Copyright and Declaration

Congratulations you have become a VIP client for Guilin URIT Medical Electronic Co., Ltd., and welcome to use Smart-V5 Auto hematology Analyzer, it will bring you the new experience and convenience.

Declaration

All contents in this manual were strictly compiled according to related laws and regulations in China, as well as the specific condition of Smart-V5 Auto hematology Analyzer, covering all the updated information before printing. URIT Medical Electronic Co., Ltd. is fully responsible for the revision and explanation of the manual, and reserves the right to renovate the relevant contents without separate notification. Some of the demonstration pictures are for reference and subject to real object if any differences.

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

Limited Responsibility for Quality Warranty

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

The manual for Smart-V5 Auto Hematology Analyzer, defines the rights and obligations between the URIT and the customers about the responsibility for quality warranty and after-sale service, also the related agreements on commencement and termination.

URIT warrants the Smart-V5 sold by the URIT and its authorized agents to be free from defects in workmanship and materials during normal use by the original purchaser. This warranty shall continue for a period of one year since the date of installation. The analyzer life is ten years.

Must meet the following requirements

1. According to this manual to operate the instrument.

2. The software and hardware which installed on the analyzer must comply

with the provisions of this manual.

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

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

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

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

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

URIT 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 URIT.

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

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

e) Components are been dismounted, stretched or readjusted.

f) Operators not been trained.

Smart-V5 Auto Hematology Analyzer hereinafter referred to as "Smart-V5" or "analyzer".

CAUTION

THE ANALYZER IS FOR PROFESSIONAL AND PRESCRIPTION USE ONLY.

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

offer you timely service when necessary.

URIT Medical Electronic Co., Ltd.

Address: No.D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P. R. China

Tel: +86（773）2260203

Fax: +86（773）2260204

Web: www.urit.com

Email: sales@uritest.com

Supplied By: URIT Medical Electronic Co., Ltd.

EC REP **Wellkang Ltd (www.CE-marking.eu)**

16 Castle St, Dover, CT16 1PW, UK

Version : 05/2019 (Revised on May 2019)

Catalogue

Copyright and Declaration I

1 Introduction 1

1.1 Overview 1

1.2 Applicable Scope 1

1.3 Hazard Sign 2

1.4 Guidance 3

1.5 Parameters 4

2 Safety Information for Operation 7

2.1 Overview 7

2.2 Special Requirements 7

2.3 General Requirements 7

2.4 Electromagnetism Security 8

2.5 Installation 8

2.6 Infection Prevention 9

2.7 Reagent 9

2.8 Maintenance 10

2.9 Laser 11

2.10 Consumables 11

2.11 Security Sign 11

2.12 Operators 12

3 Chapter 3 System and Function 13

3.1 Overview 13

3.2 Parameter 13

3.3 Structure 15

3.4 Boot interface 22

3.5 Test Interface 24

3.6 Reagents, Control Materials and Calibrators 27
3.6.1 Diluent 28
3.6.2 Sheath 28
3.6.3 Lyse 28
3.6.4 Detergent 29
3.6.5 Probe Detergent 29
3.6.6 Control Material and Calibrator 30
4 Installation 31
4.1 Overview 31
4.2 Unpacking and Inspection 32
4.3 Space Requirements 32
4.4 Power Supply Requirements 32
4.5 Environment Requirements 33
4.6 Waste Requirements 34
4.7 System Installation 34
4.7.1 Tubing Installation 34
4.7.2 Printer Installation 36
4.8 Transport and Storage Condition 36
5 Principles of Operation 38
5.1 Overview 38
5.2 Sample Aspiration 38
5.3 Sample Dilution 38
5.3.1 Whole Blood Sampling & 5Diff 40
5.3.2 Pre-diluent CBC & 5Diff 41
5.4 WBC Test Principle 43
5.4.1 Multi-Angle Laser Light Scatter Technology 43
5.4.2 WBC Differential 44

5.5 Test Principle of Hemoglobin Concentration 45
5.5.1 Colorimetry Principle 45
5.5.2 HGB Parameter 46
5.6 RBC /PLT Test Principle 46
5.6.1 Electrical Impedance Principle 46
5.6.2 Volumetric Metering 47
5.6.3 RBC Parameters 48
5.6.4 PLT Parameters 49
5.7 Principles of Reticulocyte Analysis 50
5.7.1 RBC Development Process 50
5.7.2 Characteristics of Reticulocyte 51
5.7.3 Testing Principle of Reticulocyte 51
5.7.4 RETIC_ABS 53
5.7.5 IRF 53
6 Settings 55
6.1 Overview 55
6.2 Settings 55
6.3 System Maintenance 56
6.4 X-B QC 58
6.5 X-R QC 58
6.6 X QC 58
6.7 Limit 58
6.8 Time 60
6.9 Parameter 61
6.10 Print 62
6.11 Transmit 63
6.12 Maintenance 64

6.13 Version 66
6.14 User 66
6.15 Service 68
6.16 Reagent 68
6.17 Display 70
7 Daily Operation 72
7.1 Overview 72
7.2 Preparations 73
7.3 Startup 74
7.4 Quality Control 76
7.5 Collection of Blood Samples 76
7.5.1 Whole blood collection 77
7.5.2 Diluent Sample Preparation 78
7.5.3 Sample Stability 79
7.6 New Next Blood Sample 79
7.7 Sample Test 81
7.7.1 Mode 81
7.7.2 Counting and Analysis 82
7.8 Data Query 83
7.8.1 Data Query 83
7.8.2 Data Selection 86
7.8.3 Data Deletion 86
7.9 Reticulocyte analysis 87
7.9.1 Preparation for reticulocyte sample 88
7.9.2 Reticulocyte test 88
7.10 Edit Information 89
7.11 Export 90

7.12 CV Value and Trend graph 91
7.13 Shutoff and Logout 93
8 Quality Control 95
8.1 Overview 95
8.2 Quality Control Options 96
8.3 L-J QC 97
8.3.1 Setup 97
8.3.2 QC Graph 99
8.3.3 QC List 103
8.4 X-B QC 104
8.4.1 X-B QC Edit 104
8.4.2 X-B QC Run 106
8.4.3 X-B QC Review 106
8.5 X-R QC 109
8.5.1 X-R QC Edit 110
8.5.2 X-R QC Graph 112
8.5.3 X-R QC List 114
8.6 X QC 116
8.6.1 X QC Edit 116
8.6.2 X QC Edit 117
8.6.3 X QC Graph 119
8.6.4 X QC Graph List 120
9 Calibration 122
9.1 Overview 122
9.2 Calculation Frequency 123
9.3 Preparation 123
9.4 Calibration Modes 125

9.4.1 Manual Calibration 125
9.4.2 Standard Calibration 127
9.4.3 Blood Calibration 129
10 Maintenance and Care 132
10.1 Overview 132
10.2 Routine Maintenance 132
10.2.1 Daily Maintenance 132
10.2.2 Weekly Maintenance 133
10.2.3 Monthly Maintenance 134
10.3 Maintenance procedure 136
10.3.1 Change Lyse 136
10.3.2 Change Diluent 137
10.3.3 Change Detergent 137
10.3.4 Change Sheath 138
10.3.5 Cauterize Aperture 138
10.3.6 Flush Aperture 139
10.3.7 Soak Impedance Sample Cup 139
10.3.8 Prepare Shipping 140
10.3.9 Other Maintenances 140
10.4 Components Maintenance 141
10.5 Components Replacement 142
11 Troubleshooting 143
11.1 Overview 143
11.2 Troubleshooting Guidance 143
11.3 Obtaining Technical Assistance 144
11.4 Troubleshooting 145
Appendix 150

A Specifications 150
A.1 Reagents 150
A.2 Model of Blood Sampler 150
A.3 Technical Specifications 150
A.3.1 Parameters 150
A.3.2 Test Speed 152
A.3.3 QC Modes 152
A.3.4 Calibration Modes 152
A.3.5 Parameters Measurement and Calculation 152
A.3.6 Input/output Devices 152
A.4 Physical Specifications 153
A.4.1 Power Requirements 153
A.4.2 Fuse 153
A.4.3 Electromagnetic compatibility 153
A.4.4 Sound pressure 153
A.4.5 Environment Requirements 153
A.4.6 Storage Environment 154
A.4.7 Size and Weight 154
A.4.8 Contraindications 154
A.4.9 Overvoltage Category and Pollution Level 154
A.4.10 Waste 154
A.4.11 Minimum Sample Volume 154
A.4.12 Dilution Ratio 154
A.4.13 Diameter 155
A.4.14 HGB measurement 155
A.5 Performance Index 155
A.5.1 Precision 155

A.5.2 Linear Range 155
A.5.3 Accuracy of WBC Classification 156
A.5.4 Carryover 156
A.5.5 Blank Test 156
A.5.6 Indication error 157
A.5.7 Display Range of Main Parameters 157
A.6 Reagent Specifications 157
A.7 Abnormal Results 158
B External communication protocol 165
B.1 Communication Protocol 165
B.2 Information Grammar 165
B.2.1 Delimiter 165
B.2.2 Data Type 165
B.3 Field Meaning 166
B.3.1 MSH 167
B.3.2 PID--- Definition of animal data field 168
B.3.3 PV1---Definition of animal visiting record field 169
B.3.4 OBR--- Definition of Doctor's Advice 169
B.3.5 OBX 171
B.3.6 MSA 172
B.3.7 ERR 174
B.3.8 QRD 174
B.3.9 QRF 175
B.3.10 QSP 176
B.4 Communication process 177
B.4.1 Analyzer transmits test results to lis server 177
C Toxic and Hazardous Substances or Elements 180

D Daily Operation Procedure 182
D.1 Startup and Run 182
D.2 Shutoff Procedures 182
D.3 Daily Maintenance (perform it before shutoff) 182
D.4 Weekly Maintenance 182
D.5 Monthly Maintenance 183
D.6 Other Maintenances 183
E Key Components 184
F Attachment list 185

1 Introduction

1.1 Overview

Welcome to read the Operation Manual of Smart-V5 5-Part-Diff Automated Hematology Analyzer, this manual including analyzer operation, Maintenance instructions and matters needing attention, in order to keep the analyzer has a good performance, you must according to this manual to do the operation and maintenance.

Smart-V5 5-Part-Diff Automated Hematology Analyzer is an in vitro diagnostic medical device. It can analyze and output 25 parameters, 6 research parameters, 3 RETIC parameters, 2 scatter diagrams and 2 histograms. The Optical detection section uses Multi-angle laser scattering flow cytometry to analyze the five part differential of white blood cells (WBC), uses coulter theory to analyze red blood cells (RBC), platelet (PLT), and uses colorimetry for hemoglobin (HGB) concentration.

NOTE

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

1.2 Applicable Scope

This manual applies to medical examiners, trained doctors, nurses and

labors. Unedited personnel may not operate the analyzer. Read this manual to learn about Smart-V5'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	Meaning
 **WARNING**	Denotes the operator should follow the instruction under this symbol, or it may have a personal injury.
 **CAUTION**	Denotes potential hazards that could result in a minor injury, also used for conditions or activities which could interfere with proper function of the analyzer.
NOTE	Prompts to operate according to symbols, emphasize the important information in operation procedures and the contents needed to pay attention to.
 **WARNING**	Denotes potential bio-hazard.
 **WARNING**	Denotes a laser hazard 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

- Smart-V5 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 use, maintain and move this analyzer.
- Please strictly follow this manual to operate.
- Operating this analyzer in the dry environment, especially the man-made materials (artificial fabrics, carpets, etc.), may cause damaged electrostatic discharge and wrong test results.
- Prohibit the use of this analyzer in the vicinity of strong radiation sources, otherwise it may be interfered.

1.4 Guidance

Operator can find the information needed according to the chapters.

Information	Reference
Parameters	Chapter 1 Introduction
Notices for Operation	Chapter 2 Safety Information for Operation
Structure and Use	Chapter 3 System and Function
Installation	Chapter 4 Installation
Measurement Principle and Procedure	Chapter 5 Principles of Operation
System Parameter Setting	Chapter 6 Settings
Daily Operations	Chapter 7 Daily Operation
Requirement and Method of QC	Chapter 8 Quality Control
Requirement and Method of Calibration	Chapter 9 Calibration

Maintenance	Chapter 10 Maintenance and Care
Troubleshooting	Chapter 11 Troubleshooting
Detailed Specification	Appendix A
Communications Protocol	Appendix B
Name and content of poisonous and harmful substances or elements	Appendix C
Daily operation procedures	Appendix D
Key components	Appendix E
List of Annexes	Appendix F

1.5 Parameters

Item	Content	Explanation
Test Parameter	38 parameters(with RETIC parameters and graphics)	Scatter diagram, histogram
Operation	Open type sample injection mode	
Language	English	Software supports online and U disk upgrade.
Display Setting	Equipped with 10.4 inchLCD monitors.	Data management and networking are convenient.
Data Storage	≥ 200,000 test results (with graphics)	
Speed	60 / h	
Output Mode	External printer, choose to print the histogram. Different warning signs prompt probable abnormalities of	Reference range can be printed out in English and Chinese report format.

	specimen.	
Blood Volume	Whole Blood Sampling Mode 20 μL	Anticoagulation with EDTA-K2/EDTA-K3 in whole blood.
	Diluent Sampling Mode 20 μL	
Reagent	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 sample aspiration	High precision and Wear resistance
Unit Selection	With two units selection for WBC, RBC, HGB, PLT and other items.	Meet the parameters unit requests for different countries and places.
HGB Test	Cyanide-free quaternary ammonium salt hemoglobin. LED light source, 540nm wavelength colorimetry.	Environmental regents can avoid the effects of operators' health, and be good for environmental protection. If use the toxic reagents, you need to purchase specialist processing equipment, which will increase costs.
RETIC Test	Test RETIC percentage by multi-laser scattering method.	
Control and Calibration	With standard, blood and manual calibration, With L-J, X, X-R and X-B control modes.	
Structure	Adopt separately removable syringe	Enhance accuracy and Maintain easily

	structure.	
Maintenance	With automatic monitoring function to prompt the operator to perform automatic Maintenance or troubleshooting procedures.	Improve the lifetime of equipment, and Maintain the best working conditions
Reference Range	With 13 different groups Animals range parameter setting function.	Can be adjusted according to different Animals, and the analyzer will automatically identify and match the best reference.
Flush	High-voltage cautery. Removable ruby aperture plate is easy to clean. Positive and negative pressure recoil and intelligent automatic cleaning.	
Security	Have a good electrical security with the flow electricity isolation system.	
Host Size	L508mm×W270mm×H412mm	
Power	250VA	
Fuse	250V/3.15AH	
weight	26kg	

NOTE

- There are no RETIC parameters in specific machines.These machines only contain 35 parameters(with graphics)

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

- Smart-V5 5-Part-Diff Automated Hematology Analyzer is for blood cell count, WBC five part differential and hemoglobin concentration measurement in clinical laboratory.
- Only allow to use the reagents and detergents mentioned in this manual. Operating requirements also include regular cleaning and Maintenance.

2.3 General Requirements

- Read the operation manual before using. Understand all the important signs. Please keep manual for future reference.
- Following the manual instructions to start the analyzer, otherwise 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 with a certain distance.
- 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 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 receptacle 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 we should take other equipment that generate strong ionizing radiation into consideration, such as X-ray, γ-ray which 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, 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 the 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 with 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 with the reagent, rinse it with plenty of water immediately.
- If eye contacts with the reagent, rinse it with plenty of water and seek medical advice immediately.
- Establish a set of emergency measures in laboratory is very necessary.

- Protect the reagents from being polluted by dust, dirt and germs.
- Reagents must be used within the validity period.
- Handle the reagents properly to prevent bubble. Do not shake! The reagent cannot be used immediately after transport.
- Do not let the reagents spilt. 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 being spilt next to the wire or device, it may cause electric shock. Please turn off the power, unplug the plug and clean the diluent.
- The probe cleaning solution or detergent is strongly alkaline cleaner. Do not let it contact the skin or clothes. If that happens, rinse the skin and clothes with plenty of water immediately.
- Probe cleaning solution contains sodium hypochlorite. If it contacts the analyzer surface, wipe up with a cloth immediately, otherwise it will corrode the surface.
- Ensure that the reagents keep the same level with the analyzer or lower Do not put reagents on the top of the 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 manual operation.
- Do the daily, weekly, monthly Maintenance in accordance with the manual operation.
- If the analyzer is not used for a long time, empty the rinsing flow according to the procedure before disuse. Ensure the analyzer is in a good working condition before reuse.

◆ Reinstallation can only be done when replacing standby parts.

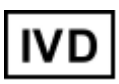
2.9 Laser

 The instrument adopts semiconductor laser which is visible laser. It's a kind of 3B laser product. The wavelength λ is 531-533nm, and maximum output is Power：11mW. To avoid laser exposure, there is a shell and protective cover. Taking away protective cover will cause harmful radiant exposure and burn your eyes. Only maintenance personnel assigned by URIT can open this cover.

2.10 Consumables

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

2.11 Security Sign

	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. If being operated incorrectly by non-skilled staff, inaccurate measurement may be caused, and it also causes misdiagnosing, delaying patient's treatment or doing harm to the operator himself, even damaging the instrument.
- 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 result from unauthorized technicians and nonstandard Maintenance.
- Invalid hardware/software affects the accuracy of test results. The operator needs to contact the after-sale service personnel as soon as possible

3 Chapter 3 System and Function

3.1 Overview

Smart-V5 5-Part-Diff Automated Hematology Analyzer is a 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 fully automated. The analyzer automatically starts testing after aspirating samples. Three-dimensional graphics data and results can be displayed in the LCD screen in about 60 seconds. The results can be printed or transmitted to the LIS system.

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.

Smart-V5 generates the following 38 test parameters in Table 3-1(including 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	Reticulocyt	%
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.The above parameters are not output for all animals.

3.3 Structure

CAUTION

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

The analyzer is consisted of analysis part, information management part, result output and an external printer (optional).

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

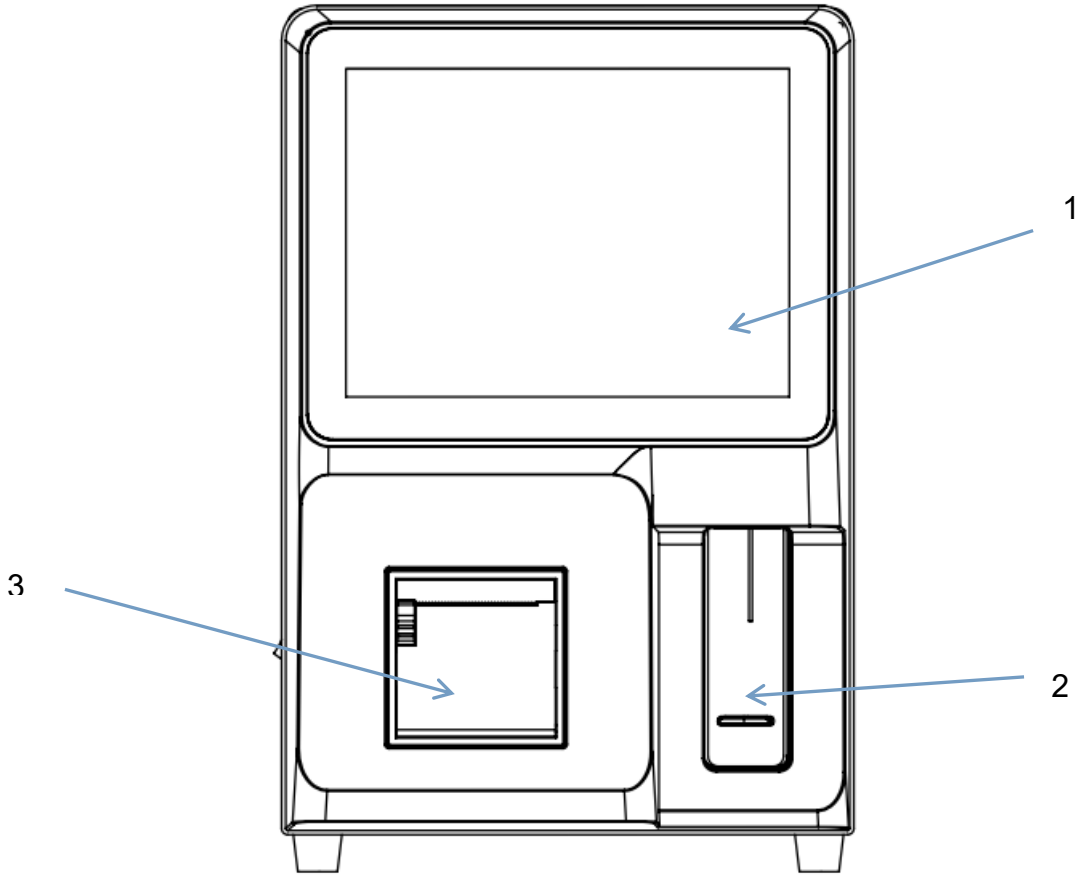


Figure 3-1A Front View

1--- Screen

2--- Counting Button Switch

3--- Printer

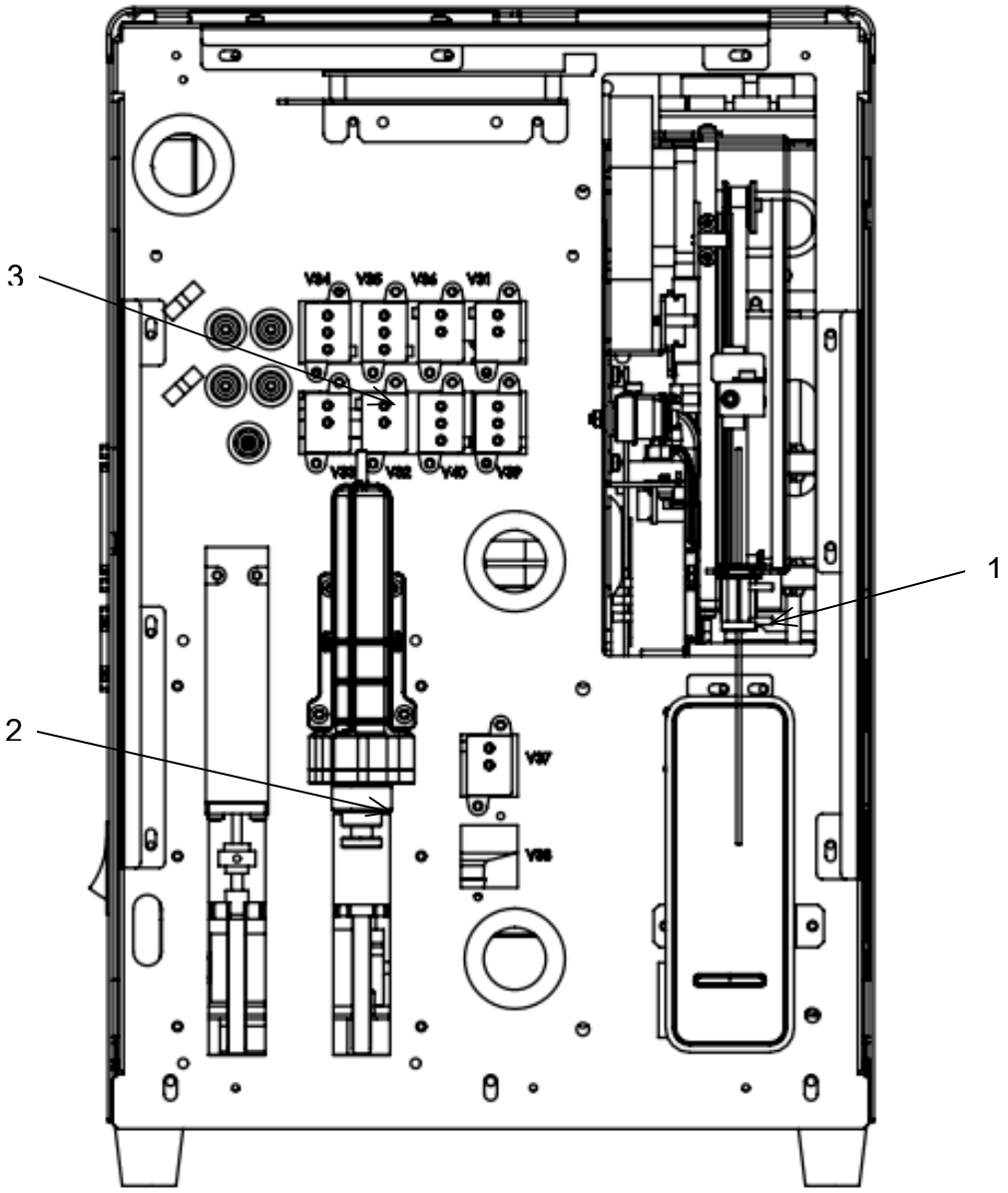


Figure 3-1B Front View (Remove the front housing)

1--- Sampling Unit

2--- Syringe Mechanism

3--- Solenoid Valve

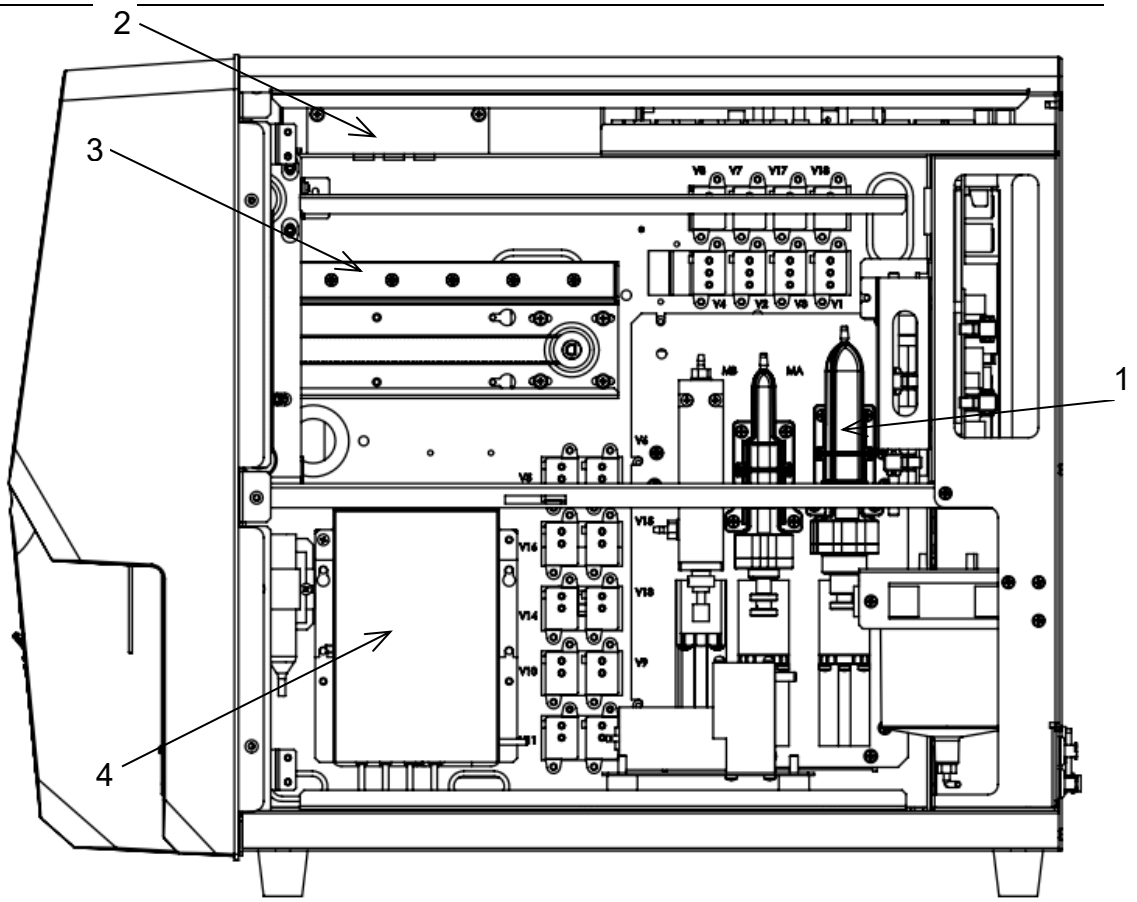


Figure 3-2 Right Side View (Remove the right side door)

1--- Syringes Module

2--- Optical Module

3--- Sampling Unit

4--- Sample Cup

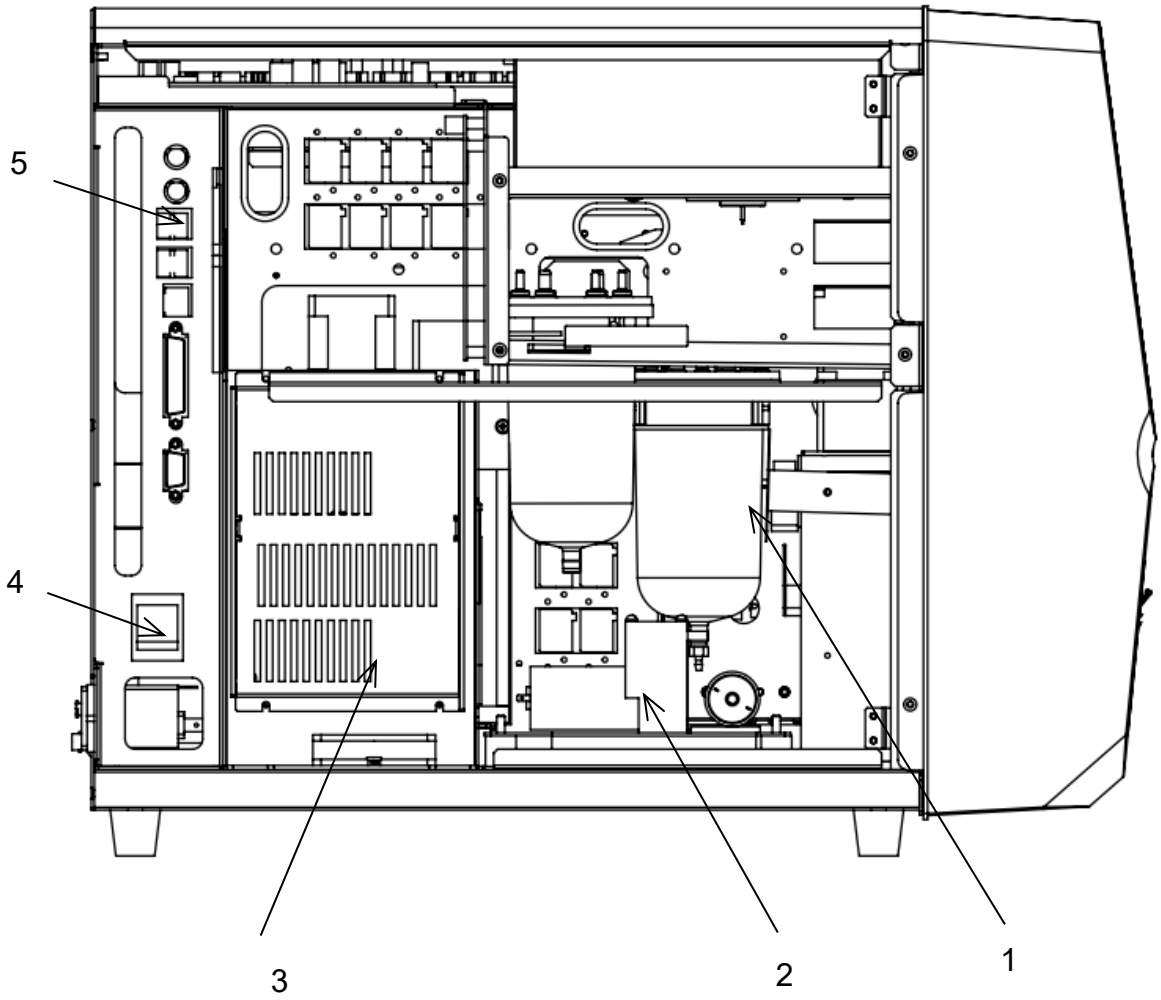

5
4
3
2
1

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

1--- Liquid storage tank

2--- Pump

3--- Power Regulator

4--- Power Switch

5--- Serial Port and USB Interface

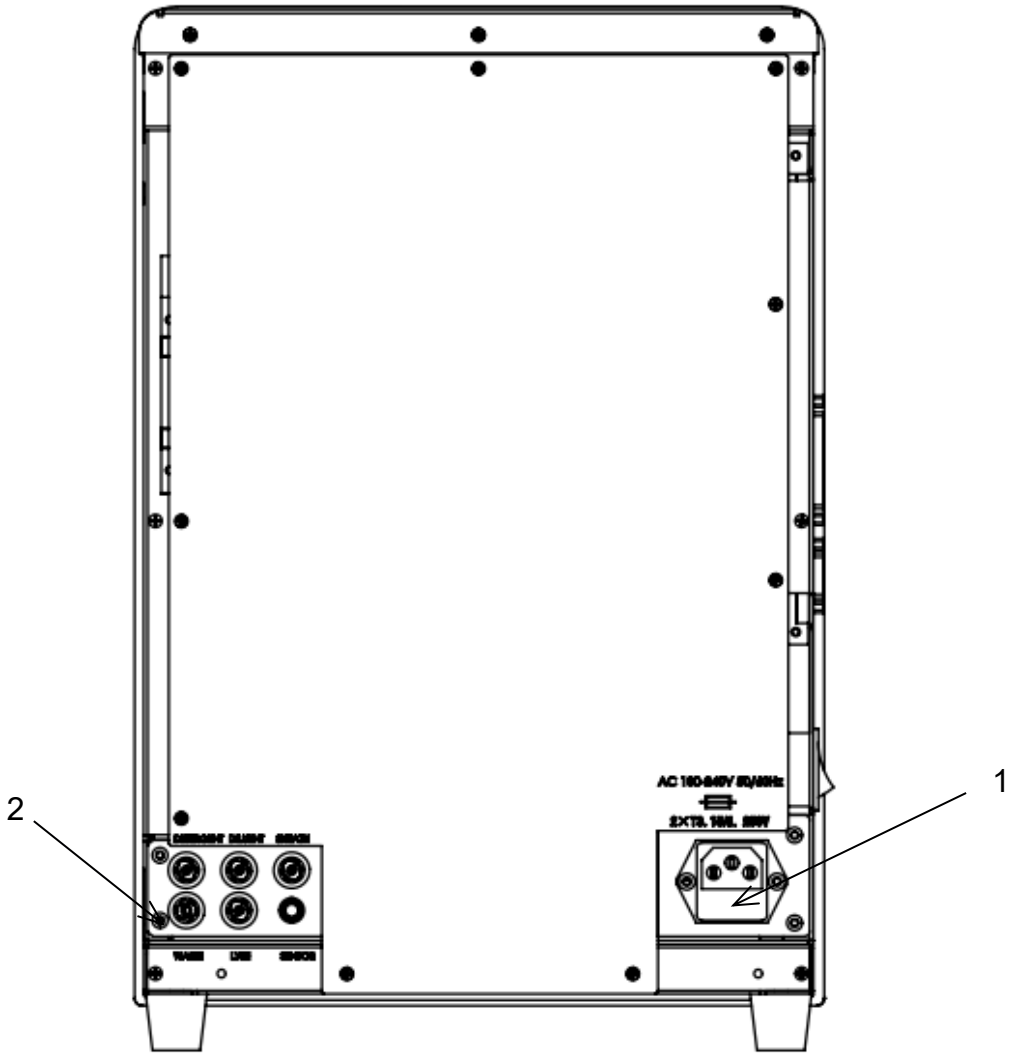


Figure 3-4 Rear View

1---Power Socket

2---Liquid interfaces

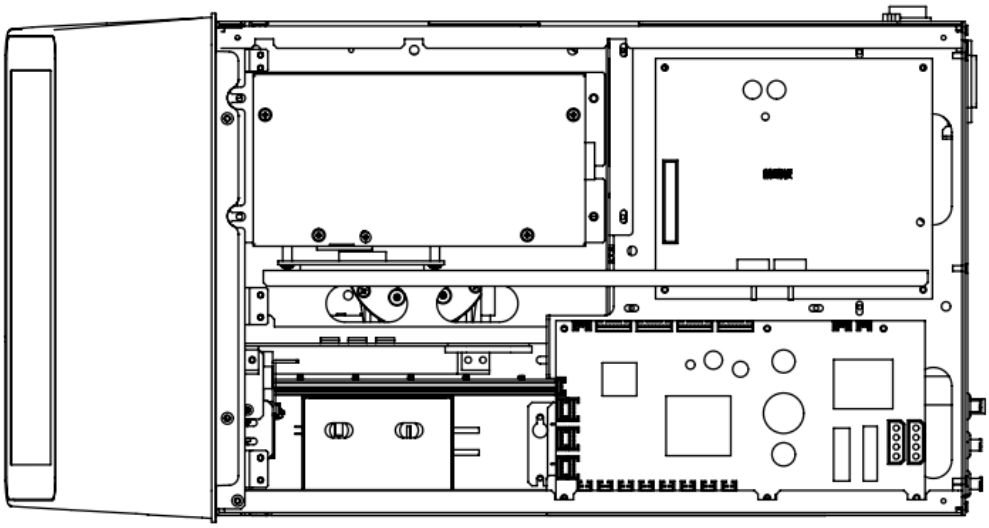


Figure 3-5 Vertical View

WARNING

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

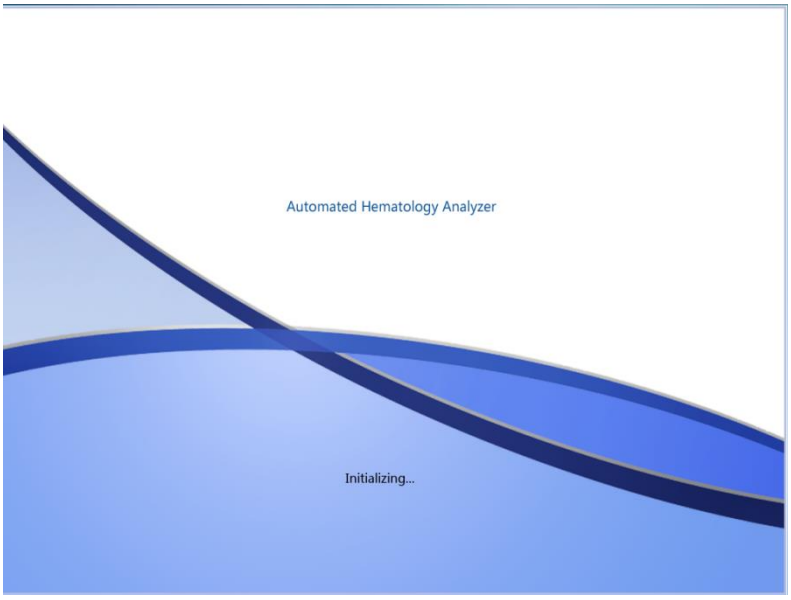


Figure 3-6 Initializations

Normal user operation mode is default. The user name is User. after initializing.Key parameters can not be set in this mode. Click Logout in setting menu to log in with other account. The default name and password is admin. Click “Login” to enter test interface, click “Shutdown” to turn it off. See Figure 3-7.

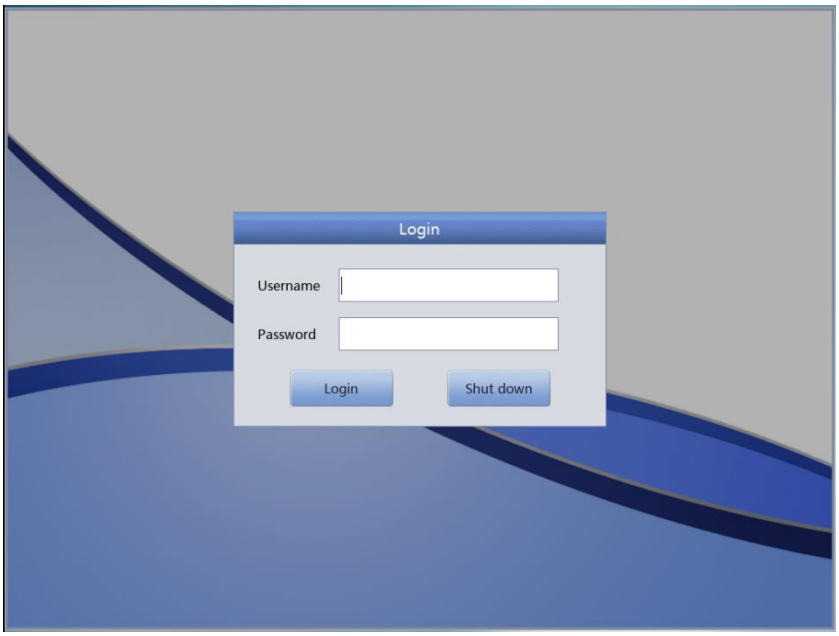


Figure 3-7 Login Interface

3.5 Test Interface

After initialization, enter User operation interface with User account by default, as shown in following figure.

图 3-8 User 用户主界面

In this mode, click “new” to create a sample before test. A information input dialog appears, as shown in the figure below.

Figure 3-8A New Sample Creation

Input corresponding information according to the prompt. The red items are required fields. Click “Run” to test samples according to the prompt after edition.

Other features of the “user” account are included in the administrator account，Please refer to the introduction to the administrator account.

After logging into the administrator account, the analyzer enters test interface. See Figure 3-9.

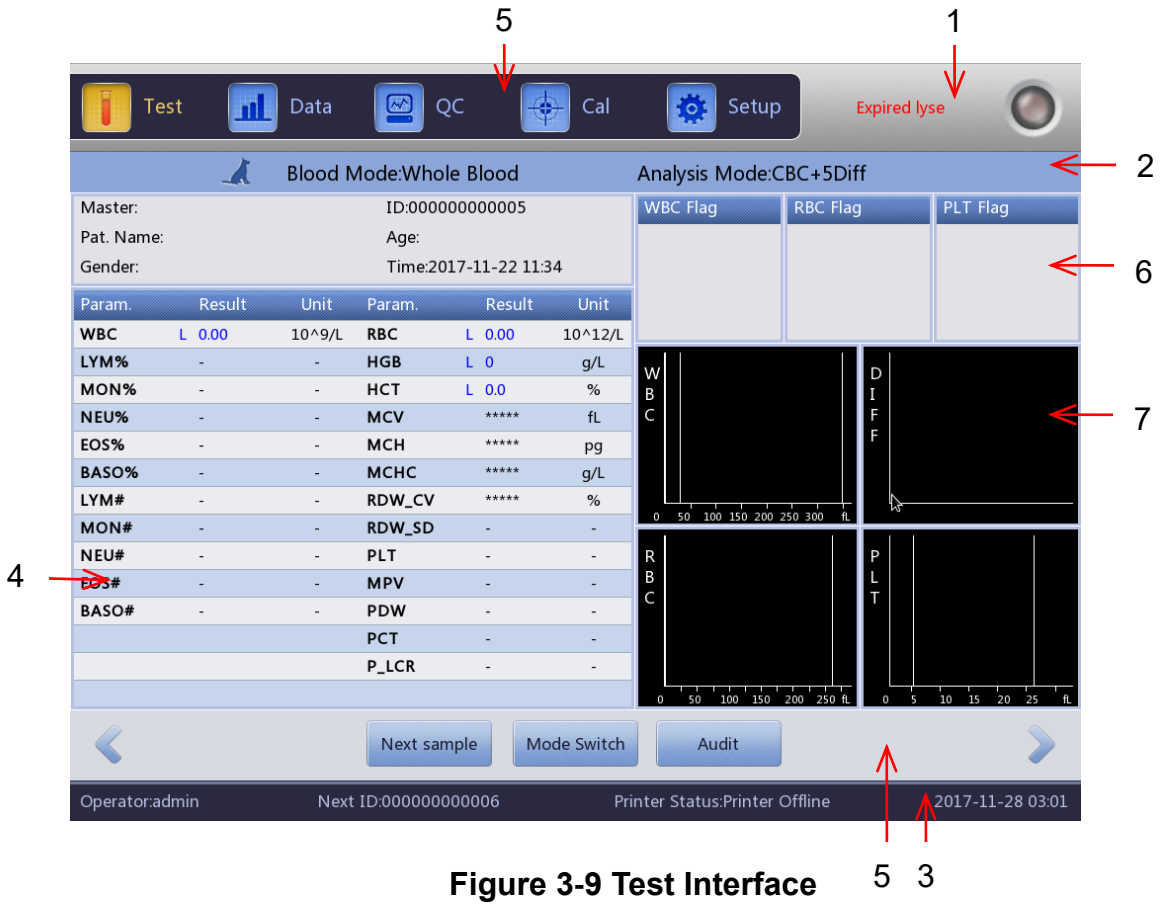


Figure 3-9 Test Interface

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 mode of blood sample area

Select and indicate the system running state: Whole blood sampling mode and Diluents mode. Analysis mode: CBC, CBC+5DIFFor CBC+5DIFF+RRBC.

3. System status area

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

4. Parameter information display area

Display each parameter results.

5. Function button area

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

The first set:

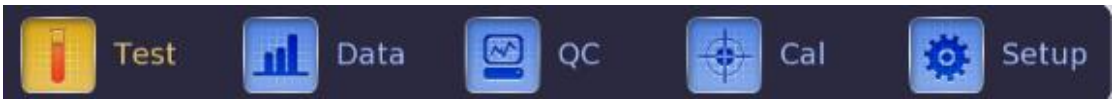


Figure 3-9A Function Button 1

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: new sample SN and edit it

Mode switch: Switch the test mode to whole blood sampling mode or diluent mode, switch the analysis mode to CBC, CBC+5DIFF or CBC+5DIFF+RRBC

Check: check the sample

The third set:

Figure 3-9C Function Button 3

Click  and  to see the above figure.

Previous record: to see the last record

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

Check: check 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 Smart-V5 flow system in order to provide optimal system performance. Each Smart-V5 is checked at the factory using the specified reagents and all performance claims were generated using these reagents. Thus non-URIT reagents may affect analyzer performance, or result serious mistakes, even accidents. Reagents mentioned in this Manual refer to matching reagents of the analyzer.

NOTE

- Reagents must be stored at room temperature to ensure optimal performance. All reagents should be protected from direct sunlight, undercooling and overheating during storage.
- The 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 which is a tasteless transparent isotonic fluid can be used for blood cells counting and classification. It has the following functions.

(1) Dilute whole blood samples.

(2) Keep the shape of cells during test process.

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

(4) Provide a conductive environment for testing.

Keep the diluent under 5℃~35℃ after opening. It can be used to the validity period on the label. Once opened (connected to the instrument), 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, but the RBC and sheath have the same refractive index, and it showed under the laser virtually.

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

3.6.3 Lyse

Lyse which doesn’t contain the azide and cyanide is a new reagent. 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 centre on 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.

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

3.6.4 Detergent

Detergent which contents activity protease can be used to clean WBC and RBC cups and flow system.

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

3.6.5 Probe Detergent

The probe detergent contains the active enzyme to clean the agglomerated protein in the WBC and RBC cups.

CAUTION

Detergent and probe detergent is alkali cleaning agent.

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

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

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

(4) If ingested, inducing 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. It is with low, normal and high value. Three kinds of control materials 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 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 URIT. Users can purchase from URIT or agents designated by URIT

4 Installation

4.1 Overview

CAUTION

- Environment Requirements

  Temperature: 15℃~ 35℃

  Relative humidity: ≤ 85%

- Place the analyzer on a smooth and big enough platform which is easy to operate. Away from direct sunlight.
- Try to use a separate AC receptacle, and install stabilized voltage supply or UPS (Uninterruptible Power Supply). Do not share an AC receptacle with centrifuges, room temperature shower (thermostat), refrigerators, air conditioners or ultrasonic cleaning equipment or other equipment which may interfere with the analyzer.

CAUTION

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

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

4.2 Unpacking and Inspection

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

(1) Quantity of accessories according to the packing list

(2) Leakage or soakage

(3) Mechanical damage

(4) Bare lead, inserts and accessories

Please contact URIT Customer Support Center 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) Choose a place near the power supply.

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

(3) There should be 50 cm of space above 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 URIT) 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 URIT) should be taken before operation.

4.5 Environment Requirements

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

(2) Relative humidity: ≤ 85%

(3) Recommend to install heating and cooling air conditioning

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

(5) Away from direct sunlight.

(6) Choose a well-ventilated place.

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

(8) Electromagnetic compatibility design for class B 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 liquid interfaces on the back panel, which are DETERGENT, DILUENT, LYSE, SHEATH and WASTE. Each of them is wrapped with a cap to avoid contamination by the URIT 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 bottle cannot be used if there is damage, leakage, expiration and other anomalies. Please contact with local suppliers or after-sale service department of URIT 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 position.

---

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 back 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 back 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 back 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 back 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 back panel. Inset BNC plug to the SENSOR connector on the left panel. Tightly twist the tube’s cap clockwise onto the waste container. Place the waster container on the level at least 50cm lower than the analyzer.

4.7.2 Printer Installation

Please install the printer according to the following steps.

1. Place the printer in an appropriate location adjacent to the analyzer so as to operate easily.
2. Take out the printer from transport package.
3. Check the printer, if being damaged, please contact supplier.
4. Check the printer power.
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 analyzer 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 Condition

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

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

NOTE

- Storage temperature: -20℃~ 55℃
- Relative Humidity: ≤ 95%

- Atmospheric pressure: 50kPa-106kPa
- Before delivery, external disinfection is needed.

5 Principles of Operation

5.1 Overview

Smart-V5 uses electrical impedance method (also known as Coulter theory) to detect the amount and volume distribution of RBC and PLT. The colorimetry is for determining the content of HGB. The Multi-angle laser scattered method is for the five part differential of WBC. Three separated channels are used for getting the blood cells counting results respectively.

(1) WBC and five part differential data of sheath flow regulator are detected by laser.
(2) HGB is detected by colorimetric assay in WBC/HGB cup.
(3) The data of RBC and PLT is detected by electrical impedance method in RBC cup.

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

5.2 Sample Aspiration

Smart-V5 supports two modes of blood cell counting analysis.

1. Whole blood sampling mode

2. Diluent sampling mode

The aspiration volumes

Whole blood sampling	20μL
Diluent sampling	20μL

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

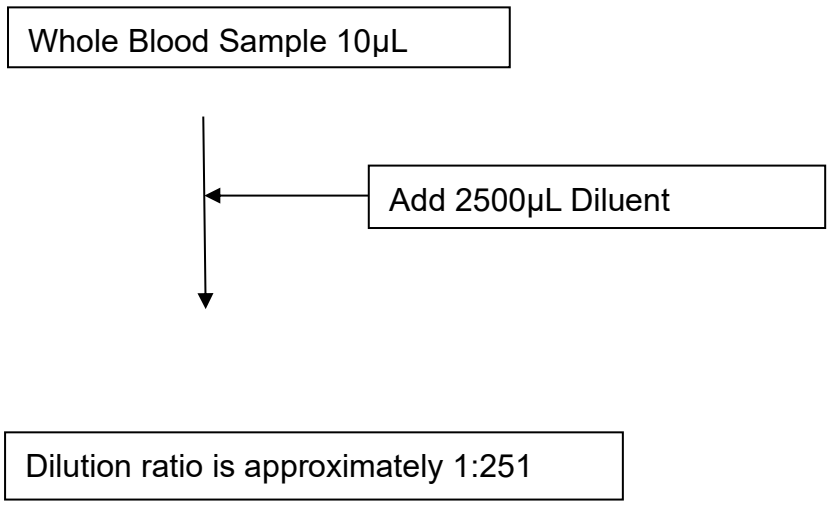
5.3 Sample Dilution

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. Then finally getting

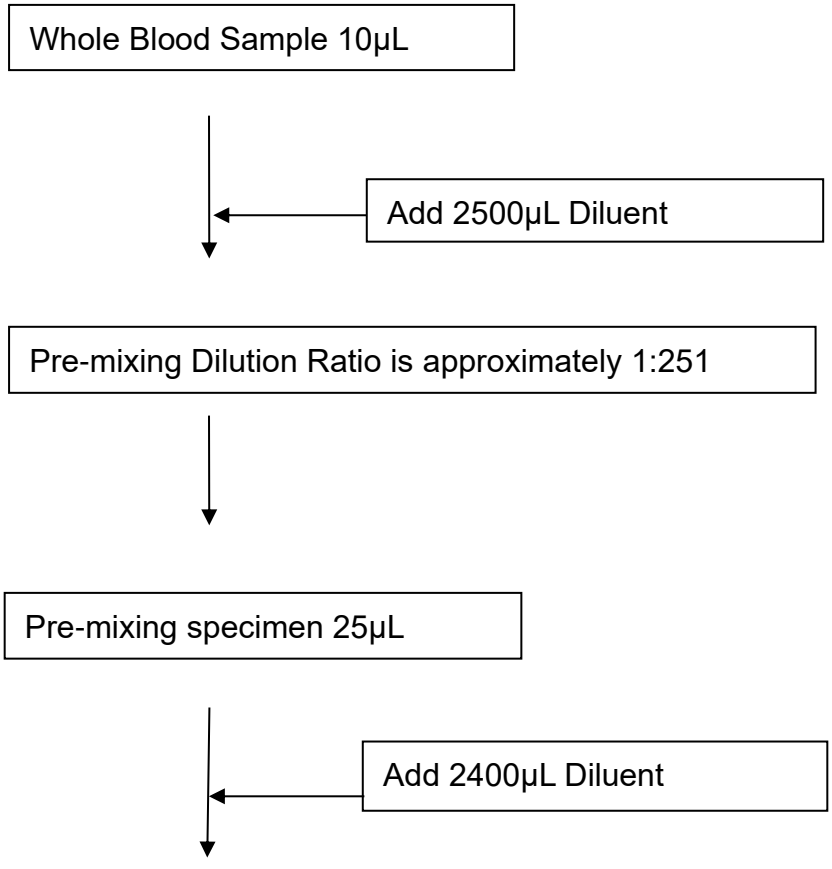
the results of WBC count/HGB test, WBC/PLT count and WBC five part differential.

5.3.1 Whole Blood Sampling & 5Diff

1) WBC / HGB Dilution Process

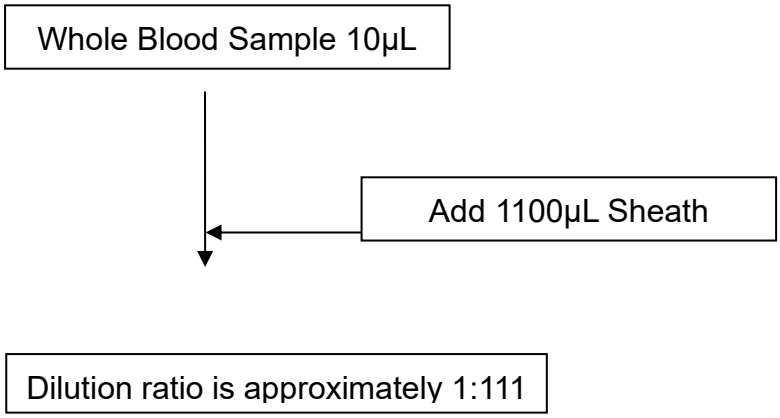


2) RBC / PLT Dilution Process



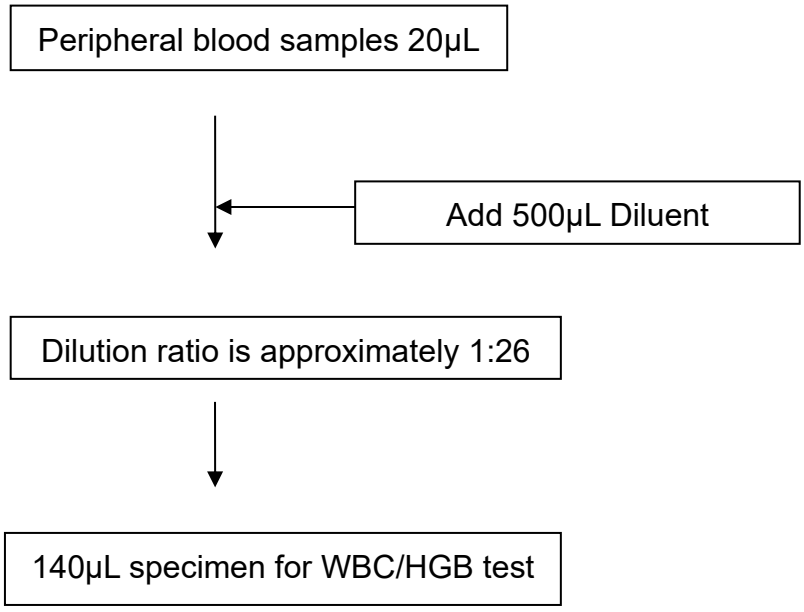
Dilution ratio is approximately 1:24347

3) WBC Differential Dilution Process

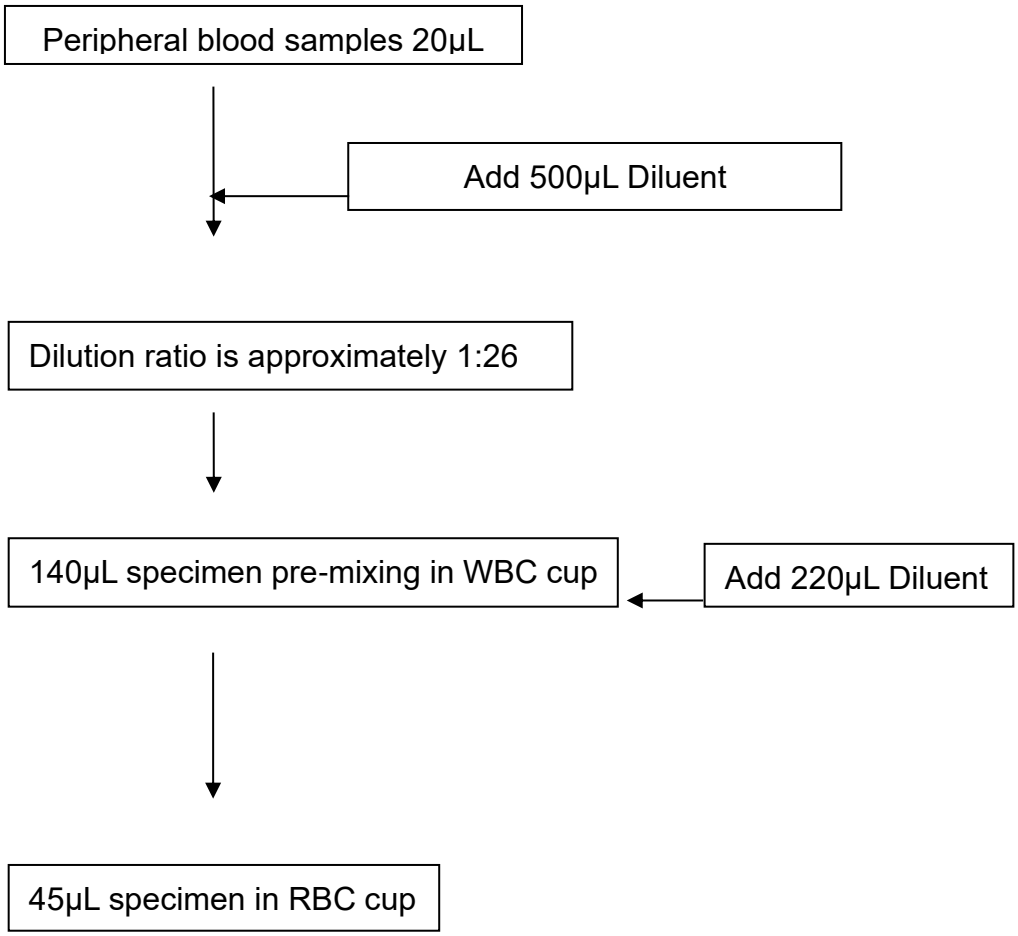


5.3.2 Pre-diluent CBC & 5Diff

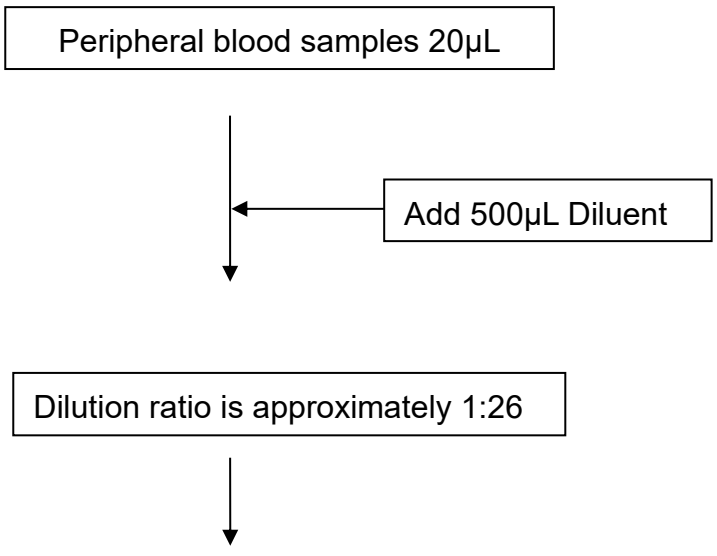
1) WBC / HGB Dilution Process



2) RBC / PLT Dilution Process



3) WBC Differential Dilution Process



80μL specimen for WBC differential

5.4 WBC Test Principle

5.4.1 Multi-Angle Laser Light Scatter Technology

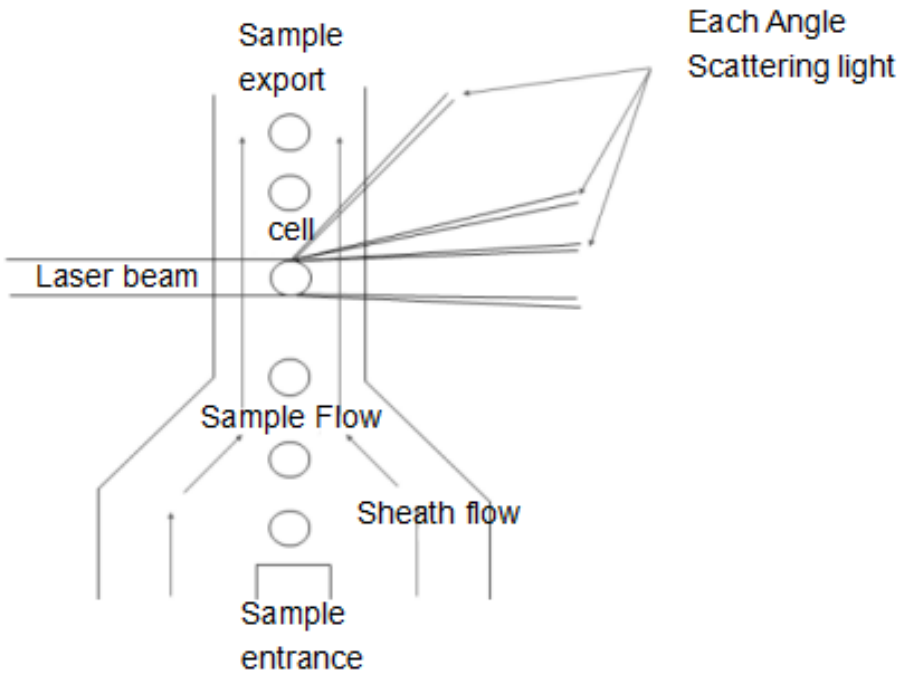


Figure 5-1 Sheath Flow Regulator

The whole blood samples are diluted with an appropriate proportion of sheath, 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. Different types of cells at different angles scattered light intensity 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 different amplitudes of the pulse signals. 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.

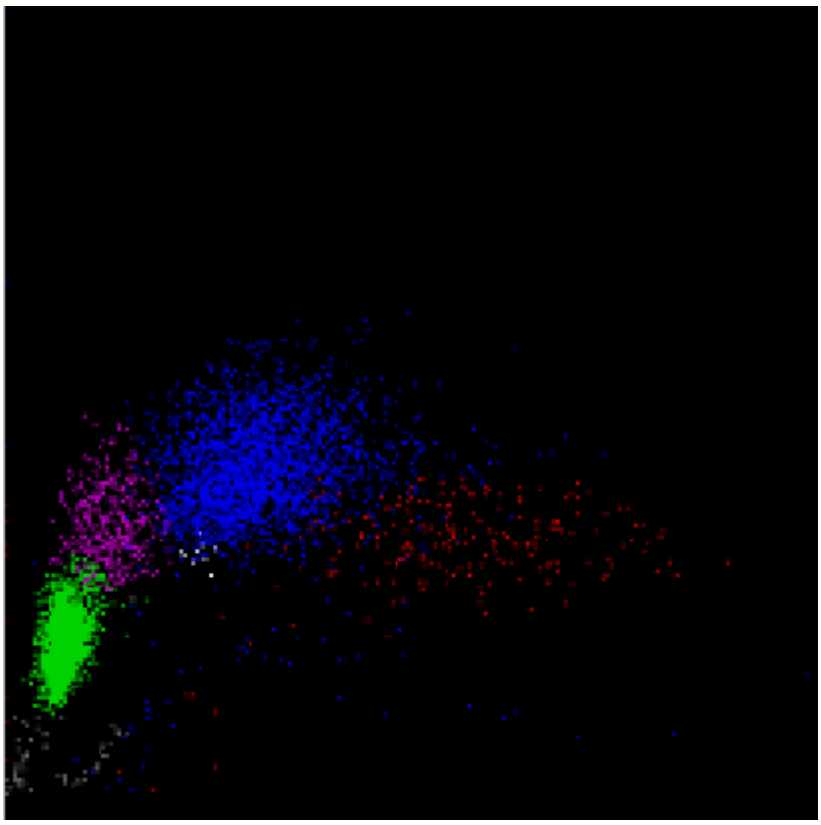


Figure 5-2 Scatter Diagram

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

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

5.5.2 HGB Parameter

Hemoglobin (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 method for the blood cells testing and counting. 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.

As the number of pulses corresponds to the number of cells pass through the pores, 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.

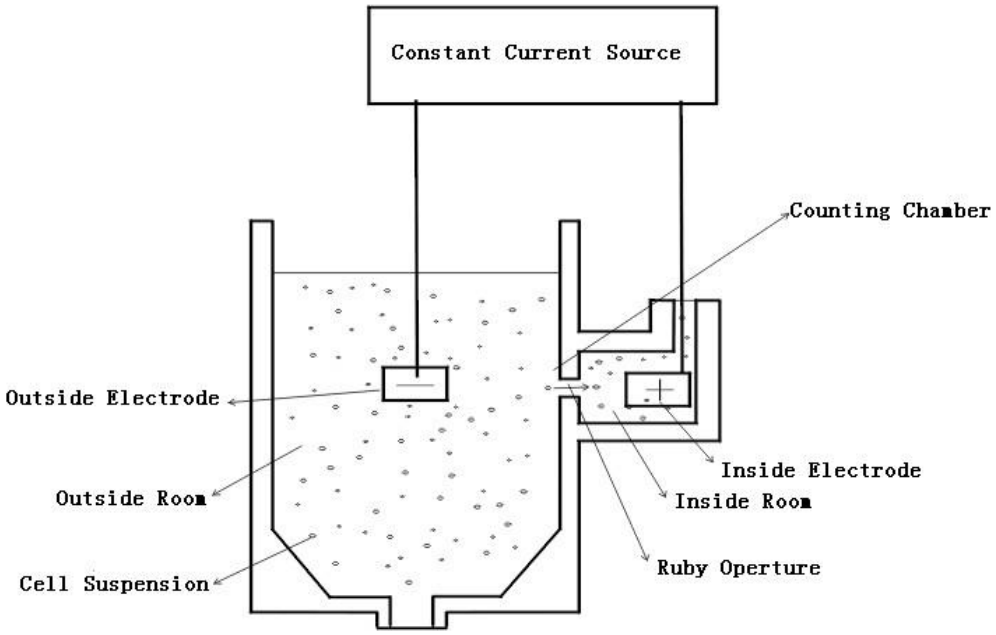


Figure 5-4 Electrical Impedance Method

5.6.2 Volumetric Metering

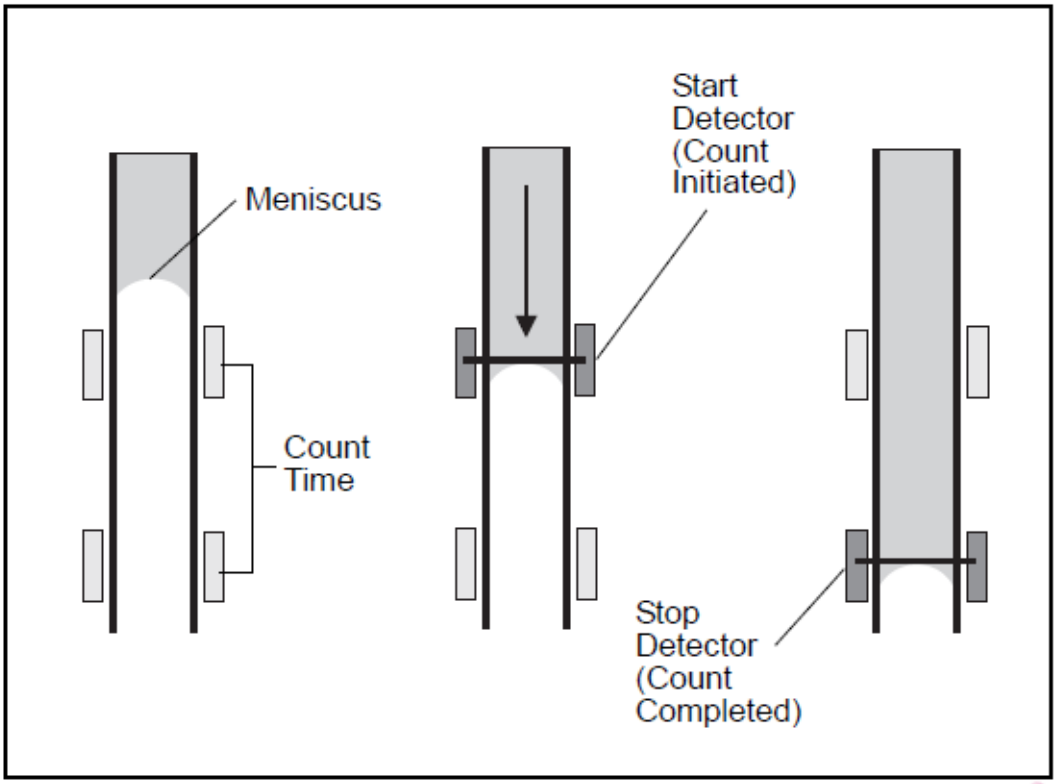


Figure 5-5 Volumetric Metering

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

As shown in Figure 5-5, 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 flow 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. The 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. The 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 being expressed in pg. The 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.

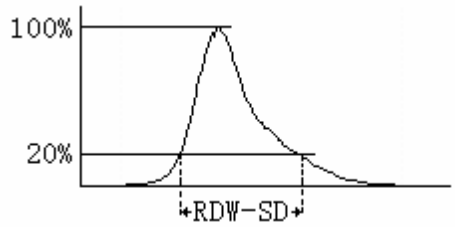
$$MCHC = \frac{HGB}{HCT} \times 100$$

- RDW-CV

The RDW-CV is derived from the RBC histogram and being expressed in 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) which is gotten from the RBC histogram 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 derived from the PLT histogram after the PLT count has been determined. The unit is fL.

- PDW

The platelet distribution width (PDW) is a measure of the heterogeneity of the PLT population. It is expressed as the geometric standard deviation. (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.

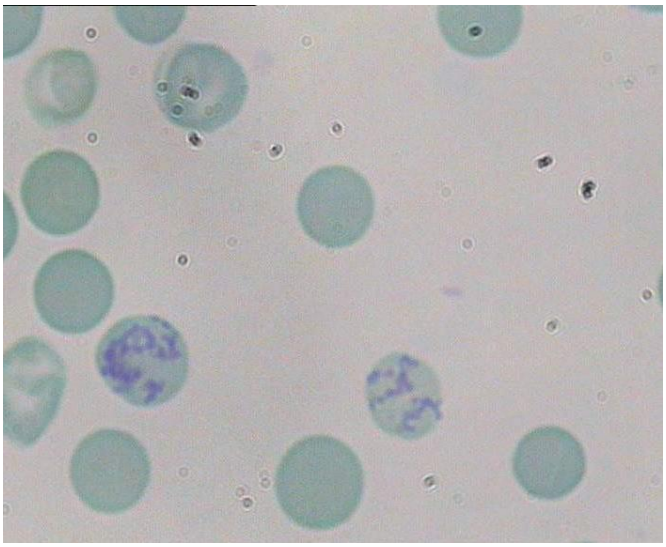


Figure 5-6 Dyed Reticulocytes

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:

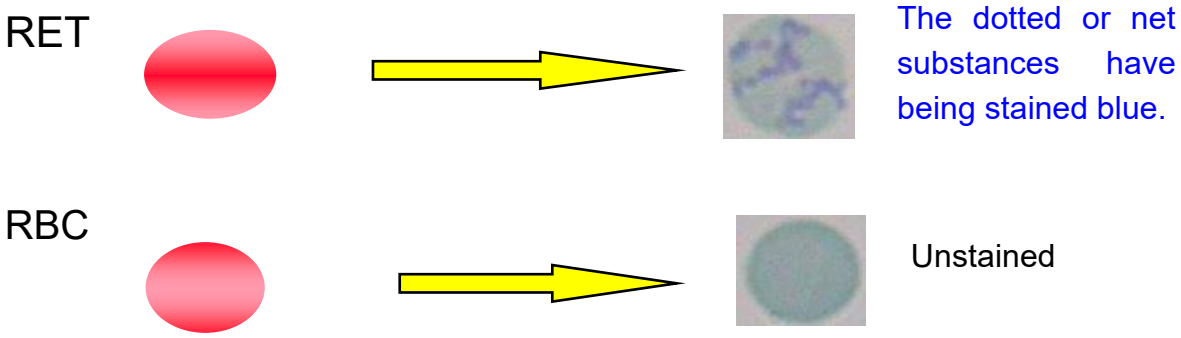


Figure 5-7 Staining

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

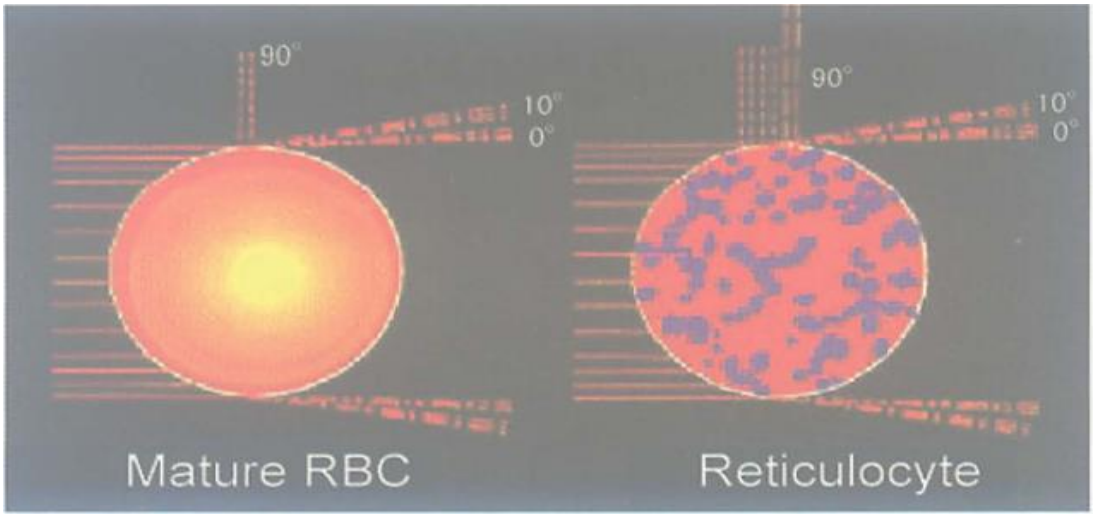


Figure 5-8 Cells scatting of light

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.

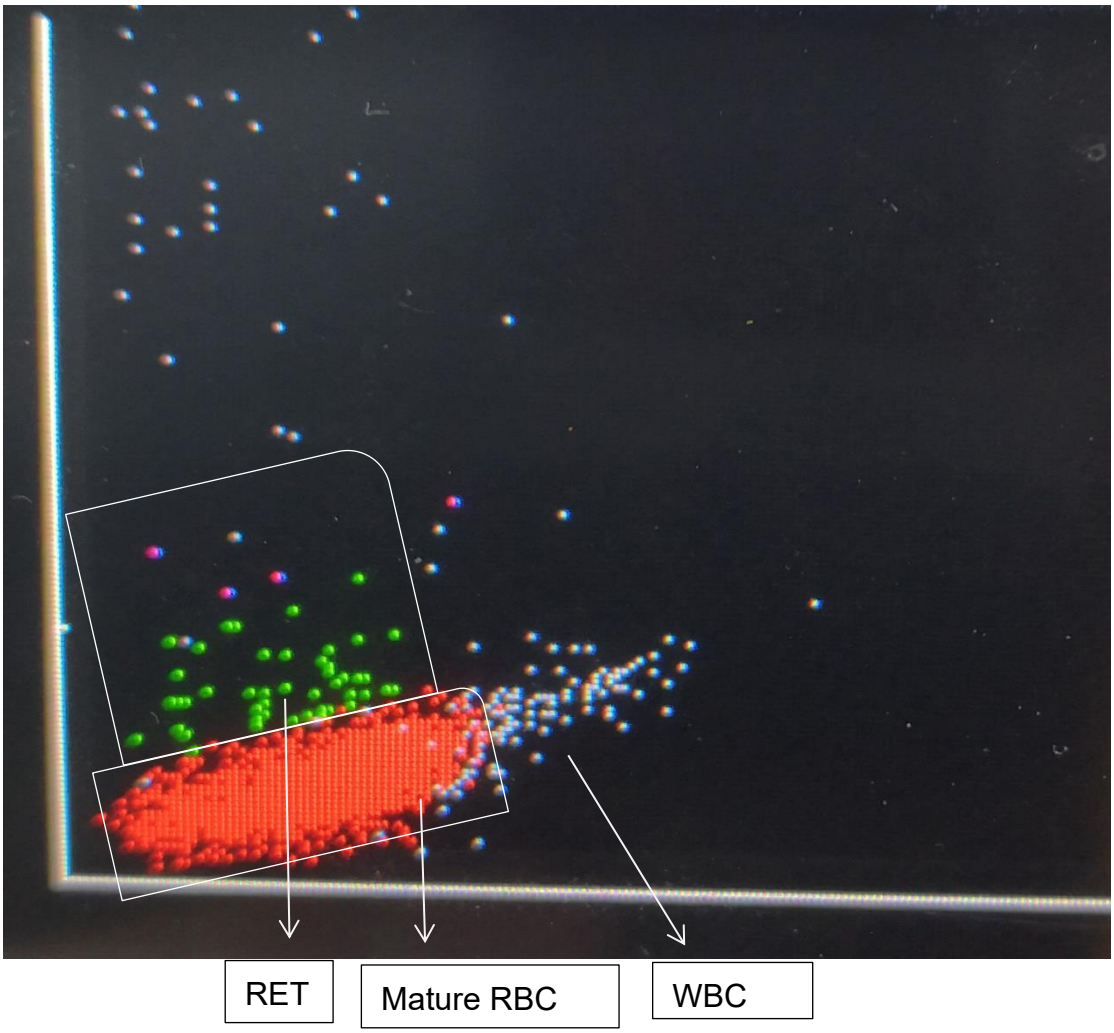


Figure 5-9 RTIC scatter diagram

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.

6 Settings

6.1 Overview

Initialization setting of Smart-V5 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.

NOTE

- Key parameters will be hidden from everyone but administrators.Please log in administrator account for settings. Administrator account will be introduced in following sections.

6.2 Settings

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

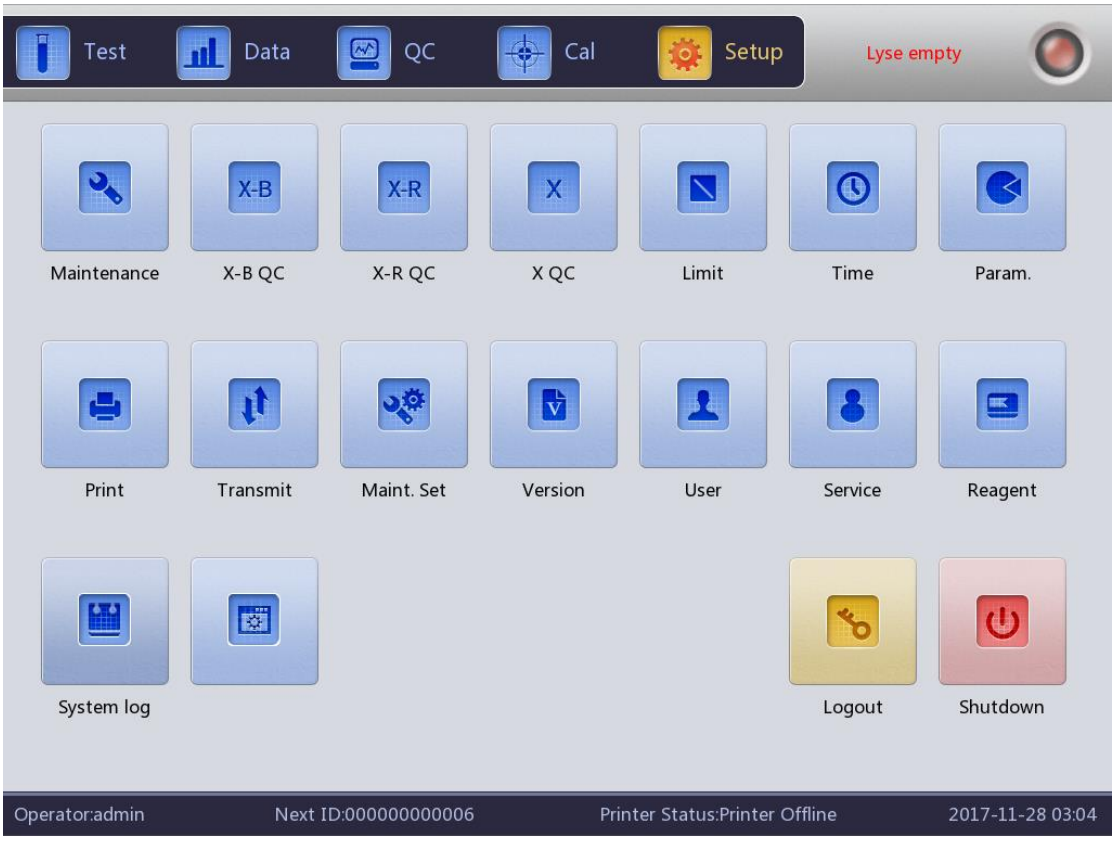


Figure 6-1 Setup Interface

6.3 System Maintenance

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

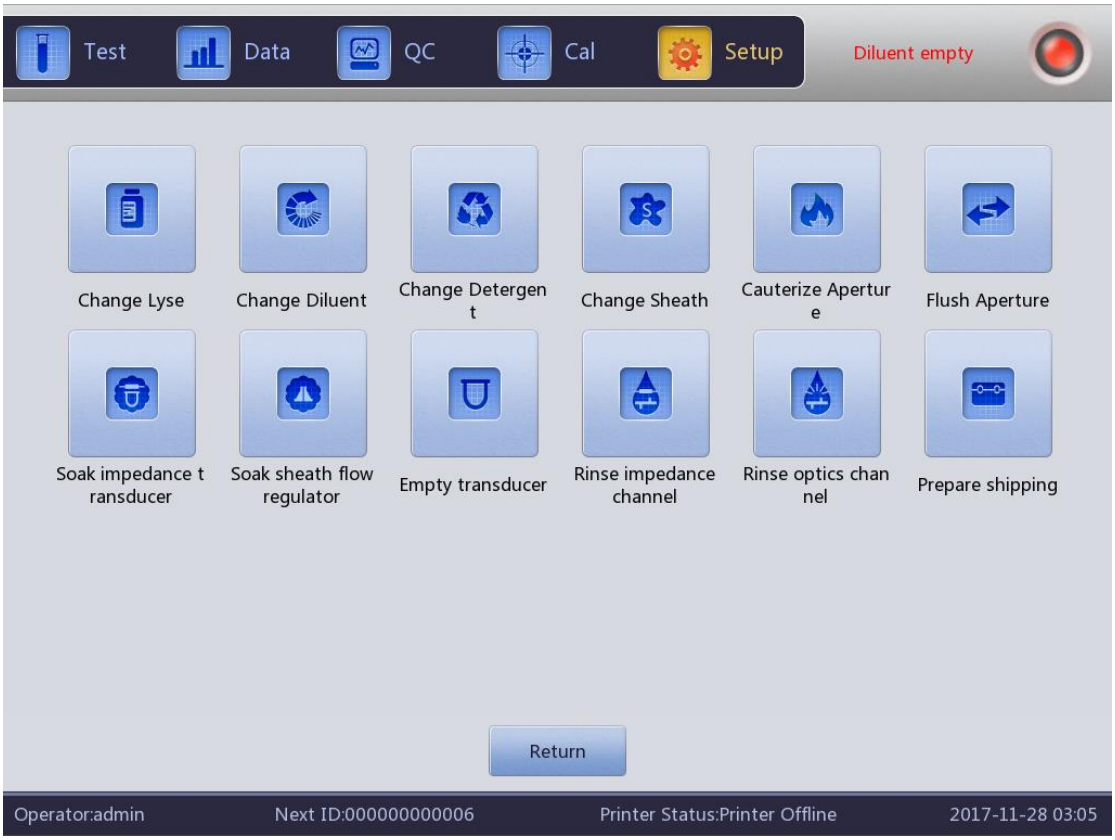


Figure 6-2 Maintenance

Change lyse: click “Change Lyse” to primes lyse automatically after replacement.

Change diluent: click “Change Diluent” to primes diluent automatically after replacement.

Change detergent: click “Change Detergent” to primes detergent automatically after replacement.

Change sheath: click “Change Sheath” to primes sheath automatically after replacement.

Cauterize aperture: click this button to eliminate clogging

Flush aperture: click this button to eliminate clogging.

Soak impedance cup: click this button as it clogged or getting high blank test result.

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

Empty sample cup：click this button to empty the sample cup

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	6.00	17.00	HGB	110	190
LYM%	12.00	33.00	HCT	36.0	56.0
MON%	2.00	13.00	MCV	62.0	78.0
NEU%	52.00	81.00	MCH	21.0	28.0
EOS%			MCHC	300	380
BASO%			RDW_CV	11.5	15.9
LYM#	0.830	4.690	RDW_SD		
MON#	0.140	1.970	PLT	117	460
NEU#	3.620	11.320	MPV	7.3	11.2
EOS#			PDW		
BASO#			PCT		
RBC	5.10	8.50	P_LCR		

Figure 6-3 Limits

Click “Group” to choose patient group, Dog, Cat, Horse, Rat, Mouse, Rabbit, Monkey, Cow, Pig, Buffalo, Sleep, Carmel, Goat, user1, user 2 and user 3. See Figure 6-4.

Figure 6-4 Limits

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

Click “OK” to save current edited limits.

Click “Export” to export current group limits.

Click “Print” to print current group limits.

Click “Back” to go back to setup interface.

6.8 Time

Click “Time” to set it.

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 modified settings.

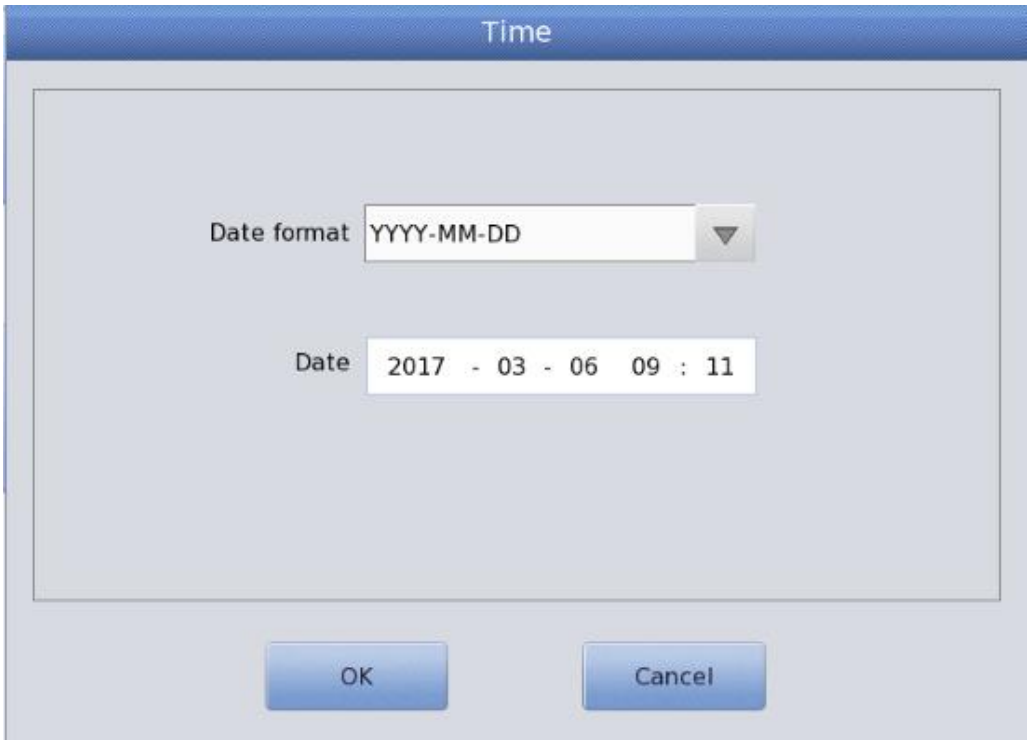


Figure 6-5 Time and Date

6.9 Parameter

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

Choose unit of WBC, RBC, PLT and HGB/MCHC and modify the reaction time of RRBC. Click “Default” to revert RRBC reaction time to factory settings. Click “OK” to save modified settings.

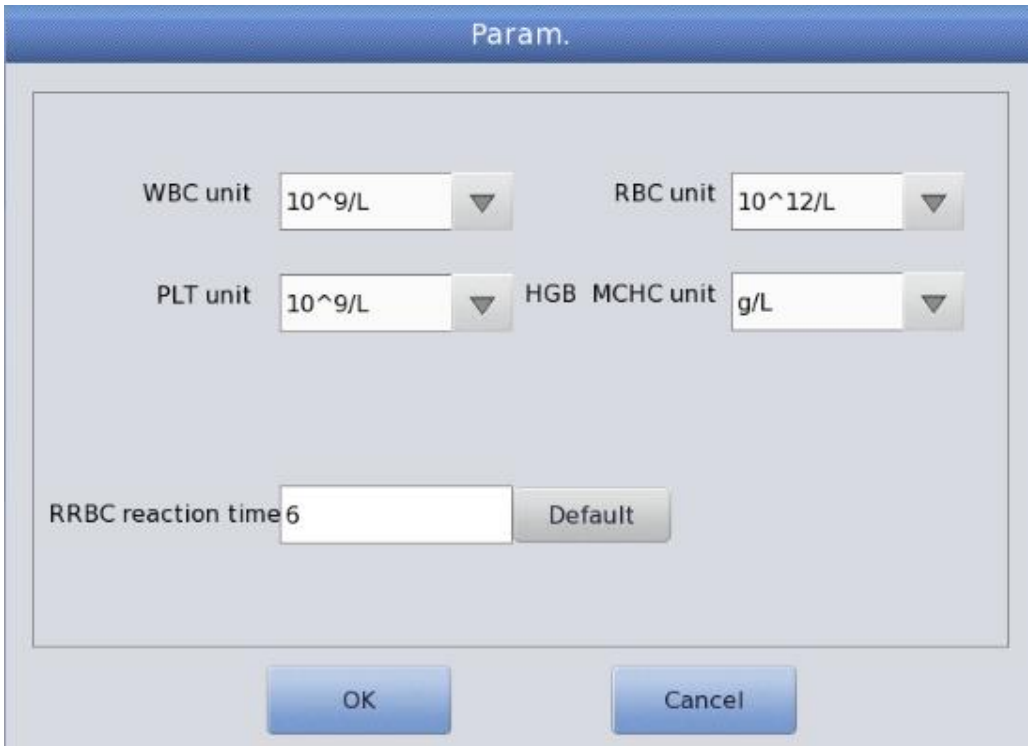


Figure 6-6 Parameters

6.10 Print

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

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

Print format: print with histogram, print without histogram

Auto print: open/close auto print. If it’s open, test result is auto printed after counting. If it’s closed, it needs to manual print.

Printer title: input hospital name here, hospital name displays in printed report title. Click “OK” to save the modified settings.

Figure 6-7 Print

6.11 Transmit

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

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.

Select either “On” or “Off” auto transmit as connecting with LIS system. “Trans Histo” and “Trans Scatter” can be selected.

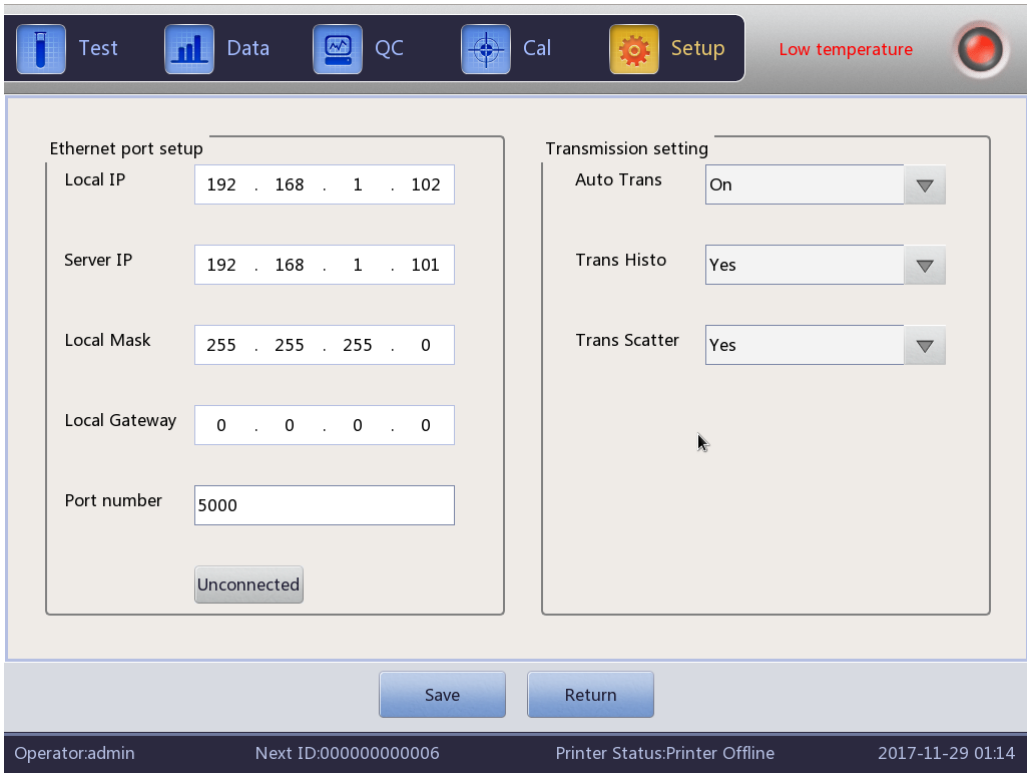


Figure 6-8 Transmit

6.12 Maintenance

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

Figure 6-9 Maintenance

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 shut down the analyzer 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 without any operation for an interval of time. Users can adjust dormancy length according to the necessary.

Soak and exit: prompts do not pop up if “ Off” is selected. Soak is performed when shutting down, if “On” is selected. The analyzer prompts to put the detergent under the sample probe which absorbs it to soak sample cup.

Shut down the analyzer after soaking.

Auto soak: click  to choose counting times. The analyzer reminds users of putting detergent under the sample probe and absorb it to soak sample cup, 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 “Back” to return to setup 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 to edit new user’s name, password and group. “Group” is divided into “Ordinary user” and “Administrator”, which are given different permissions. The administrator's permissions are higher than the Ordinary user’s. The administrator can operate all the functions, while the general user can not delete data, use the export function or calibrate the analyzer. See Figure 6-12.

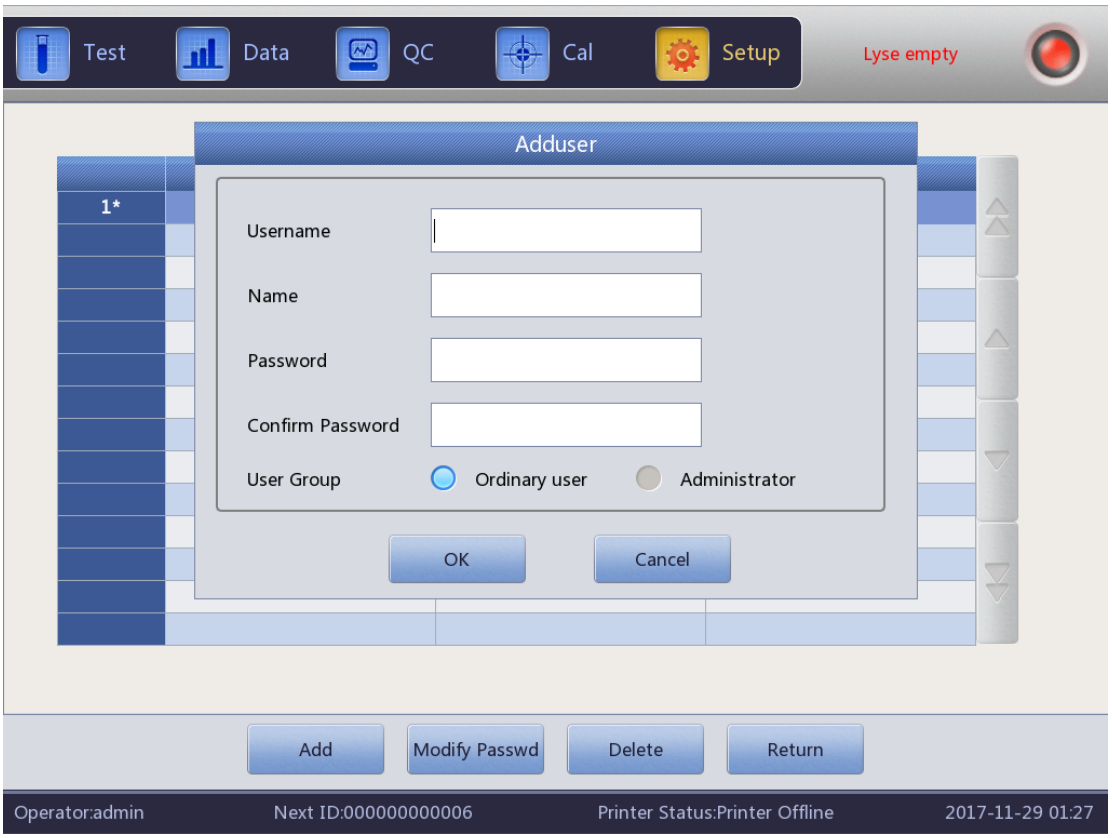


Figure 6-12 Add User

6.15 Service

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

Figure 6-13 Service

6.16 Reagent

Click “Setup” as changing reagent. Click “Reagent” to pop up below dialog.

See Figure 6-14.

The activation date, reagent amount, valid period of lyse, sheath, diluents and detergent. For example, click “Change” of diluent to change 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 hear 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 reagent balance is the current maximum reagent dose. 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 Display

Click “Display”, and you can select the parameters which are required for current animal, as Figure 6-17.

图 6-17 显示界面

CAUTION

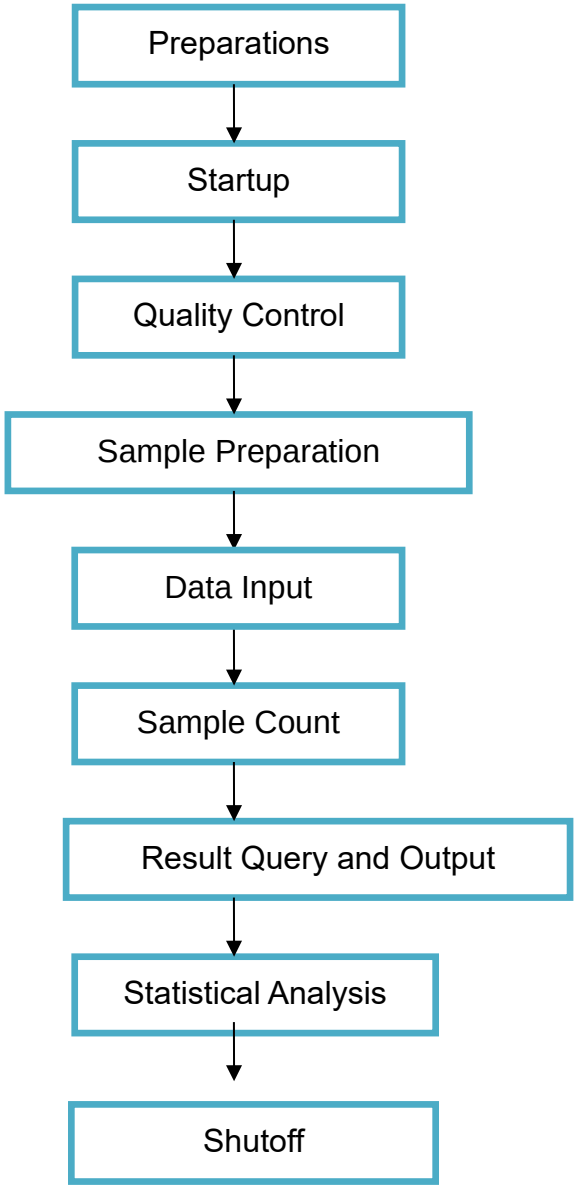
- Transmit setup is already set before delivery. As a rule, there is no need to reset, or the data transmission will be affected. Necessary modification should be done under the guidance of URIT engineers.

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:



CAUTION

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

7.2 Preparations

Check the analyzer as the following steps before startup.

1. Check the Waste Container

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

2. Check the Reagents, Tubing and Power

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

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

Ensure the power plugs of instrument, computer and outlet connection is reliable.

3. Check the Printer

Ensure printing paper is sufficient and the installation is proper.

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

WARNING

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

7.3 Startup

Turn on the power switch on the 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 flow system. It takes about 4 minutes to finish this process. Status indicator turns blue after initiation.User account is logged in by default. Click “Log out” to log in administrator account.See Figure 7-1.

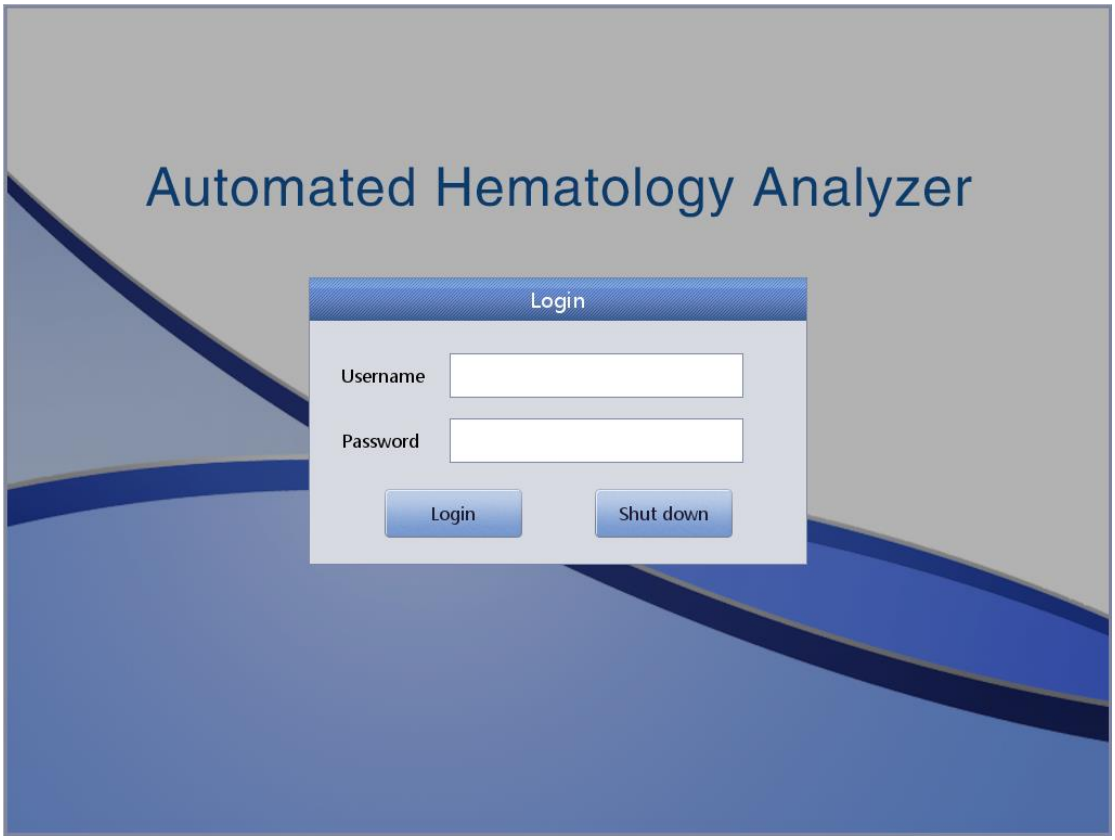


Figure 7-1 Login

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 user's name. 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

- Considering all the clinical specimens, control materials and calibrators that contain animal blood or serum as being potentially infectious, wear lab coats, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials.
- Do not directly contact blood samples, control materials or calibrators. Please follow required procedures when disposing.

CAUTION

- Blood collection and disposal should be performed according to the local and national environmental regulations or laboratory's requirements.
- Ensure the whole procedure of blood collection is clean and contamination-free. All specimens must be properly collected in tubes containing the EDTA (EDTA-K_2·$2H_2O$) anticoagulant.
- Do not shake the sample tube violently.
- Venous blood can only be stored for 4 hours at room temperature. URIT recommends the blood sample be kept 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 which keeps the configuration of WBC and RBC inhibits PLT aggregation. Gently shake the tube 5~10 times and ensure to mix it well.

The following anticoagulants are commonly used in whole blood collection.

1. **Heparin**

   Lead to cell aggregation and change the cytoplasm'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 when a suspect EDTA causes spurious thrombocytopenia.

3. **ACD and CPDA**

   Most widely used in cell Concentration (especially platelet concentrates), usually not used for cell counts.

4. **EDTA**

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

5. Fluoride

Use 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.

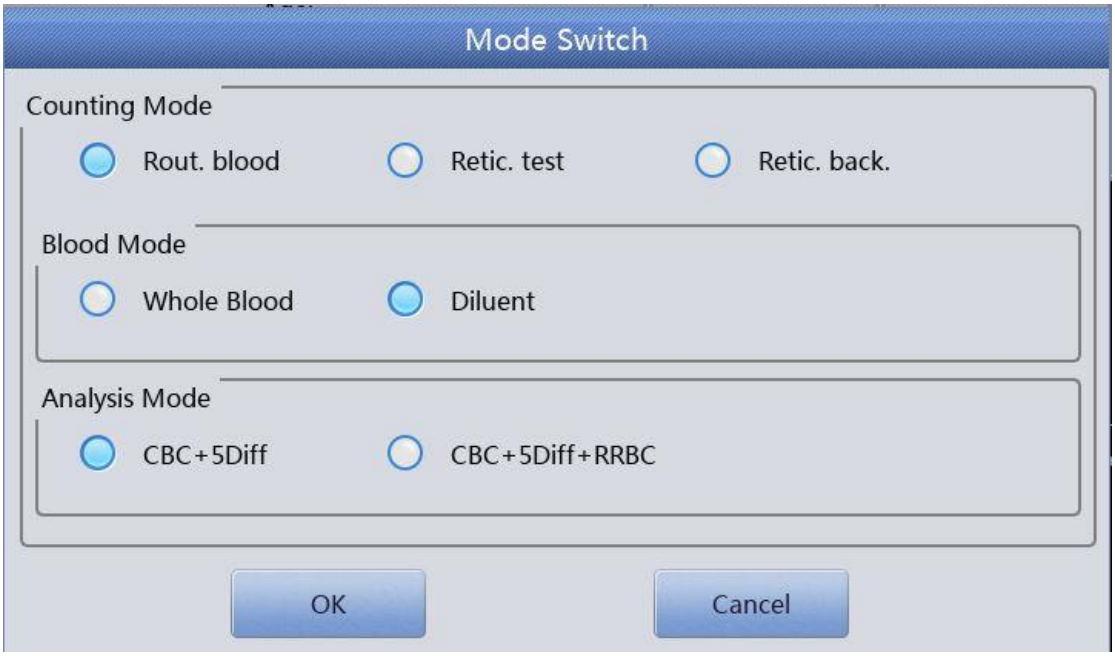


Figure7-4 Mode Switch operations

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

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

CAUTION

- Avoid the collected diluent mixing with dust; otherwise it may cause analytical error.
- Peripheral blood and diluent after full reaction, should be placed for 3 minutes, and then only after blending again that can do the analyze.
- Ensure that the sample has been analyzed within 30 minutes after dilution, otherwise the analysis results are not reliable.
- Each laboratory should according to their respective sample number, sampling method and the technical level to evaluate the stability of the results under the diluent mode.

7.5.3 Sample Stability

Better to use fresh whole blood. ICSH (International Committee for Standardization of Hematology) defined fresh blood as, samples processed within 4 hours after collecting. When whole blood samples are mixed well, placed in EDTA-tubes, and tested within 8 hours after collecting, the accuracy of each parameter will be highest. Test samples within 5 to 20minutes or over 8 hours, the WBC volume distribution will offset.

7.6 New Next Blood Sample

User can either input detailed sample information before sample analysis or after sample analysis. See Figure 7-5.

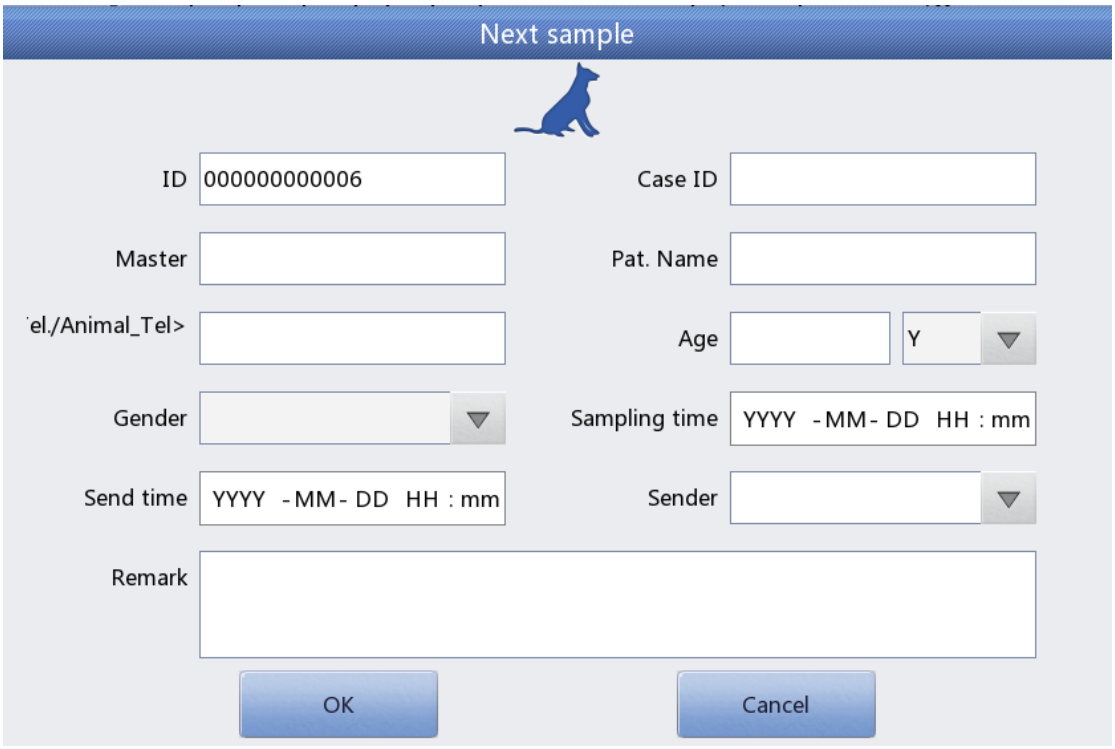


Figure7-5 New Next Blood Sample

The system comes with English input method, clicking on the corresponding input box shall pop up the virtual keyboard. If necessary, the user can connect to external PS2 or USB interface keyboard to help enter the information. See Figure 7-6.

Figure7-6 Virtual keyboard

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

Case ID: input the case number.

Master: input Animal owner's name
Pat.Name: input the name of the animal
el./Animal.: input The animal owner's phone
Age: year, month, day and hour can be selected.
Gender: male and female, the default is blank if not selected.
Sampling time: Input the blood sample collection time
Sending time: time of sending sample to the department
Sender: input sender’s name or code.

NOTE

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

CAUTION

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

7.7 Sample Test

7.7.1 Mode

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

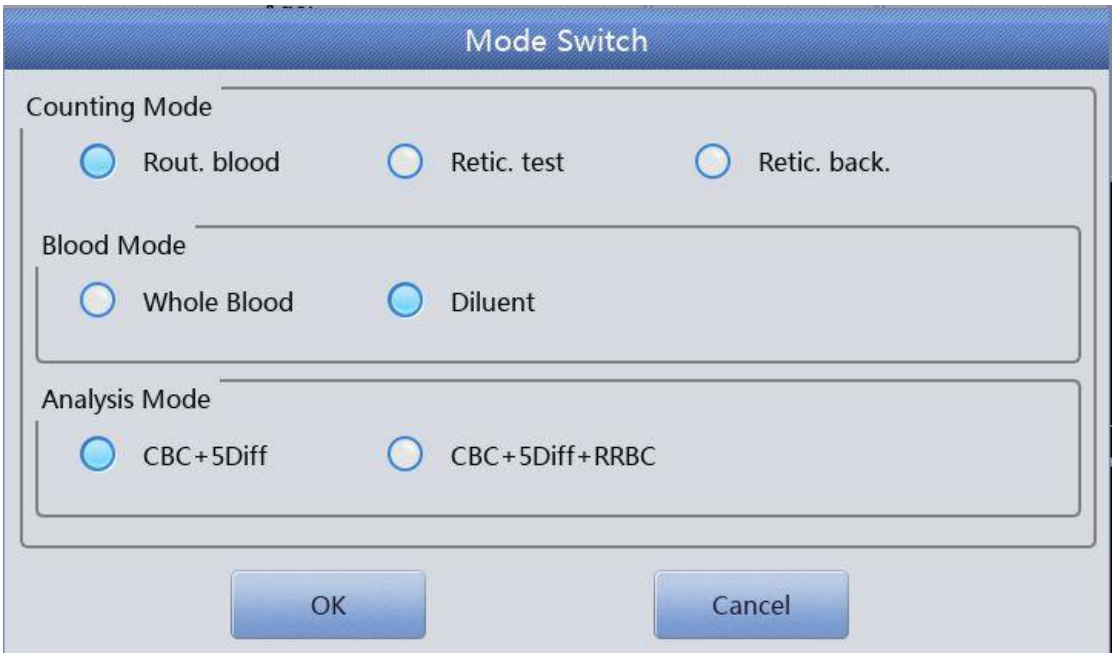


Figure7-7 Mode Switch

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 16 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 far less than that of the first counting, it shows that this specimen contains indissolvable red blood cells.

7.7.2 Counting and Analysis

WARNING

- The sharp sample probe contains residues of clinical specimens, controls or calibrators which probably have potential infectivity. Do not directly contact the sample probe.

NOTE

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

CAUTION

- Please use the specified vacuum blood tube, centrifuge tube, capillary tube and other disposable products when collect the blood sample.
- Do not open the front panel after start counting.

7.8 Data Query

After each counting, the results are automatically saved in a database that could store at least 200,000 results include 38 parameters (2 scatter diagrams, 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.

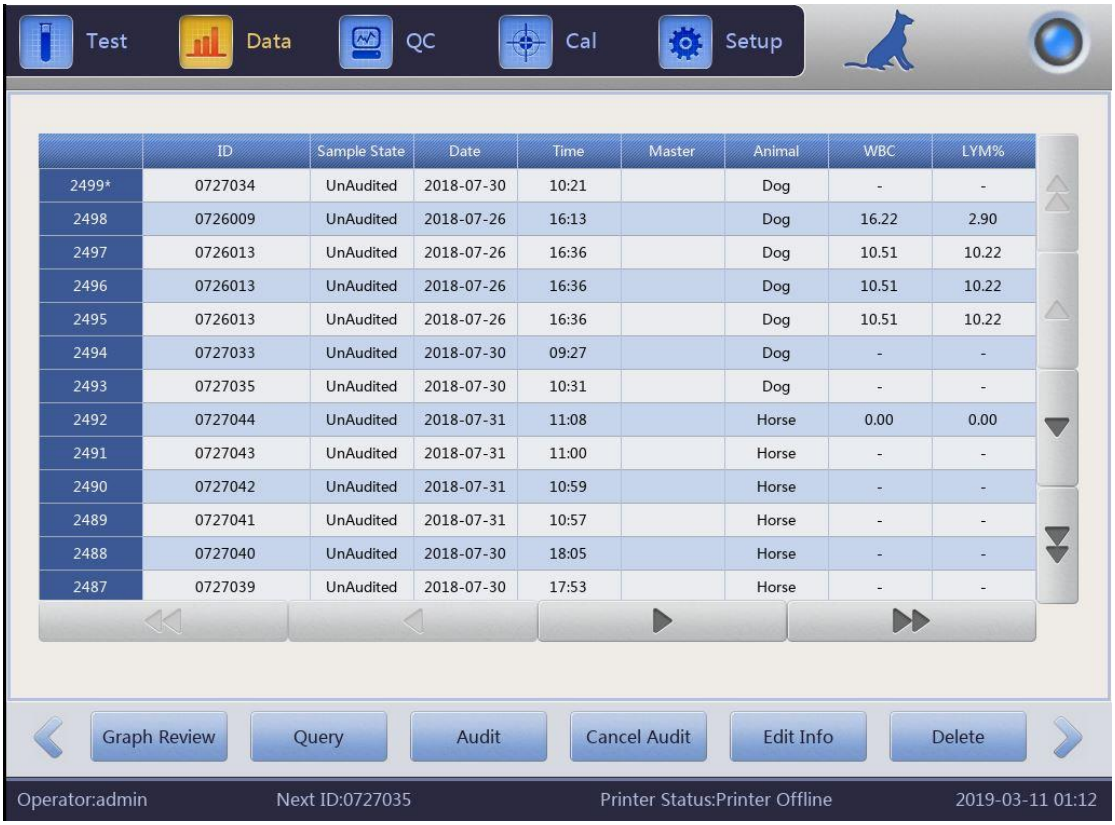


Figure 7-8 Data Query

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

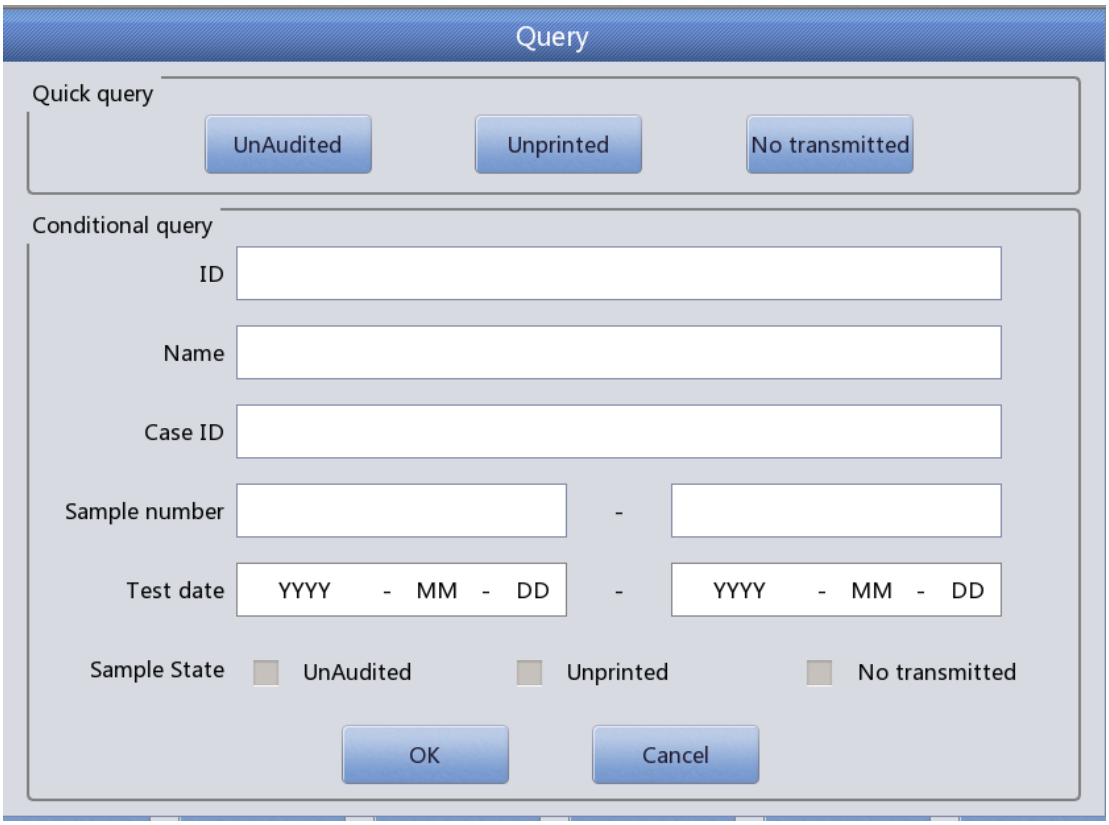


Figure 7-9 Query

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

  Conditional query can achieved the function of exact search by input the specified “Case ID”, “Master” or “ID”. It also can query through the range of “Sample number”, or query through the range of “Test date”.

  Conditional query can achieved the function of exact search by cooperate with “Sample State”.

7.8.2 Data Selection

There's a "*" in front of selected sample ID. As shown in Figure 7-6, it shows records of sample 0726009. 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 according to the requirement of the operator. 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

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 “Reticulocyte test” to start reticulocyte analysis. As Figure 7-11:

Figure 7-11 Reticulocyte analysis interface

In reticulocyte analysis interface of URIT-5160 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 “Reticulocyte background” to enter reticulocyte test interface. See Figure 7-12:

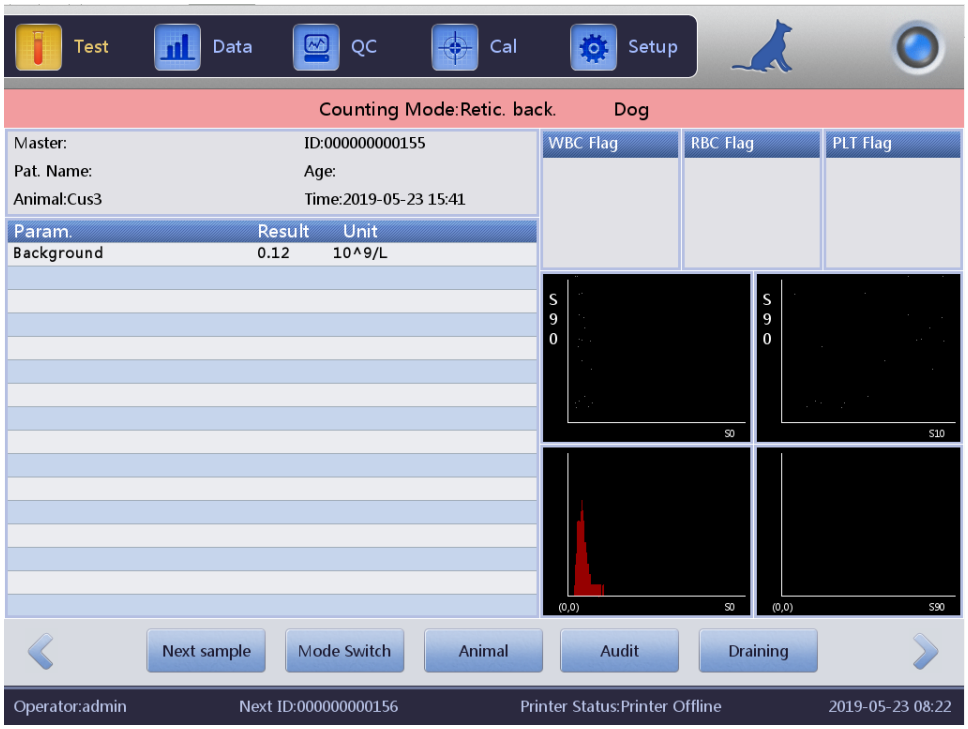


Figure 7-12 Reticulocyte background interface

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 “Reticulocyte test” to enter reticulocyte test interface. See Figure 7-13;

Figure 7-13 Reticulocyte test interface

NOTE

- 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.
- There is no reticulocyte test mode in some specific machine.

7.10 Edit Information

Choose sample ID and click “Edit information” to pop up dialog box, see

Figure 7-14.

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

The audited sample cannot be edited, if it needed to be edited, please cancel the audit first. Please refer to ***Section 7.6 New Next Sample*** for information edit.

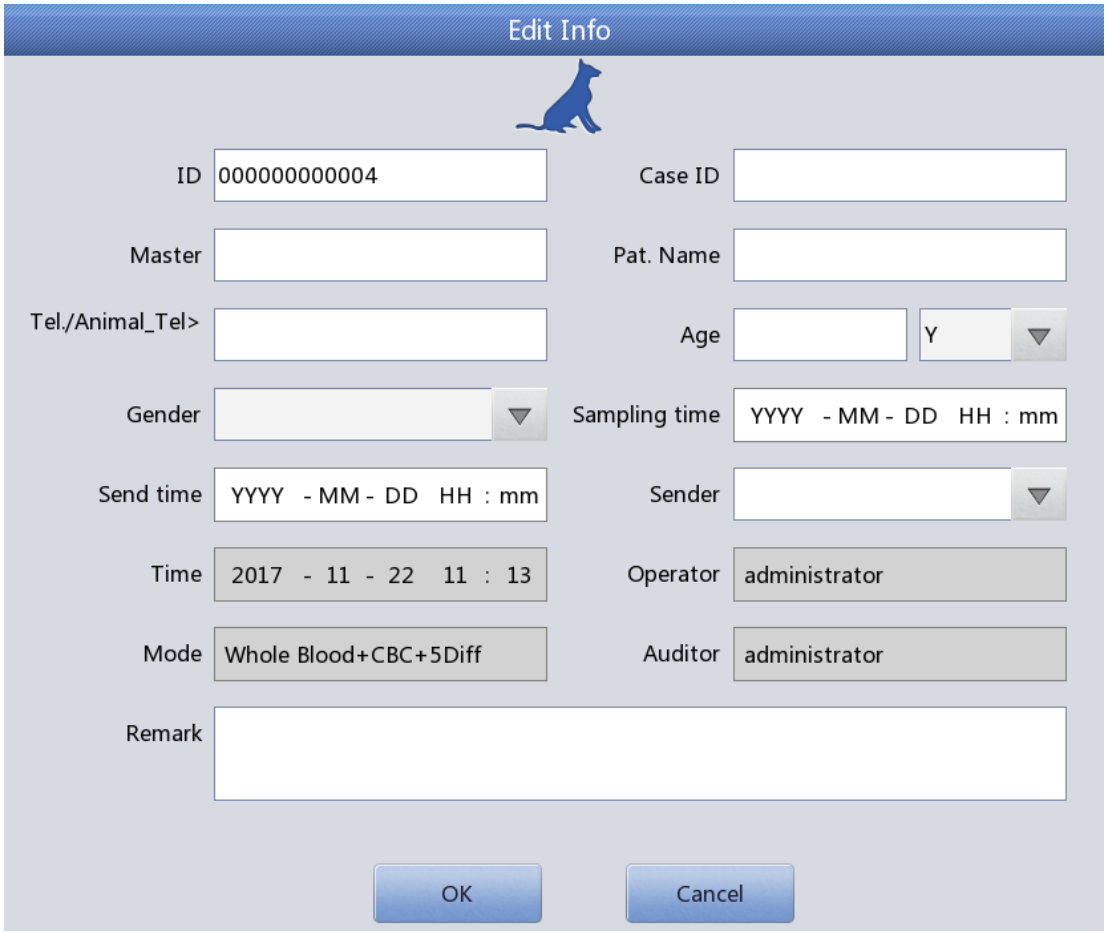


Figure 7-14 Edit Information

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 of one same blood sample. Removed the first test result, choose the remaining results and click “CV” to see the CV value. See Figure 7-16.

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

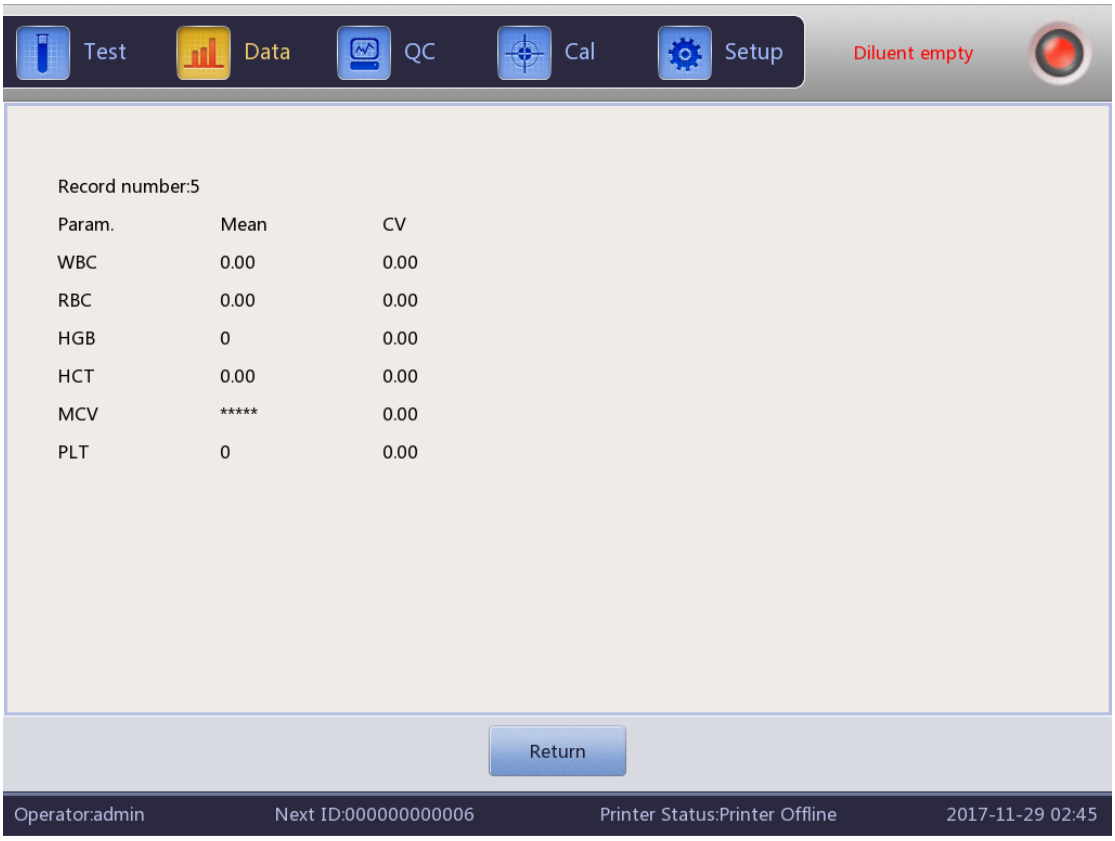


Figure7-16 CV

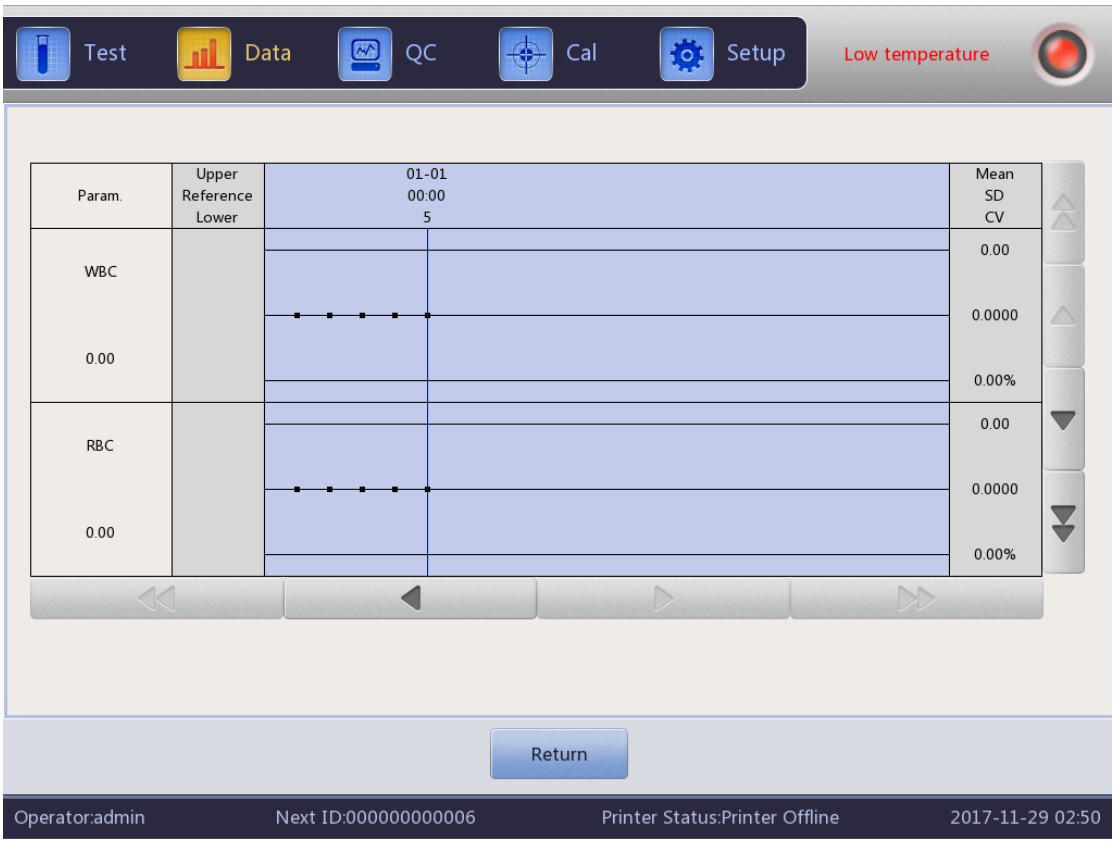


Figure7-17 Trend Graph

7.13 Shutoff and Logout

Shutoff procedure should be performed after finishing all the tests and before turning off the power. Execute the shutdown procedure to clean sample cups and tubing. Execute the shutdown procedure 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 “Shutoff” 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 logon with new user name.

CAUTION

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

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 URIT .

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 low temperature storage and there's no damage to the container.
2. Please mix the control material in the method recommended by manufacturer.
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 high, normal, low control materials between current batch and previous batch.

 **WARNING**

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

procedures when handling these materials.

8.2 Quality Control Options

(1) L-J QC

L-J QC (Levey-Jennings graph) is a simple and visual QC method with which operator can draw QC value directly on graph after getting the Mean, SD 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 the concentration of dilution, human blood pathology and technical factor, but the hemoglobin content in specific unit is hardly interfered by those preceding factors. According to this characteristic, quality control of the samples is being done by surveying the value of MCV, MCH and MCHC.

(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 other than one value. On this foundation, it calculates the Mean, SD and CV.

8.3 L-J QC

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

Figure 8-1 L-J 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 set. Users can set several groups if needed. Click “New” to setup one group of QC. See Figure 8-3.

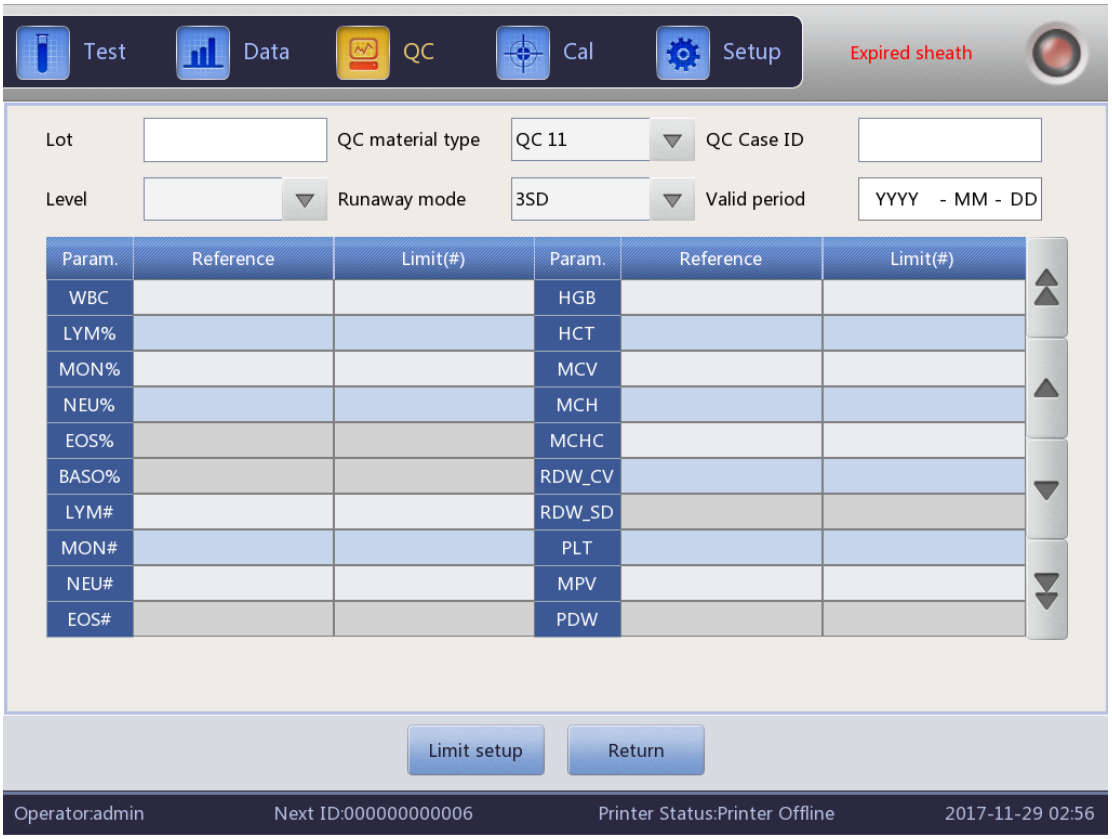


Figure 8-3 Edit

Edit information: lot, QC material, QC sample NO., level, runaway mode, valid period, reference and SD.

SD setup: calculated by absolute value and calculated as a percentage, click “SD setup” to choose it.

Click “Return” after editing. Click “OK” in popup dialog box.

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

Reference is the standard value of QC count. SD gives the allowable deviation range. Please note that the SD cannot be greater reference, otherwise, the new SD 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.

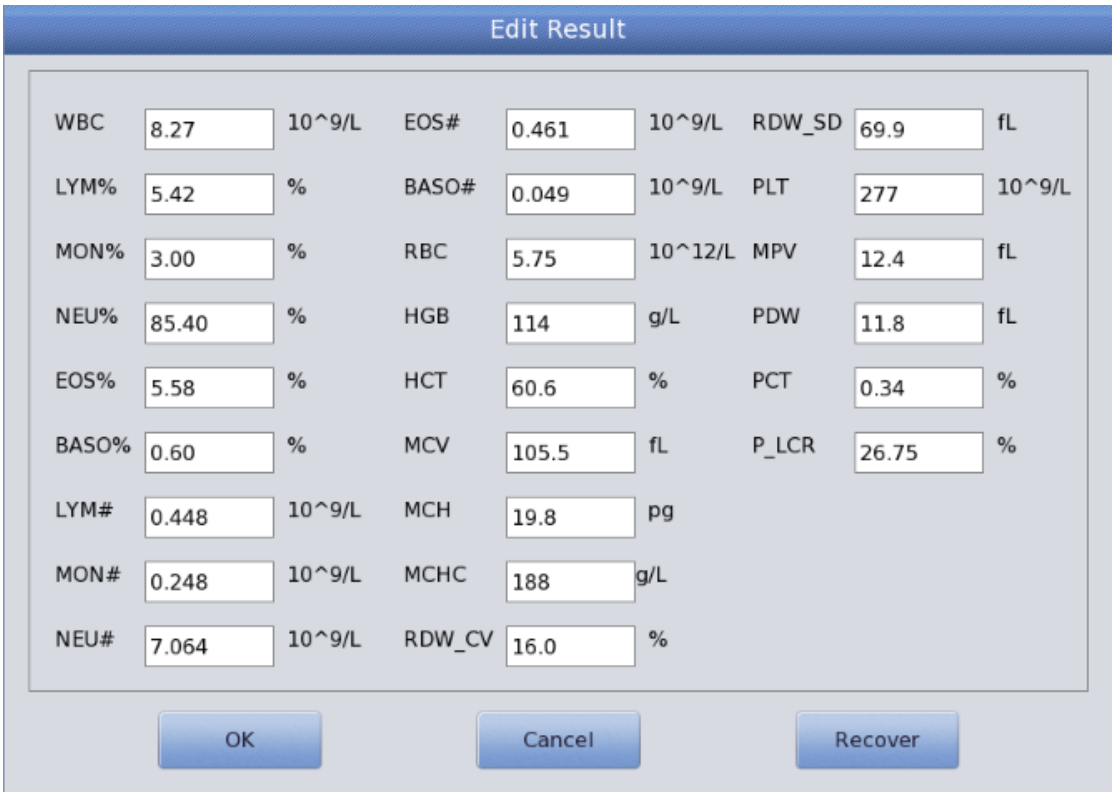


Figure 8-4 Edit Results

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

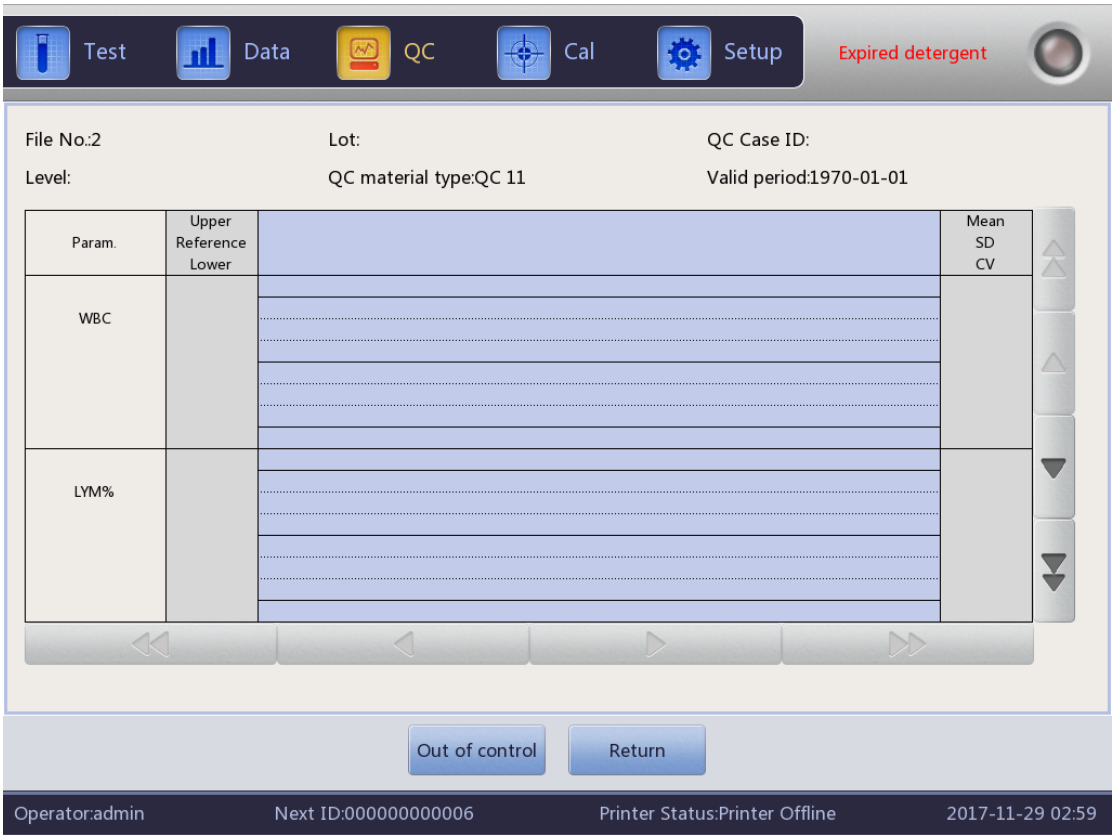


Figure 8-5 QC Graph

If the data is not in control area, choose this data dot 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 your settings.

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. Every parameter graph displays 20 dots, page turning to see other dots.
3. The above line of every parameter graph means Reference plus SD.
4. The below line of every parameter graph means Reference value subtract SD.
5. The 3 values on the left side of parameter graph mean
   a) upper limit ——Reference + SD
   b) middle line ——Reference
   c) lower limit ——Reference –SD

If the control dot falls in the area between upper and lower limit of the corresponding graph, it means the dot is under control range, if not, the dot is not under control range. Each QC graph can only store up to 100 dots.

8.3.3 QC List

Click “QC list” to see the test 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 SD shown in this interface are the value input in editing. The reference and SD in QC list changes according to that in editing.

QC list save 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, which are 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.

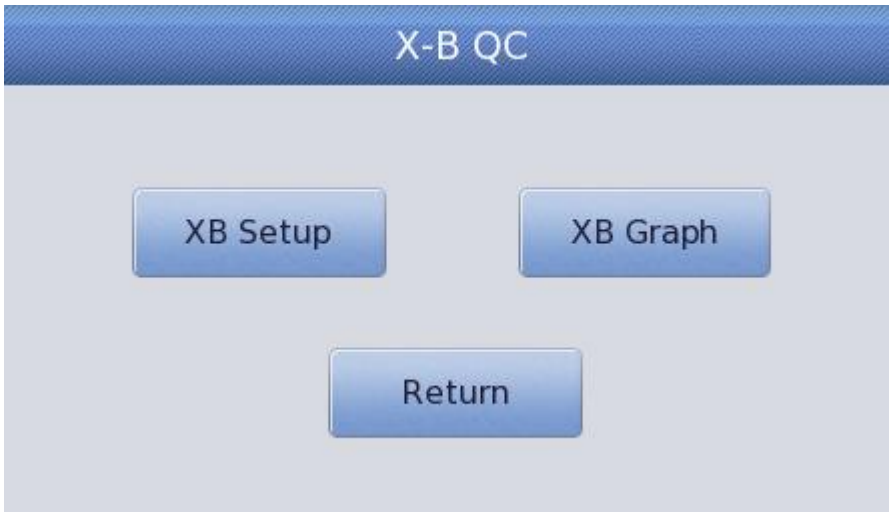


Figure 8-8 X-B QC

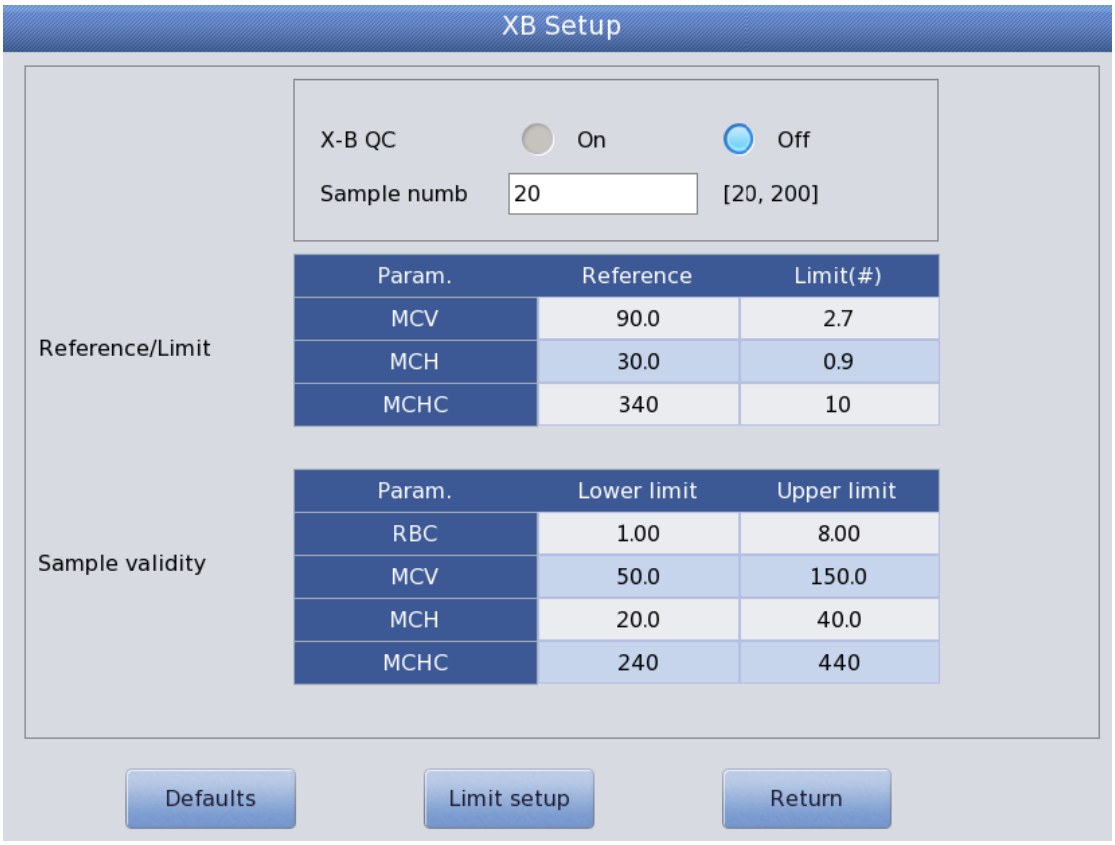


Figure 8-9 X-B Setup

Click relevant text box to input reference and SD 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 SD is valid. “Absolute value” and “Percentage” can be selected in SD setup interface. See Figure 8-10.

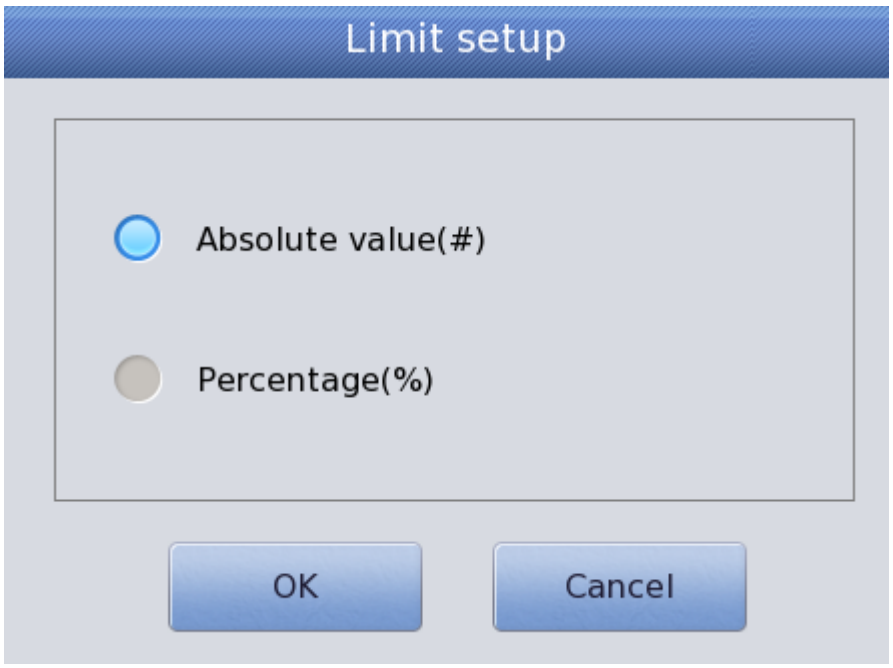


Figure 8-10 SD Setup

Reference is the standard value of QC count. SD gives the allowable deviation range. Please note that the SD cannot be greater reference, otherwise, the new SD 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 run. 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, which are 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 group, 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 display date and time are subject to the final data’s date and time within one group.

QC Graph Instruction

1. It’s a graph with times of QC count on horizontal axis and results of QC count on vertical axis.
2. Every parameter graph displays 20 dots, page turning to see other dots.

3. The above line of every parameter graph means Reference plus SD.
4. The below line of every parameter graph means Reference value subtract SD.
5. The 3 values on the left side of parameter graph mean

    d) upper limit ——Reference + SD

    e) middle line ——Reference

    f) lower limit ——Reference –SD

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

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

8.5 X-R QC

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

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

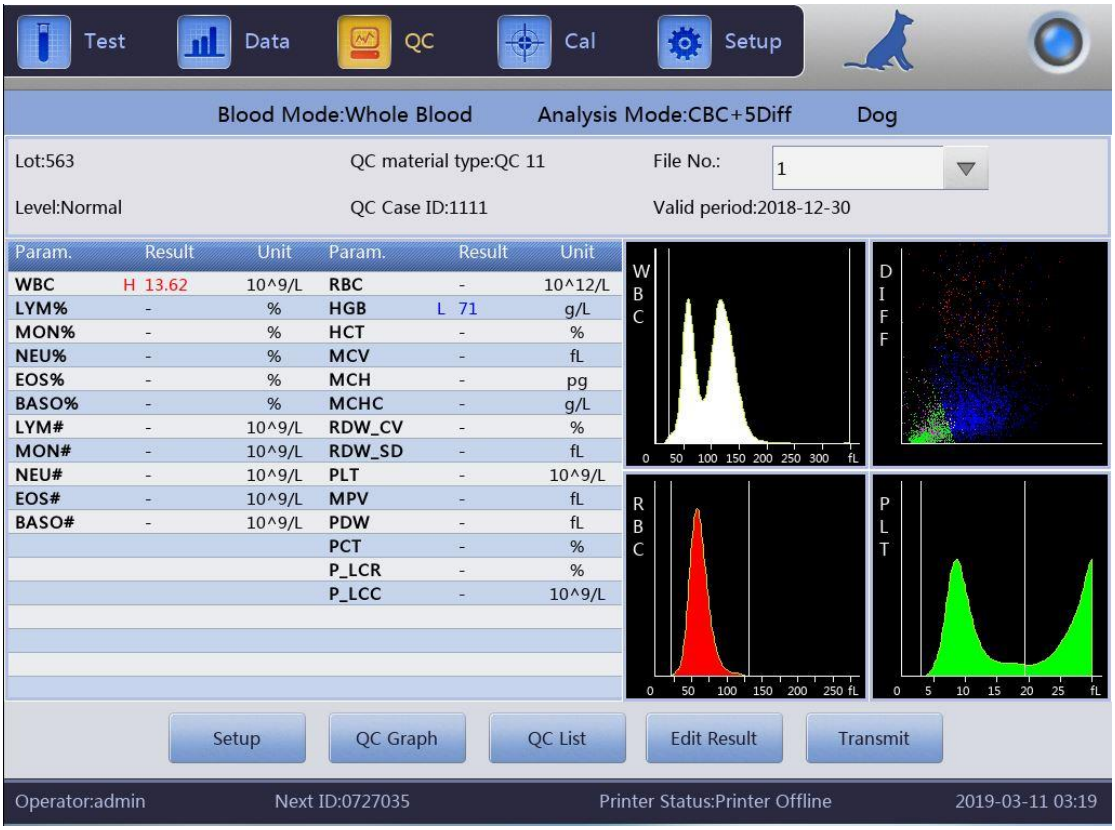


Figure 8-13 QC Interface

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 QC information which has already been edited

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 sample NO., level and valid period can be edited. Click “OK” to save your edit, on the contrary, click “Cancel”.

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

Click “Return” to go back to X-R QC interface to do QC test. The QC run interface displays two QC test results separately and automatically calculates twice 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

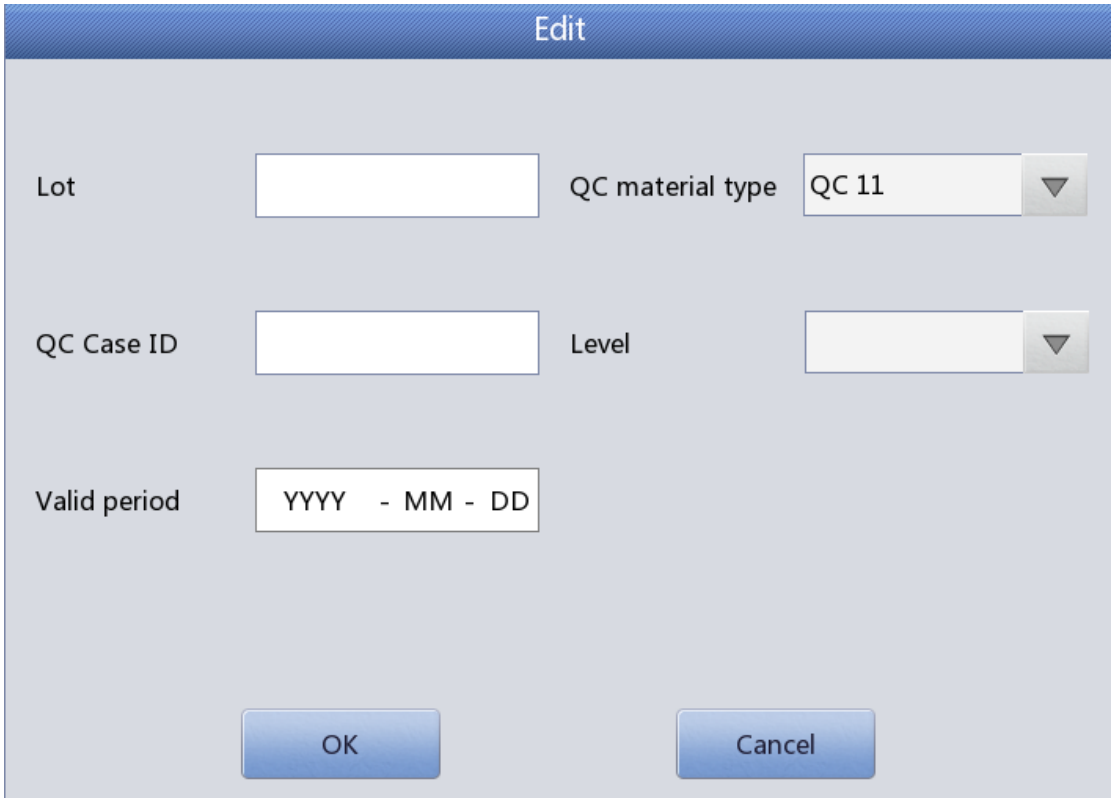


Figure 8-15 Edit

8.5.2 X-R QC Graph

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

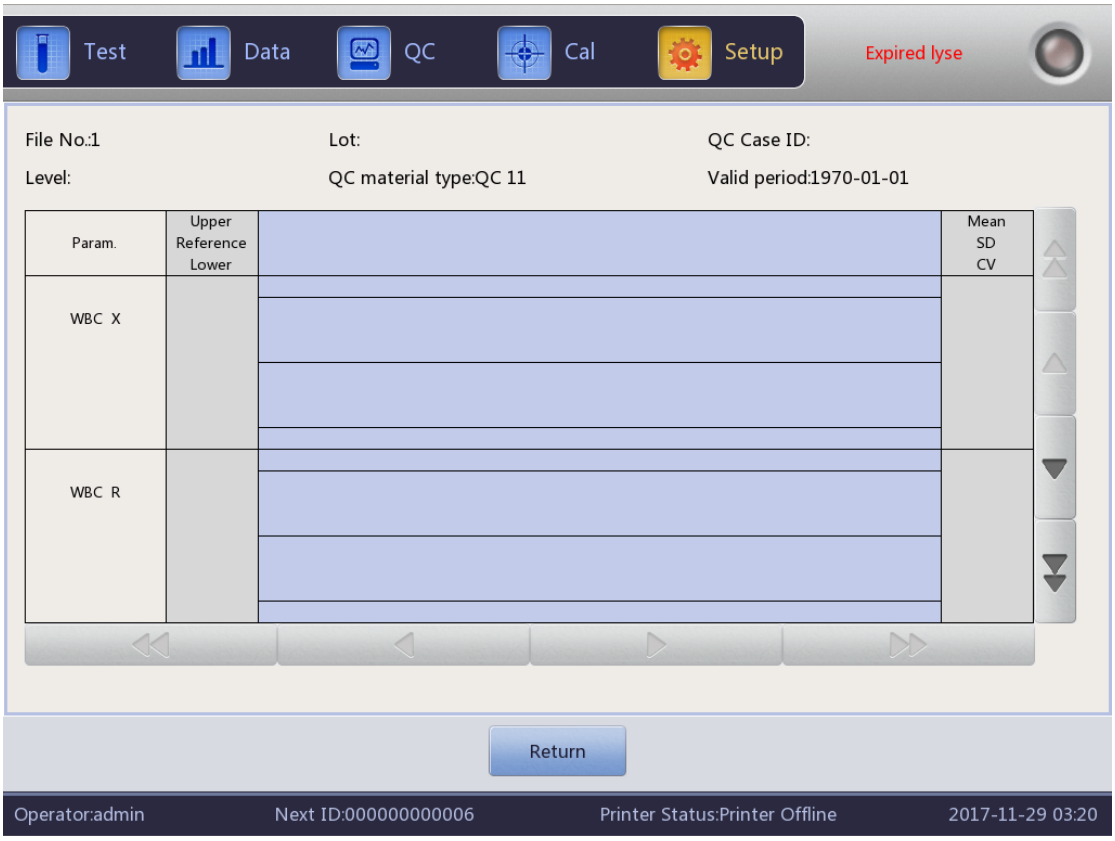


Figure 8-16 X-R QC Graph

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

X graph Instruction

1. Graph abscissa indicates QC run times, ordinate indicates QC result.
2. Every parameter graph can display 100 dots.
3. Every parameter graph’s center line indicates X (overall mean value of QC results).
4. Above line of every parameter graph means X upper limit＝X＋A×R.
5. Below line of every parameter graph means X lower limit＝X－A×R.
6. The 3 values on the left side of parameter graph mean

   a) upper limit —— X upper limit＝X＋A×R

b) middle line —— X

c) lower limit —— X lower limit＝X－A×R

R graph Instruction

1. It's a graph with QC times on horizontal axis and QC results on vertical axis.
2. Every parameter graph displays 100 dots.
3. Every parameter graph's center line indicates R (mean value of QC result range).
4. Above line of every parameter graph means R upper limit＝B×R.
5. Below line of every parameter graph means R lower limit＝C×R.
6. The 3 values on the left side of parameter graph mean
   a) upper limit —— R upper limit＝B×R
   b) middle line —— R
   c) lower limit —— R lower limit＝C×R

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

Click  ,  ,  and  to review test results. 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 reviewed in QC list. Click  ,  ,  ,  ,  ,  ,  and  to review test results.

The difference between X and L-J QC Query is each page in the X-R QC Query interface display three QC results that includes mean value and range. First page of the first two columns is total mean and average range in the X-R QC Query.

The QC data would update after running two new controls. The data displayed in the QC list is the average of the two QC count results.

8.6 X QC

X QC which has the control material is one of the methods of QC. The analyzer aspirates control material to operate QC. The operator could perform QC to 24 parameters. Considering the different needs, it is available to do the QC to some parameter. 3 QC documents of high, normal and low are provided for saving.

8.6.1 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 QC information which has already been edited

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 sample NO., level, runaway mode, reference, SD and valid period can be edited. Click “SD setup” to choose method. See Figure 8-21.

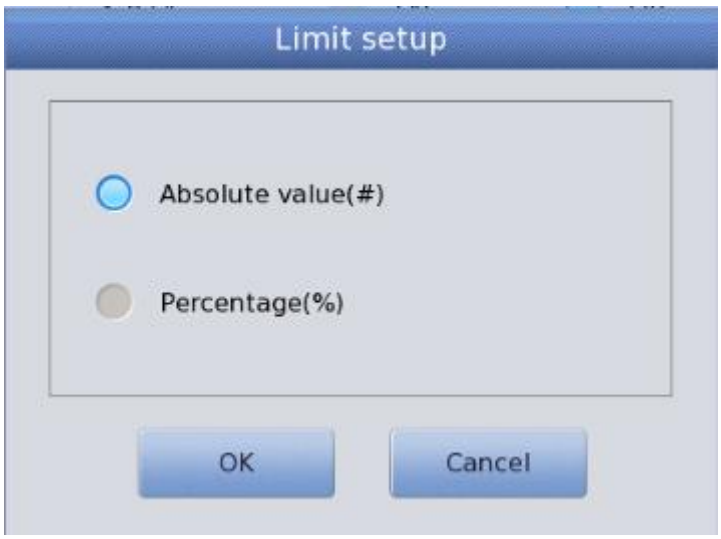


Figure 8-21 Limit Setup

The QC run interface displays two QC test results separately and automatically calculates twice 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.

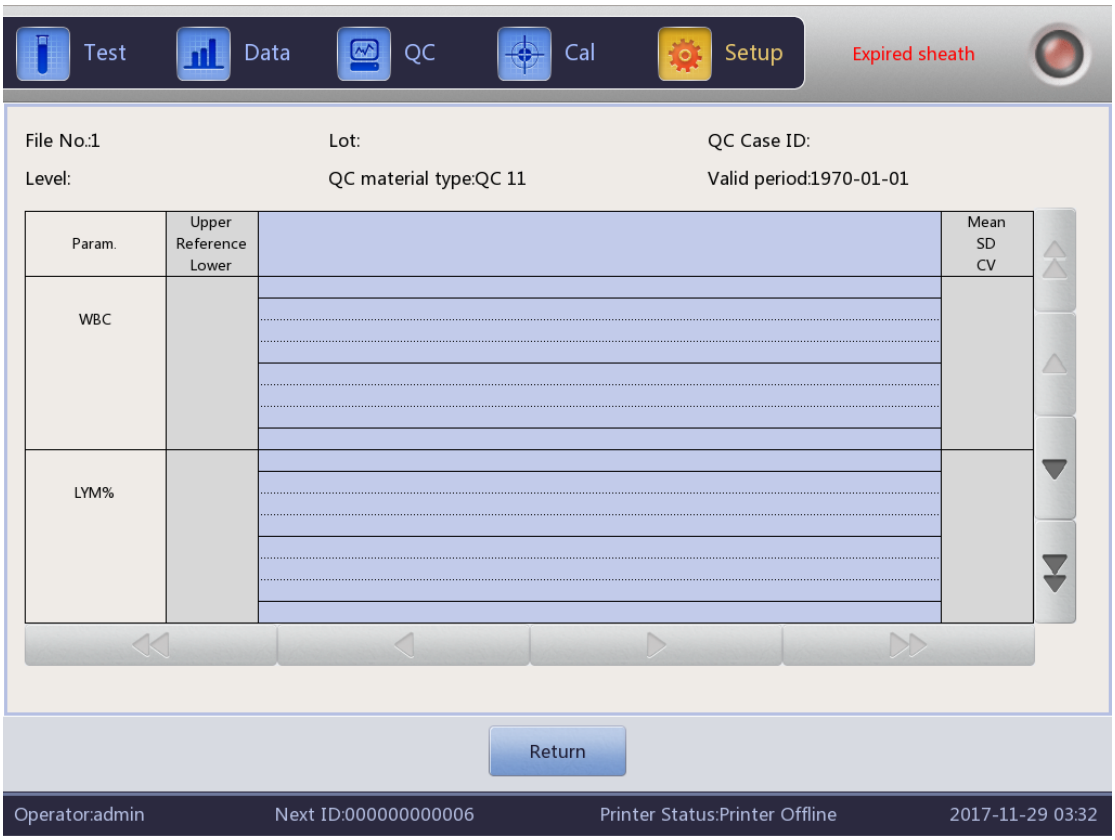


Figure 8-22 X QC Graph

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

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

QC graph Instruction

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

axis.

2. Every parameter graph displays 100 dots.
3. Above line of every parameter graph means Reference plus SD.
4. Below line of every parameter graph means Reference subtract SD.
5. The 3 values on the left side of parameter graph mean.

a) upper limit ——Reference + SD

b) middle line ——Reference

c) lower limit ——Reference - SD

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

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 reviewed in QC list. Click  ,  ,  ,  ,  ,  ,  and  to review test results.

9 Calibration

9.1 Overview

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

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

CAUTION

- Only calibrators recommended by URIT can be used to accomplish the calibration.
- Follow the use instruction to store and use calibrator.
- Check if the container is broken or cracked before using the calibrator.
- Make sure the calibrators are brought to room temperature and well mixed slowly before use.
- Make sure the calibrators are within the expiry date.
- Make sure the analyzer without problem and precision meet the requirement before calibration.
- Never apply to the laboratory or clinic use unless all the parameters are accurately calibrated.

NOTE

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

9.2 Calculation Frequency

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

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

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

 **WARNING**

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

9.3 Preparation

Before calibration, inspect the analyzer as the following requirements.

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

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 error.

4. Verify the accuracy of precision. Run continuous counting with mid-value control material or human blood for 11 times, take the results from the second to eleventh, and check CV in data interface. Make sure the CVs are accordance with Table 9-2.

Table 9-2 CV

Parameter	Range	CV
WBC	4.0 ×10^9/L ~15.0×10^9 /L	≤3.0%
RBC	3.00 ×10^12 /L ~6.00×10^12/L	≤2.0%
HGB	100 g/L ~180 g/L	≤2.0%
PLT	100 ×10^9 /L ~149×10^9 /L	≤6.0%
	150 ×10^9 /L ~500×10^9 /L	≤5.0%
HCT /	35%~50%	≤2.0%
MCV	70 fL ~120 fL	≤1.0%

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

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

Table 9-3 Carryover

Parameter	Result

WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.6%
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 value is 103% and mean value is 230, thus the new calibration value is

New calibration value =103%×220/230

=98.52%

Input calibration value after calculation and click “OK” to save it.

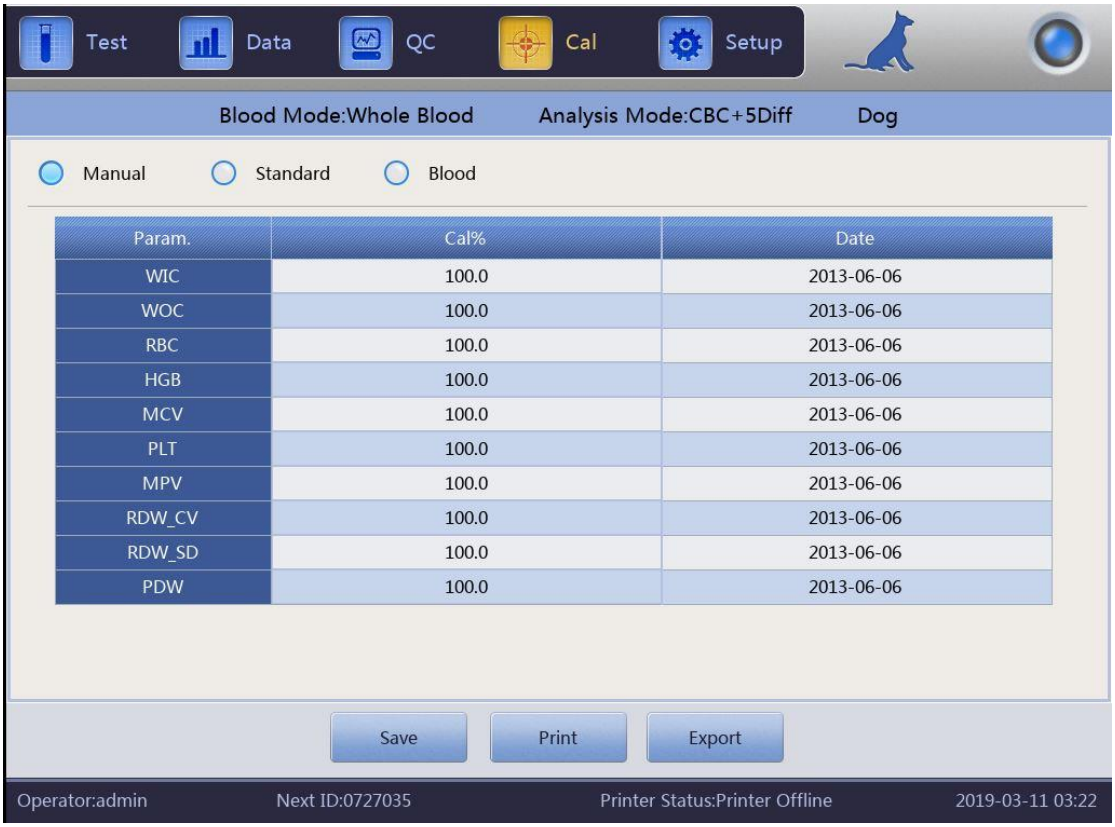


Figure 9-1 Manual Calibration

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

Click “Print” to print calibration value.

Click “Export” to export data sheet.

NOTE

- The analyzer can calibrate a certain or all parameters of WIC, WOC, RBC, HGB, MCV, MPV, RDW_CV, RDW_SD, PLT and PDW.
- Do remember click “OK” to save calibration value before exiting Cal interface.

Validation of Calibration coefficient

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

1. Test the calibrators three times, and check whether the results are within the allowed range.
2. Test level “High”, “Normal” and “Low”, and each of it should be tested for three times at least. Check whether the results are within the allowed range.
3. Analyze three normal fresh blood samples, three times for each at least.

NOTE

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

9.4.2 Standard Calibration

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

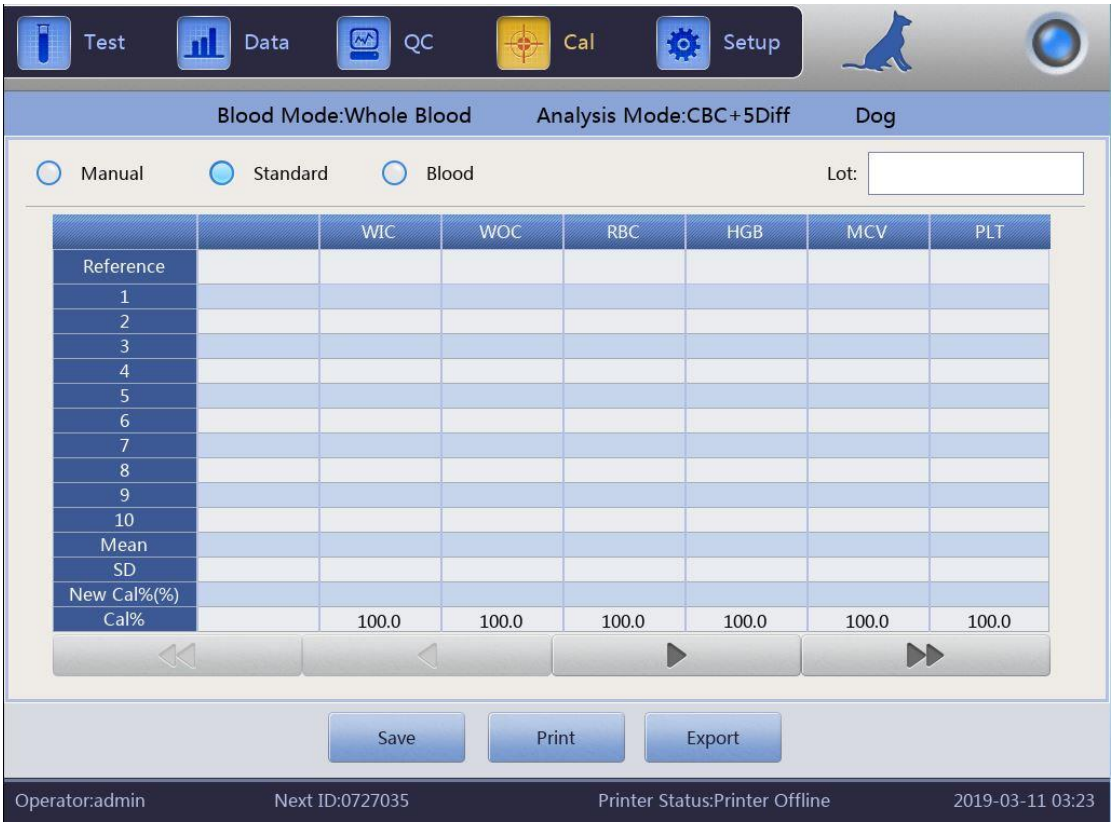


Figure 9-2 Standard Calibration

Please calibrate according to the following procedures.

1. Input batch number according to Operation Manual.
2. Input reference according to Operation Manual, those reference values of parameters which do not need to be calibrated is blank.
3. Click “Test” to start calibration. The analyzer could automatically calculate the mean value of 10 tests at most. URIT recommend testing 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 “OK” 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, URIT recommends to follow the steps to validate the calibration coefficients.

1. Test the calibrators three times, and check whether the results are within the allowed range.
2. Test level “High”, “Normal” and “Low”, and each of it should be tested for three times at least. Check whether the results are within the allowed range.
3. Analyze three normal fresh blood samples, three times for each at least. And check whether the results are within the allowed range.

Input reference in standard mode. Put the prepared calibrator under the sample probe and press button on the front housing. Counting starts and display test results in box. 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.

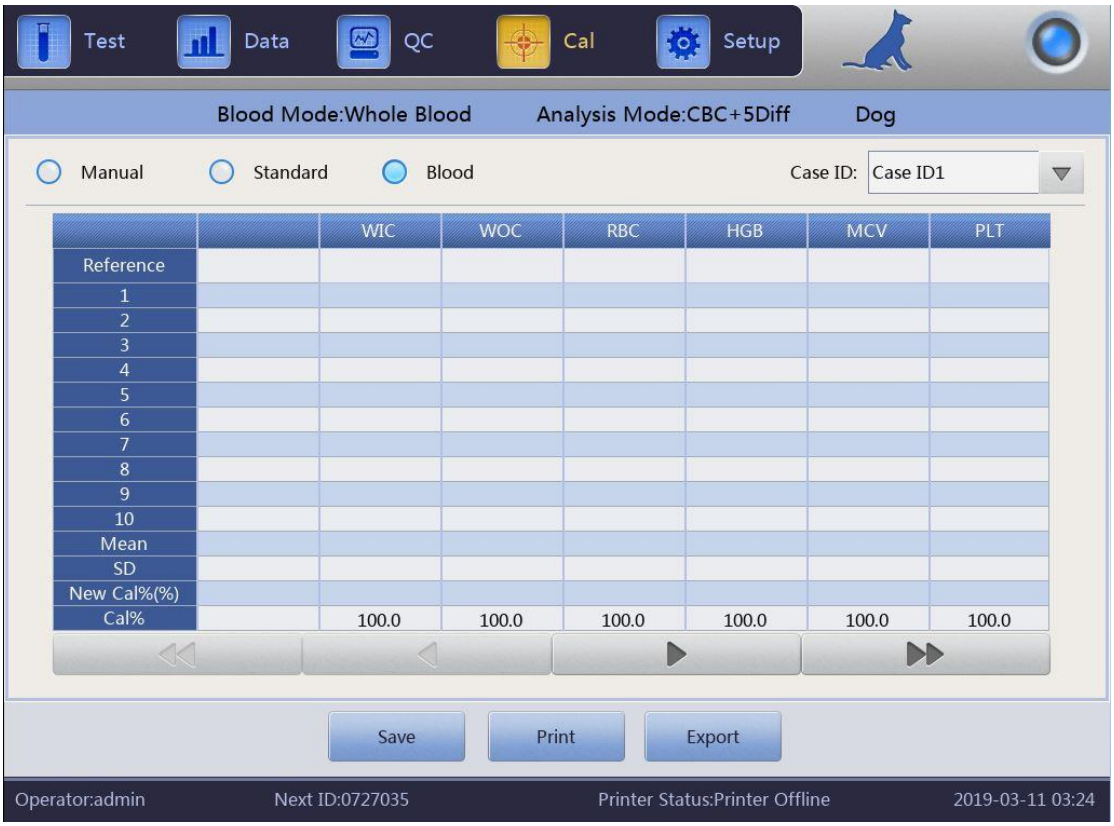


Figure 9-3 Blood Calibration

Calibrate the analyzer as follows.

1. Prepare 5 normal whole blood samples and test each of the prepared samples at least 5 times via other types of analyzer to get the mean and take the mean value as the reference value.
2. Select SN1 sample 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. Select SN 2 sample and make 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 via reference, mean value and calibration coefficient.
4. Click “OK” to save new calibration coefficient, click “Print” to print it.
5. Click “Export” to export the backup calibration coefficient data
6. Click “Save” to save the new calibration coefficient.

- 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 “OK” to save counting results before exit.

10 Maintenance and Care

10.1 Overview

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

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

 **WARNING**

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

---

10.2 Routine Maintenance

10.2.1 Daily Maintenance

1) Auto Clean

The analyzer is designed with auto clean program. Operator makes auto clean according to sample testing. Please make a blank test every day after boot. Choose "On" in "Auto blank". It's suggested to use "Soak and exit" and "Auto soak" if there's lots of samples to be tested. Operator chooses times to make auto soak. See Figure 10-1.

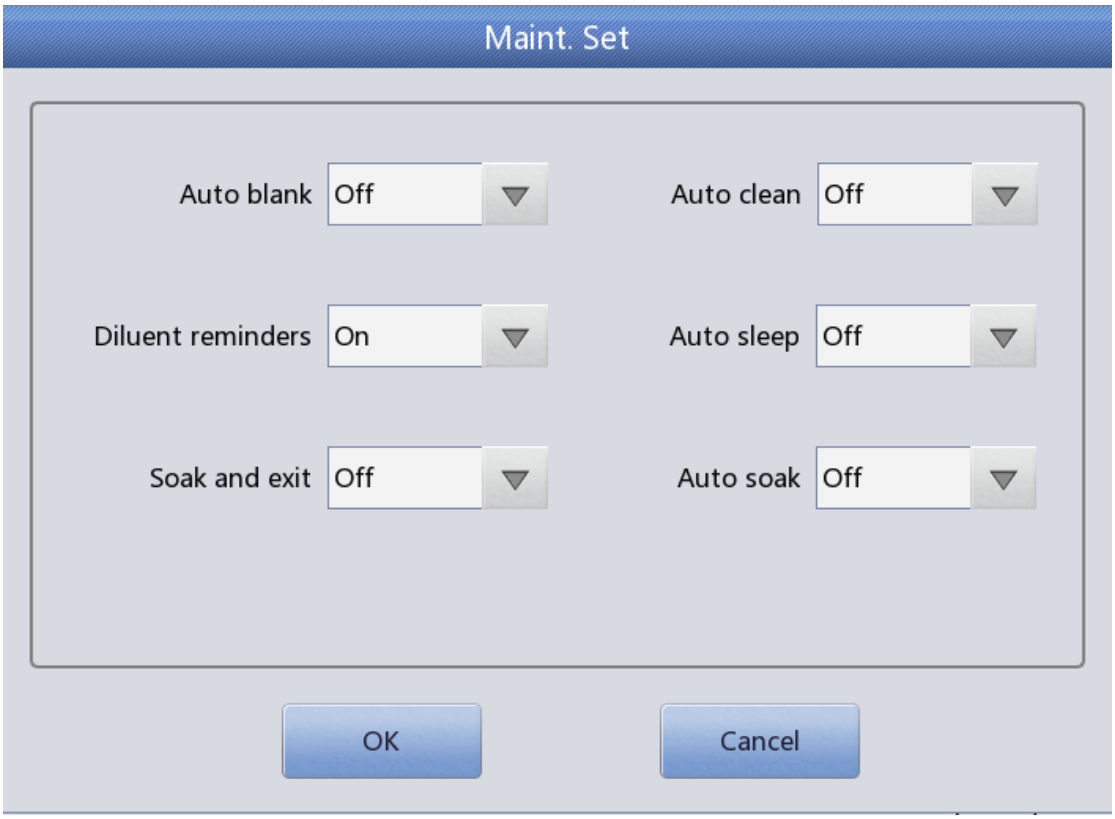


Figure 10-1 Maintenance

2) Shutoff

To get correct results, it's necessary to clean counting chambers and rinse the flow system to prevent measurement errors caused by residues. Shutoff program should be performed when the analyzer tests more than 500 specimens or finish today's work. 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 on the sample probe, which prevents protein deposition and mildewing. Wipe the surrounding area of probe and the probe with cleaning cloths soaked by neutral detergent.

CAUTION

- Never use corrosive acids, alkali or volatile organic solvent (such as acetone, aether and chloroforms) to wipe the outside of the analyzer, but only 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 and ensure to put it in correct position.

Materials Requirements

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

Clean Procedures

1) Empty the flow system.
2) Open the front housing and left door to find the syringe.
3) Pull the syringe out from the pluggable bracket.
4) Aspirate the deionized water into the syringe till full. Pull the piston until it is removed from the syringe tube.
5) Rinse the syringe piston and tube thoroughly with deinoized water. Replace the seal ring if it gets worn.
6) Carefully reinsert the piston into the wet syringe tube

7) When the syringe has been reinstalled, observe and run several times of blank test. The piston should move smoothly up and down and the syringe should not leak.

CAUTION

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

---

2) Maintenance of mechanical parts

It mainly aims at mechanism maintenance, including lubricate electricity axis, X guide rod of sampling unit and Y guide rod of sampling unit etc. See Figure 10-2.

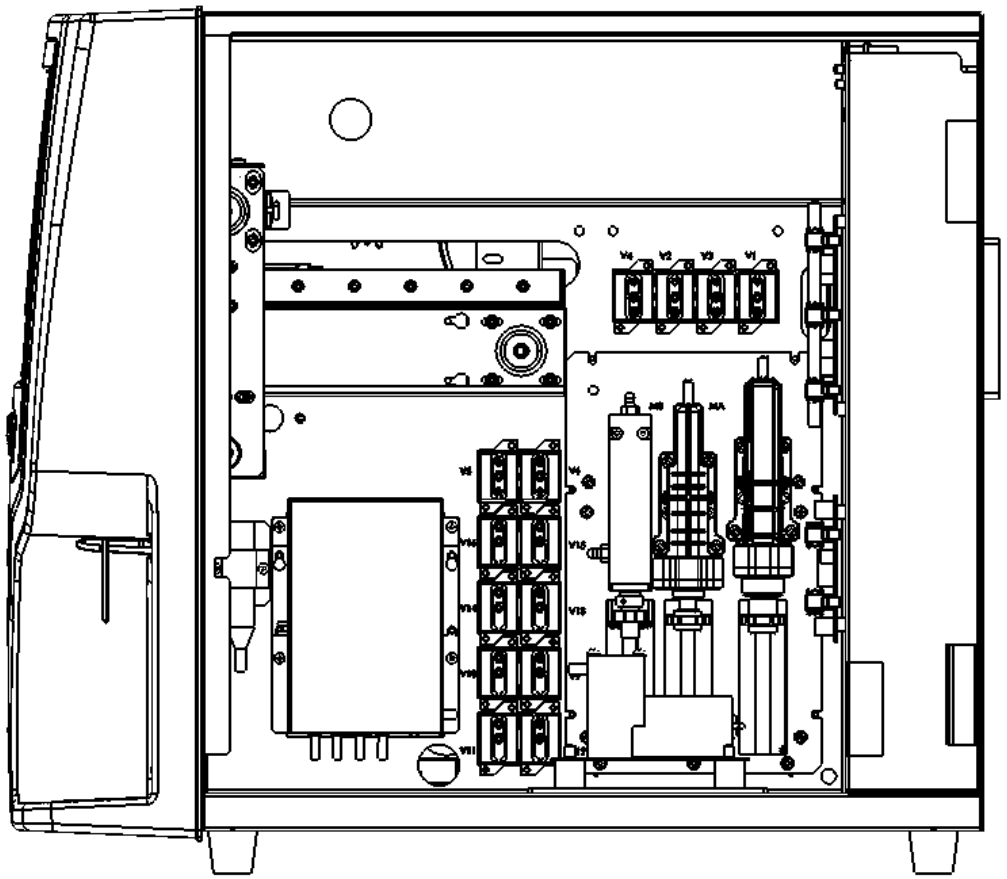


Figure 10-2 Maintenance of Mechanical Parts

10.3 Maintenance procedure

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

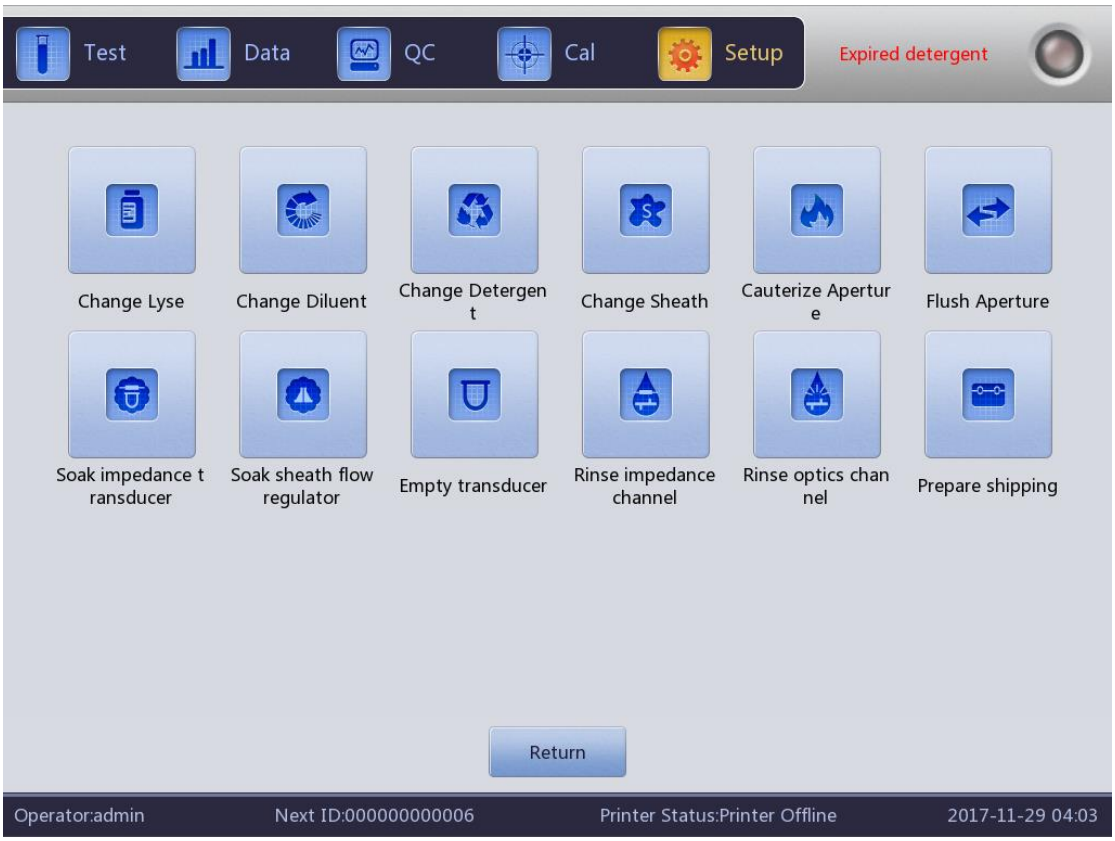


Figure 10-3 Maintenance Interface

Introduction to each above function 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 Prime 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

- Considering all the specimens, control materials, calibrators and waste

that contain human blood or serum as being potentially infectious, wear lab coats, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials.

NOTE

- Keep the reagent still for a certain time to ensure it stable.
- After replace the diluent, detergent, sheath or lyse, perform blank test 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 blockage. 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 clogging. 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 Sample Cup

 **WARNING**

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

It is used to soak impedance sample cup in probe cleaner. The procedures are as follows.

1. Click “Soak impedance sample cup” in the “Maint” interface.
2. The analyzer starts to performthe 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 Sample Cup” procedure in the MAINT interface, and then put the probe detergent under the sample probe, the analyzer will automatically inhale the probe detergent into the sample cup to soak the ruby aperture.

CAUTION

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

10.3.8 Prepare Shipping

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

1. Take out the diluent inlet tube connecting with the “DELUENT” on the rear panel from container.
2. Take out the lyse inlet tube connecting with the “LYSE” on the rear panel from container.
3. Take out the detergent inlet tube connecting with the “DETERGENT” on the rear panel from the container.
4. Take out the sheath inlet tube connecting with the “SHEATH” on the rear panel from container.
5. Keep all tubing well and store well.
6. Keep the remaining reagents in their containers and store them according to instructions. Operator should establish and confirm to the effective storage measures to prevent reagent from deteriorated, misusage or misdrinking. The reagent should be away from temperature extremes.
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 Other Maintenances

Empty transducer: empty liquid in the sample cups

Rinse impedance channel: clean impedance channel

Rinse optics channel: clean optics channel

Soak sheath flow regulator: soak the sheath flow regulator in probe cleaner

10.4 Components Maintenance

Time and required tools for Smart-V5 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 department or local agent for replacement if it needs components maintenance.

10.5 Components Replacement

Time and required tools for Smart-V5 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 department or local agent for replacement if it needs components replacement.

11 Troubleshooting

11.1 Overview

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

NOTE

- This manual is not the maintenance manual, this manual only provides the measures when the analyzer malfunction alarms.

WARNING

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

11.2 Troubleshooting Guidance

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

Please follow these three steps to do troubleshooting.

(1) Problem confirmation

(2) Problem classification

(3) Troubleshooting

Step1 Problem Confirmation

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

Step2 Problem Classification

Problems are divided into three types.

(1) Hardware-related failures

(2) Software-related failures

(3) Failures of sample analysis measurement

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

Step3 Troubleshooting

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

11.3 Obtaining Technical Assistance

Technical assistance is obtained by calling the URIT Customer Support Centre. When assistance is needed, please be prepared to provide the following information for Customer Support Specialists.

1. The analyzer model
2. Serial number and version number
3. Description of the problem and surroundings, including status and operation
4. The lot number of the reagents (sheath, diluent, lyse, etc.)
5. Related data and report of the problem

Familiar problems and handling methods are given in this Chapter. The operator can identify the cause according to the warning information and operate according to Troubleshooting Guidance.

11.4 Troubleshooting

Familiar problems and corrective actions are listed as follows. If the problems cannot be corrected, or technical assistance is needed, please contact our after-sale 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 department.
MB 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 department.
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 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 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 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. 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 department.
Expired diluent	Diluent is expired.	1.Click "Fault clearing" to clear faults automatically. 2.If the fault still exist, please contact our after-sale 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 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 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 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 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 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 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 department.。
WBC Clog	1.Aperture is clogged. 2.Tubes are bent. 3.Reagent replacement error.	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

	4.Solenoid valve problem.	after-sale 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 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 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 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 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 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 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 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 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 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 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 department.

Appendix

A Specifications

A.1 Reagents

Diluent, lyse, detergent and sheath. Please refer to *A.6 Reagent Specification* for details.

A.2 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.3 Technical Specifications

A.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	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.3.2 Test Speed

60 / hour

A.3.3 QC Modes

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

A.3.4 Calibration Modes

Standard Calibration
Blood Calibration
Manual Calibration

A.3.5 Parameters Measurement and Calculation

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

(2) Colorimetry 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.3.6 Input/output Devices

(1) Keyboard (optional)

(2) External barcode scanner (optional)

(3) External printer (optional)

CAUTION

- Be sure to use the specified devices only.

A.4 Physical Specifications

A.4.1 Power Requirements

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

A.4.2 Fuse

CAUTION

- Please use the specified specifications of fuse.

Fuse specifications: 250V T3.15AH

A.4.3 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.4.4 Sound pressure

Maximum sound pressure: 65 dBA

CAUTION

- Ensure to store and use the analyzer under specified environmental conditions.

A.4.5 Environment Requirements

(1) Temperature: 15°C~35°C

(2) Relative Humidity: 30~80％

(3) Barometric Pressure: 60kPa~106kPa

A.4.6 Storage Environment

(1) Temperature: -20°C~55°C

(2) Relative Humidity: ≤95%

(3) Barometric Pressure: 50kPa~106kPa

A.4.7 Size and Weight

(1) Length: about 508mm

(2) Height: about 412mm

(3) Width: about 270mm

(4) Weight: about 26Kg

A.4.8 Contraindications

NO

A.4.9 Overvoltage Category and Pollution Level

Overvoltage category: Class II

Pollution level: Level 2

A.4.10 Waste

Dispose the waste according to the national or local standards.

A.4.11 Minimum Sample Volume

Whole Blood Sampling Mode 20μL

Diluent Sampling Mode 20μL

A.4.12 Dilution Ratio

(1) WBC: approximately 1:111

(2) RBC/PLT approximately 1:24347

A.4.13 Diameter

(1) WBC: 100μm

(2) RBC/PLT: 68μm

A.4.14 HGB measurement

(1) Measure HGB in WBC/HGB cup

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

A.5 Performance Index

A.5.1 Precision

Parameter	Precision Range	Acceptable Limits (CV)
WBC	3.5×10^9/L ~15.0×10^9/L	≤3.0%
RBC	3.00×10^12/L ~6.00×10^12/L	≤2.0%
HGB	100 g/L ~180 g/L	≤2.0%
PLT	100×10^9/L ~149×10^9/L	≤6.0%
	150×10^9/L ~500×10^9/L	≤5.0%
HCT / MCV	35%~50%（HCT）/ 70fL ~120fL（MCV）	≤2.0% ≤1.0%

A.5.2 Linear Range

Parameter	Linear Range	Acceptable Limits	correlation coefficent R
WBC	0 ×10^9/L～10.0×10^9/L	±0.5 ×10^9/L	≥0.990

	10.1 $\times10^9$/L～400.0$\times10^9$/L	±6%	
RBC	0.10 $\times10^{12}$/L～1.00$\times10^{12}$/L	±0.06 $\times10^{12}$/L	≥0.990
	1.01 $\times10^{12}$/L～8.00$\times10^{12}$/L	±6%	
HGB	0 g/L～70 g/L	±3 g/L	≥0.990
	71 g/L～250 g/L	±3%	
PLT	0$\times10^9$/L1～100$\times10^9$/L	±15 $\times10^9$/L	≥0.990
	101 $\times10^9$/L～5000$\times10^9$/L	±12%	

A.5.3 Accuracy of WBC Classification

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

Note: when the test result of reference method is 0, and the test result of instrument is ≤1.0%, the test conclusion is qualified.

A.5.4 Carryover

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

A.5.5 Blank Test

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.5.6 Indication error

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

A.5.7 Display Range of Main Parameters

Parameter	Display Range
WBC	0～999 x 10^9/L
RBC	0～99 x 10^12/L
HGB	0～350g/L
HCT	0%～99%
PLT	0～5000 x 10^9/L

A.6 Reagent Specifications

Name	Specification
Diluent	20/10L/5L
Detergent	20/10L/5L
Sheath	20/10L/5L

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.7 Abnormal Results

All information for reference only.

Classification or abnormal shape alarm.

Alarm information	Interpretation	Measures
Abnormal WBC scatter diagram	WBC scatter diagram is abnormal.	Check stain smear in accordance with your laboratory inspection standard to see if abnormal WBC exists.
Neutropenia	Neu# < 1.00×10^9/L Low Neu count	Check stain smear in accordance with your laboratory inspection standard to see if abnormal WBC exists.
Neutrophilia	Neu# > 11.00×10^9/L High Neu count	Check stain smear according to your laboratory inspection standard to see if abnormal WBC exists.
Lymphopenia	Lym# < 0.80×10^9/L Low Lym count	Check stain smear in accordance with your laboratory inspection standard to see if abnormal WBC exists.
Lymphocytosis	Lym# > 4.00×10^9/L High Lym count	Check stain smear in accordance with your laboratory inspection standard to see if abnormal WBC exists.
Monocytosis	Mon# > 1.50×10^9/L High Mon count	Check stain smear in accordance with your laboratory inspection standard to see if abnormal WBC exists.

Eosinophilia	Eos# > 0.70×10^9/L High Eos	Check stain smear in accordance with your laboratory inspection standard to see if abnormal WBC exists.
Basophilia	Bas# > 0.20×10^9/L High Bas	Check stain smear in accordance with your laboratory inspection standard to see if abnormal WBC exists.
Leukopenia	WBC < 2.50×10^9/L Low WBC count	Check stain smear in accordance with your laboratory inspection standard to see if abnormal WBC exists.
Leukocytosis	WBC > 18.00×10^9/L High WBC count	Check stain smear in accordance with your laboratory inspection standard to see if abnormal WBC exists.
NRBC increase	NRBC：Nucleated red blood cells The following conditions may cause NRBC alarm: WIC count>WOC count, NRBC exist is suspectable.	Check stain smear according to your laboratory inspection standard to see if abnormal NRBC exists. If exist, they should quantify in accordance with your laboratory inspection standard. You don’s have to correct WBC count.If the WBC? and NRBC signs appear together, please test samples again in CBC+5DIFF+RRBC mode so as to remove interfering substances in any RRBC in which NRBC exist.
Immature erythrocyte	Immature erythrocyte might exist.	Check stain smear in accordance with inspection standard to see if immature erythrocyte exists.
RRBC appears	RRBC：Refractory red blood cells The following conditions may cause RRBC alarm: WOC count >WIC count, RRBC exist is suspectable.	Test samples again in CBC+5DIFF+RRBC mode so as to remove interfering substances in any possible RRBC.Select corresponding RBC value according to the instruction in description box. If WBC? sign appears, please check stain smear to determine the interference causes. Examine WBC value by transforming methods in accordance with your laboratory inspection standard.

Suspect WBC results	WBC sign indicates WBC result is suspect. 1.WBC exceeds linearity range. 2.There is clinical difference between WIC value and WOC value, and accurate WBC value cannot be determined by algorithm.	If NRBC and(or)RRBC sign appear with WBC? Together, please test samples again in CBC+5DIff+RRBC mode, so as to remove interfering substances caused by RRBC. If the sign still exists, please check the stained smear to see if NRBC exists which might affect WIC count, and examine LYM value. Examine WBC value by transforming methods in accordance with your laboratory inspection standard.
Abnormal WBC differential count	DFLT：Leukocyte categories abnormal (NLMEB：N＝NEU, L＝LYM, M＝MON, E=EOS, B＝BASO) The following conditions may cause DFLT alarm: 1.There is no detection of a low trough used to distinguish between the two cell populations areas. 2. The number of cells in a specific subgroup is abnormally low. Such as WBC increase & decrease, neutrophil increase & decrease, lymphocytes increase & decrease, eosinophils increase & decrease, basophils increase & decrease	Check stain smear and the verified subgroup's categorical measure by description box in accordance with your laboratory inspection standard.
Parasitic infected RBC?	RBC infected parasites might exist.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.

Parasitic infected RBC?	RBC infected parasites might exist.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Abnormal LYM?	There might be abnormal LYM.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Left shift?	Histogram shifts left.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Atypical LYM?	There might be atypical LYM.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Abnormal RBC size distribution	Height of histogram at parting line is over 20. Height of histogram at parting line is over 20. Histogram between parting lines distributes double peaks.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Bimodal RBC distribution	Histogram between parting lines distributes double peaks. RBC histogram has two or more histograms.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Abnormal RET distribution	scatter histogram distribution is abnormal.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
RETIC increase	RET% > 5% or RET# > 0.2×10^12/L High RET count	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.

Anisocytosis	RDW-SD > 65fL or RDW-CV > 20% Anisocytosis	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Microcytic RBC	MCV < 70fL Small MCV	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Macrocytic RBC	MCV > 110fL Large MCV	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Hypochromic	MCHC < 296g/L Low pigment	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Anemia	HGB < 100g/L Anemia	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Polycythemia	RBC > 6.5×10^12/L RBC increase	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
RBC aggregation?	RBC < 3.5×10^12/L and MCH > 34 pg Maybe prompt Macrocytic RBC or Abnormal RBC size distribution	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Chylemia affects HGB?	MCHC > 400g/L	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.

Iron deficiency?	MCV < 73fL and MCH < 21pg and MCHC < 320g/L Maybe hypoferric anemia	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Abnormal HGB?	MCV < 75fL and MCH < 25pg and RDW-SD < 45fL Maybe HGB anomaly or interference factors exist.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Fragmented RBC?	Abnormal output sign of PLT size distribution, and microcyte alarm. Doubt erythroclasis.	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Light β-thalassemia?	Judge by original signal and test results. Maybe anemia	Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Sideroblastic anemia?		Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Megaloblastic anemia?		Check stain smear to see if there is abnormal RBC value or PLT morphology in accordance with your laboratory inspection standard.
Abnormal PLT size distribution	Abnormal PLT size distribution	Check stain smear in accordance with your laboratory inspection standard, to see if there is abnormal value PLT morphology or PLT aggregation, and check PLT count.
Thrombocytopenia	PLT < 60×10^9/L Thrombocytopenia	Check stain smear in accordance with your laboratory inspection standard, to see if there is abnormal value PLT morphology or PLT aggregation, and check PLT count.

Thrombocytosis	PLT > 600×10^9/L Thrombocytosis	Check stain smear in accordance with your laboratory inspection standard, to see if there is abnormal value PLT morphology or PLT aggregation, and check PLT count.
PLT aggregation?	Calculate and compare special analysis parameters PLT aggregation may appear.	Check stain smear in accordance with your laboratory inspection standard, to see if there is abnormal value PLT morphology or PLT aggregation, and check PLT count.

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 which check digit

CE code element

CM composite

CQ composite quantity with units

DR date time range

DT data

DLN driver’s license number

EI entity identifier

HD hierarchic designator

FN family name

FT formatter text

IS coded value for user-defined tables

ID coded values for HL7 tables

JCC job code

NM numeric

PT processing type

PL person location

ST string

SI sequence ID

TS time stamp

TQ timing quantity

TX text data

XAD extended address

XCN extended composite ID number and name

XON extended composite name and ID number for organizations

XPN extended person name

XTN extended telecommunications number

VID version identifier

B.3 Field Meaning

B.3.1 MSH

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

The meaning of MSH is shown as below

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

17				Retain
18	Encoder	ST		Encoding is UNICODE

MSH-10	Description
0001	Analyzertransmits results automatically.
1001	LIS responses, analyzertransmits results automatically.

Example: MSH|^~\&|URIT |Smart-V5|LIS|PC|20100930100436||ORU^R01|0001|P|2.3.1|1||||UNICODE

B.3.2 PID--- Definition of animal data field

No.	Field	Data Type	Length	Explanation
1	Set ID PID	SI	4	Identify different fields, fill with 1 generally.
2	Patient ID	EI	20	Patient ID., hospital No., set null
3	Patient Identifier List	CX	20	Indicate batch number when QC
4	Alternate Patient ID	CX	20	Bed No.
5	Patient Name	XPN	48	Name
6	Mother’s Maiden Name	XPN	48	Mother’s Maiden Name, set null
7	Date/Time of Birth	TS	26	Birthday；Indicate validity when QC
8	Sex	IS	1	Male or female
9	Patient Alias	XPN	48	Retain patient alias

10	Race	CE	80	Retain race
11	Patient Address	XAD	106	Retain patient address
12	County Code	IS	4	Retain county code
13	Phone Number	XTN	40	Retain phone No.
13	Phone Number Bus	XTN	40	Retain office phone No.
14	Primary Language	CE	60	Retain mother tongue
15	Marital Status	CE	80	Retain Marital Status
16	Religion	CE	80	Retain religion
…	The rest part is not needed to be filled.			

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

B.3.3 PV1---Definition of animal 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 |

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

No.	Field	Data Type	Length	Explanation
1	Set ID OBR	SI	4	Identify different fields, fill with 1

				generally.
2	Placer Order Number	EI	22	Serial number
3	Assigned Patient Location	EI	22	Sample number
4	Universal Service ID	CE	200	Universal service ID
5	Priority	ID	2	Priority set null
6	Requested Date Time	TS	26	Application time
7	Observation Date Time	TS	26	Inspection starting time, set null
8	Observation Date Time end	TS	26	Inspection end time
9	Collection Volume	CQ	20	Specimen collection capacity, set null
10	Collector Identifier	XCN	60	Sender name
11	SPE Action Code	ID	1	Sample handling code, set null
12	Danger Code	CE	60	Danger code alarm
13	Relevant Clinical Info	ST	200	"Diagnosis" ^ "Remark", each length should not be more than 100 bytes
14	SPE Received Date Time	TS	26	Sample receiving time
15	SPE Source	CM	300	Sample classification, blood, urine etc.
16	Ordering Provider	XCN	120	Inspector name
17	Order Callback Phone Number	XTN	40	Callback phone, set null
18	Placer Field1	ST	60	Sender field 1, Inspection department

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

Example：

OBR|1|1010051|000001|URIT^Smart-V5||20101010093000||20101010093500||sender||| diagnosis^remark||BLD|Inspector||||||||||verifier|

B.3.5 OBX

No.	Field	Data Type	Length	Explanation
1	Set ID OBX	SI	4	Identify different fields, fill with 1 generally.
2	Value Type	ID	3	NM means figure type, ST means value type
3	Observation Identifier	CE	590	Observe identifier name
4	Observation Sub ID	ST	20	Observe sub-id project name
5	Observation value	ST	65535	Check result
6	Units	CE	90	Unit
7	References Range	ST	90	Reference range is from small to big, QC means reference value and SD.
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 is clogged, B indicates bubble, when normal, set null
11	Observe Status	ID	1	Observe results, take F for final result.
12	Date Last Observe	TS	26	The time for observing normal value, set null
13	User Defined Access Checks	ST	20	Original results

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

B.3.6 MSA

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

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

MSA-1	MSA-6	MSA-3	False Description
AA	0	Message accepted	Receive successfully
AE	101	Segment sequence error	The fields order in message is not correct, or the necessary fields are lost.
	102	Required field missing	Necessary fields of a paragraph are lost.
	103	Data type error	Data type of fields is false. For example, digital is changed into character.
	104	Key not found	Key identifier is not found
	105	Resend	Resend data
AR	201	Unsupported message type	Unsupported message type
	202	Unsupported event code	Unsupported event code
	203	Unsupported processing id	Unsupported processing ID
	204	Unsupported version id	Unsupported version ID
	205	Unknown key identifier	Unknown key identifier，For example, transmit an inexistent patient information.
	206	Duplicate key identifier	Duplicate key identifier
	207	Application record locked	Affairs in application storage level can't be carried out. For example, database is locked
	208	Application internal error	Other errors in unknown application.

	209	Application unready	Application is not ready

B.3.7 ERR

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

ERR-1

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

B.3.8 QRD

No.	Field	Data Type	Length	Explanation
1	Query Date/Time	TS	26	Query time
2	Query Format Code	ID	1	D （display format）
3	Query Priority	ID	1	I（Immediate）
4	Query ID	ST	10	Distinguish different queries ,accumulate with query times. The initial value is 1.

5	Deferred Response Type	ID	1	Set null
6	Deferred Response Date/Time	TS	26	Set null
7	Quantity Limited Request	CQ	10	RD（Records）
8	Who Subject Filter	XCN	60	Take as a test tube code \ sample number.
9	What Subject Filter	CE	60	OTH
10	What Department Data Code	CE	60	Set null
11	What Data Code Value Qual.	CM	20	Set null
12	Query Results Level	ID	1	

B.3.9 QRF

No.	Field	Data Type	Length	Explanation
1	Where Subject Filter	ST	20	Smart-V5
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

B.3.10 QSP

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

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

Set ID – DSP	Message
1	Sample SN
2	Name
3	Gender
4	Age
5	Blood type
6	Group
7	Patient Number
8	Bed Number
9	Patient Type

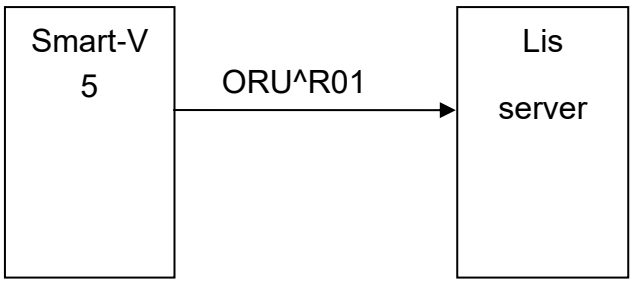
10	Department
11	Sender
12	Inspector
13	Auditor
14	BLDV is for venous blood, BLDC is for peripheral blood.
15	Remark
16	Sampling time, sending time
17	inspection time

Example

DSP|1||Mary||<CR>

B.4 Communication process

B.4.1 Analyzer transmits test results to lis server



<SB>

MSH

PID

PV1

OBR

OBX

OBX

……

<EB><CR>

OBX fields can be repeated. Transmitted test results include patient information, 28 parameters, 2 histograms and 2 scatter diagrams. The 2 histograms and 2 scatter diagrams are BMP format and transmitted with base64 code.

For example：

Analyzer transmits test results to lis server

<SB>

MSH|^~\&|URIT|Smart-V5|LIS|PC|20110627144458||ORU^R01|0001|P|2.3.1|||||UNICODE<CR>

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

PV1|1|||<CR>

OBR|1||BAR101010101|URIT^AUTO ANALIZADOR HEMATOLÓGICO 5 DIF Smart-V5||||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||Smart-V5^Image^BMP^Base64^Qk32lgMAAA……<CR>

OBX|26|ED|PLTHistogram|Smart-V5 ^Image^BMP^Base64^Qk32lgMAAA……<CR>

OBX|27|ED|S0_S10DIFFScattergram||Smart-V5 ^Image^BMP^Base64^Qk32lgMAAA……<CR>

OBX|28|ED|S90_S90DDIFFScattergram||Smart-V5^Image^BMP^Base64^Qk32lgMAAA……<CR>

<EB><CR>

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.

Memo：Printed circuit board Assembly is consist of printed circuit board, capacitance, connector and other parts. Lithium cell is detachable and recyclable part.

Pollution control signs of electronic information products

The electronic information products sold in the territory of the People's Republic of China must mark this mark, and the numbers in the mark represent the environment-friendly use period of the product under normal use.

D Daily Operation Procedure

D.1 Startup and Run

(1) Make sure the power cord 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 test 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) 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 sample cup" 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 sample 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 clogged severely, please select “Clean Sample cup” procedure in the MAINT interface, and then put the probe detergent under the sample probe, and then according to the prompt dialog box to operate, and then the analyzer will automatically inhale the probe detergent into the sample cup to soak the counting hole.

E Key Components

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

F Attachment list

NO.	Name	Unit	Quantity
1	Operation Manual of Smart-V5 5-Part-Diff Automated Hematology Analyzer	Piece	1
2	Power cord	Piece	1
3	Ground wire	Piece	1
4	BNC Waste detection line*1 Waste outlet tube*1	Piece	2
5	Disposable plastic test tube	Piece	200
6	Fuse T3.15AL 250V	Piece	2
7	Diluent inlet tube	Piece	1
8	Lyse inlet tube	Piece	1
9	Sheath inlet tube	Piece	1
10	Detergent inlet tube	Piece	1
11	Rubber drum	Piece	1
12	Concentrated Probe Cleaner（100mL）	Bottle	1
13	Grease	Piece	1
14	Filter	Piece	2
15	sealing ring of large needle tube	Piece	2
16	sealing ring of small needle tube	Piece	2
17	Card sets of product maintenance records	Piece	1
18	URIT maintenance record card	Piece	1
19	rubber bucket lid wrench	Piece	1