.00
RETIC	0.50	2.50	P_LCC	11	135
RETIC_ABS	15	140	IRF	10.00	40.00
NRBC#	0.00	999.99	NRBC%	0.00	99.99
ALY#	0.000	99.999	ALY%	0.00	99.99
LIC#	0.000	99.999	LIC%	0.00	99.99

Figure 6-3 Limits

Click “Group” to choose patient group, including male, female, children, newborns, infants, General, Custom 1, Custom 2 and Custom 3. See Figure 6-4.

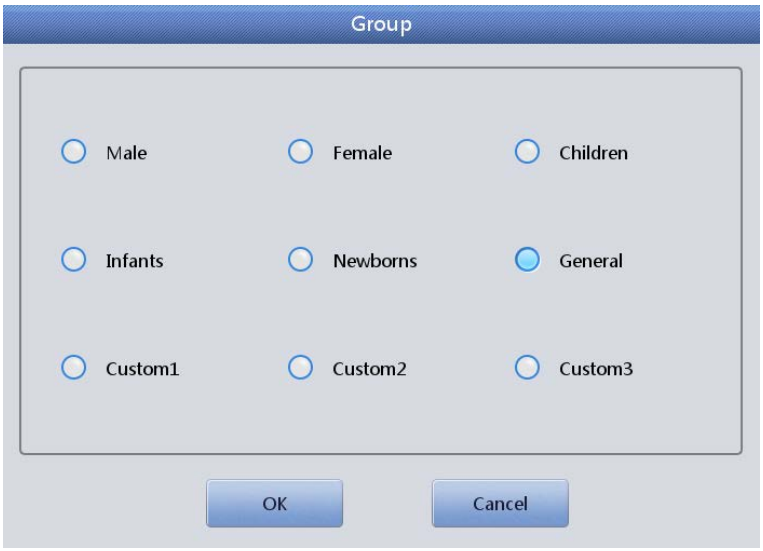


Figure 6-4 Limits

Click “Default” to restore factory settings, for example, click “Default” in group of Male, “Male” limits restore to factory settings.

Click “Save” to save the edited limits.

Click “Export” to export current group limits.

Click “Print” to print current group limits.

Click “Return” to go back to setting interface.

6.8 Time

Click “Time” to enter setting interface of time and date.

There are three formats of date, which are YYYY-MM-DD, MM-DD-YYYY and DD-MM-YYYY. Y indicates Year, M indicates Month and D indicates Day. See Figure 6-5.

Date display format changes according to date format.

Click “OK” to save the modified settings.

Figure 6-5 Time and Date

6.9 Parameter

Click “Param.” to enter the interface. See Figure 6-6.

Choose unit of WBC, RBC, PLT, HGB/MCHC and HCT.

Select the representation of IRF as a decimal or percentage.

Modify the reaction time of RRBC: Click “Default” to restore RRBC reaction time to factory settings.

Click “OK” to save modified setting.

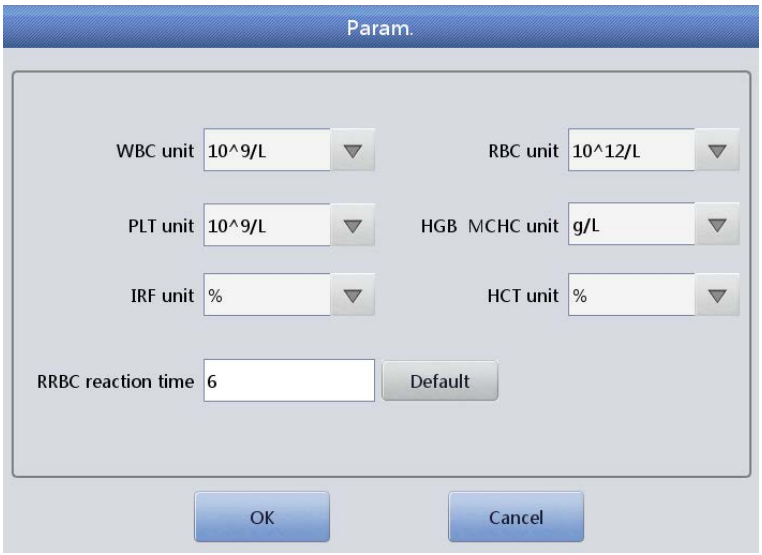


Figure 6-6 Parameters

6.10 Print

Click “Print” to enter the interface. See Figure 6-7.

Printer type: USB port printer (A5), USB port printer (A4).

Print format: print with histogram, or print without histogram

Auto print: turn on/off auto print. If it’s on, test result is printed automatically after counting. If it’s off, it needs to manual print.

Color: color, or grayscale.

Print title: input hospital name here, and the hospital name will be displayed. Click “OK” to save the modified settings.

TOP margin: enter the distance of top margin. Unit: pixel, 1inch=72 pixels.

Print List: indicates the state of the print list. Including ID, Content, Printer, Submist Time, Status.

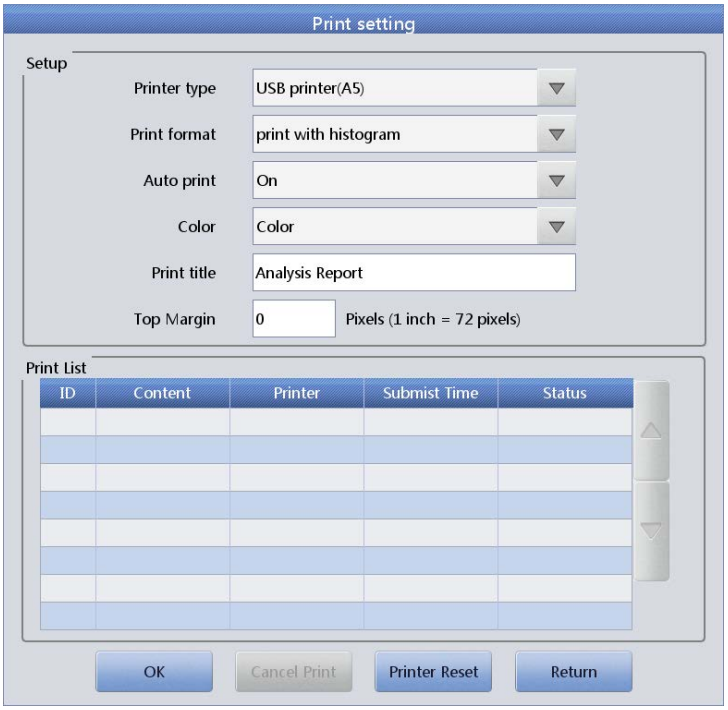


Figure 6-7 Print

6. 11 Transmit

Click “Transmit” to enter the interface as shown in Figure 6-8.

Ethernet port setup: set the local IP, server IP, local mask, local gateway and port number as connecting with LIS system. The native mask and the local gateway can be selected by default, the others shall be reset.

Transmission setting: select either “On” or “Off” auto transmit as connecting with LIS system. “Trans Histo”, “Trans Scatter”, “Trans Mode” and “Trans Select” can be selected.

Serial Port: the default port is /dev/ttyO0. Rate can be set from 110 to 115200. The number of “StopBit” and “DataBits”, the parity checking can also be set.

Figure 6-8 Transmit

NOTE

- Only specific machines can use serial port.

6.12 Maintenance Setting

Click “Maint.Set” to enter the interface. See Figure 6-9.

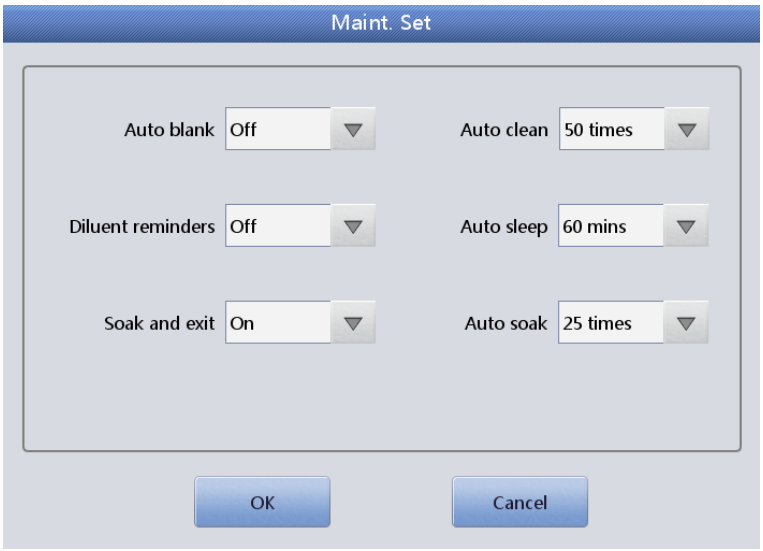


Figure 6-9 Maint. Set

Auto blank: click  to select “On” or “Off” and then click “OK” to save settings as blank test is necessary in each boot. The analyzer does not perform it if it is “Off”.

Auto clean: the analyzer does not perform it if it is “Off”. Click  to select “Auto clean” and choose times (50 times, 75 times, 100 times, 125 times and 150 times) according to your necessary. Auto clean is performed after 50 sample testing, if 50 times is selected. If the analyzer is shut down in the condition of sample test times being less than 50, the analyzer shall re-count after rebooting.

Diluent reminders: dialog box pops up in each counting if “On” is

selected.

Auto sleep: the analyzer automatically enters the dormant state if there is not any operation for some time. Users can adjust dormancy length according to the necessary.

Soak and exit: prompts will not pop up if " Off" is selected. Soaking is performed when shutting down, if "On" is selected. The analyzer prompts to put the detergent under the sample probe to aspirate it for soaking sample cup. Shut down the analyzer after soaking.

Auto soak: click  to choose times. The analyzer reminds users to put detergent under the sample probe, when counting times is over selected times.

6.13 Version

Click "Version" to pop up version dialog. See Figure 6-10.

The current version information displays here. Version upgrade can be achieved.

Click "Return" to enter setting interface.

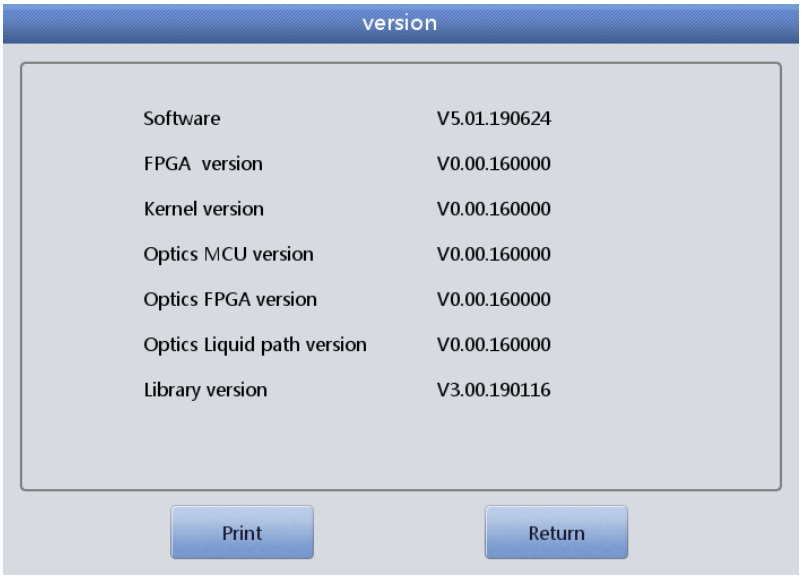


Figure 6-10 Version Information

6.14 User

Click “User” to enter the interface. See Figure 6-11.

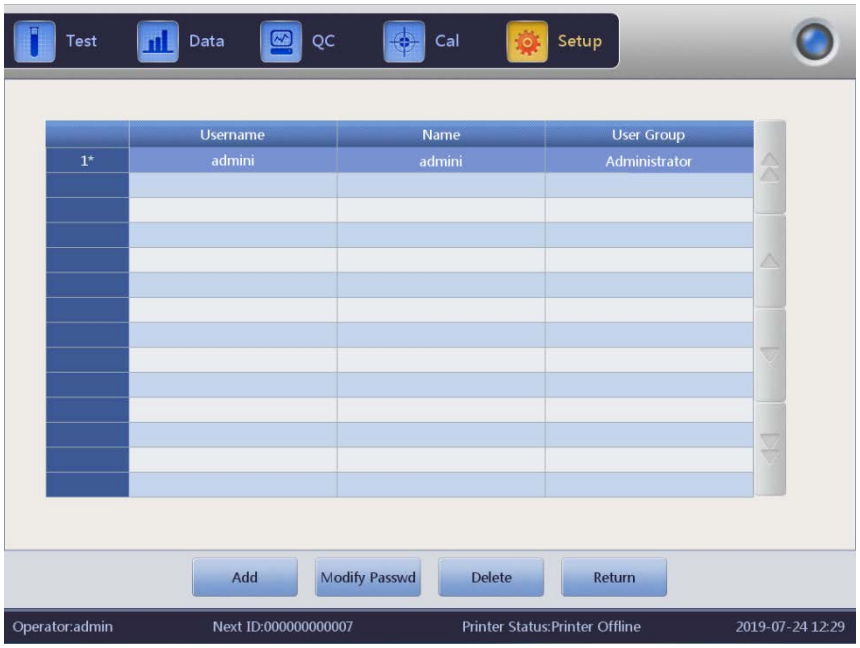


Figure 6-11 User

Click “Delete” to delete selected user.

Click “Add” to pop up “Add user” dialog. New user’s username,name,

password and group can be edited. “Group” is divided into “Ordinary user” and “Administrator”, which are given different permissions. The administrator's permissions are higher than Ordinary user’s. Administrator can operate all the functions, while the ordinary user can not delete data, export data and calibrate the analyzer. See Figure 6-12.

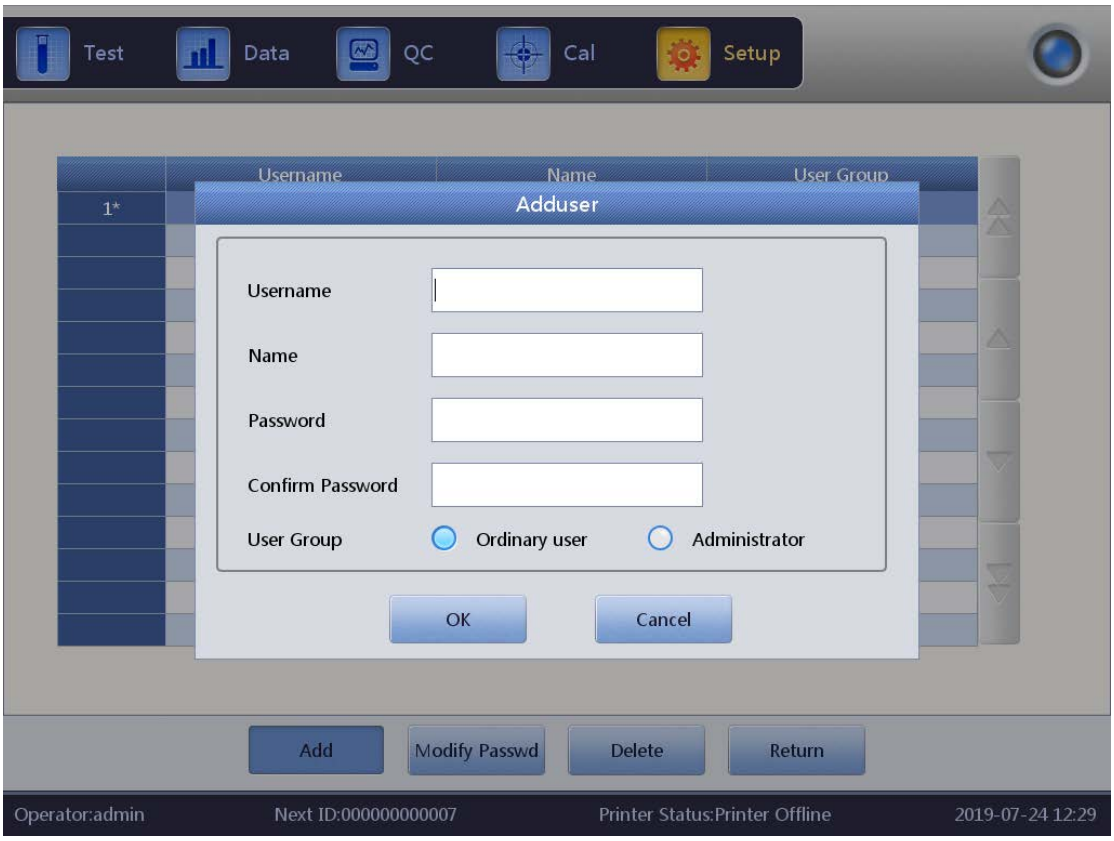


Figure 6-12 Add User

6.15 Service

Click “Service” to pop up the following dialog. Only the supplier service engineers can perform this function in maintenance.

Figure 6-13 Service

6.16 Reagent

Click “Setup” when replacing new reagent. Click “Reagent” to pop up below dialog. See Figure 6-14.

The activation date, total amount, Lot, valid period and remaining amount of lyse, sheath, diluent and detergent are displayed here. For example, click “Replace” of diluent when replacing diluent, see the popup dialog in Figure 6-15.

- Take out the diluent activation card from the diluent container and click “Activate”. 15 seconds countdown starts. Put the IC card onto card reader and there is a "tick" sound, which means successful card read. Successful activation displays in dialog box. The activation date is the current date after activating. The valid period is three months. The total amount of reagents returns to the same amount as the reagents themselves. The remaining amount subtracts the amount consumed by the analyzer during operation. The activation method of other reagents is the same as diluent’s.

Figure 6-14 Reagents

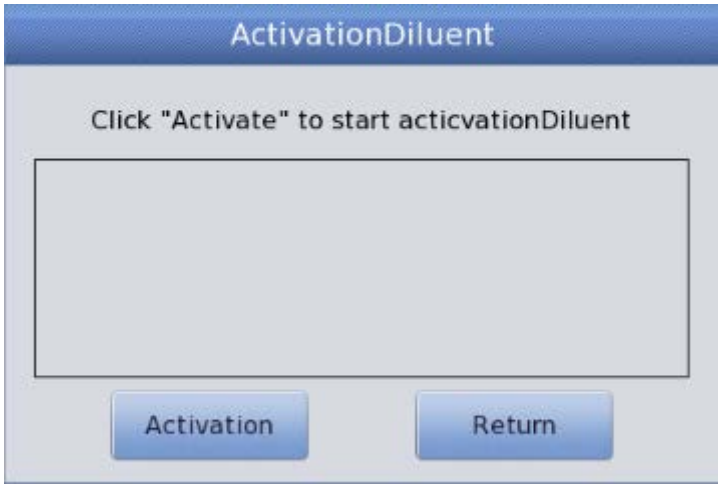


Figure 6-15 Activation

6. 17 System Log

Click ”System log”， we can check the warnings and the status of the instrument and so on.See figure 6-16.

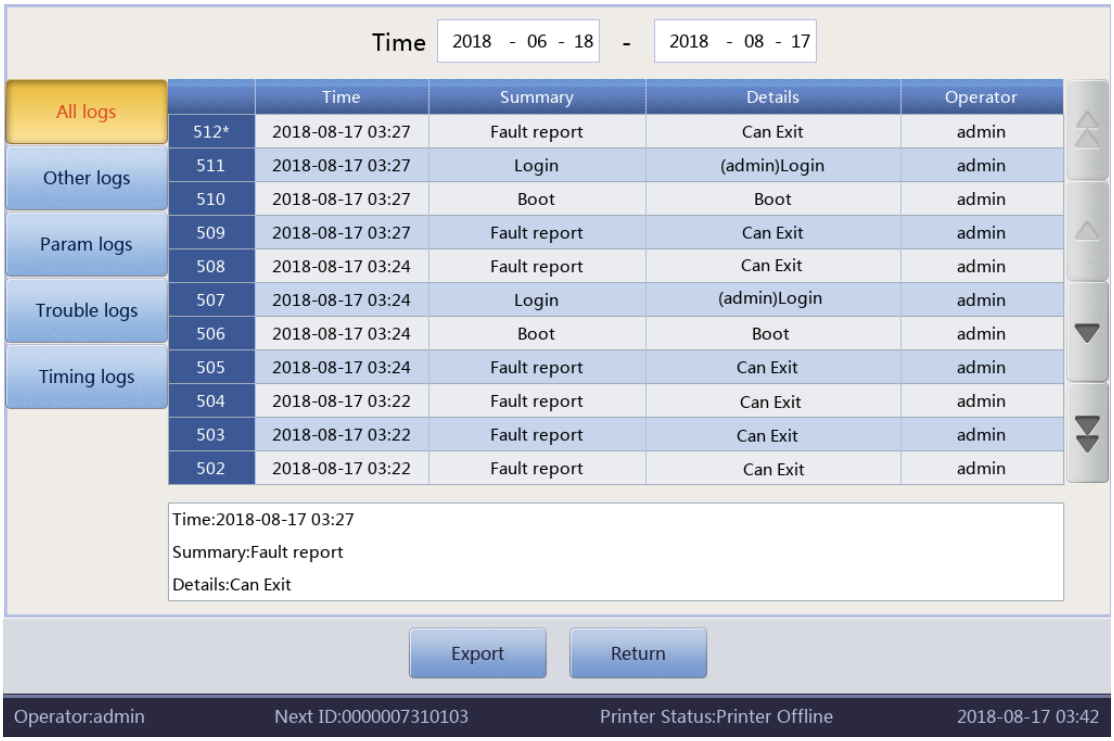


figure 6-16 System log

6. 18 Display

Click “Display” to choose the parameters to display or print, which depends on our requirement. See figure 6-17.

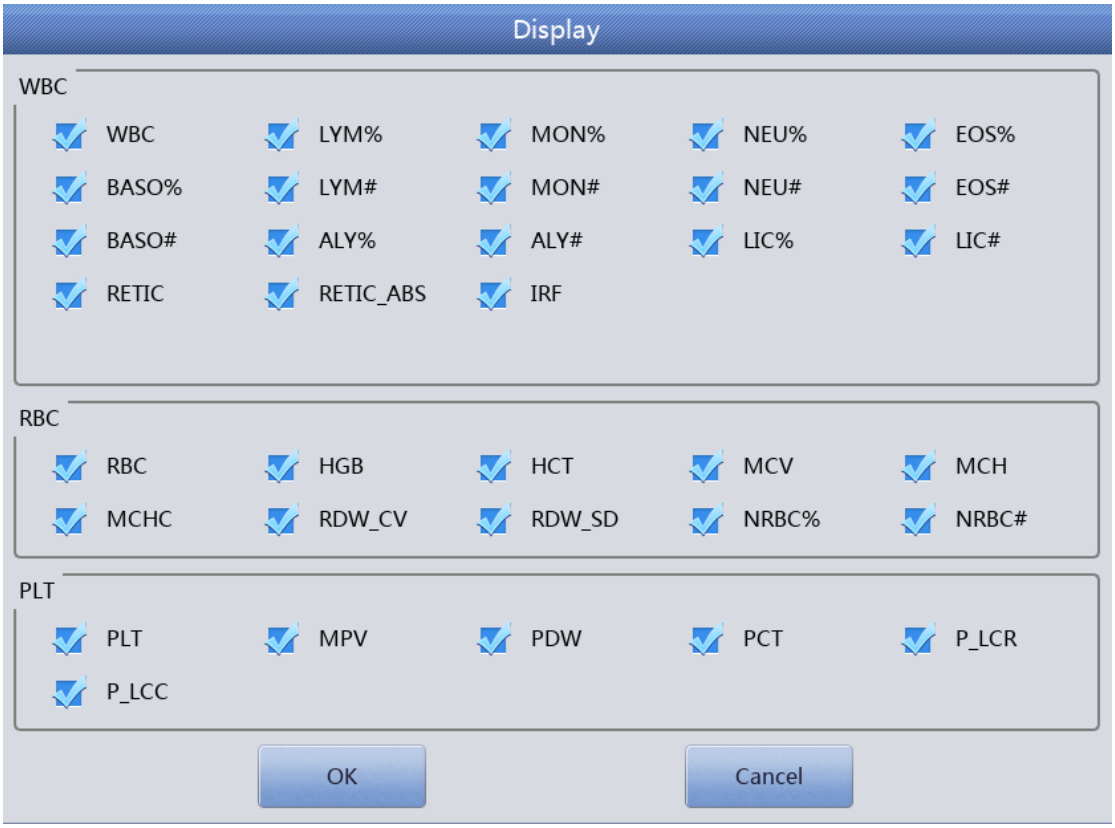


figure6-17 Display

NOTE

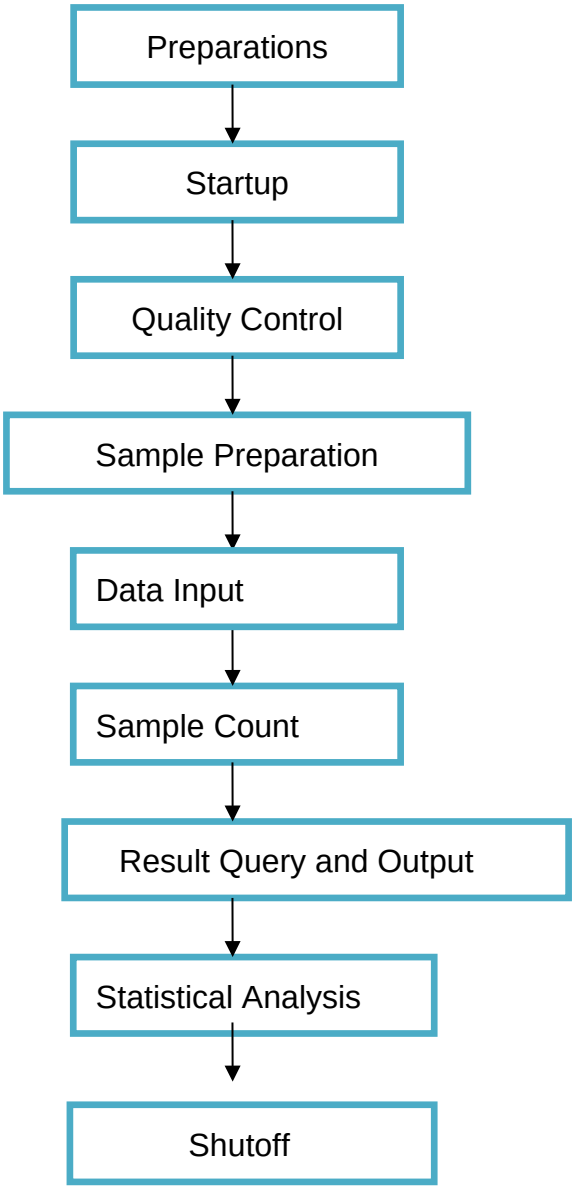
- Transmit parameter is already set before delivery. As a rule, there is no need to reset, or the data transmission will be affected. Necessary modification should be done under the guidance of supplier engineers.

Chapter 7 Daily Operation

7.1 Overview

This chapter describes the whole procedures of daily operation from startup to shutoff, and explains the process of different modes of sample analysis in detail.

Daily Operation Flow Chart as follows:



Note

- 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 handled properly and cleaned up before startup every day.

2. Check the Reagents, Tubing and Power

Check if diluent, lyse, detergent and sheath meet the test requirements.

Check if the tubing of reagents and waste connected well and without bending.

Check if the power plugs is inserted power outlet safely.

3. Check the Printer

Check if printing paper is sufficient and the installation is proper.

Check if the power plugs is inserted power outlet and the cable has been connected with the analyzer properly.

WARNING

- All clinical specimens, control materials, calibrators and wastes have potential infectious hazard. 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 left panel, then the status indicator on the

front panel turns orange. The analyzer automatically checks the operation of the components when self-checking and initialization after loading. Then it rinses the fluid system. It takes about 4 minutes to finish this process. Status indicator turns blue after initialization. See Figure 7-1.

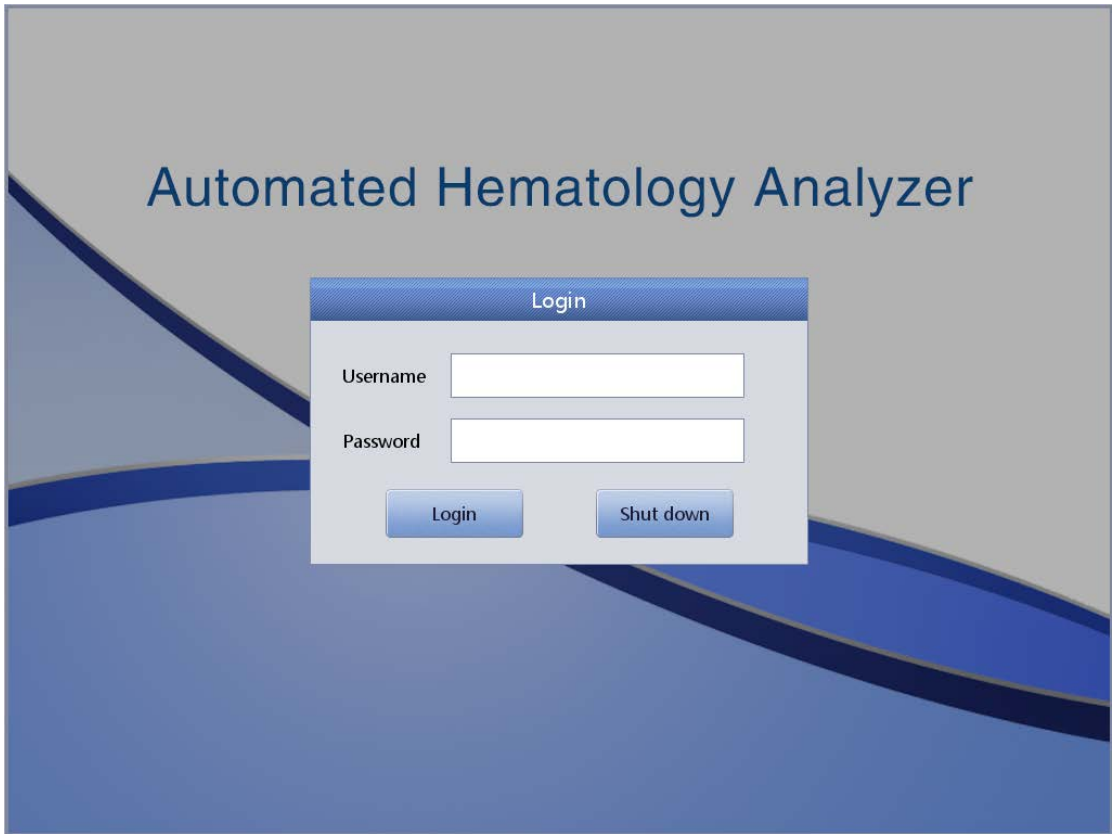


Figure 7-1 Login

Virtual keyboard pops up as entering password and user's name. See Figure 7-2.

Figure 7-2 Virtual keyboard

The analyzer enters test interface after entering password and username. See Figure 7-3.

Figure 7-3 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

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

PLT	≤10.0x10^9 /L

If the blank result is out of this range, please repeat the above procedures until it is in this range. If the results are still out of this range after repeating five times, 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

- All clinical specimens, control materials and calibrators may contain human blood or serum and are potentially infectious, so wear lab coats, gloves and safety glasses and follow the established laboratory or clinical procedures when handling these materials.
- Do not directly contact blood samples, control materials or calibrators. Please handle these in accordance with related operating rules.

Note

- 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_2·2H_2O) anticoagulant.
- Do not shake the sample tube violently.

- Venous blood can only be stored for 4 hours at room temperature. It's recommended to keep blood sample at the temperature between 2℃~8℃ for longer storage.

7.5.1 Whole blood collection

Collect whole blood sample by vein-puncture and store it in a clean sample tube which contains EDTA-K2·2H2O (1.5~2.2mg/mL). The EDTA-K2·2H2O can keep the shape of WBC and RBC, and inhibit 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's color of Romanowsky staining. The concentration of high heparin > 7.5uL/ capillary will lead to increase in HCT and MCV.

2. **Sodium citrate**

   Since sodium citrate is liquid, it may be diluted to 10/11 of the original in the tube filled with whole blood. This anticoagulant is used for agglutination. It's also used when there a suspected false thrombocytopenia caused by EDTA.

3. **ACD and CPDA**

   It's widely used in cell concentration (especially platelet concentrates), but not used for cell counts.

4. **EDTA**

   For the salt of EDTA, use EDTA K2（United States and Japan）and EDTA K3（United States and Europe）,sometimes NA2EDTA. Recommend by ISCH in1993, EDTA K2 and EDTA K3 are most widely used in the blood test of the world. But other EDTA salts can also be used. EDTA could lead to false thrombocytopenia through platelet aggregation. (Incidence rate is about 1/800)

5. Fluoride

Use before EDTA. Without side effects according to the survey.

7.5.2 Diluent Sample Preparation

1. Set the current test mode to “Diluent” in “Test” interface, as shown in Figure 7-4.

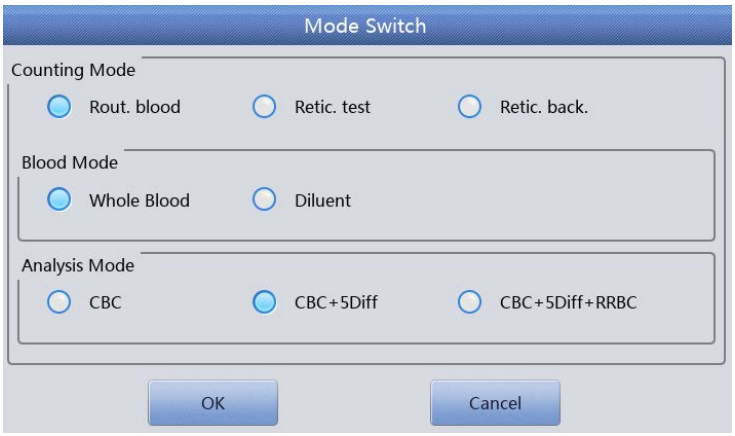


Figure7-4 Mode Switch Operations

2. Put a clean test tube under the sample probe, and press “Drain” button on front panel. 500 μL diluent is drained from sample probe automatically. It is recommended to put the test tube close to the sample probe, so as to avoid bubbles or spillage.

3. Please quickly inject the sampled 20uL peripheral blood into the test tube filled with diluents and mix it well.

Note

- Avoid the collected diluent mixing with dust; otherwise it may cause analytical error.
- After full reaction of peripheral blood and diluent, it should be placed for 3 minutes, and then remix it before test.

- Ensure that the sample is analyzed within 30 minutes after dilution, otherwise the analysis results are not reliable.
- Each laboratory should evaluate the stability of the results according to their sample number, sampling method and the technical level in diluent mode.

7.5.3 Stability of Samples

It's recommended to use fresh whole blood. ICSH (International Committee for Standardization of Hematology) defined fresh blood as samples which is processed within 4 hours of collecting. Mix the whole blood samples well and place it in EDTA-tubes. The accuracy of each parameter is the highest when the sample is tested within 8 hours of collecting. If the sample is tested within 5 to 20minutes or over 8 hours of collecting, the WBC volume distribution will offset.

7.6 Create Next Blood Sample

Next sample can be created in blood cell analysis window. User can either input detailed sample information before sample analysis or after sample analysis. See Figure 7-5.

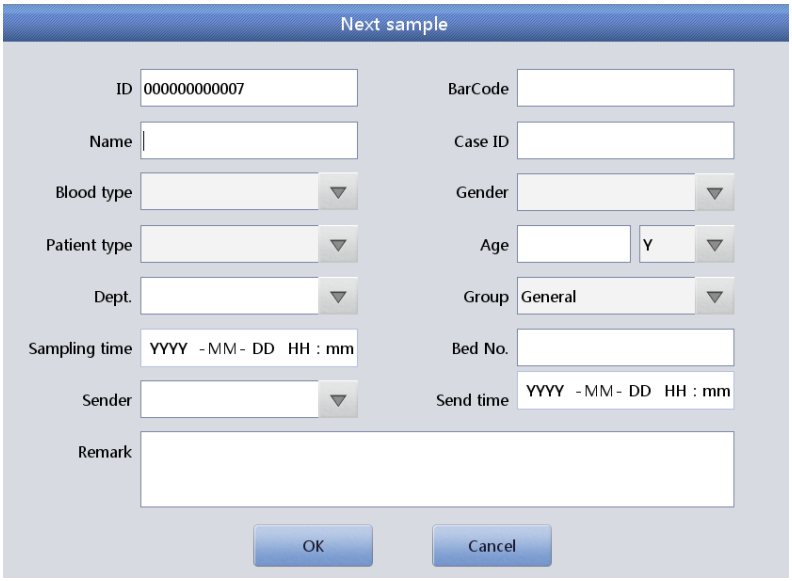


Figure7-5 New Next Blood Sample

The system provides English input method. Click the corresponding input box and the virtual keyboard pops up. If necessary, external keyboard with PS2 or USB interface can be connected to help enter information. See Figure 7-6.

Figure7-6 Virtual keyboard

Name: input patients' name

Gender: male and female. It's blank by default if not selected**.**

Age: year, month, day and hour can be selected.

Blood Type: A, B, O, AB, A Rh+, A Rh-, B Rh+, B Rh-, AB Rh+, AB Rh-, O Rh+ and O Rh- can be selected. The default is blank if not selected**.**

Group: divided into male, female, Children, infants, newborns, general, Custom 1, Custom 2 and Custom 3.

System automatically selects corresponding group as age and gender are input. The reference values are listed as Table 7-2.

Table 7-2 Reference Value

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

Female	≥16 years	Female
Children	>1 month and ＜16 years	Blank, Male, Female
Infants	>1 month and ＜1 years	Blank, Male, Female
Newborns	<1 month	Blank, Male, Female

ID: Only numbers can be input here. If there's no SN input, the analyzer automatically plus 1 on the basis of the last SN and take it as the new SN.

Case ID: Input the case number.

BarCode: Input bar code.

Bed ID: Input bed ID.

Dept.: Input department name or SN code.

Sender: Input sender's name or code.

Patient type: Select the patient type, in which outpatient, hospital, physical examination or emergency can be selected.

Sampling time: Input the blood sample collection time.

Send time: Time of sending sample to the department

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 "Mode switch" in test interface to choose needed blood mode and analysis mode. See Figure 7-7.

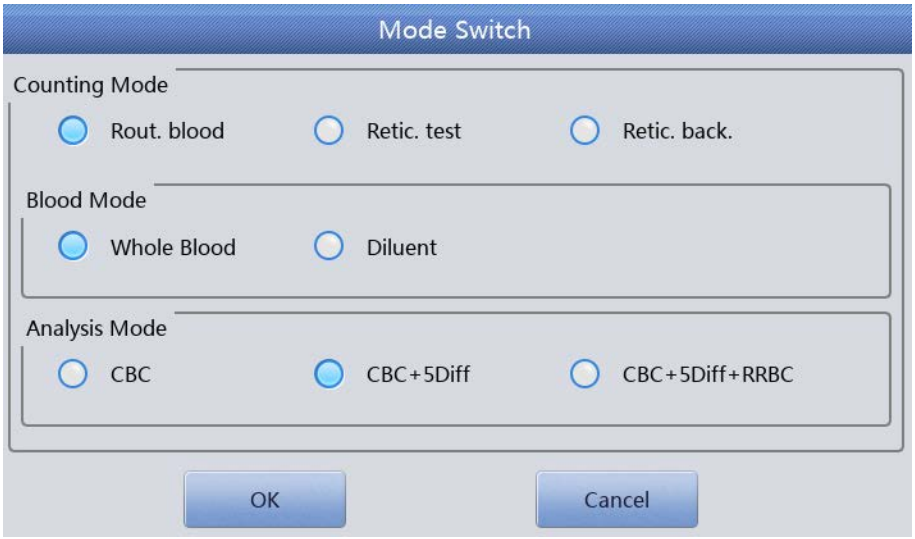


Figure7-7 Mode Switch

Click “OK” to save settings.

NOTE

- CBC can be chosen both in “Whole Blood” and “Diluent”. CBC mode-- is only for WBC counting but without five part differentials. The counting result includes 14 parameters and the histograms of RBC and PLT. "CBC+5Diff"--- For WBC counting and five part differentials.
- "CBC+5Diff+RRBC"--- For counting after dissolving the indissolvable red blood cells. It is suggested that when RRBC? alarm appears, switch counting mode to CBC+5Diff+RRBC, and then run counting again so as to eliminate the interference from indissolvable red blood cells. If WBC total number is much less than that of the first counting, it shows that this

specimen contains indissolvable red blood cells.

7.7.2 Process of Counting and Analysis

WARNING

- The sharp sample probe may contain blood samples, quality controls or calibrators which probably have potential infectivity. Do not directly contact the sample probe.

CAUTION

- Do not reuse disposables.
- Ensure the inputted ID number corresponds with the sample.

NOTE

- Please use the specified vacuum blood tube, centrifuge tube, capillary tube and other disposable products when collect the blood sample.

7.8 Data Query

After each counting, the results are automatically saved in a database that could store at least 200,000 results include 34 parameters,2 scatter diagrams and 2 histograms.Operator could review all of the results, scatter diagrams and histograms that store in the database through query and statistics.

7.8.1 Data Query

Click “Data” to enter the query interface. See Figure 7-8.

Figure 7-8 Data Query

Click “Query” to pop up the following dialog box. See Figure 7-9.

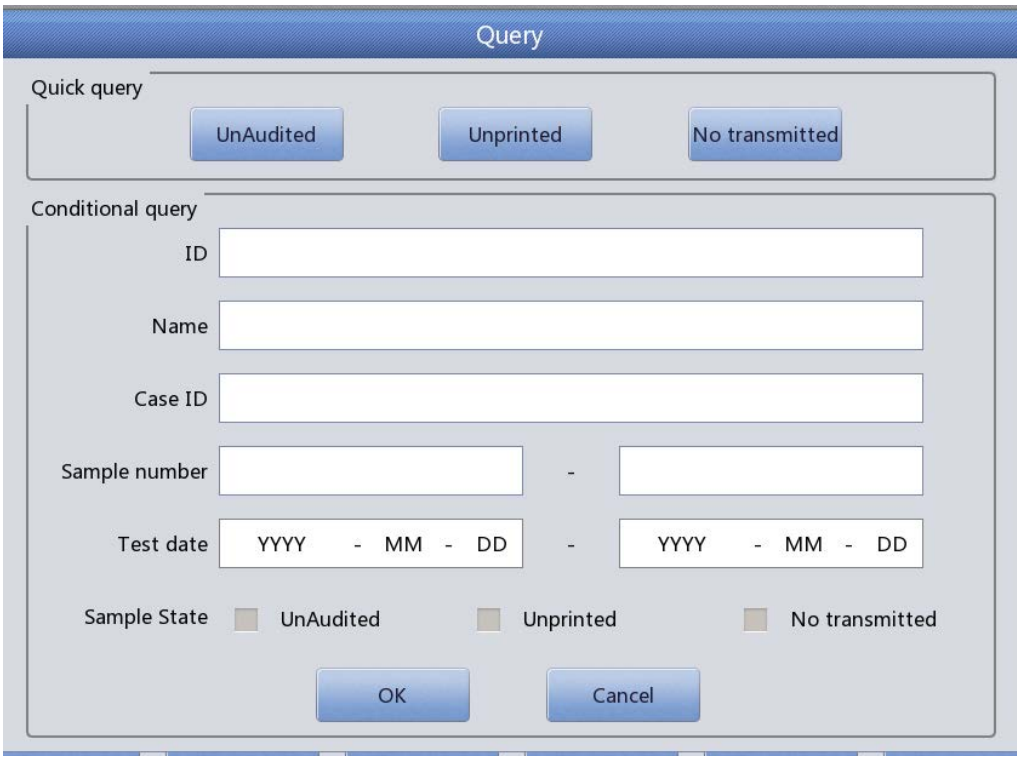


Figure 7-9 Query

Data query: quick query, conditional query

- Quick query

  Unchecked: display current unaudited sample

  Unprinted: display current unprinted sample

  No transmitted: display current not transmitted sample

- Conditional query

You can query according to ID, Name, Case ID, or the range of selected ID and test data.

For more precise query, you can use conditional query and quick query together.

7.8.2 Data selection

There's a "*" in front of selected ID. As shown in Figure 7-8, the ID of

selected sample is 000000000004. Click “Graph Review” to see detailed data and graphs. See Figure 7-10.

Figure 7-10 Detailed Data

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 termly. Both delete all and delete one are available. Click “Delete” to delete chosen data.

NOTE

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

7.9 Reticulocyte analysis

NOTE

- There is no reticulocyte test mode in specific machines.

System operator can use reticulocyte software to analyze reticulocyte for blood samples. Reticulocyte sample is a kind of blood sample diluted and dyed by reticulocyte reagent.

In test interface, click “Mode” and “Retic. test” to start reticulocyte analysis. As Figure 7-11:

Figure 7-11 Reticulocyte analysis interface

In reticulocyte analysis interface of analyzer system, the test result of reticulocyte sample is reticulocyte rate，Reticulocyte absolute value and IRF.

7.9.1 Preparation for reticulocyte sample

Matters need attention

1．Add 20μL blood sample into the reticulocyte reagent tube.Place it into an incubator which the temperature inside was 35℃ for 15 minutes after mixing enough.The blood volume should approach 20 μL as much as possible.

2．Take out the sample and mix it(15 times),finish the test in 10 minutes.If take out the sample without mixing,the duration can be lengthen to 30 minutes.

7.9.2 Reticulocyte test

The reticulocyte background shall be tested first to make sure it meets the requirements, and then test reticulocyte.

Click “Mode” and select “Retic. back” to enter reticulocyte background interface. See Figure 7-12:

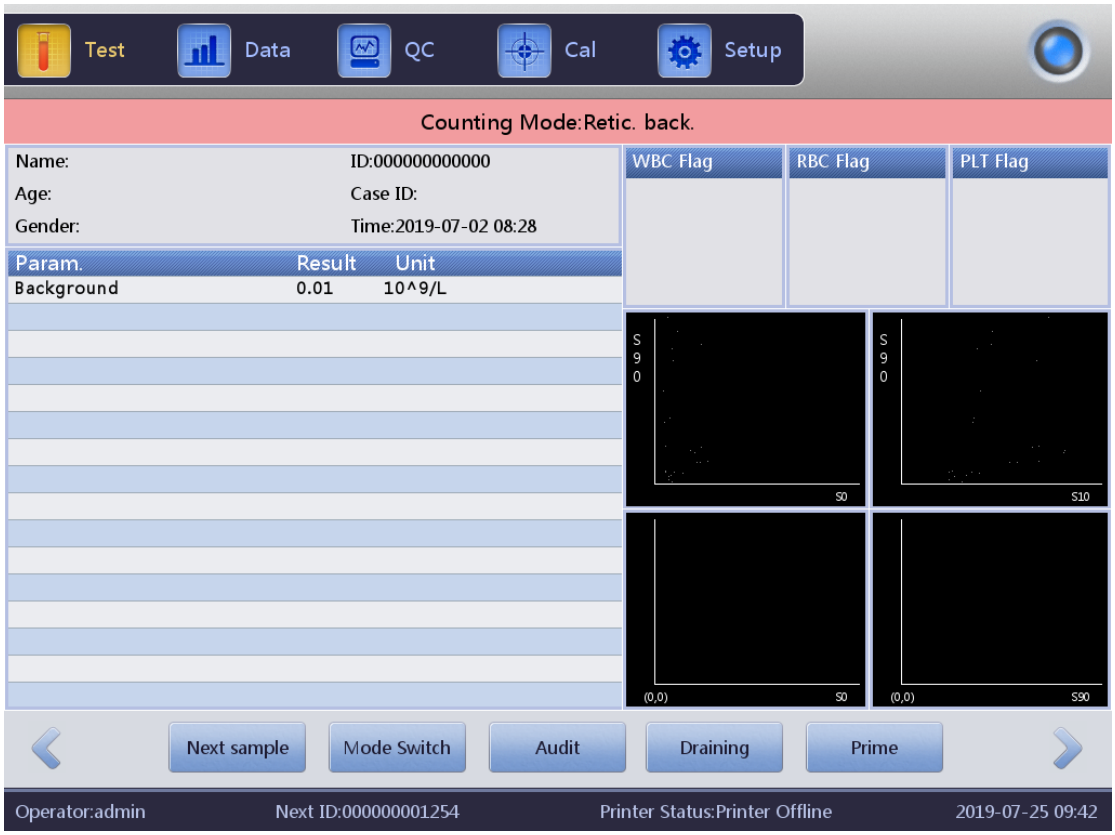


Figure 7-12 Reticulocyte background interface

In reticulocyte background interface, get the reticulocyte background numerical value by blank test. Only when the numerical value is lower than 0.5 can reticulocyte be tested. If the value is higher than 0.5, blank test shall be made again until reticulocyte background meets requirement.

Click “Mode” and select “Retic. test” to enter reticulocyte test interface. See Figure 7-13;

Figure 7-13 Reticulocyte test interface

WARNING

- Avoid contact skin and clothes when operator uses reticulocyte reagent. New mathylene blue contained in the reagent can result in skin, clothes and other surfaces pollution.

7.10 Edit Information

Choose ID and click “Edit info” to pop up dialog box, see Figure 7-11.

Click “OK” to save edit, while click “Cancel” to give up saving.

The checked sample cannot be edited. Please cancel the check first before you edit it. Please refer to Section 7.6 Create Next Blood Sample for information edit.

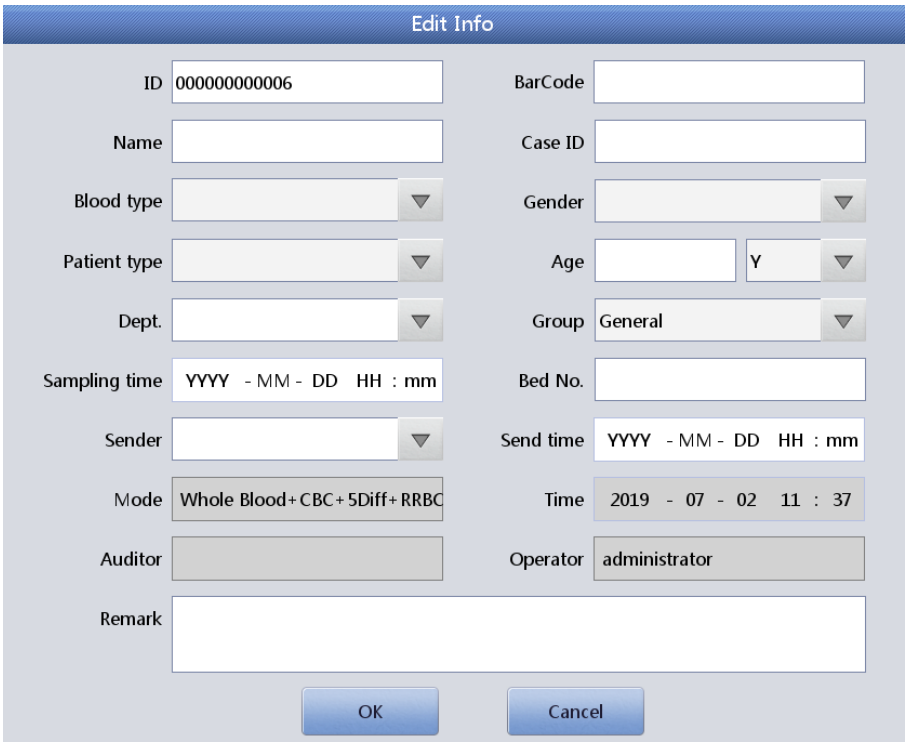


Figure 7-14 Edit Information

7.11 Export

Click “Export” to pop up the following dialog box, see Figure 7-15. Select “Chosen record” and “All records” in “Range”, tick relevant items in “Content”.

Please insert the U disk before exporting. Click “OK” to start export. The exported data is in Excel form. Click “Cancel” to cancel export.

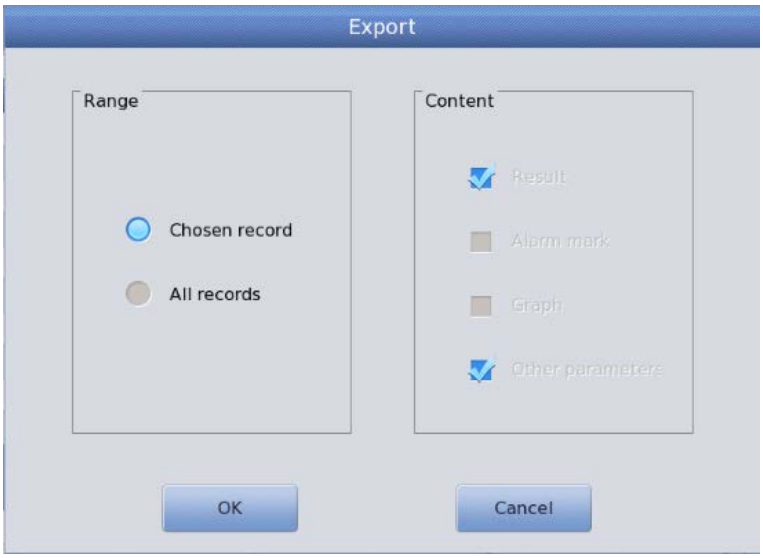


Figure7-15 Export

7.12 CV Value and Trend Graph

To check the CV value, please do 11 times test for one blood sample. Select all test results except for the first one and click “CV” to display CV value. See Figure 7-16.

Click “Trend graph” to see the trend graph of parameter. See Figure 7-17.

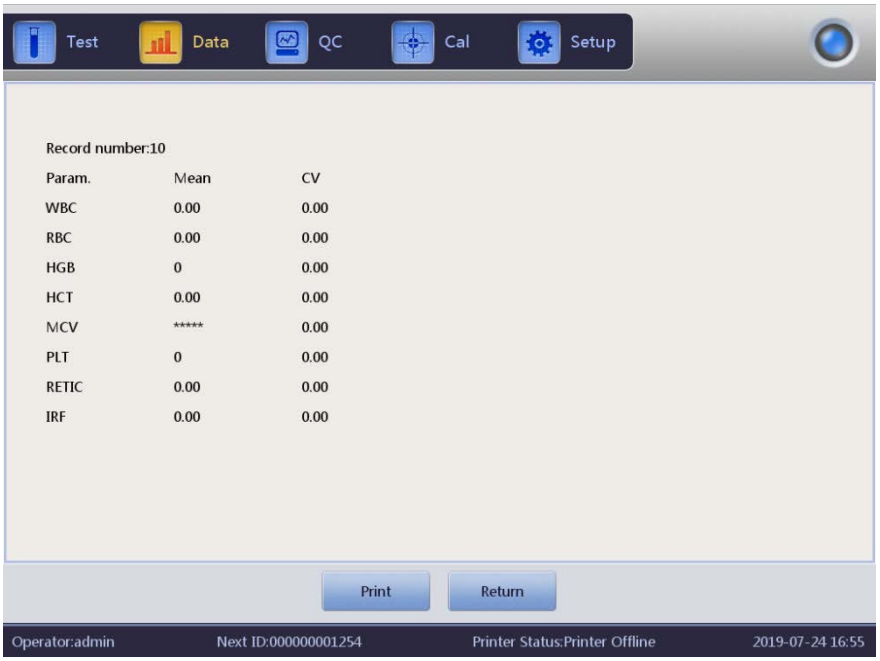


Figure7-16 CV

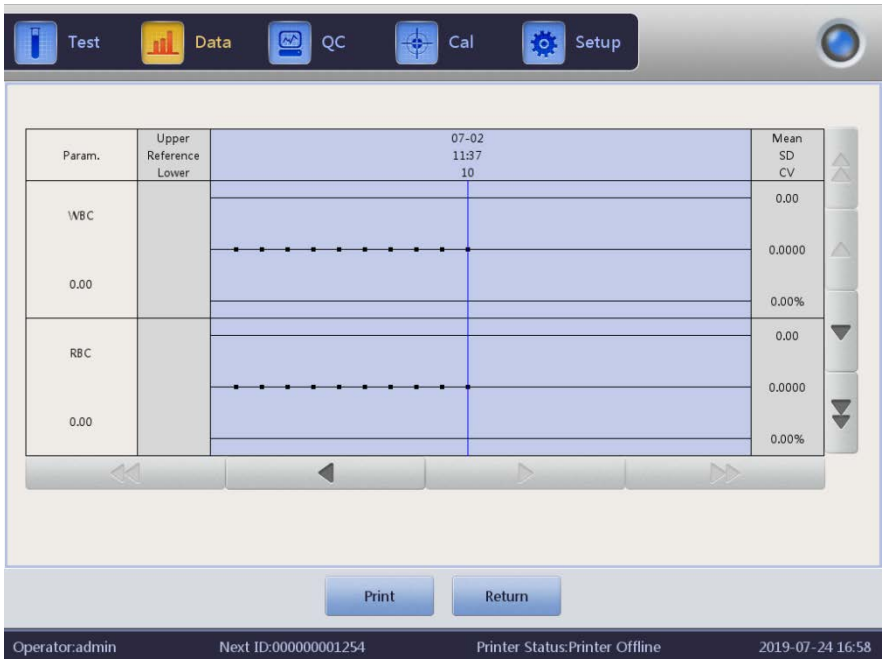


Figure7-14 Trend Graph

7.13 Shutoff and Logout

Shutoff procedure should be performed after finishing all the tests and before turning off the power. Sample cups and tubes will be cleaned by shutoff procedure. Perform it at least once every 24 hours in continuous use or after the whole day testing.

Shutdown Procedures

1. Click “Setup” to enter the interface.
2. Click “Shutdown” and click “OK” in popup dialog.
3. Rinse starts.
4. Turn off the power after rinsing.

Logout Procedures

1. Click “Setup” to enter the interface.
2. Click “Logout” and input new user name and password.
3. Click “OK” to login with new user name

NOTE

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

Chapter 8 Quality Control

8.1 Overview

In order to maintain the analyzer precision and eliminate system errors, it's necessary to perform quality control (QC). This analyzer provides four QC methods, which are L-J QC mode, X-B QC mode, X-R QC mode and X QC mode. In the following conditions, perform quality control with control materials recommended by supplier.

1. After daily start-up procedures completed
2. The reagent lot number changed
3. After calibration
4. After maintenance, or component replacement
5. In accordance with the laboratory or clinical QC protocol
6. In suspicion of abnormal parameter value

For accurate quality control results, please pay attention to the following items while using control materials.

1. Ensure that the control materials are stored at low temperature and the container is not damaged.
2. Please mix the control material following manufacturer's recommendations.
3. Do not use it if it opened and placed in a long time (the time is longer than recommended duration).
4. Do not heat or violently shake it.
5. Check value difference via comparison of high, normal, low control materials of current batch with previous batch.

WARNING

- All clinical specimens, control materials, calibrators and wastes have potential infectious hazard. Operator should comply with the safe operation provisions in laboratory and wear personal protective equipment (lab coats, gloves etc.) when handling these materials.

8.2 Quality Control Options

(1) L-J QC

L-J QC (Levey-Jennings graph) is a simple and visual QC method, with which QC value can be drawn directly on graph after getting the Mean, SD and CV. Mean($\overline{X}$), SD and CV are derived from following formulas.

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

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

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

(2) 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 concentration, dilution, human blood pathology and technical factor, but the volume and hemoglobin content of every RBC or hemoglobin in specific corpuscular volume is hardly interfered by those preceding factors. According to this characteristic, quality control of the samples is done by surveying the value of MCV, MCH and MCHC.

(3) 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.

(4) 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 rather than one value. Based on the mean value, $\overline{X}$, SD and CV can be calculated.

8.3 8.3 L-J QC

Click “QC” to enter “L-J QC” interface. See Figure 8-1.

Figure 8-1 QC Interface

8.3.1 Setup

Click “Setup” to enter corresponding interface. See Figure 8-2.

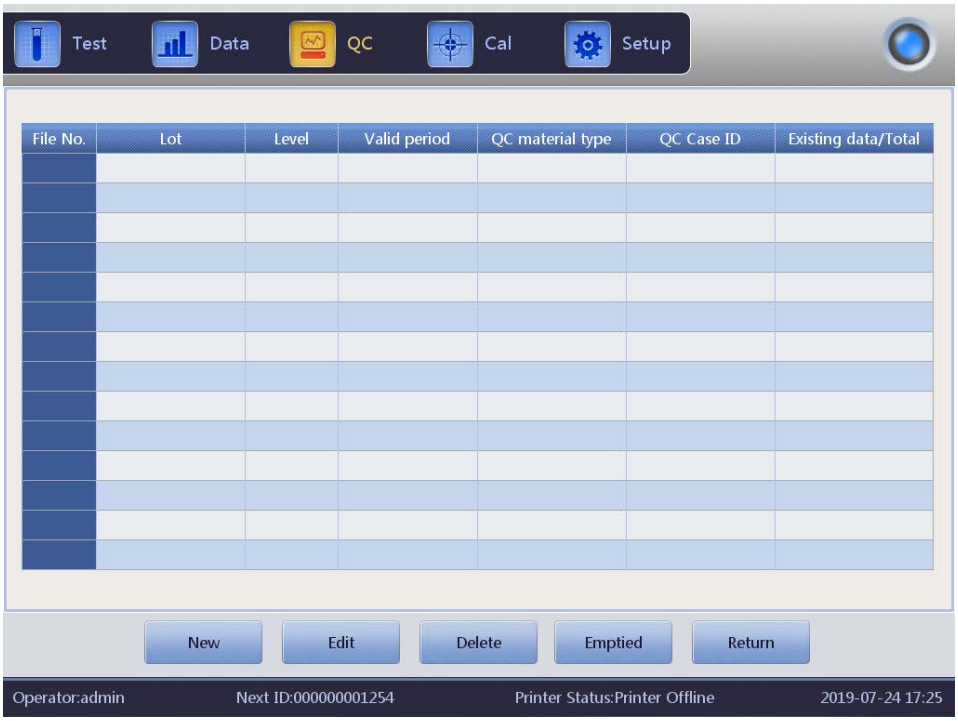


Figure 8-2 Setup

There are 14 different QC groups can be set. Users can set several groups as needed. Click “New” to set up one group of QC. See Figure 8-3.

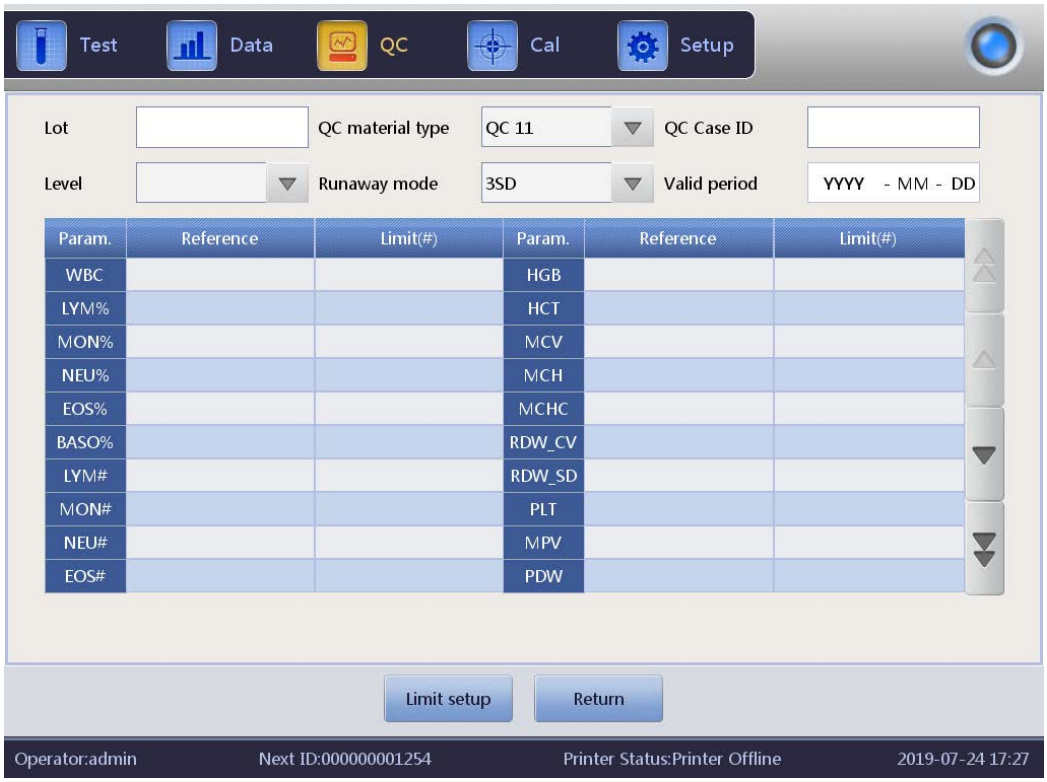


Figure 8-3 Edit

Edit information: Lot, QC material type, QC case ID, level, runaway mode, valid period, reference and limit

Limit Setup: calculated by absolute value and calculated by percentage, click “Limit setup” to choose it.

Click “Return” after editing. Click “OK” in popup dialog box to save it and return to setting interface.

Choose one group and click “Test” to test in QC interface. Click “Edit” to edit selected group, click “Delete” to delete the selected group, and click “Empty” to delete all groups.

Reference is the standard value of QC count. Limit gives the allowable deviation range. Please note that the limit cannot be greater than reference, otherwise, the new limit cannot be saved in database.

Format of valid period: year/month/day

8.3.2 QC Graph

Click “Test” after editing. Return to QC interface and start to QC count. Click “Edit Result” to modify results. See Figure 8-4.

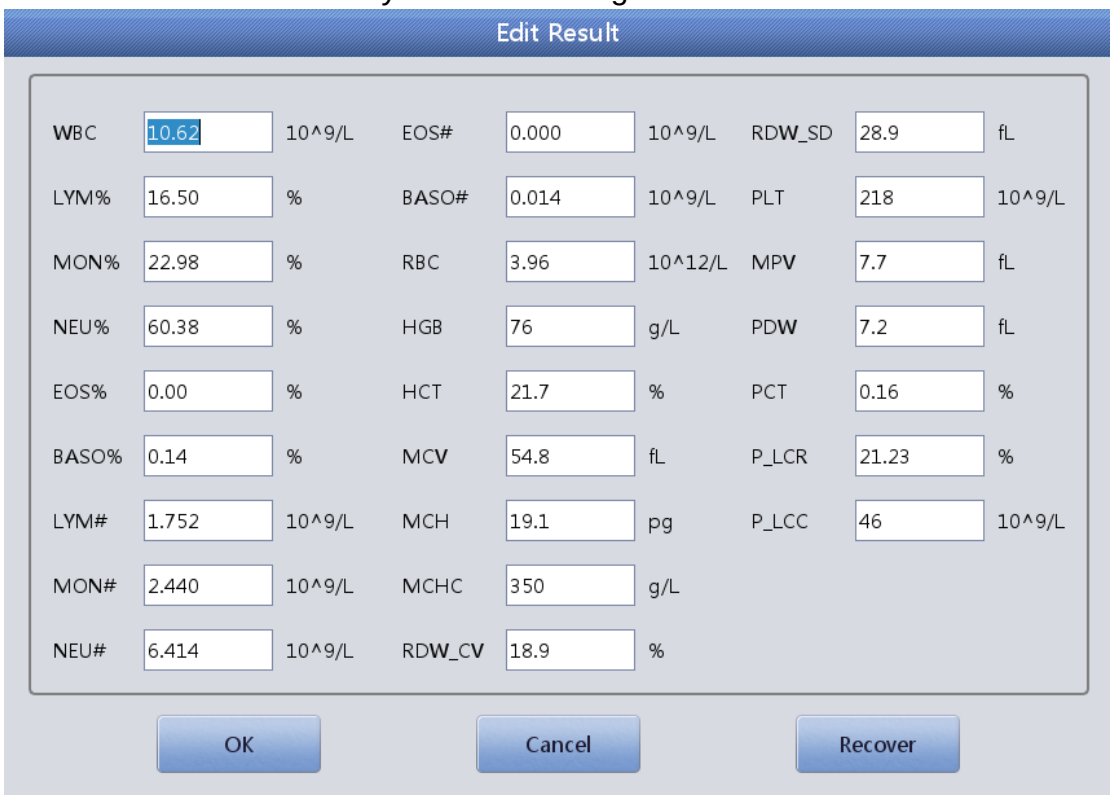


Figure 8-4 Edit Results

Click “QC Graph” to check it. See Figure 8-5.

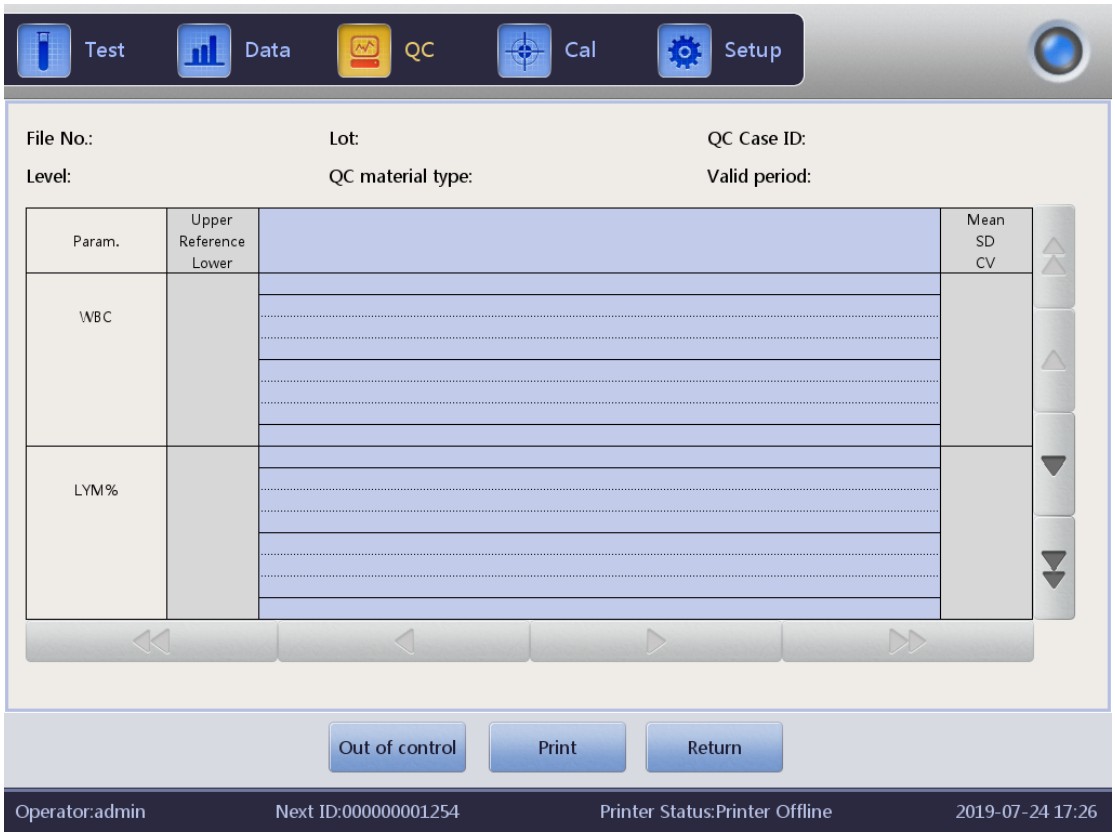


Figure 8-5 QC Graph

If there is a dot not in control area, choose it and click “Out of control” to enter the interface. See Figure 8-6.

Choose the reasons of out of control and write it down. Click “OK” to save it.

Figure 8-6 Out of Control

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. 20 dots can be displayed on each page for each parameter. Turn another page to see other dots.
3. The above line on the graph means Reference plus limit.
4. The below line on the graph means Reference value subtract limit.
5. The 3 values on the left side of parameter graph mean
    a) upper line ——Reference + limit
    b) middle line ——Reference
    c) lower line ——Reference –limit

If the control dot falls in the area between upper and lower limit of the corresponding graph, it means the dot is under control; if not, the dot is out of

control. Each QC graph can only store 100 dots at most.

8.3.3 QC List

Click “QC list” to see the tested sample data. See Figure 8-7.

Figure 8-7 QC List

There are at most 100 pieces of data can be reviewed in QC list. Click , , , , , , and to review test results.

Click “Delete” to delete the selected test results.

The reference and limit shown in this interface are the value inputted when editing. The reference and limit in QC list changes according to that in editing.

QC list saves every QC test results.

8.4 X-B QC

8.4.1 X-B QC Edit

X-B QC is different to others. Only three parameters are edited：MCV, MCH and MCHC.

Click “X-B QC” to pop up dialog box as shown in Figure 8-8.

Click “X-B setup” to enter edit interface. Click “On” in XB setup, the number between 20 to 200 is available in sample number. See Figure 8-9.

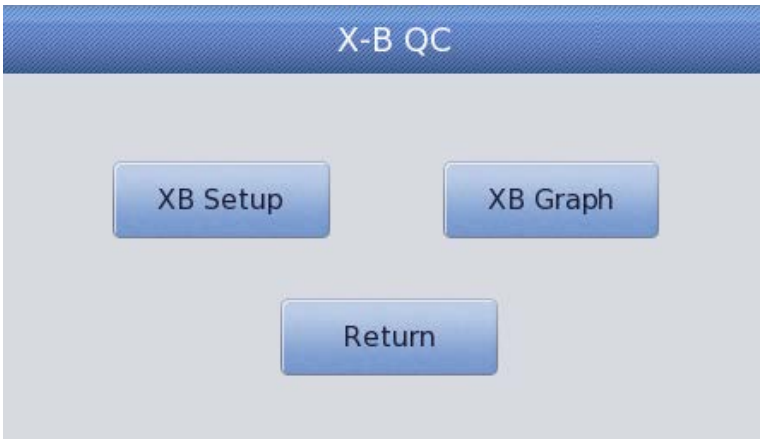


Figure 8-8 X-B QC

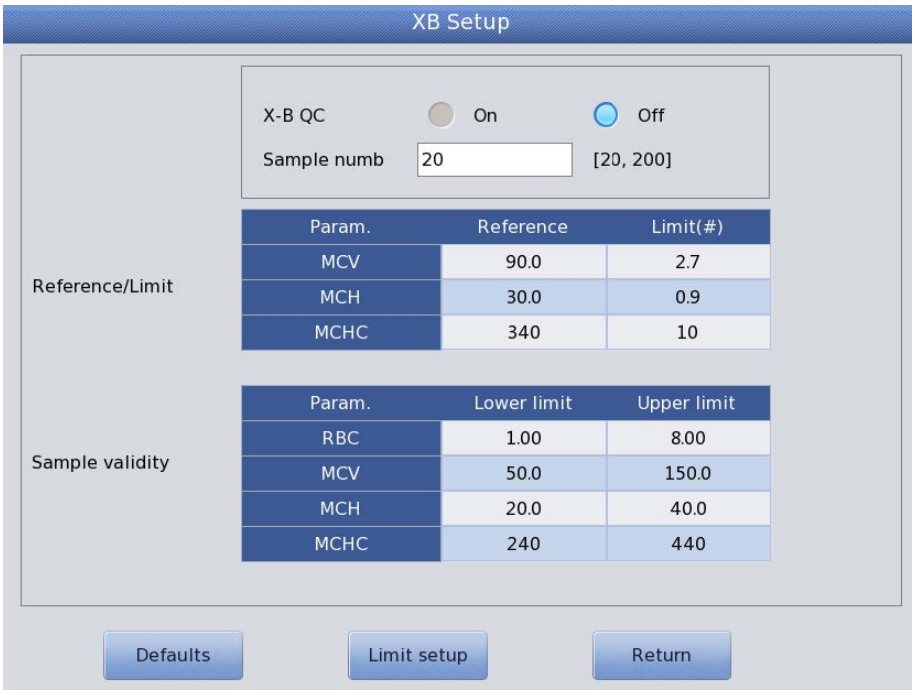


Figure 8-9 X-B Setup

Click relevant text box to input reference and limit of MCV, MCH and MCHC. At the same time please give the sample validity of RBC, MCV, MCH and MCHC. It provides the upper limit and lower limit of RBC, MCV, MCH and MCHC. The value which is within limits is valid. “Absolute value” and “Percentage” can be selected in limit setup interface. See Figure 8-10.

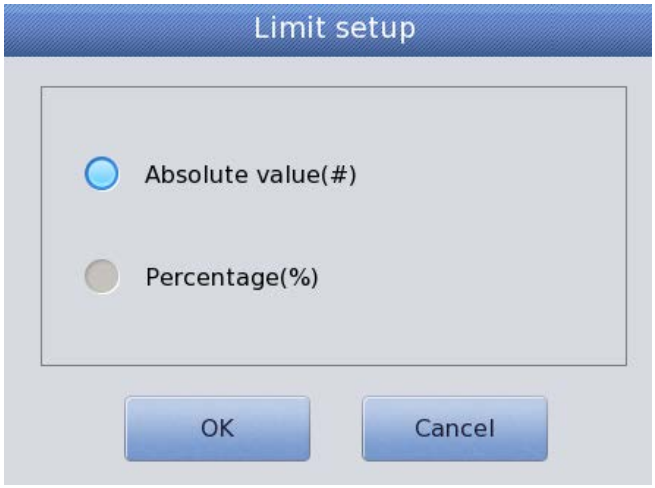


Figure 8-10 Limit Setup

Reference is the standard value of QC count. Limit gives the allowable deviation range. Please note that the limit cannot be greater than reference, otherwise, the new limit cannot be saved in database. Click “Return” after setup. Click “OK” to save your settings in popup dialog.

8.4.2 X-B QC Run

X-B QC is a QC without control materials. The basic method of measuring X-B QC is the floating mean method.

In X-B QC setup interface, “On” and “Off” is to open and close X-B QC running. Select “On” to run the X-B QC. Sample number is to control sample amount of one group. For example, there are 20 samples in one group, the analyzer makes 20 times of X-B QC testing as choosing “On”.

8.4.3 X-B QC Review

There are two ways of review: QC graph review and QC list review.

QC graph review

Operator can review QC results of three parameters through graphs. Click “X-B graph” to review it.

Dots of MCV, MCH and MCHC are drawn on the QC graph after a set of sample testing. For example, there are 20 samples in one set, the analyzer makes 20 times of X-B QC testing as choosing “On”. One X-B QC result is automatically calculated and gets corresponding QC dot. See Figure 8-11.

Figure 8-11 X-B QC Graph

There are three graphs of MCV, MCH and MCHC. The graphs updates at once after each set of QC counting.

Click  ,  ,  and  to review more test results. Each dot in graph has the corresponding date and time. The displayed date and time are subject to the final data's date and time within one set.

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. 20 dots can be displayed on each page for each parameter. Turn another page to see other dots.
3. The above line on the graph means Reference plus limit.
4. The below line on the graph means Reference value subtract limit.
5. The 3 values on the left side of parameter graph mean
    a) upper line ——Reference + limit
    b) middle line ——Reference
    c) lower line ——Reference –limit

If the control dot falls in the area between upper and lower limit of the corresponding graph, it means the dot is under control; if not, the dot is out of control.

QC list review

Operator can review QC results of three parameters through graphs. Click "QC list" in "X-B Graph" to enter the interface. See Figure 8-12.

Figure 8-12 X-B QC List

Click  ,  ,  and  to review test results. The average of a set of data is saved after testing. Click “Delete” to delete the selected test results. Click “Emptied” to delete all results. Click “Export” to export all data. Click “Return” to go back to X-B graph interface.

The reference and limit shown in this interface are the value input in editing. The reference and limit in QC list changes according to that in editing.

8.5 X-R QC

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

Click “X-R QC” in setup interface, see Figure 8-13.

Figure 8-13 QC Interface

Setup: enter QC edit interface

QC Graph: check QC dots

QC List: check QC data

Return: go back to setup interface

8.5.1 X-R QC Edit

Click “Setup” to edit it. See Figure 8-14.

New: create a new set of QC

Edit: modify the edited QC information

Delete: delete the selected QC

Emptied: delete all QC

Return: go back to X-R QC interface

Click “New” to pop up the dialog box as shown in Figure 8-15.

Lot, QC material type, QC Case ID, level and valid period can be edited. Click “OK” to save and click “Cancel” to cancel the edit.

The edited QC information can be seen in edit interface. There are at most 100 sets of QC data can be tested.

Click “Return” to go back to X-R QC interface to do QC test. The QC running interface displays two QC test results separately and automatically calculates mean and range after finishing the second QC count. The mean of two QC test data is one set of data.

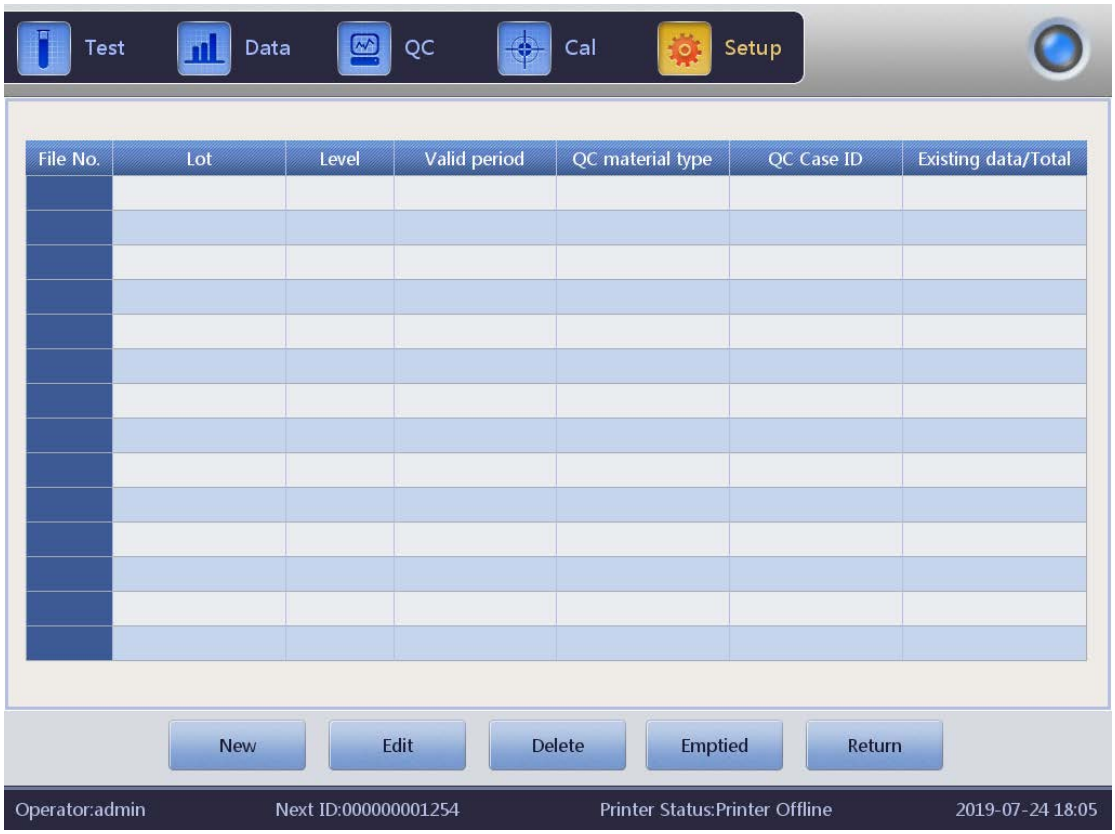


Figure 8-14 X-R Setup Interface

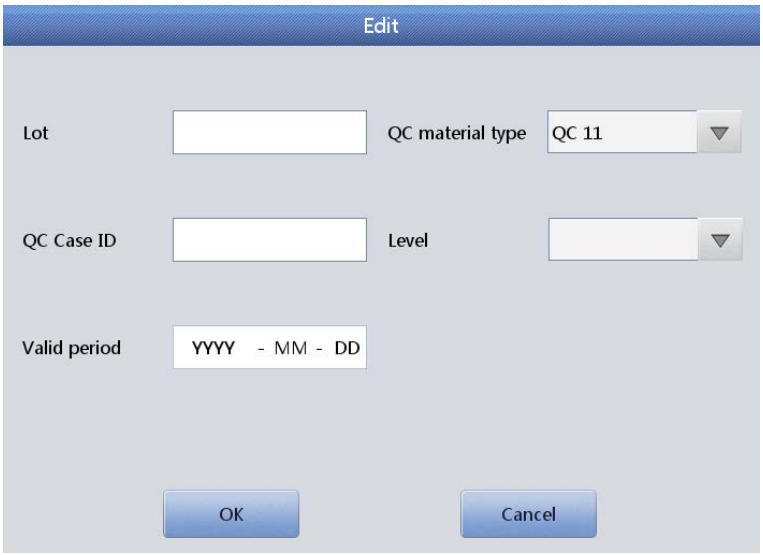


Figure 8-15 Edit

8.5.2 X-R QC Graph

Click “QC graph” in X-R QC interface, see Figure 8-16.

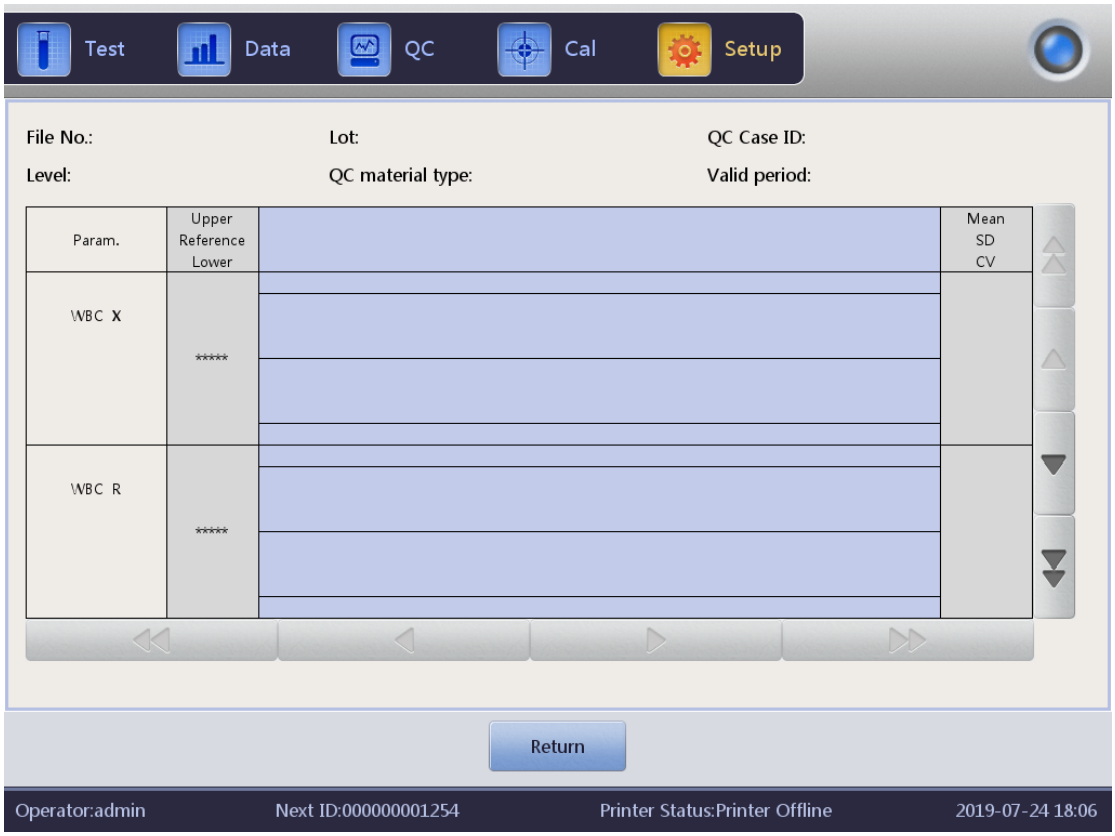


Figure 8-16 X-R QC Graph

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 sets—the dot correspond with range are within corresponding R graph.

X graph Instruction

1. It’s a graph with times of QC count on horizontal axis and results of QC count on vertical axis.
2. For every parameter, 100 dots can be displayed.
3. For every parameter, center line indicates X (overall mean of QC results).
4. Above line means X upper limit＝X＋A×R.
5. Below line means X lower limit＝X－A×R.
6. The 3 values on the left side of parameter graph mean
   a) upper line —— X upper limit＝X＋A×R
   b) middle line —— X
   c) lower line —— X lower limit＝X－A×R

R graph Instruction

1. It’s a graph with times of QC count on horizontal axis and results of QC count on vertical axis.
2. For every parameter, 100 dots can be displayed.
3. For every parameter, center line indicates R (overall mean of QC results range).
4. Above line means R upper limit＝B×R.
5. Below line means R lower limit＝C×R.
6. The 3 values on the left side of parameter graph mean

a) upper line —— R upper limit＝B×R

b) middle line —— R

c) lower line —— 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. If not, the dot is out of control.

Click , , and to review graphs of different parameters. Click “Return” to go back to X-R interface.

8.5.3 X-R QC List

Select one set of QC in edit interface and click “QC list” in X-R QC interface. The displayed data is the selected QC data. See Figure 8-17.

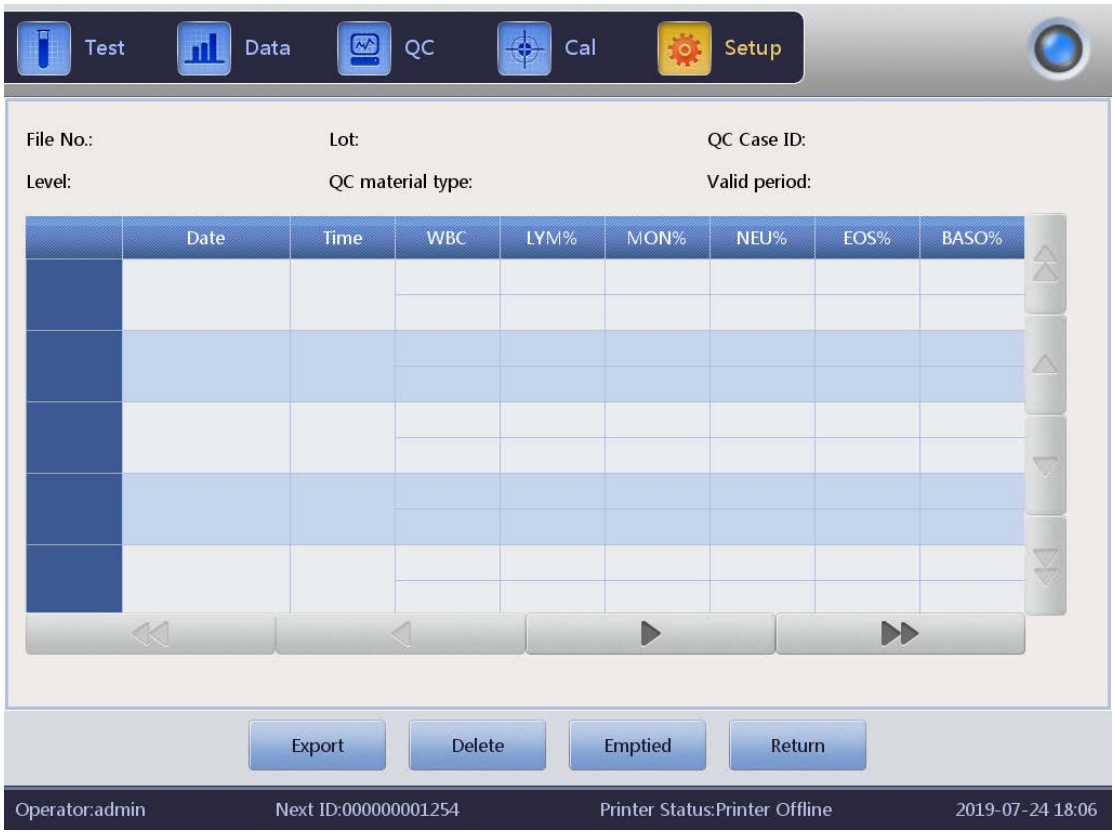


Figure 8-17 X-R QC List

Export: export QC data

Delete: delete selected data

Emptied: delete all data

Return: go back to X-R interface

There are at most 100 pieces of data can be reviewed in QC list. Click  ,  ,  ,  ,  ,  ,  and  to review test results.

Different from X and L-J QC, only 3 pieces of QC result can be displayed in X-R QC List review interface. Every QC result contains mean value and range. The first two columns on first page of the list is total mean and average range.

The list updates after two times of QC test. The data displayed in the QC list is the average of the two times of QC count results.

8.6 X QC

X QC is a kind of the QC method with control materials. The analyzer aspirates control materials to do QC test. Operator could do QC test for 24 parameters. Considering different needs, operator can do QC test for some of them only. 3 QC documents of high, normal and low are provided for saving.

8.6.1 X QC Edit

Click “X QC” in setup interface, see Figure 8-18.

Figure 8-18 X QC Interface

Setup: enter QC edit

QC Graph: check QC dots

QC List: check QC data

Return: go back to setup interface

8.6.2 X QC Edit

Click “Setup” to enter edit interface. See Figure 8-19.

New: create a new set of QC

Edit: modify the edited QC information

Delete: delete the selected QC

Emptied: delete all QC

Return: go back to X QC interface

Figure 8-19 X QC Setup

Click “New” to enter edit interface. See Figure 8-20.

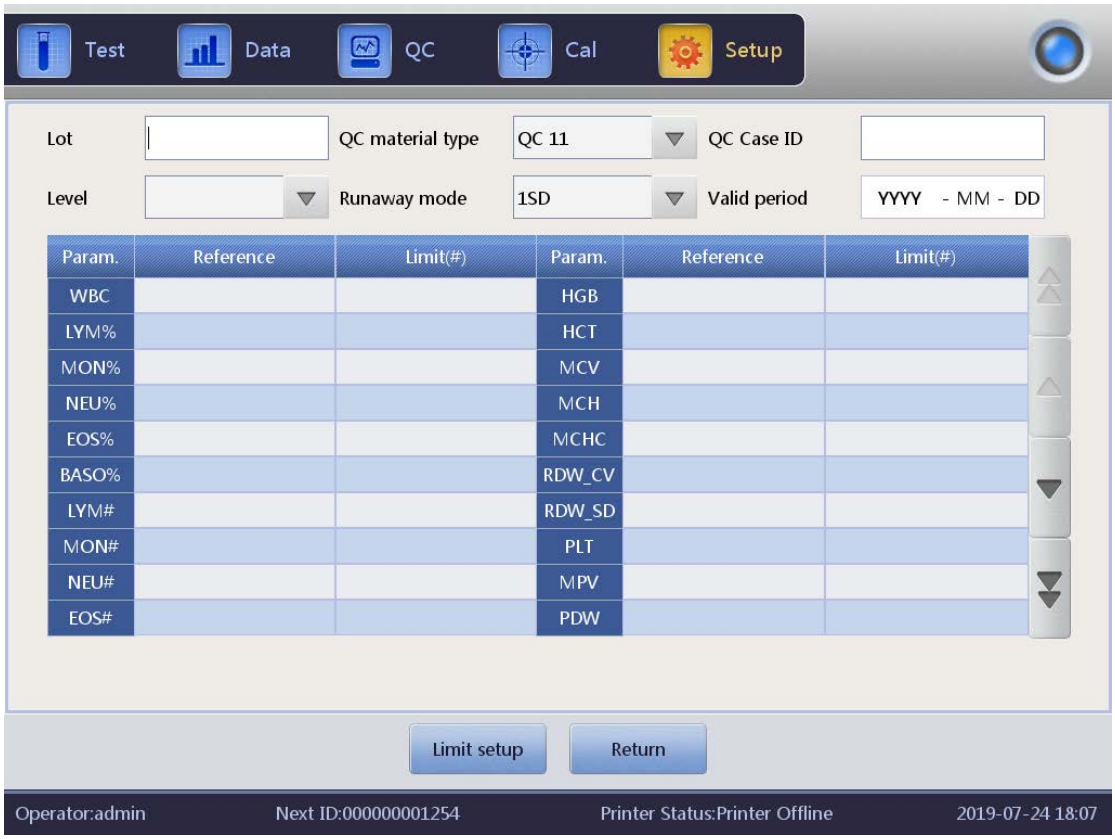


Figure 8-20 X QC Edit

Lot, QC material type, QC Case ID, level, runaway mode, reference, limit and valid period can be edited. Click “Limit setup” to choose method. See Figure 8-21.

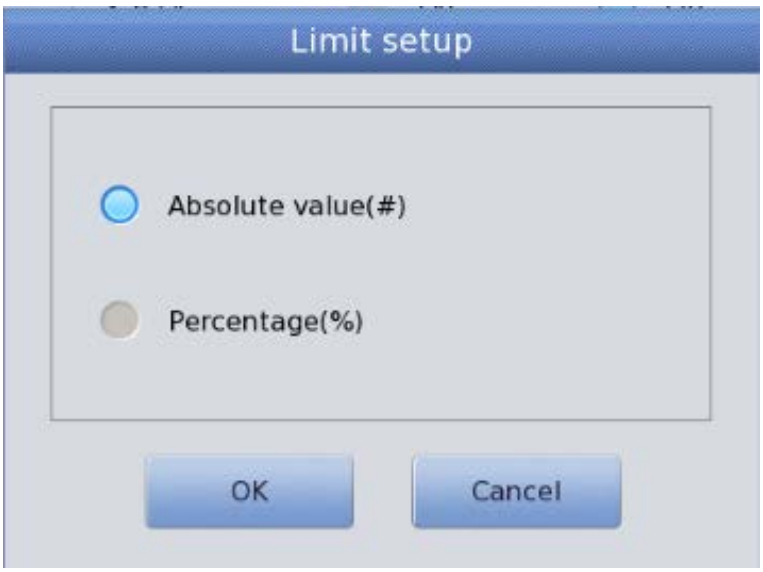


Figure 8-21 Limit Setup

The QC running interface displays two QC test results separately and automatically calculates mean and range after finishing the second QC count. The mean of two QC test data is one set of data.

8.6.3 X QC Graph

Click “QC Graph” in X QC interface, see Figure 8-22.

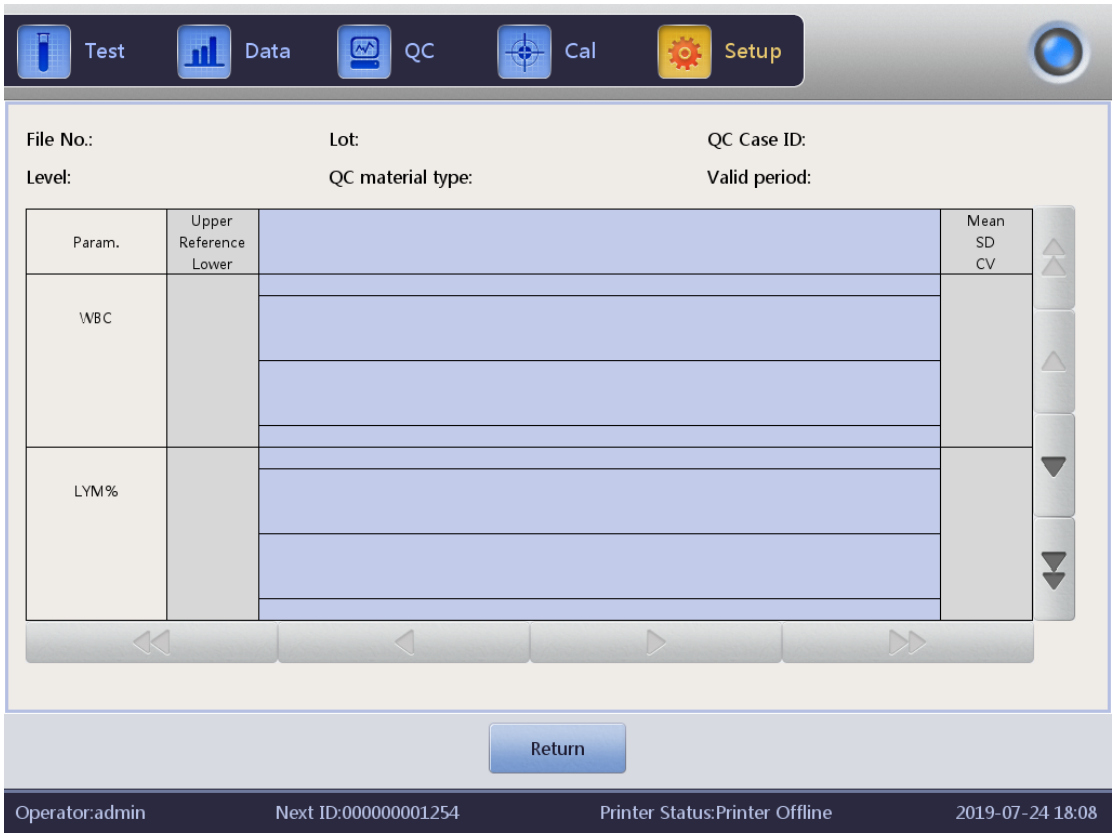


Figure 8-22 X QC Graph

The operator could review 24 parameters’ result via QC graph.

Different from L-J QC, every dot on the X QC Graph indicates mean value of two times of QC results. According to different types of quality controls, there are low, normal and high graphs. If select “Low” to do control test twice, the control dot corresponding to mean value presents in low graph. Other

types present in corresponding graph.

QC graph Instruction

1. It’s a graph with QC times on horizontal axis and QC results on vertical axis.
2. For every parameter, 100 dots can be displayed.
3. Above line means Reference plus limit.
4. Below line means Reference subtract limit.
5. The 3 values on the left side of parameter graph mean.
   a) upper limit ——Reference + limit
   b) middle line ——Reference
   c) lower limit ——Reference - limit

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

8.6.4 X QC Graph List

Select one set of QC in edit interface and click “QC list” in X QC interface. The displayed data is the selected QC data. See Figure 8-23.

Figure 8-23 X QC List

Export: export QC data

Delete: delete selected data

Emptied: delete all data

Return: go back to X QC interface

There are at most 100 pieces of data can be reviewed in QC list. Click  ,  ,  ,  ,  ,  ,  and  to review test results.。

Chapter 9 Calibration

9.1 Overview

Analyzer is inspected 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, and calibration factor.

The analyzer provides three kinds of calibration modes: Standard, Blood and Manual.

WARNING

- Only calibrators recommended by supplier 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 recover to room temperature and well mixed slowly before use.
- Make sure the calibrators are within the expiry date.
- Make sure the there is no fault prompt and precision meets the requirement before calibration.
- Never apply to the laboratory or clinic use unless all the parameters are calibrated accurately.

NOTE

- Take calibrator out from refrigerator, and warm to room temperature by rubbing.

- Shake the vial filled with calibrator up and down 30 times at least to mix plasma and blood cells well.

9.2 Calculation Frequency

To ensure 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 offsets.
3. Component that affects the measurement results is replaced after heavy repair.
4. Reuse after long storage.
5. The laboratory or the clinic requires.
6. The reagent has been replaced.
7. There is obviously deviation when doing quality control test.

MCV and HCT are correlative parameters. The value of one can be calculated from the other by the analyzer. So only MCV can be calibrated by the analyzer. Usually the manufacturer gives the reference value of MCV and HCT at the same time.

WARNING

- All clinical specimens, control materials, calibrators have potential infectious hazard. Operator should comply with the safe operation provisions in laboratory and wear personal protective equipment (lab coats, gloves etc.) when handling these materials.

9.3 Preparation

Before calibration, inspect the analyzer as the following steps.

1. Ensure the reagents are sufficient, uncontaminated and in the shelf life.
2. Run a blank test and make sure the results are accordance with Table 9-1.

Table 9-1 Blank Range

Parameter	Range
WBC	≤0.20×10^9 /L
RBC	≤0.02×10^12 /L
HGB	≤1g /L
PLT	≤10.0×10^9 /L

3. Make sure there's no fault prompt.
4. Access whether the precision of instrument is acceptable. Test control material in normal level or human blood 11 times continuously. Take the results from the second to the eleventh, and check CV in data interface. Make sure the they are accordance with Table 9-2.

Table 9-2 CV

Parameter	Range	CV
WBC	4.0 ×10^9/L ~15.0×10^9 /L	≤2.0%
RBC	3.00 ×10^12 /L ~6.00×10^12/L	≤1.5%
HGB	100 g/L ~180 g/L	≤1.5%
PLT	100 ×10^9 /L ~149×10^9 /L	≤6.0%
	150 ×10^9 /L ~500×10^9 /L	≤4.0%
HCT /	35%~50%	≤2.0%
MCV	70 fL ~120 fL	≤1.0%

5. Test control materials in high level three times and then test control materials in low level three times immediately. Calculate carryover by the

following formula and the result should comply with 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	≤0.6%
PLT	≤1.0%

9.4 Calibration Modes

9.4.1 Manual Calibration

Click “Manual” in “Cal” interface. See Figure 9-1.

The principles of new calibration value

- Mean value=(value1+value2+value3+value4)/4
- New calibration value=(reference/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 reference value of PLT of the calibrator is 220, current calibration coefficient is 103%, and the test result is 230, thus the new calibration coefficient is

New calibration coefficient =103%×220/230

=98.52%

Input new calibration coefficient and click “Save” to save it.

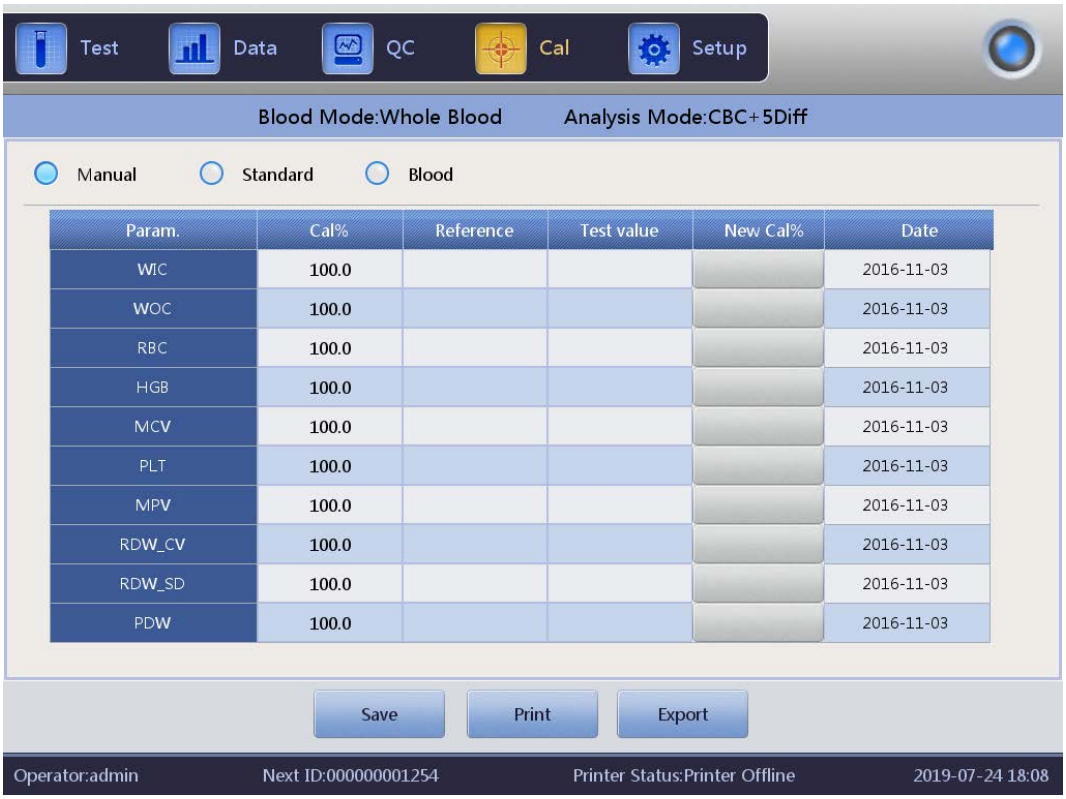


Figure 9-1 Manual Calibration

Click “Save” to save the new calibration coefficient in database.

Click “Print” to print calibration value.

Click “Export” to export data sheet.

NOTE

- The analyzer can calibrate one or all parameters of WBC，RBC，HGB，MCV，MPV, RDW_CV, RDW_SD, PLT and PDW.
- Do remember click “Save” to save calibration value before exiting Cal

interface.

Validation of calibration coefficient

After calibration, it's recommended to validate the calibration coefficients as following steps.

1. Test the calibrators three times, and check whether the results are within the allowed range.
2. Test calibrators in High, Normal and Low level respectively three times at least. Check whether the results are within the allowed range.
3. Analyze three normal fresh blood samples three times for each at least. Check whether the results are within the allowed range.

NOTE

- The calibration coefficient is allowed in the range of 70%~130%. If the new calibrator coefficient is out of the range, the critical value of the limit range should be regarded as the new calibration coefficient. In that case, operator should find out reasons and calibrate again.

9.4.2 Standard Calibration

Click “Standard” in “Cal” interface as Figure 9-2.

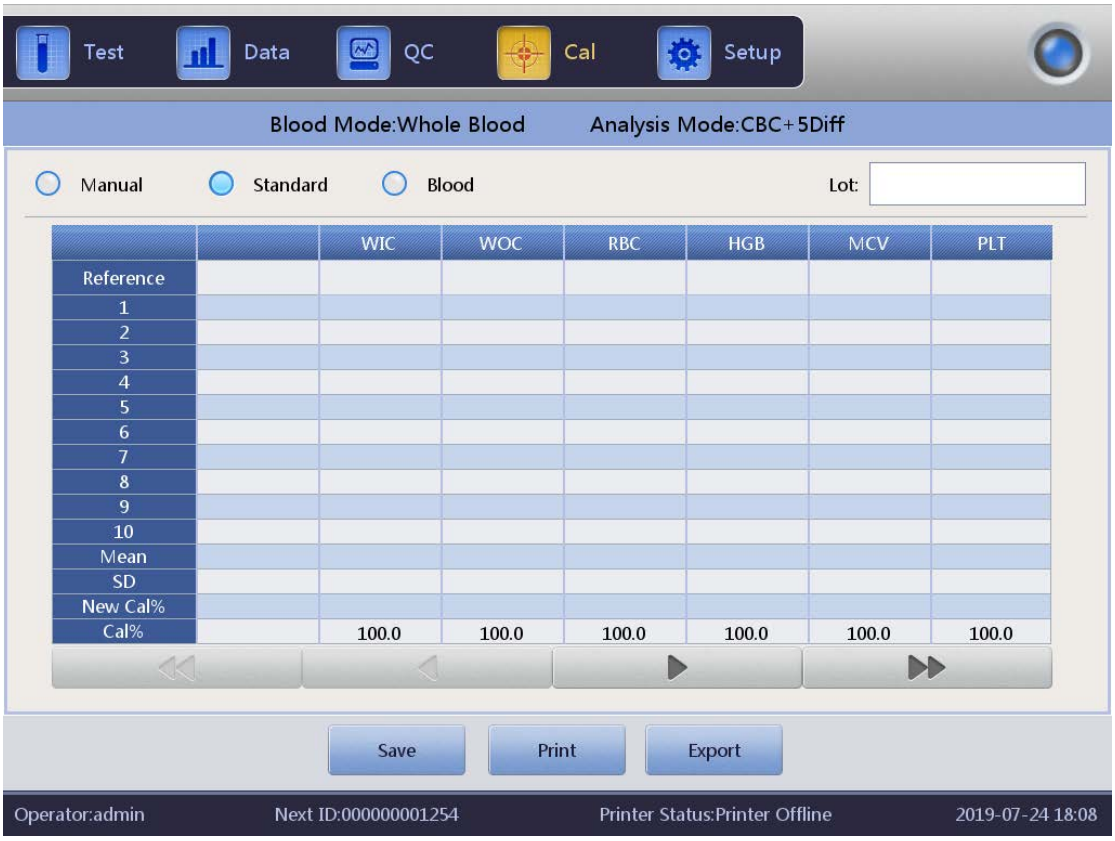


Figure 9-2 Standard Calibration

Please calibrate according to the following procedures.

1. Input lot number of calibrator.
2. Input reference of parameters which need calibration. For those parameters which needn’t calibration, their reference is blank.
3. Click “Test” to start calibration. The analyzer could automatically calculate the mean value of 10 tests at most. It’s recommend to test 3 to 5 times at least.
4. The new calibration coefficient is automatically calculated according to the reference value of calibrators and mean.
5. Click “Save” to save new calibration coefficient, click “Print” to print the new calibration coefficient.

6. Click “Export” to export the backup calibration coefficient data.

Validation of Calibration coefficient

After calibration, it’s recommended to validate the calibration coefficients as following steps.

1. Test the calibrators three times, and check whether the results are within the allowed range.
2. Test calibrators in High, Normal and Low level respectively three times at least. Check whether the results are within the allowed range.
3. Analyze three normal fresh blood samples three times for each at least. Check whether the results are within the allowed range.

   Input reference in standard mode. Put the prepared calibrator under the sample probe and press Count button on the front housing. The test results are displayed in box of measured value. The first calibration test result display in value 1, and so on. The analyzer recalculates the new calibration value based on the reference and the measured mean after each counting.

The principles of new calibration value

$$\text{Mean}=\frac{\sum_{i=1}^{n} X_i}{n}$$

- New calibration value=(reference/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%

9.4.3 Blood Calibration

Click “Blood” in “Cal” interface. See Figure 9-3.

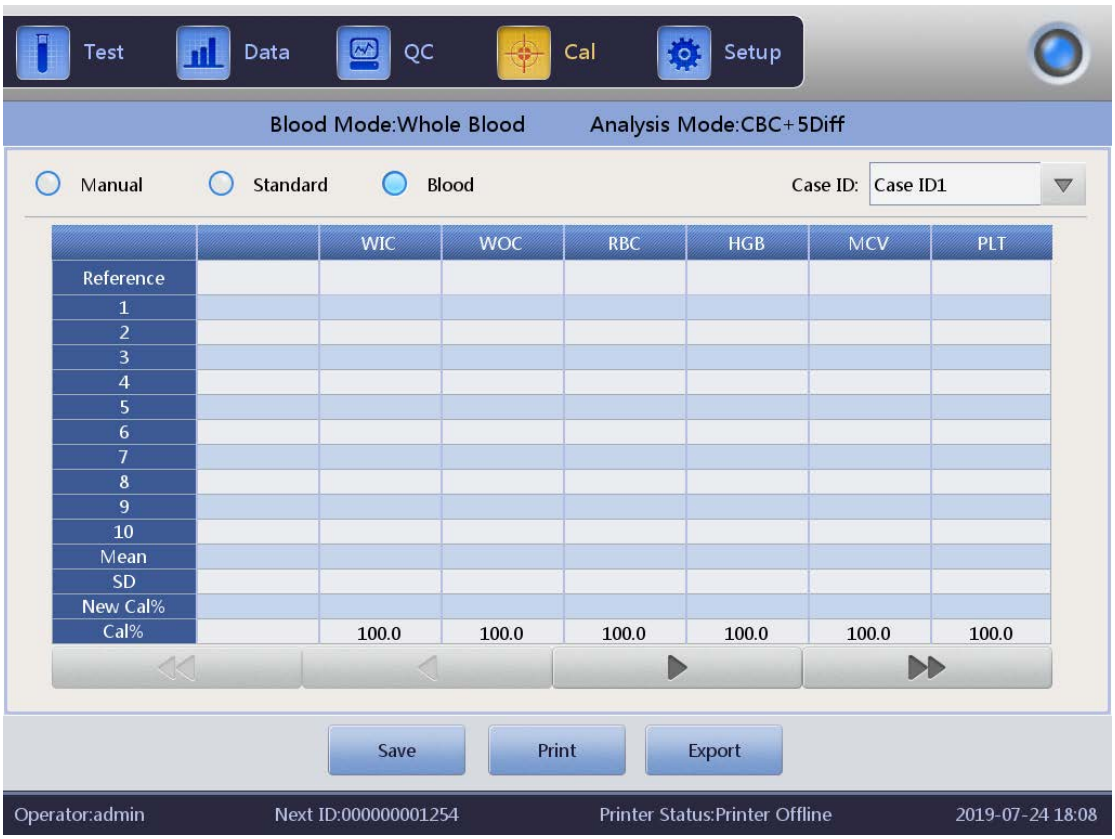


Figure 9-3 Blood Calibration

Calibrate the analyzer as follows.

1. Prepare 5 normal whole blood samples and test each of them at least 5 times by other types of analyzer. Calculate the mean and input it into reference box.
2. Select Case ID 1 on the right corner and press Count button on the front housing to make at most 10 times of counting and get mean value. Please test it no less than 5 times. Then Select Case ID 2 on the right corner and press Count button on the front housing to make at most 10 times of counting and get mean value. Please test it no less than 5 times, and so on.
3. The system adds the measured values and calculates the average of parameters. System automatically calculates new calibration coefficient according to reference, mean value and calibration coefficient.
4. Click “Save” to save new calibration coefficient, and click “Print” to print it.
5. Click “Export” to export the backup calibration coefficient data

- New calibration value=(reference/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%

NOTE

➢ Please remember click “Save” to save counting results before exit.

Chapter 10 Service

10.1 Overview

Routine care and regular maintenance are essential for instrument to ensure its accuracy, keep in good condition for a long time, increase its service life and minimize system problems. Procedures and instruction for preventive maintenance are described in this chapter. Contact our after-sale service department for more information.

According to different requirements, preventive maintenance is divided into daily maintenance, weekly maintenance, monthly maintenance and specific maintenance base on actual situation.

 **WARNING**

- All components' surface may be potentially infectious. Safety protective measures should be taken to avoid infection, electric shock or burn. Wear gloves for cleaning and maintenance. Clean hands with disinfectant after work.

10.2 Routine Maintenance

10.2.1 Daily Maintenance

1. Auto Clean

Auto cleaning program makes you needn't bother about daily maintenance. Based on the number of samples, operator set time for auto clean. Please make a blank test every day after boot. Choose "On" in "Auto blank". For the users with plenty of samples to be tested, it's suggested to turn on "Soak and

exit" and "Auto soak" .Times of "Auto soak" can be chosen. See Figure 10-1.

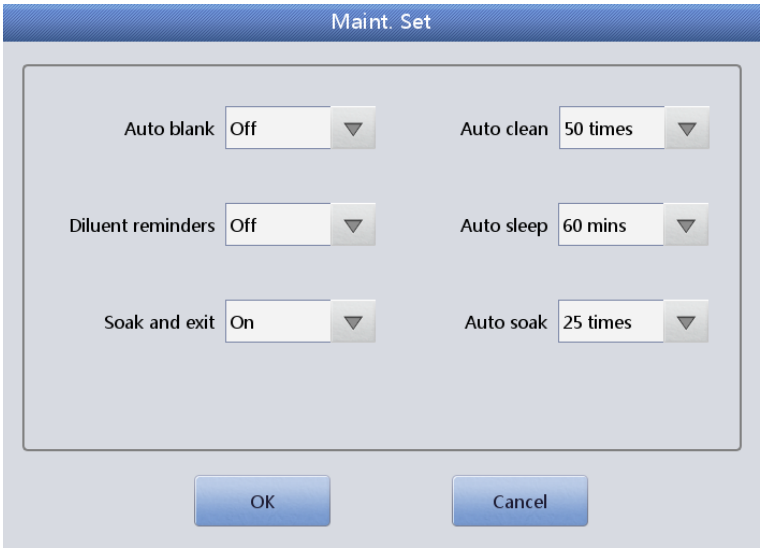


Figure 10-1 Maint. Set

2. Shutoff

To get correct results, it's necessary to clean counting chambers and rinse the fluid system to prevent measurement errors caused by residues. Shutoff program should be performed when the analyzer tests more than 500 specimens or after work everyday. If continuously use the instrument, shutdown program should be performed once at least every 24 hours. For detail instructions, please refer to *chapter 7 Daily Operation.*

10.2.2 Weekly Maintenance

Surface Maintenance

Clear the smudge on the surface, especially the blood around the sample probe to prevent protein deposition and mildewing. Wipe the surface with cleaning cloths with neutral detergent.

NOTE

- Never use corrosive acids, alkali or volatile organic solvent (such as

acetone, aether and chloroforms) to wipe the surface of the analyzer, but only use neutral detergent.

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 in order to ensure all of them can be put back.

Materials Requirements

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

Clean Procedures

1) Empty the fluid system.
2) Open the front housing and right 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.

NOTE

- Do not push or pull the piston when the syringe is dry, as it may damage the piston. Avoid touching the piston because oil from the fingers may cause it move erratically.

2. Maintenance of mechanical parts

It mainly aims at maintenance of mechanical parts, including lubricating motor shaft, X and Y guide rod of sampling device etc. See Figure 10-2.

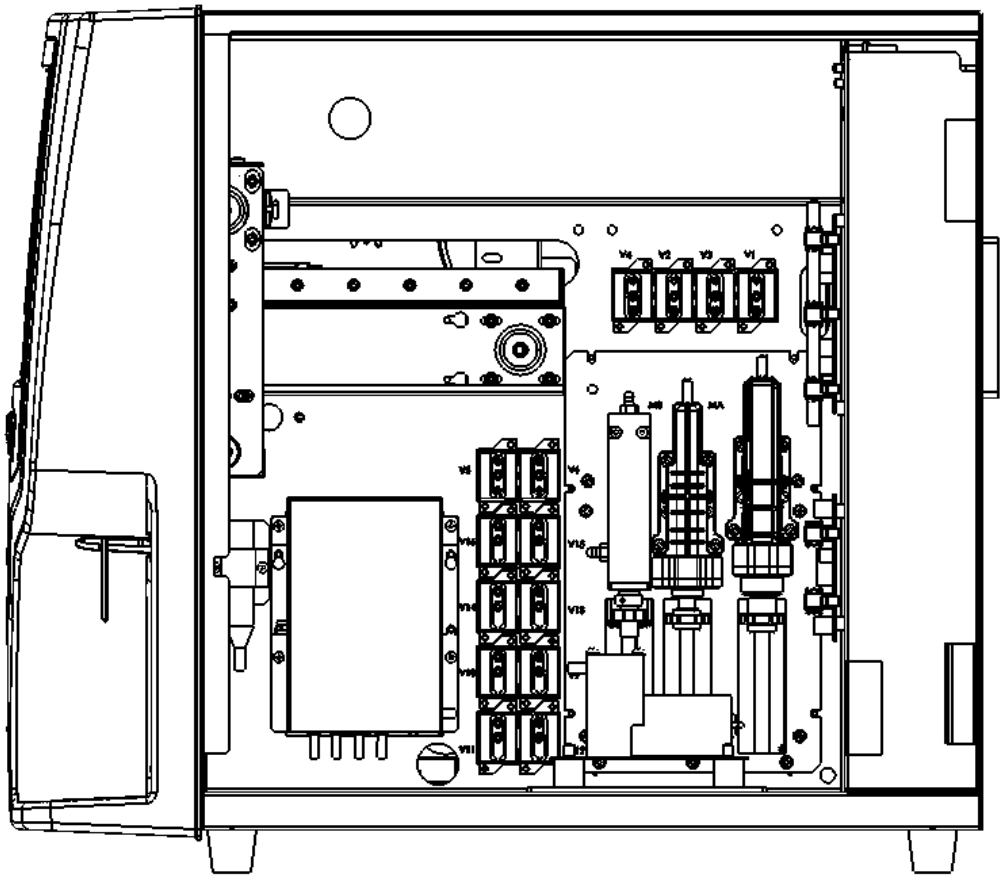


Figure 10-2 Maintenance of Mechanical Parts

NOTE

- To make sure it's not in running status, please turn off the instrument before performing monthly maintenance.
- Only trained personnel can open the front housing of instrument and clear X, Y guide rod of sampling device.

10.3 Maintenance procedure

Click "Maintenance" in Setup interface, see Figure 10-3.

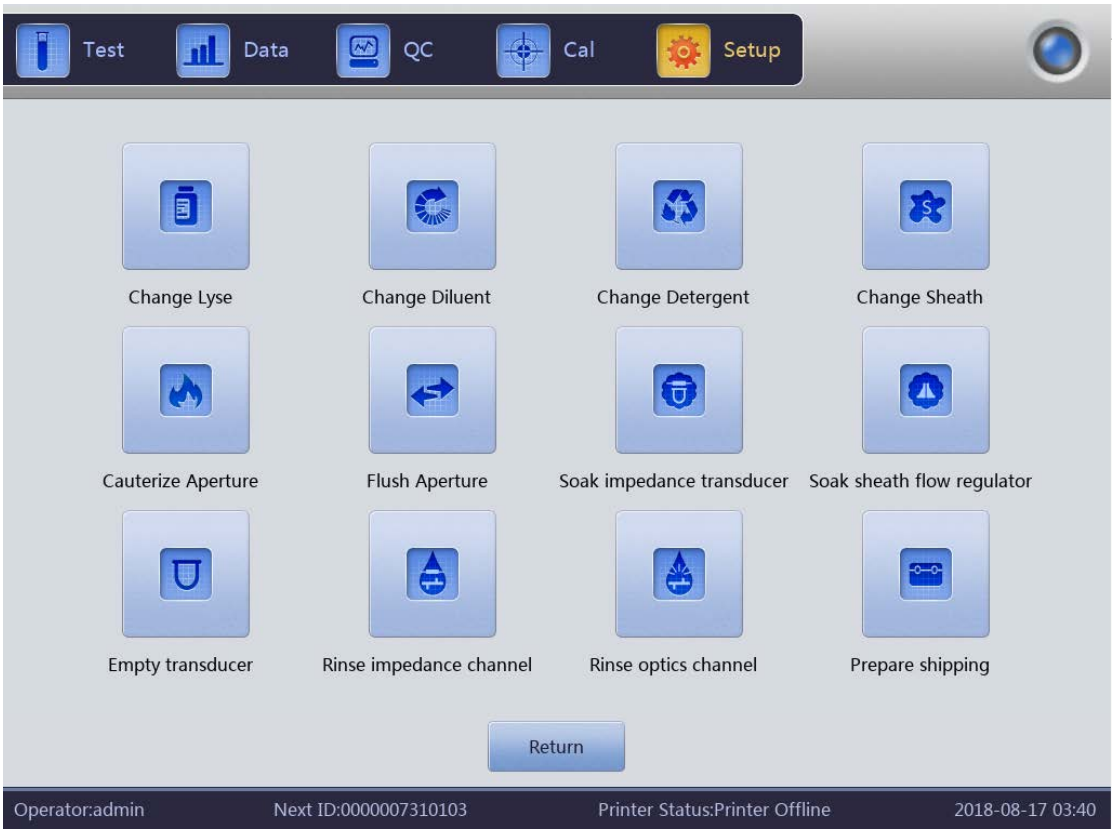


Figure 10-3 Maintenance Interface

Function and operation of them are as below.

10. 3. 1 Change Lyse

Please change lyse in following conditions.

- There are bubbles in the lyse tubing.
- Lyse in tubing is contaminated.
- Lyse is used up.

Operation Procedures

1. Click “Change Lyse” in “Maint” interface.
2. The analyzer starts to execute it. All buttons turn gray.

3. The operation is completed and buttons return to normal.

10.3.2 Change Diluent

Please change diluent in following conditions.

- There are bubbles in the diluent tubing.
- The diluent in tubing is contaminated.
- Diluent is used up.

Operation Procedures

1. Select Change Diluent in “Maint” interface.
2. The analyzer starts to execute it. All buttons turn gray.
3. The operation is completed and buttons return to normal.

10.3.3 Change Detergent

Please change detergent in following conditions.

- There are bubbles in the detergent tubing.
- The detergent in tubing is contaminated.
- Detergent is used up.

Operation Procedures

1. Select “Change Detergent” in “Maint” interface.
2. The analyzer starts to execute it. All buttons turn gray.
3. The operation is completed and buttons return to normal.

WARNING

- All clinical specimens, control materials, calibrators and waste have potential infectious hazard. Operator should comply with the safe operation provisions in laboratory and wear personal protective equipment (lab coats, gloves, safety glasses, etc.) when handling these materials.

NOTE

- Keep the reagent still for a while to let it stable.
- After replacement of diluent, detergent, sheath or lyse, perform blank count to ensure the blank values are in the acceptable range.

10.3.4 Change Sheath

Please change sheath in following conditions.

- Three are bubbles in the sheath flow regulator.
- The sheath in tubing is contaminated.
- Sheath is used up.

Operation Procedures

1. Click “Change Sheath” in “Maint” interface.
2. The analyzer starts to execute it . All buttons turn gray.

3. The operation is completed and buttons return to normal.

10.3.5 Cauterize Aperture

Cauterize both sides of the ruby aperture with a high voltage to clear protein and dust adhering or blocking on the aperture. It prevents and eliminates clogging. The procedures are as follows.

1. Click “Cauterize Aperture” in the “Maint” interface.
2. The analyzer starts to execute it and all buttons turn gray.
3. The operation is completed and buttons return to normal.

10.3.6 Flush Aperture

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

1. Click “Flush Aperture” in “Maint” interface.
2. The analyzer starts to perform the function and all buttons turn gray.
3. The operation is completed and buttons return to normal.

10.3.7 Soak Impedance Transducer

WARNING

- All clinical specimens, control materials, calibrators have potential infectious hazard. Operator should comply with the safe operation provisions in laboratory and wear personal protective equipment (lab coats, gloves, safety glasses, etc.) when handling these materials.

Soak impedance transducer with probe cleaner. The procedures are as

follows.

1. Click “Soak impedance transducer” in the “Maint” interface.
2. The analyzer starts to perform the function and all buttons turn gray.
3. The operation is completed and buttons return to normal.

If the ruby aperture is clogged severely, please select “Soak Impedance Transducer” in “Maint.” interface, and then put the probe detergent under the sample probe. The analyzer will automatically aspirate the probe detergent into the sample cup to soak the ruby aperture.

NOTE

- Probe detergent is corrosive, so operator should wear lab coats, gloves, and follow required laboratory or clinical procedures.

10.3.8 Prepare Shipping

Perform this function before shipping or long term storage. The procedures are as follows.

1. Take out the diluent inlet tubing connecting with the “DELUENT” on the rear panel.
2. Take out the lyse inlet tubing connecting with the “LYSE” on the rear panel.
3. Take out the detergent inlet tubing connecting with the “DETERGENT” on the rear panel.
4. Take out the sheath inlet tubing connecting with the “SHEATH” on the rear panel.
5. Unscrew the cap of reagent containers and keep the tubes well.
6. Keep the remaining reagents in their containers and store them

according to instructions. Operator should establish and confirm to the Storage measures should be established and maintained to prevent reagent from deteriorating, misusing or accidental ingestion. The reagent should be away from temperature extremes.

7. Click “Prepare Shipping” in “Maint” interface, click “OK” in popup dialog box.
8. The analyzer starts to perform the function.
9. The operation is completed and back to the “Maint” interface.

10.3.9 Others

Empty transducer: empty liquid in the transducers

Rinse impedance channel: clean impedance channel

Rinse optics channel: clean optics channel

Soak sheath flow regulator: soak the sheath flow regulator with probe detergent.

10.4 Components Maintenance

Time and required tools for Spincell 5compact components maintenance

Components	Maintenance Time	Required Tools
Syringe module	After 6000 sample tests	Grease, brush, cloth
Sample injection mechanism	After 6000 sample tests	Grease, brush, cloth
Sample cup	After 6000 sample tests	Probe detergent, cross screwdriver
Sheath regulator	After 6000 sample tests	Probe detergent
Waste filter for WOC cup	After 6000 sample tests	Probe detergent, cross screwdriver
Waste filter for WIC cup	After 6000 sample tests	Probe detergent, cross screwdriver
Waste filter for RBC cup	After 6000 sample tests	Probe detergent, cross screwdriver
Tubes fixers	After 6000 sample tests or 18 months after installation	Cable ties, cross screwdriver, pincer

Click “Statistics” in data interface, and you can select time intervals of start time and end time. Select “All” for query type. Click “Statistics” button and the number of test times is shown. Users can check installation time to verify maintenance opportunity.

Please contact our after-sale service department or local agent for replacement if it needs components maintenance.

10.5 Components Replacement

Time and required tools for Spincell 5compact components replacement

Components	Replacement Time	Required Tools
Probe wiper	After 60000 sample tests	Tweezers, cross screwdriver
Waste filter for WOC cup	After 60000 sample tests	Tweezers, cross screwdriver
Waste filter for WIC cup	After 60000 sample tests	Tweezers, cross screwdriver
Waste filter for RBC cup	After 60000 sample tests	Tweezers, cross screwdriver

Syringe seal ring	After 100000 sample tests	Tweezers, cross screwdriver

Click “Statistics” in data interface, and you can select time intervals of start time and end time. Select “All” for query type. Click “Statistics” button and the number of test times is shown.

Please contact our after-sale service department or local agent for replacement if it needs components replacement.

Chapter 11 Troubleshooting

11.1 Overview

This chapter gives instructions for fault identifying and troubleshooting. If the malfunction is not solved according to the guidance, or if more detail information is needed, please contact our after-sale service department.

NOTE

- This manual is not service manual. It only provides the measures when there are failure warnings.

 **WARNING**

- Potential biohazard. Maintain, repair and troubleshoot according to the established safe operation procedures.

11.2 Troubleshooting Guidance

Troubleshooting guidance is used to assist operator to identify and resolve analyzer problems. Also it offers you method of obtaining technical assistance from our after-sale service department. Excellent troubleshooting skills are derived from deep understanding of the instrument and rich operation experience. Please follow these three steps to do troubleshooting.

(1) Problem identification

(2) Problem classification

(3) Troubleshooting

Step1 Problem Identification

Operator can not only identify what is wrong, but also know what it should be in normal circumstance. Troubleshooting depends on proper problem identification.

Step2 Problem Classification

Problems are divided into three types.

(1) Hardware-related failures

(2) Software-related failures

(3) Failures related to sample analysis

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

Step3 Troubleshooting

Engineers take appropriate action to deal with the problem. Solve problems by operator himself or with supplier engineer's assistance can save you much time.

11.3 Obtaining Technical Assistance

Please contact our after-sale service department or local agency for technical assistance. Offer us detailed problem description and related information, specific as follow:

1. The analyzer model
2. Serial number and version number
3. Detailed problem description and operating environment, including status and operation.
4. The lot number of the reagents (sheath, diluent, lyse, etc.)

5. Related data and report of the problem

Common problems and handling methods are given in this Chapter. Operator can identify the cause according to the alarm prompt and operate according to Troubleshooting Guidance.

11.4 Troubleshooting

Common problems and corrective actions are listed as follows. If the problems cannot be corrected, or technical assistance is needed, please contact our after-sale service department.

Fault	Probable Cause	Corrective Action
MA motor fault	1.Motor signal line poor contact. 2.Limit optocoupler. 3.Motor fault. 4.Motor drive circuit fault. 5.Motor power fault. 6.Motor guide rod is not lubricating enough.	1.Lubricate motor guide rod. 2.Click "Fault clearing" to clear faults automatically. 3.If the fault still exist, please contact our after-sale service department.
MB motor fault	1.Motor signal line poor contact. 2.Limit optocoupler. 3.Motor fault. 4.Motor drive circuit fault.	1.Lubricate motor guide rod. 2.Click "Fault clearing" to clear faults automatically. 3.If the fault still exist, please contact our after-sale service department.

	5.Motor power fault. 6.Motor guide rod is not lubricating enough.	
MC motor fault	1.Motor signal line poor contact. 2.Limit optocoupler. 3.Motor fault. 4.Motor drive circuit fault. 5.Motor power fault. 6.Motor guide rod is not lubricating enough.	1.Lubricate motor guide rod. 2.Click "Fault clearing" to clear faults automatically. 3.If the fault still exist, please contact our after-sale service department.
MD motor fault	1.Motor signal line poor contact. 2.Limit optocoupler. 3.Motor fault. 4.Motor drive circuit fault. 5.Motor power fault. 6.Motor guide rod is not lubricating enough.	1.Lubricate motor guide rod. 2.Click "Fault clearing" to clear faults automatically. 3.If the fault still exist, please contact our after-sale service department.
MG motor fault	1.Motor signal line poor contact. 2.Limit optocoupler. 3.Motor fault. 4.Motor drive circuit fault. 5.Motor power fault. 6.Motor guide rod is not lubricating enough.	1.Lubricate motor guide rod. 2.Click "Fault clearing" to clear faults automatically. 3.If the fault still exist, please contact our after-sale service department.
MH motor fault	1.Motor signal line poor contact. 2.Limit optocoupler. 3.Motor fault. 4.Motor drive circuit fault. 5.Motor power fault.	1.Lubricate motor guide rod. 2.Click "Fault clearing" to clear faults automatically. 3.If the fault still exist, please contact our after-sale service department.

	6.Motor guide rod is not lubricating enough.	
Expired diluent	Diluent is expired.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
Expired sheath	Sheath is expired.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
Expired lyse	Lyse is expired.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
Expired detergent	Detergent is expired.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
Diluent empty	1.Diluent is run out. 2.Tube joint leakage or bubble 3.Connecting tubes are bent or clogged.	1.Check if the diluent is run out. 2.Tighten the tube joint. 3.Neaten and unchoke tubes. 4.Click "Fault clearing" to clear faults automatically. 5.If the fault still exist, please contact our after-sale service department.
Sheath empty	1.Sheath is run out. 2.Tube joint leakage or bubble. 3.Connecting tubes are bent or clogged.	1.Check if the sheath is run out. 2.Tighten the tube joint. 3.Neaten and unchoke tubes. 4.Click "Fault clearing" to clear faults automatically.

		5.If the fault still exist, please contact our after-sale service department.
Lyse empty	1.Lyse is run out. 2.Tube joint leakage or bubble. 3.Connecting tubes are bent or clogged.	1.Check if the lyse is run out. 2.Tighten the tube joint. 3.Neaten and unchoke tubes. 4.Click "Fault clearing" to clear faults automatically. 5.If the fault still exist, please contact our after-sale service department.
Detergent empty	1.Detergent is run out. 2.Tube joint leakage or bubble. 3.Connecting tubes are bent or clogged.	1.Check if the detergent is run out. 2.Tighten the tube joint. 3.Neaten and unchoke tubes. 4.Click "Fault clearing" to clear faults automatically. 5.If the fault still exist, please contact our after-sale service department.。
WBC Clog	1.Aperture is clogged. 2.Tubes are bent. 3.Reagent replacement error. 4.Solenoid valve problem.	1.Click "Fault clearing" to clear faults automatically. 2. Click “Setting”, and perform “Soak impedance transducer” in Maint.”interface. 3.If the fault still exist, please contact our after-sale service department.
WBC Bubble	1.Insufficient liquid in sample cup front chamber/ after chamber. 2.Tubes joint is leaky. 3.Reagent replacement error. 4.Solenoid valve problem.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.

RBC Clog	1.Aperture is clogged. 2.Tubes are bent. 3.Reagent replacement error. 4.Solenoid valve problem.	1.Click "Fault clearing" to clear faults automatically. 2.Click “Setting”, and perform “Soak impedance transducer” in Maint.”interface. 3.If the fault still exist, please contact our after-sale service department.
RBC Bubble	1.Insufficient liquid in sample cup front chamber/ after chamber. 2.Tubes joint is leaky. 3.Reagent replacement error. 4.Solenoid valve problem.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
Low HGB Blank voltage	HGB blank voltage is low.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
High HGB Blank voltage	HGB blank voltage is high.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
Low vacuum	1.Vacuum tank is leaky. 2.Tubes are leaky.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
Optical pressure Abnormity	1.Pressure tank is leaky. 2.Tubes are leaky.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
Low temperature	Temperature is below 15°.	1.Check if indoor temperature is too low. 2.If indoor temperature is normal but alarm still exist, please restart the instrument.

		3.If the fault still exist, please contact our after-sale service department.
High temperature	Temperature is over 35°.	1.Check if indoor temperature is too high. 2.If indoor temperature is normal but alarm still exist, please restart the instrument. 3.If the fault still exist, please contact our after-sale service department.
Waste full	1.Waste container is full. 2.Waste sensor is in fault.	1.Empty waste container or replace a new one. 2.If the fault still exist, please contact our after-sale department.
Optical communication error	Optical communication is abnormal. Cannot receive and send data.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale service department.
Printer no responds	1.Connecting line. 2.Printer error.	1.Check the if the printer power cord and USB cable contacts well. Re-plug USB cable and power cord, and restart the printer. 2.If the fault still exist, please contact our after-sale service department.

Appendix A Specification

A.1 Product classification

According to the CE classification, the analyzer is an In Vitro Diagnostic device.

A.2 Reagents

Diluent, lyse, detergent and sheath. Please refer to *A.7 Reagent Specification* for details.

A.3 Model of Blood Sampler

Apply to whole blood mode: Φ12～15×75mm (no cover size)

Apply to diluent and peripheral blood test: Φ11×40mm (1.5m centrifuge tube) and 0.5ml Centrifuge tube

Apply to peripheral blood test: Φ10.7×42mm (no cover size), 0.5ml closed anticoagulant tube, can open the cover and test. The recommendation tube: BD 0.5ml closed anticoagulant tube, SN: 365974

A.4 Technical Specifications

A.4.1 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 value	10^12/L
RETIC	Reticulocyt	%
IRF	Immature Reticulocyte Fractio	%
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_LCR	Large Platelet Percent	%
P_LCC	Large Platelet Count	10^9/L
ALY%	Abnormal Lymphocyte Percent	%
ALY#	Abnormal Lymphocyte Count	10^9/L
LIC%	Large Immature Cell Percent	%
LIC#	Large Immature Cell Count	10^9/L
NRBC%	Nucleated Red Blood Cell Percent	%
NRBC#	Nucleated Red Blood Cell Count	10^9/L

A.4.2 Test Speed

60 / hour

A.4.3 QC Modes

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

A.4.4 Calibration Modes

Standard Calibration

Blood Calibration

Manual Calibration

A.4.5 Parameters Measurement and Calculation

(1) WBC total amount and 5Diff using laser method

(2) Colorimetric method for the determination of HGB

(3) Electrical impedance method for RBC and PLT

(4) MCV, HCT, RDW_CV, RDW_SD, MPV, PDW, MCH, MCHC and PCT are obtained directly by calculating the stored data.

A.4.6 Input/output Devices

(1) Keyboard (optional)

(2) External barcode scanner (optional)

(3) External printer (optional)

WARNING

- Be sure to use the specified devices only.

A.5 Physical Specifications

A.5.1 Power Requirements

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

A.5.2 Fuse

WARNING

Please use the specified specifications of fuse.

Fuse specifications: T3.15AL 250V

A.5.3 Electromagnetic compatibility

It is advisable to check the electromagnetic environment before using the analyzer. Do not use this equipment near strong radiation sources, such as unshielded RF sources; otherwise it may interfere with the normal operation of the analyzer.

A.5.4 Sound pressure

Maximum sound pressure: 65 dBA

CAUTION

- Be sure to use the specified devices only.

A.5.5 Environment Requirements

(1) Temperature: 15°C~35°C

(2) Relative Humidity: 30~80％

(3) Barometric Pressure: 60kPa~106kPa

A.5.6 Storage Environment

(1) Temperature: -20°C~55°C

(2) Relative Humidity: ≤95%

(3) Barometric Pressure: 50kPa~106kPa

A.5.7 Size and Weight

(1) Length: about 490mm

(2) Height: about 459mm

(3) Width: about 332mm

(4) Weight: about 35Kg

A.5.8 Contraindications

NO

A.5.9 Overvoltage Category and Pollution Level

Overvoltage category: Class II

Pollution level: Level 2

A.5.10 Waste

Dispose the waste according to the national or local standards.

A.5.11 Minimum Sample Volume

Whole Blood Sampling Mode	20μL
Diluent Sampling Mode	20μL

A.5.12 Dilution Ratio

(1) WBC: approximately 1:251

(2) RBC/PLT approximately 1:24347

A.5.13 Diameter

(1) WBC: 100μm

(2) RBC/PLT: 68μm

A.5.14 HGB measurement

(1) Measure HGB in WBC/HGB cup

(2) The illuminant is led, and the wavelength is 540nm.

A.6 Performance Index

A.6.1 Precision

Parameter	Precision Range	Acceptable Limits (CV）
WBC	3.5×10^9/L ~15.0×10^9/L	≤2.0%
RBC	3.00×10^12/L ~6.00×10^12/L	≤1.5%
HGB	100 g/L ~180 g/L	≤1.5%
PLT	100×10^9/L ~149×10^9/L	≤5.0%
	150×10^9/L ~500×10^9/L	≤4.0%
HCT / MCV	35%~50%（HCT）/ 70fL ~120fL（MCV）	≤2.0% ≤1.0%

A.6.2 Linearity

Parameter	Linearity Range	Acceptable Limits	correlation coefficent r

WBC	0 $\times10^9$ /L～10.0$\times10^9$ /L	±0.5 $\times10^9$ /L	≥0.990
	10.1 $\times10^9$ /L～100.0$\times10^9$ /L	±5%	
RBC	0.10 $\times10^{12}$ /L～1.00$\times10^{12}$ /L	±0.05 $\times10^{12}$ /L	≥0.990
	1.01 $\times10^{12}$ /L～8.00$\times10^{12}$ /L	±5%	
HGB	0 g/L～70 g/L	±2 g/L	≥0.990
	71 g/L～250 g/L	±2%	
PLT	0$\times10^9$ /L1～100$\times10^9$ /L	±10 $\times10^9$ /L	≥0.990
	101 $\times10^9$ /L～1000$\times10^9$ /L	±8%	

A.6.3 Accuracy of WBC Classification

Neutrophils, lymphocytes, monocytes, eosinophils and basophils were measured within the allowable range (99% confidence interval).

Note:When the reference result equals to 0 and the result of the analyser ≤1.0%,the conclusion is PASS.

A.6.4 Carryover

Parameter	Measurement Result
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.6%
PLT	≤1.0%

A.6.5 Blank Count

Parameter	Measured Value Range
WBC	≤0.20×10^9 /L
RBC	≤0.02×10^12 /L

HGB	≤1g/L
PLT	≤10.0×10^9 /L

A.6.6 Indication error

Parameter	Indication error
WBC	≤±10.0%
RBC	≤±6.0%
HGB	≤±7.0%
PLT	≤±15.0%

A.6.7 Accuracy

Parameter	Result Range	Acceptable Deviation Range
WBC	3.5×10^9/L ～ 9.5×10^9/L	≤±8.0%
RBC	3.8×10^12/L ～ 5.8×10^12/L	≤±4.0%
HGB	115g/L ～ 175g/L	≤±4.0%
PLT	125×10^9/L ～ 350×10^9/L	≤±10.0%
HCT/MCV	35% ～ 50% （ HCT ） / 80fL～100fL（MCV）	≤±5.0%(HCT)/ ≤±3.0%(MCV)

A.6.8 Display Range of Main Parameters

Parameter	Display Range
WBC	0～99.00×10^9/L
RBC	0～99.00×10^12/L
HGB	0～300g/L

HCT	0%～99%
PLT	0～2000×10^9/L

A.7 Reagent Specifications

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

CAUTION

- Do not pour the remaining reagent in it when replacing reagent, otherwise it will lead to cross contamination of the reagents.

A.8 Reagent Consumption

Operation	Diluent	Detergent	Sheath	Lyse	Probe detergent
Startup	44mL	62mL	16mL	6.4mL	/
Test	18mL	9mL	9mL	0.5mL	/
Prime (Clean)	45mL	42mL	14mL	5mL	/

Shutdown	16mL	16mL	11mL	/	/
Soak	29mL	25mL	14mL	/	4.5mL

A.9 Parameters Alert Messages

Parameter	Alarm	Suspicious parameter tag	Suspicious group tag	Interpretation
WBC	Shown in blue and marked with “L” if it’s lower than lower limit	WBC	WBC NWBC FWBC NRBC RRBC	WBC WBC increased Switch to RRBC mode and test again as RRBC? alarms
NEU LYM MON EOS BASO	The same as WBC	DFLT (NLMEB)	BAND IG BLAST VARLYM	Neutrophil reduction Immature granulocytes Neutrophils increased Lymphatic reduction Increased lymphoid

				cells Increased mononuclear cells Addicted to eosinophil Basophils increased
PLT MPV	The same as WBC	LRI URI LURI PLTR	MPV disabled (not shown or cannot print)	Thrombocytopenia PLT enlargement Erythrocyte PLT Red blood cell PLT

Appendix B External communication protocol

B.1 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.2 Information Grammar

B.2.1 Delimiter

| --- Fields Delimiter

^ ---Component Delimiter

& --- Subcomponent Delimiter

~ --- Repeat Delimiter

\ --- Escape Character

B.2.2 Data Type

CX extended composite id whith check digit

CE code element

CM composite

CQ composite quantity with units

DR datetime 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 addres

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

B.2.3 Field Meaning

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	DateTime Message	TS	26	Current message event, system time
8	Security	ST	40	Security
9	MessageType	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	VersinID	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	Analyzertransmits results automatically.
1001	LIS responses, analyzertransmits results automatically.

Example:

MSH|^~\&|supplier|analyzer|LIS|PC|20100930100436||ORU^R01|0001|P|2.3.1|1|||||UNICODE

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	PatientName	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、**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 |

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 DateTime	TS	26	Application time
7	ObservationDatetime	TS	26	Inspection starting time, set null
8	Observation DateTime 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 ActionCode	ID	1	Sample handling code, set null
12	Danger Code	CE	60	Danger code alarm
13	Relecant Clinical Info	ST	200	"Diagnosis" ^

				"Remark", each length should not be more than 100 bytes
14	SPE Received DateTime	TS	26	Sample receiving time
15	SPE Source	CM	300	Sample classification, blood, urine etc.
16	Ordering Provider	XCN	120	Inspector name
17	OrderCallback 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|supplier^UT-analyzer||20101010093000||20101010093500||sender||| diagnosis^remark||BLD|Inspector||||||||||verifier|

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 SubID	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	ST	20	Original results

	Checks			

Example:

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

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

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.	Analyzerfails to read test tube number.

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	

9、QRF

No.	Field	Data Type	Length	Explanation
1	Where Subject Filter	ST	20	Take analyzer

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

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.

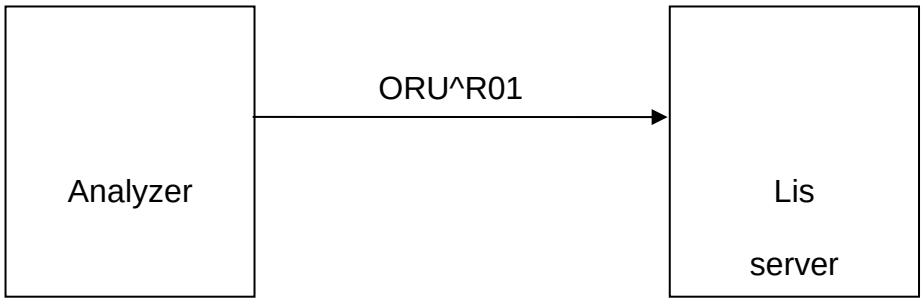
Set ID – DSP	Message
1	Sample SN
2	Name
3	Gender
4	Age
5	Blood type
6	Group
7	Patient Number
8	Bed Number
9	Patient Type
10	Department
11	Sender
12	Inspector
13	Auditor
14	BLDV is for venous blood, BLDC is for peripheral blood.
15	Remark
16	Sampling time, sending time
17	inspection time

Example

DSP|1||Mary||<CR>

B.3 Communication process

B.3.1 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, 34 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|^~\&|supplier|analyzer|LIS|PC|20110627144458||ORU^R01|0001|P|2.3.1|||||UNICODE<CR>

PID|1|||||||<CR>

PV1|1|||<CR>

OBR|1||BAR101010101|supplier^Analyzer||||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|25|ED|RBCHistogram||Analyzer^Image^BMP^Base64^Qk32lgMAAA……<CR>

OBX|26|ED|PLTHistogram||Analyzer^Image^BMP^Base64^Qk32lgMAAA……<CR>

OBX|27|ED|S0_S10DIFFScattergram||Analyzer^Image^BMP^Base64^Qk32lgMAAA……<CR>

OBX|28|ED|S90_S90DDIFFScattergram||Analyzer^Image^BMP^Base64^Qk32lgMAAA……<CR>

<EB><CR>

Appendix C　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.

Pollution control signs of electronic information products

The electronic information products sold in the territory of the People's Republic of local must mark this mark, and the numbers in the mark represent the environmental protection period of the product under normal use.

Appendix D Daily Operation Procedure

D.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 4 minutes.

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

(5) Whole Blood Automated 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.

D.2 Shutoff Procedures

(1) Click "Shutoff" 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.

D.3 Daily Maintenance (perform it before shutoff)

(1) 1. The analyzer will automatically perform 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” and “Soak impedance transducer” procedures in the “Maint” interface.

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

D.4 Weekly Maintenance

(1) The surface Maintenance of the analyzer.

(2) Clean the aspiration probe.

D.5 Monthly Maintenance

(1) Check and clean the reagent syringes.

(2) Mechanical parts Maintenance.

D.6 Other Maintenances

If the ruby aperture is block aging severely, please select “Clean Transducers” procedure in the MAINT interface, and then put the probe detergent under the aspiration probe, and then according to the prompt dialog box to operate, and then the analyzer will automatically inhale the probe detergent into the specimen cup to soak the counting hole.

Appendix E Key Components

SN	Key Components
1	AMP board
2	Aspiration probe
3	One-way valve
4	Syringe
5	Stepper motor
6	Piston pump
7	Optocoupler
8	Solenoid Valve
9	Transducer

Appendix F Attachment list

NO.	Name	Unit	Quantity
1	Operation Manual of 5-Part-Diff Auto Hematology Analyzer	Piece	1
2	Power cord	Piece	1
3	Ground wire	Piece	1
4	Serial line	Piece	1
5	BNC Waste detection line*1 Waste outlet tubing*1	Piece	2
6	Disposable plastic test tube	Piece	200
7	Fuse T3.15AL 250V	Piece	2
8	Diluent inlet tubing	Piece	1
9	Lyse inlet tubing	Piece	1
10	Sheath inlet tubing	Piece	1
11	Detergent inlet tubing	Piece	1
12	Rubber drum	Piece	1
13	Concentrated Probe Cleaner（100mL）	Bottle	1
14	Grease	Piece	1
15	Filter	Piece	2
16	sealing ring of large needle tube	Piece	2
17	sealing ring of small needle tube	Piece	2
18	Socket	Piece	1
19	Card sets of product maintenance records	Piece	1

20	maintenance record card	Piece	1
21	rubber bucket lid wrench	Piece	1

Manufacturer Name: SPINREACT,S.A.U
Address: Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (Girona) España
Tel. +34 972 69 08 00
Fax +34 972 69 00 99
Web: http://www.spinreact.com
E-mail: spinreact@spinreact.com