



# **Auto Animal Hematology Analyzer**

**BK-3100VET**

**User Manual**

**Kyntel**

**Version 2023**



## How to Use this Manual

Thanks for choosing our product, our company proudly provides you with full-life cycle services including technical support, spare parts support, training, etc.

For best use, you must be fully familiar with the analyzer and its capabilities before conducting clinical diagnostic testing. This manual is the guide of BK-3100VET Auto Animal Hematology Analyzer, including installation, daily testing, quality control and daily maintenance.

**Warning:** This analyzer should not be installed or used by untrained or unauthorized personnel.

Different versions or configurations of the device have slightly different functions. This manual would be changed without notice due to the upgrade of the device version or configuration. If you have any questions during use, please contact our customer center or dealer.

|                |                                                                                                                  |
|----------------|------------------------------------------------------------------------------------------------------------------|
| <b>Caution</b> | Tips, advice or suggestions.                                                                                     |
| <b>Warning</b> | Precautions that must be strictly followed to ensure proper operation of the analyzer and accurate test results. |

### Statement

The pictures provided in this manual are only examples and may not be exactly the same as the actual product, and are for reference only. This manual should not be used for other purposes. Without the written consent of our company, no individual or organization can copy, modify or translate the contents of this manual.

Our company is responsible for the safety, reliability and performance of the product only when all the following requirements are met, namely:

- The assembly operations, re-commissioning, expansion, improvement, and maintenance are all carried out by company-approved personnel.
- Operate the device according to this manual.
- The relevant electrical equipment complies with national standards.



#### Caution

- This analyzer must be used by medical laboratory professionals or by trained physicians, nurses or laboratory technicians.



#### Warning

- If the user fails to implement a satisfactory maintenance/repair plan, it may cause the analyzer failure and may endanger personal health.
- Make sure that the analyzer is used under the conditions specified in the manual. If the operating conditions are exceeded, the analyzer may not operate normally, the measurement results would be unreliable, and it may even damage the analyzer components and cause harm to individuals.

## Warnings and Safety Tips

**For scientific research use only,** please read carefully and strictly observe the following regulations before use.

### Warning:

- If abnormal smell or smoke appear, immediately cut off the power and unplug the power cord. In this case, without hesitation apply for inspection to the dealer or our service center. Otherwise, it may result in fire, electric shock, or injury.
- Blood, reagents, metal parts such as staples or pins should not be found in the device. Otherwise, a short circuit or fire may result. If an abnormality occurs, immediately cut off the power supply and unplug the power cord. In this case, apply for inspection to the dealer or our company's service center.
- Do not touch the electronic circuits in the device, especially with wet hands, which may cause electric shock.
- Wear medical protective gloves and use the specified tools and parts when maintaining and inspecting the device. After work, disinfect your hands to prevent possible infections.
- Be very careful and wear medical protective gloves to avoid infection when handling samples. If the specimen gets into the eyes or wounds, rinse immediately with plenty of water and get checked by a doctor.
- Wear medical protective gloves before using.

## Transportation & installation of devices

- Do not squeeze or invert the device during transportation.
- Please consult the dealer or our service center if you install it for the first time or do not know how to install.
- The device should be placed on a flat and stable work surface that is larger than its bottom area, with at least a 100mm space between the front, rear, left and right edges.
- The power cord, earth wire, relevant reagent bottles and barrels should be connected strictly according to the markings on the device to ensure that the relevant connecting pipelines are unimpeded.

## Use of reagents

If the reagent gets into the eyes, rinse immediately with plenty of water and get checked by a doctor.

If you drink the reagent by mistake, you should seek medical help immediately, and drink plenty of water to spit out the reagent.

If the reagent splashes on your hands or skin, wash it off immediately with clean water.

Wastes such as used test tubes and other device consumables should be disposed of in accordance with the relevant requirements for medical wastes or infectious wastes, and should not be discarded at will. Otherwise there is a risk of biological infection.

When changing reagents, take necessary precautions.

## Power connection and earthing

Do not insert the power cord into a outlet that is not AC 220V/110V, otherwise it may cause fire or electric shock.

When installing the device, the user must use the power cable and power adapter packed with the device, and ensure that the grounding cable of the shell is well connected. Otherwise, it may cause fire or electric shock, resulting in inaccurate results.

Do not damage the insulating protective cover of the power cord, do not pull the power cord or pile heavy objects on it, otherwise it may cause a short circuit or open circuit, resulting in electric shock or fire.

When the device is connected to peripheral devices, be sure to cut off the power first, otherwise it may cause electric shock or malfunction.

Do not open the flank cover or panel during power on, otherwise it may cause damage to some sensitive components.

**Warning:** The Pharmaceutical Affairs Law prohibits the modification of medical equipment.

## Product Information Overview

**[Product Name]** Auto Animal Hematology Analyzer

**[Model and Specification]** BK-3100VET

**[Product Composition]** The device consists of aspirating buttons, aspirating components, WBC and RBC counting cells, waste valve modules, negative pressure pump components, aspirating pump components, liquid inlet valve modules, thermal printers, displays, keyboards (optional), mouse, control circuit and supporting software.

**[Range of application]** BK-3100VET Auto Animal Hematology Analyzer can be applied for detecting blood samples for blood cells (RBC, WBC, PLT) count, WBC three classification, hemoglobin concentration measurement and blood cell related parameter information calculation.

**[Contraindications]** None

**[Transportation & Storage]** Packaging and transportation conditions are required by the contract.

**[Production date]** See product label.

**[Period of use]** 8 years

**[Registrant\Manufacturer]** KYNTEL



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# 1 Manual Overview

## 1.1 Overview

This chapter tells how to use this manual. This manual is shipped with the device. It describes the purpose, function and operation of the hematology analyzer in detail.

Before using the hematology analyzer, please read this manual carefully to use the analyzer in a correct way for its best performance, and the safety of users.

## 1.2 Application Scope of the Manual

This manual is prepared for medical laboratory professionals, doctors, nurses or laboratory technicians to read:

- Learn about the hardware and software of the hematology analyzer.
- Set system parameters.
- Conduct daily operations.
- Carry out system maintenance and troubleshooting.

## 1.3 Sign

The following signs are used in this manual to indicate hazards or important information.

| Signs                                                                               | Interpretation                                                                                                                                                             |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Biological risks:<br>To remind the user to follow the instructions, otherwise there is a risk of potential biological contagion.                                           |
|  | Warning:<br>To remind the user to follow the instructions, otherwise it may cause personal injury.                                                                         |
|  | Caution:<br>To remind the user to follow the instructions, otherwise it may cause product failure, damage or influence the test results.                                   |
|  | To remind the user to follow the following steps, to emphasize the important information in the operation steps or the content that requires the user's special attention. |
|  | Risk of puncturing:<br>Sampling probes are sharp and may contain biological hazards. Take care!                                                                            |

The analyzer or the outer packaging may contain the following labels or symbols.

## NOTICE

- When using the analyzer, if the user find that the label is damaged or falls off, please contact the company or the agent to replace it in time.
- All graphics provided in this manual are only examples and should not be used for other purposes. The symbols or titles shown in the illustrations may not be exactly the same as the actual display you see on the hematology analyzer.

| Signs                                                                               | Interpretation            |
|-------------------------------------------------------------------------------------|---------------------------|
|    | Warning                   |
|    | Biological risks          |
|    | Prevent puncturing        |
|    | Protectively earth        |
|   | Manufacturer              |
|  | Keep away from rain       |
|  | Do not roll               |
|  | This way up               |
|  | Fragile, handle with care |

## 1.4 Security Information

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### Biological risks

- All items (such as samples, QCs, calibrators, reagents, waste fluids, etc) and areas where they are placed have potential dangers of bio-infections. When users touch the above items or areas in the laboratory, they should abide by the laboratory safety operation regulations and wear personal protective outfit (such as laboratory protective clothing, gloves, masks, etc).
  - In the event of a leak from the device, the leaking liquid is a biologically contagious hazard.
- 



### Warning

- Check all doors/covers/plates before running the device and make sure they would not be opened or loosened while the device is running.
  - Please use all safety measures provided by the device. Any safety device or safety sensor can not be stop from servicing.
  - Be sure to immediately respond to and handle prompts and failure messages.
  - Don't touch any running parts.
  - If there is any damage to the device, please be sure to notify our service center or agent in time.
  - Be careful when opening or closing doors/covers/panels.
  - Dispose of the equipment in accordance with local regulations.
  - Pay attention during operation to avoid being scratched or punctured by the sampling probe.
- 



### Caution

- Be sure to use this device exactly as directed in the manual.
  - Take appropriate measures to prevent reagent contamination.
-

# 2 Device Installation

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## 2.1 Overview

---



### Warning

Unpacking or installation by personnel not authorized or trained by the company may result in personal injury or damage to the analyzer. Therefore, do not unpack or install the analyzer without the help of authorized company personnel.

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### NOTICE

- In order to avoid damage to the sampling module during transportation, the sampling module is fixed with cable ties before leaving the factory, before using the device please cut the cable ties firstly.
- 

This product has been strictly tested before leaving the factory to ensure the good appearance and performance. To avoid shocks during shipping, the analyzer is carefully packaged before shipping. When the analyzer arrives, please carefully check its packaging. If there is any damage, please contact the company service center or local agent immediately.

## 2.2 Installation Personnel

The hematology analyzer can only be installed by the company's engineers or its authorized agents, and the user needs to provide the appropriate installation environment. When the analyzer needs to be moved, please contact the company or local agent.

## 2.3 Inspection for Damage

All products have undergone strict factory inspection before packaging and transportation. When receiving the product, please check carefully before unpacking, and pay attention to the following damages:

- Inverted or deformed packaging.
- Damp packaging.
- Stricken packaging.
- Seemingly opened packaging.

Immediately notify the local agent if any of the above-mentioned damages are found.

If the packaging is in good condition, please open with the help of the agent or company professional technicians, and check:

- Check that all accessories are complete according to the packing list in the box.
- Carefully inspect the appearance of all accessories for cracks, sags, or deformation.

## 2.4 Installation Requirements



### Warning

- The analyzer must be well ground connected.
- Before starting the analyzer, make sure that the input voltage meets the requirements.



### Caution

- Using a power strip may generate electrical interference and cause inaccurate analysis results. Place the analyzer near a power outlet rather than connecting a power strip.
- Please use the power cord provided in the accessory box. Using other power cords may damage the analyzer or cause inaccurate analysis results.

The installation requirements are listed in the table below.

| Installation Environment     | Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Site                         | <ul style="list-style-type: none"> <li>● The ground must be even. The operating table must be stable and firm, and the bearing capacity should be <math>\geq 100\text{kg}</math>.</li> <li>● Dust-free, no vibration, heat and wind source, no pollution, no loud noise source and power supply interference.</li> <li>● Avoid direct sunlight and have good ventilation.</li> <li>● It is recommended to evaluate the electromagnetic environment of the laboratory before operating the equipment.</li> <li>● Do not place the device close to strong electromagnetic interference sources, so as not to affect the normal operation of the equipment, and have a good protective earth environment.</li> </ul> |
| Space                        | <ul style="list-style-type: none"> <li>● The reserved space between the left/right side of the analyzer and the wall should be <math>\geq 100\text{cm}</math>.</li> <li>● The reserved space between the rear side of the analyzer and the wall is <math>\geq 50\text{cm}</math>.</li> <li>● Make sure that there is enough space near the device to place the diluent and waste barrel.</li> <li>● Place the analyzer as close to the power outlet as possible and leave the surrounding clear so that the plug can be unplugged in time.</li> </ul>                                                                                                                                                             |
| Temperature                  | $10^{\circ}\text{C} \sim 40^{\circ}\text{C}$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Relative humidity            | $\leq 80\%\text{RH}$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Atmospheric pressure         | $86.0\text{kPa} \sim 106.0\text{kPa}$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Ventilation                  | The air circulation should be settled. The wind should not blow directly to the analyzer.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Power supply                 | $\text{AC}100\text{V} \sim 240\text{V}$ , input power $\leq 150\text{VA}$ , 50/60HZ                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| External keyboard (optional) | <ul style="list-style-type: none"> <li>● Meet the appropriate safety requirements.</li> <li>● USB interface.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

| Installation Environment | Requirement                                                                                                                        |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Electromagnetic waves    | Keep away from brushed motors, flashing fluorescent lamps, and electrical contact devices that are frequently switched on and off. |
| Waste treatment          | Waste discharge follows the local requirements.                                                                                    |

## 2.5 Unpack

Please follow the steps below to unpack:

1. Open the packaging, take out the accessory box, and the analyzer together with the protective shock-absorbing material.
2. Remove protective materials such as foam and PE bags.
3. Take the device out from its package. Please place it on an even workbench.
4. Take the key from the accessory box, please open its right door with the key, as shown in Figure 2-1.
5. Open the right door (the key is in the accessory box).
6. Cut the three ties shown in figure 2-2.

**Note:** ① Avoid scratching the belt; ② Before the device is powered on, please check whether the ties are removed!

In order to prevent collision and vibration during transportation, the two motors are fixed with cable ties before leaving the factory. When unpacking, the cable ties on the motors must be removed.



Figure 2-1

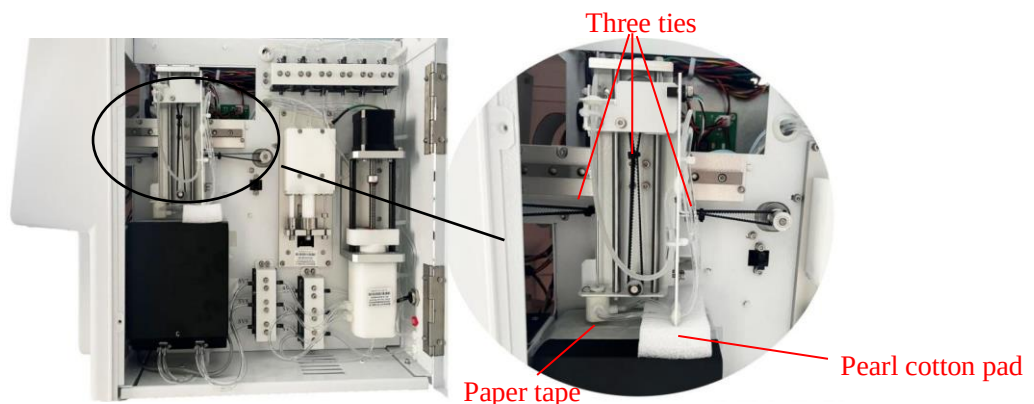


Figure 2-2

7. Pull out the pearl cotton pad to the front right and tear off the paper tape on the counting pool shield shell, as shown in Figure 2-2.

**Note:** ① Avoid foreign matter falling into the shielding shell; ② Before the instrument is powered on, please check whether the pearl cotton pad and paper tape are removed!

8. Install and lock the right door and well keep the key for use in the future.

9. Install and operate the device according to "2 Device Installation".

## 2.6 System Connection

### 2.6.1 Electrical Connections & Reagent Connections



#### Caution

- Please make sure that the length of the diluent and waste tubes used does not exceed 1500mm.
- Tighten the connector of the reagent pipeline, and the whole reagent pipeline is sealed at this time, which can prevent the leakage and seepage caused by siphon.

Referring to Figure 2-3, connect the electrical and reagent to the analyzer.

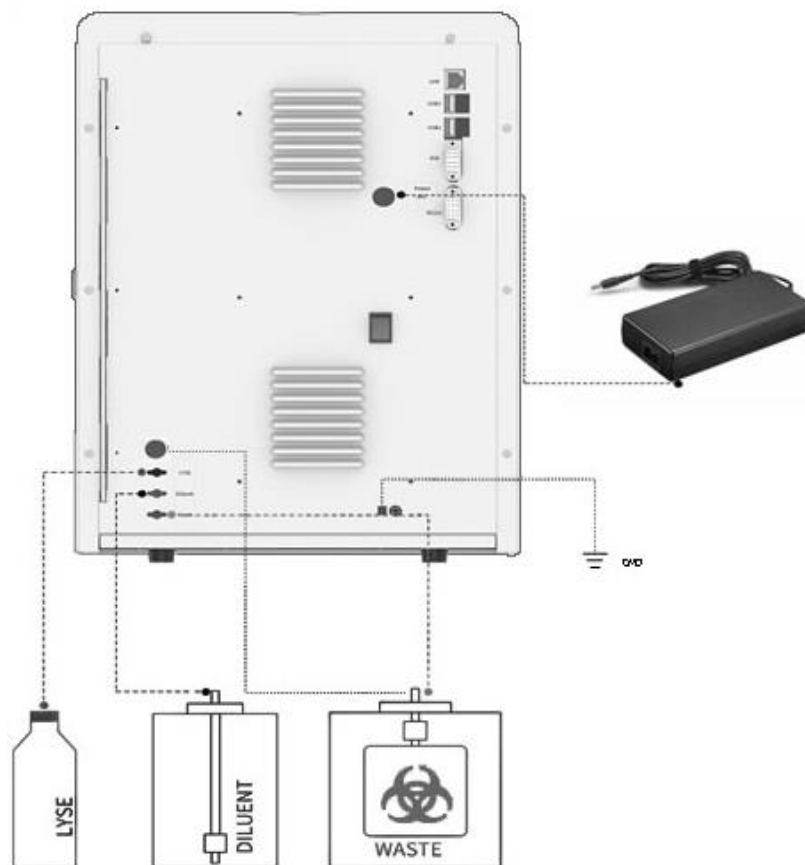


Figure 2-3 Electrical and reagent connection

### 2.6.2 Overall Structure

The analyzer is mainly composed of analysis module, information management module and result output module.

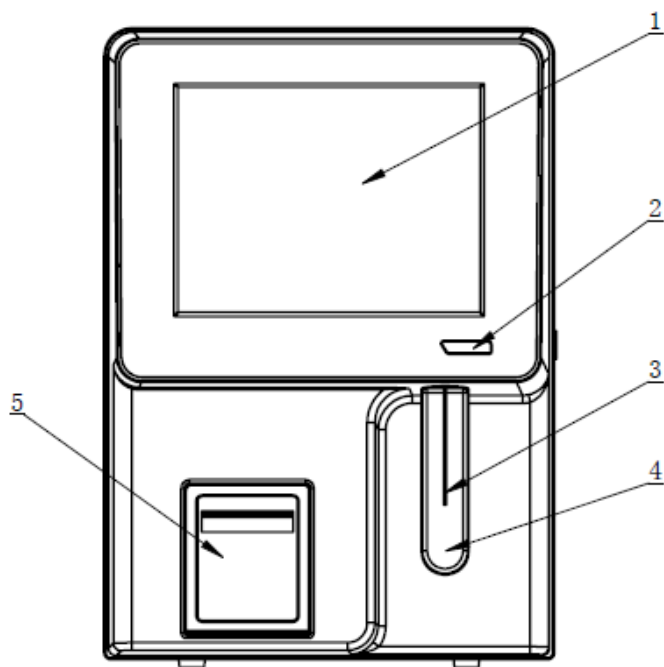


Figure 2-4 Front view

| No. | Name            | Remark                                                    |
|-----|-----------------|-----------------------------------------------------------|
| 1   | Screen          | Interface operation and display.                          |
| 2   | Indicator       | Indicate device status.                                   |
| 3   | Sampling probe  | Draw samples.                                             |
| 4   | Aspirate button | Press the button and the sampling probe draws the sample. |
| 5   | Printer         | Print result.                                             |

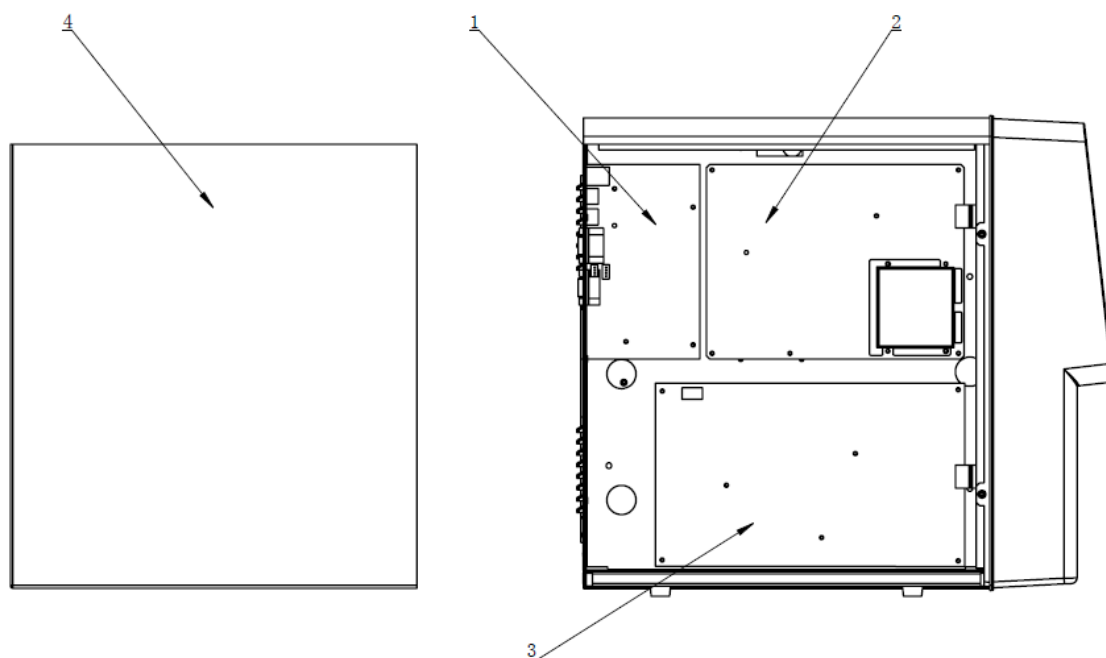


Figure 2-5 Disassembly view of the left side panel



| No. | Name          | Remark                      |
|-----|---------------|-----------------------------|
| 1   | Digital board | Circuit board.              |
| 2   | Analog board  | Circuit board.              |
| 3   | Driver board  | Circuit board.              |
| 4   | Left panel    | Protect the circuit boards. |

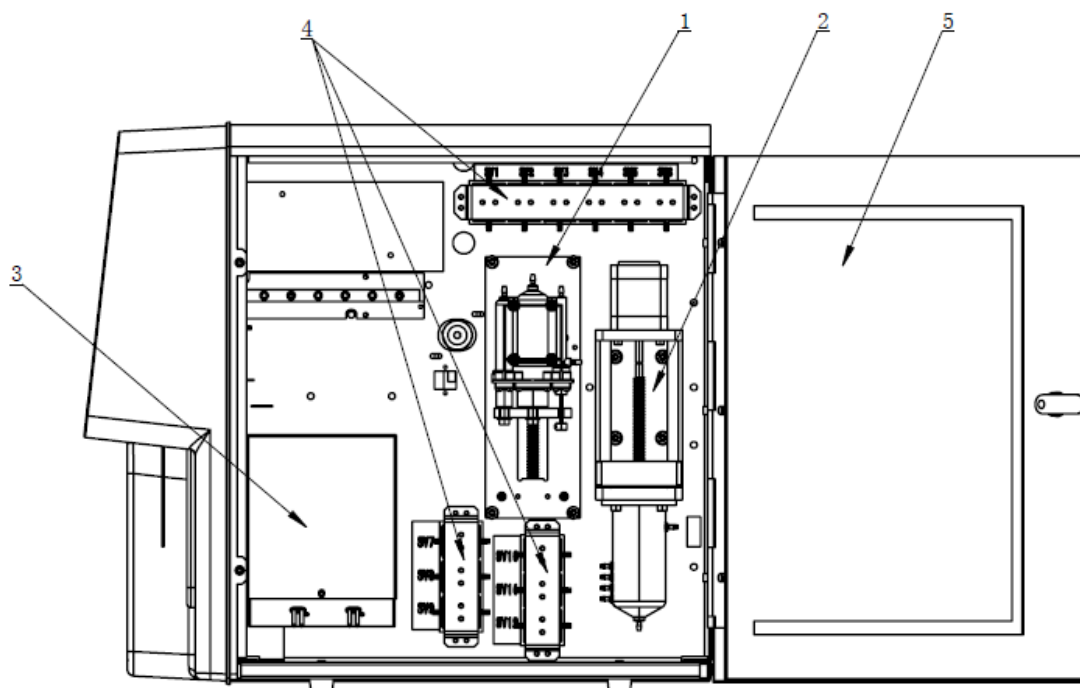


Figure 2-6 Right door opened view

| No. | Name                   | Remark                               |
|-----|------------------------|--------------------------------------|
| 1   | Suction pump           | Fluid system components.             |
| 2   | Negative pressure pump | Fluid system components.             |
| 3   | Counting chamber       | Sample cell counting.                |
| 4   | Solenoid valve group   | Fluid system components.             |
| 5   | Right door             | Protect the fluid system components. |

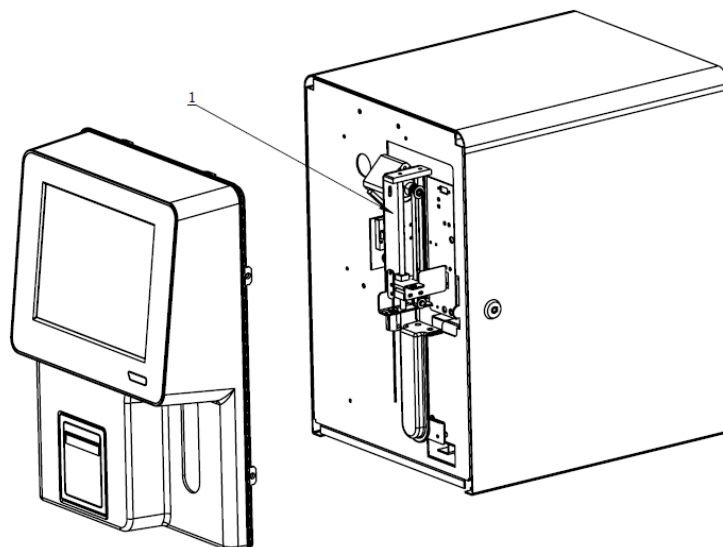


Figure 2-7 Front cover removal view

| No. | Name                | Remark              |
|-----|---------------------|---------------------|
| 1   | Sampling components | For sample suction. |

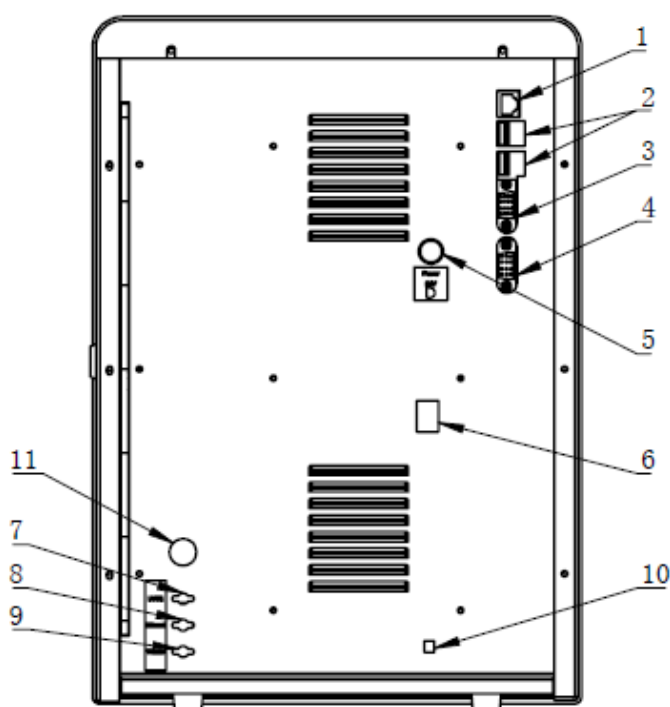


Figure 2-8 Rear view of the analyzer

| No. | Name            | Remark                                               |
|-----|-----------------|------------------------------------------------------|
| 1   | Network port    | Connect the network cable.                           |
| 2   | USB interface   | Connect mouse and keyboard.                          |
| 3   | RS232 interface | RS232 communication.                                 |
| 4   | VGA interface   | VGA communication.                                   |
| 5   | Power interface | Connect the power adapter for powering the analyzer. |

| No. | Name               | Remark                             |
|-----|--------------------|------------------------------------|
| 6   | Power switch       | Device main control power switch.  |
| 7   | LYSE interface     | Connect LYSE.                      |
| 8   | Diluent interface  | Connect the diluent.               |
| 9   | Waste interface    | Connect the waste barrel.          |
| 10  | Grounding bolt     | Connect the earth wire.            |
| 11  | Aviation connector | Connect the waste barrel to alarm. |

Indicator status description:

| Status         | Description |
|----------------|-------------|
| Green          | Standby     |
| Flashing green | Running     |
| Yellow         | Sleep state |
| Red            | Fault state |

## 2.7 Operation

### 2.7.1 Operating Procedures

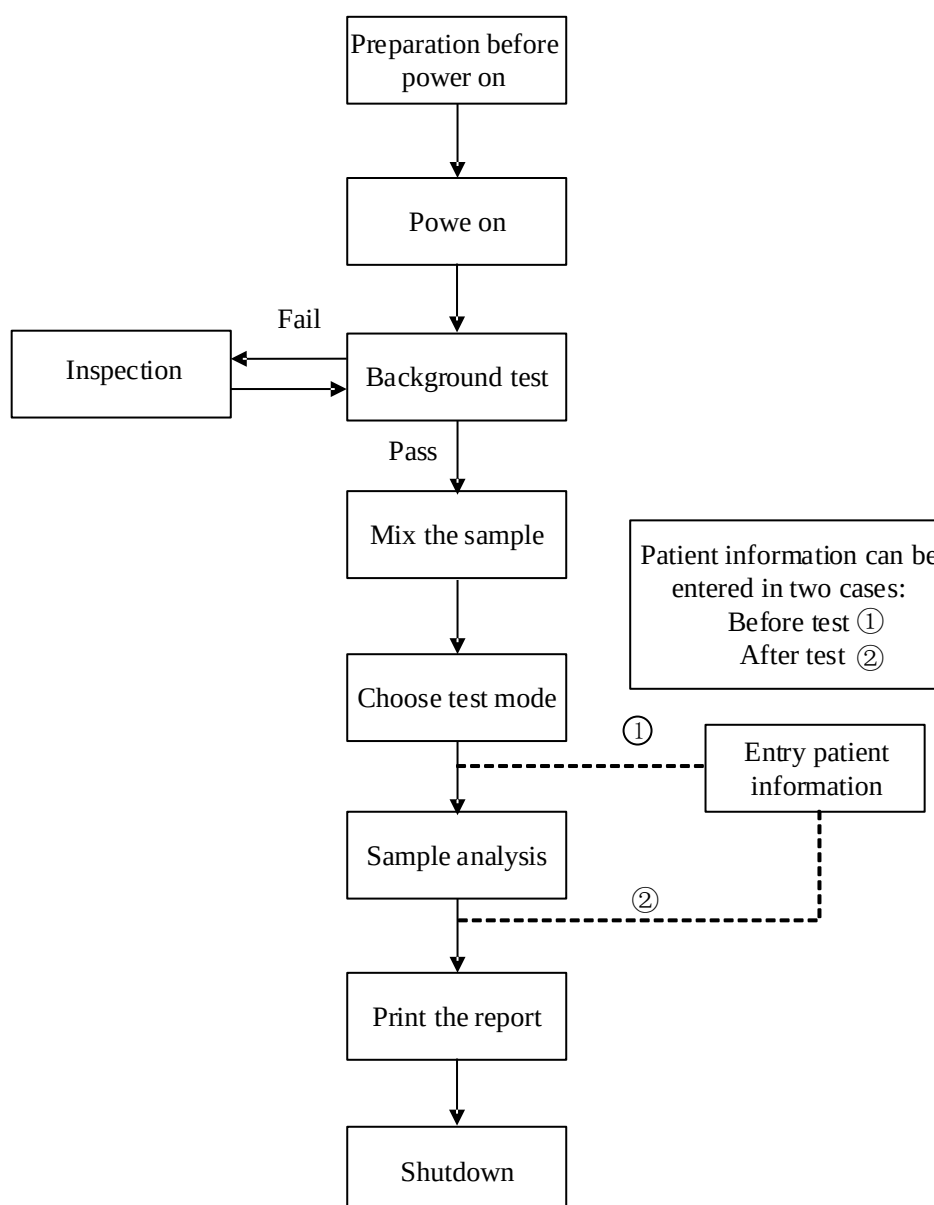


Figure 2-9 Basic operation flow chart

### 2.7.2 Preparation before Power on

#### 2.7.2.1 Check reagents

1. Check whether the diluent, LYSE and cleaning fluid can meet the test requirements, and ensure that the reagents are sufficient.
2. Check whether the pipeline connection between the reagent and the analyzer is firm.
3. Confirm that the pipeline is unobstructed, and there is no bending, twisting or liquid leakage.

#### 2.7.2.2 Check electrical connections

1. Check the power supply to confirm that the power supply can provide correct and stable voltage.
2. Check the communication and power cables between the analyzer and surrounding devices, and make sure that the connections are firm.

#### 2.7.2.3 Check the paper

Check whether there is sufficient printing paper in the printer.

### 2.7.2.4 Check the waste pipe connection

The waste liquid should be discharged through pipelines into the waste barrel, and then disposed of according to local requirements.



#### Biological risks

Be sure to wear gloves, work clothes to prevent infection, and protective glasses if necessary when checking the waste connection.

1. Check the waste barrel to see whether it is emptied. If not, please empty the waste liquid bucket.
2. Check the waste pipe connection to ensure that the waste pipe is not bent and that the drain port is no higher than the waste liquid outlet of the device.

### 2.7.3 Power on

Power on the device (On the rear of the analyzer, marked with "Power").

Press the switch up to "on" and down to "off". If the device needs to be connected to the LIS system, it is also necessary to turn on the power of the PC with LIS system.



Figure 2-10 Device power switch

After the device is powered on, it would undergo a self-check, then enter the login interface, enter the user name and password, and click "Login".

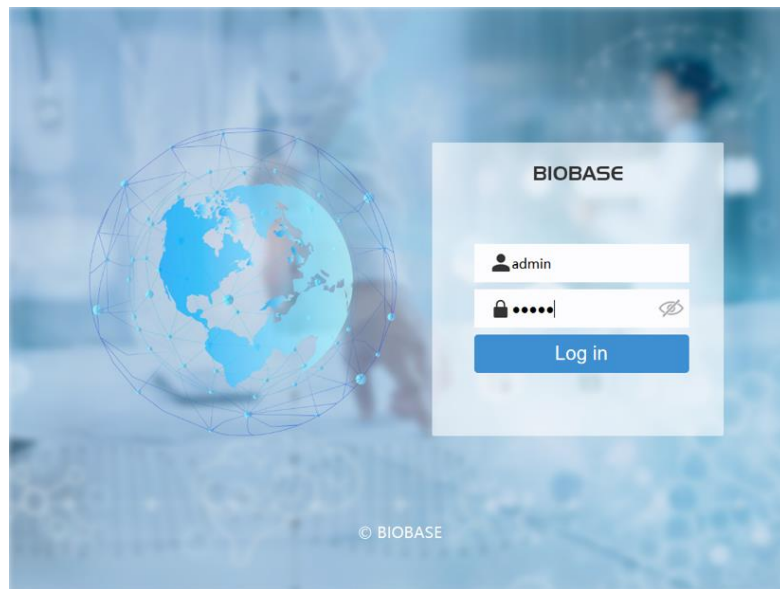


Figure 2-11 Login information interface

After logging in, the device would conduct the liquid system initialization and maintenance; when the start-up maintenance is completed, it would enter the "Report" interface.

### 2.7.4 Background Test

In the "Report" interface, click "Start" or press the "Aspirate" to start the test. The test range is as follows:

Table 2-1 Test range

| Parameter | Background range              |
|-----------|-------------------------------|
| WBC       | $\leq 0.5 \times 10^9 /L$     |
| RBC       | $\leq 0.05 \times 10^{12} /L$ |
| HGB       | $\leq 2g /L$                  |
| HCT       | $\leq 0.5\%$                  |
| PLT       | $\leq 10 \times 10^9 /L$      |

If the test value exceeds this range, repeat the above test steps until the test results fall within this range.

## 2.7.5 Self-check

If the test results still do not meet the specified requirements after testing 5 times, please check the connection of reagents and pipelines, and remove the blockage through the "Flush Apertures", "Clean Fluidics", "Fluidics Soak" and other functions in the "Service" module, and then perform the background test one more time.

## 2.7.6 Shake the Sample

The blood sample must be thoroughly shaken before the test. It is advisable that to shake upside down, turn the test tube 6-8 times, and do not shake too violently.

## 2.7.7 Edit Pet Information

Click "Pet Information" in the "Report" interface to edit (such as owner's name, age, examining doctor, etc.), and save.

## 2.7.8 Sample Test

Select "Venous Blood", "Capillary" or "Prediluted" mode in "Next Sample" of the report interface, and set the sample number. Operate as follows:

Put the mixed sample under the sampling probe, press "Aspirate button", the device takes the blood sample, and take out the sample when the sampling probe is moved into the device.

The device starts analyzing the sample, and the test results and histogram are displayed when the test is done.

**Note:** When prediluted peripheral blood, do as the following:

After selecting the prediluted mode, click "Diluent" and place the prepared tube for dilution under the needle. Press the aspirate button, inject 500  $\mu$ L of the diluent into the dilution test tube, and then pipette 20  $\mu$ L of peripheral blood into the test tube with 500  $\mu$ L of the diluent, and shake. After completing the off-machine dilution, click "Exit" to return to the prediluted mode, and then the same as whole blood, the cell counting can be performed according to the above steps.

## 2.7.9 Print Report

Clicking "Print" in the test interface would automatically print the test results. Users can also view and print history test results.

## 2.7.10 Shutdown

Daily maintenance should be done after finishing work every day, then click "Shutdown" in the upper right corner of the report interface, select "Shutdown" in the pop-up dialog box, and the system would automatically stop working (the cleaning solution needs to be absorbed during the shutdown process). After the program is stopped, the screen would show a signal to remind you to disconnect the power. Then it can be powered off at this time.

# 3 Device Overview

## 3.1 Product Introduction

- **[Product Name]** Auto Animal Hematology Analyzer
- **[Model and Specification]** BK-3100VET
- **[Application]** This device is mainly used to accurately measure the 21 parameters and 3 histograms shown in Table 3-1 in blood.

Table 3-1 Blood parameter table

| Parameter                               | Abbr.         | Unit        |
|-----------------------------------------|---------------|-------------|
| White blood cell                        | WBC           | $10^9/L$    |
| Lymphocytes                             | LYM#          | $10^9/L$    |
| Intermediate cells                      | MID#          | $10^9/L$    |
| Granulocytes                            | GRA#          | $10^9/L$    |
| Lymphocyte %                            | LYM%          | %           |
| Intermediate cells %                    | MID%          | %           |
| Granulocytes %                          | GRA%          | %           |
| Red blood cells                         | RBC           | $10^{12}/L$ |
| Hemoglobin                              | HGB           | g/L         |
| Hematokrit                              | HCT           | %           |
| Mean red blood cell volume              | MCV           | fL          |
| Mean hemoglobin content                 | MCH           | pg          |
| Mean hemoglobin concentration           | MCHC          | g/L         |
| Red blood cell distribution width SD    | RDW-SD        | fL          |
| Red blood cell distribution width CV    | RDW-CV        | %           |
| Platelets                               | PLT           | $10^9/L$    |
| Mean platelet volume                    | MPV           | fL          |
| Platelet distribution width             | PDW           | %           |
| Plateletcrit                            | PCT           | %           |
| Platelet large cell ratio               | P-LCR         | %           |
| Platelet large cell count               | P-LCC         | $10^9/L$    |
| White blood cell distribution histogram | WBC Histogram |             |
| Red blood cell distribution histogram   | RBC Histogram |             |
| Platelet distribution histogram         | PLT Histogram |             |

## 3.2 Detection Principle

### 3.2.1 Detection Principle of WBC, RBC and PLT

The detection principle of the hematology analyzer is the principle of electrical impedance (also known as the Coulter Principle). As a physical particle, blood cells are non-conductive, and when they pass through the electric field generated by the electrodes on both sides of the counting hole, the resistance changes. The

resistance increases with the increase of cell volume. Under a constant current, there is an instantaneous voltage change to generate an electrical pulse, and the number of the pulse wave can reflect the number of blood cells. The size of the pulse wave generated by the blood cells of different sizes is also different. Different blood cells can be classified and counted according to the size of the pulse wave.

The blood sample is firstly diluted after being sucked into the device, and then divided into two parts, one part is added with hemolytic agent and then enters the WBC chamber for counting, and the other part is diluted again and enters the RBC chamber for RBC and PLT measurement. Due to the difference in cell volume, the device can count RBCs and PLTs separately in the same counting chamber according to the level of electrical pulses.

The device divides the WBC volume from 15 to 400fL into 256 channels, and the WBC is divided into three categories according to the volume size: LYM, MID (which includes monocytes, eosinophils and basophils) and GRA.

The volume range of the RBC measurement is 25-250fL with 256 channels. The volume range of PLT measurement is 2-30fL with 128 channels.

### 3.2.2 Detection Principle of HGB

After adding lyse to blood, RBC dissolves and releases HGB, which combines with lyse to form stable hemoglobin cyanide (HICN). Colorimetric at a wavelength of 530 nm, the change in absorbance is proportional to the HGB content, the absorbance is measured. The HGB concentration can be calculated by the ratio with the blank absorbance.

### 3.2.3 Parameter Result Calculation

According to different calculation methods, parameters can be divided into three categories:

1. Parameters obtained by direct measurement

✧ WBC, RBC, PLT, HGB.

2. Parameters obtained from the histogram

✧ LYM%, MID%, GRA%, MCV, RDW-SD, RDW-CV, MPV, PDW, P-LCR.

3. Parameters obtained by deduction

✧ LYM#, MID#, GRA#, HCT, MCH, MCHC, PCT, P-LCC.

The calculation method of each parameter is as follows:

✧  $LYM\% = 100 \times A_L / (A_L + A_M + A_G)$

✧  $MID\% = 100 \times A_M / (A_L + A_M + A_G)$

✧  $GRA\% = 100 \times A_G / (A_L + A_M + A_G)$

Among them:

✧  $A_L$  = Number of cells in the lymphocyte area

✧  $A_M$  = Number of cells in the middle cell region

✧  $A_G$  = Number of cells in the granulocyte area

✧ MCV: Obtained from the histogram of RBC with summarizing and classifying the size of RBC.

✧ RDW-CV: The coefficient of variation of the RBC volume size is obtained from the RBC histogram.

✧ RDW-SD: The standard deviation of the RBC volume size is obtained from the RBC histogram.

✧ MPV: According to the summarization and classification of the volume size of PLT, combined with the PLT histogram to achieve the result.

✧ PDW: The standard deviation of the PLT volume distribution was obtained from the PLT histogram.

✧ P-LCR: The proportion of large platelets to total platelets was obtained from the PLT histogram.

✧  $LYM\# = LYM\% \times WBC / 100$



$$\diamond \text{ MID\#} = \text{MID\%} \times \text{WBC} / 100$$

$$\diamond \text{ GRA\#} = \text{GRA\%} \times \text{WBC} / 100$$

$$\diamond \text{ HCT (\%)} = \text{RBC} \times \text{MCV} / 10$$

$$\diamond \text{ MCH (pg)} = \text{HGB} / \text{RBC} \times 10$$

$$\diamond \text{ MCHC (g/L)} = \text{HGB} / \text{HCT} \times 100$$

$$\diamond \text{ PCT (\%)} = \text{PLT} \times \text{MPV} / 10000$$

# 4 Sample Test

## 4.1 Overview

The report interface is the main page of the analyzer, which is used for various operations after the user completes the sample analysis and before printing the report.

Before printing the test report, the user can check, edit the test results or input the animal information corresponding to the samples on the "Report" interface.

## 4.2 Interface Introduction

Click "Report" to enter the "Report" interface, as shown in Figure 4-1.

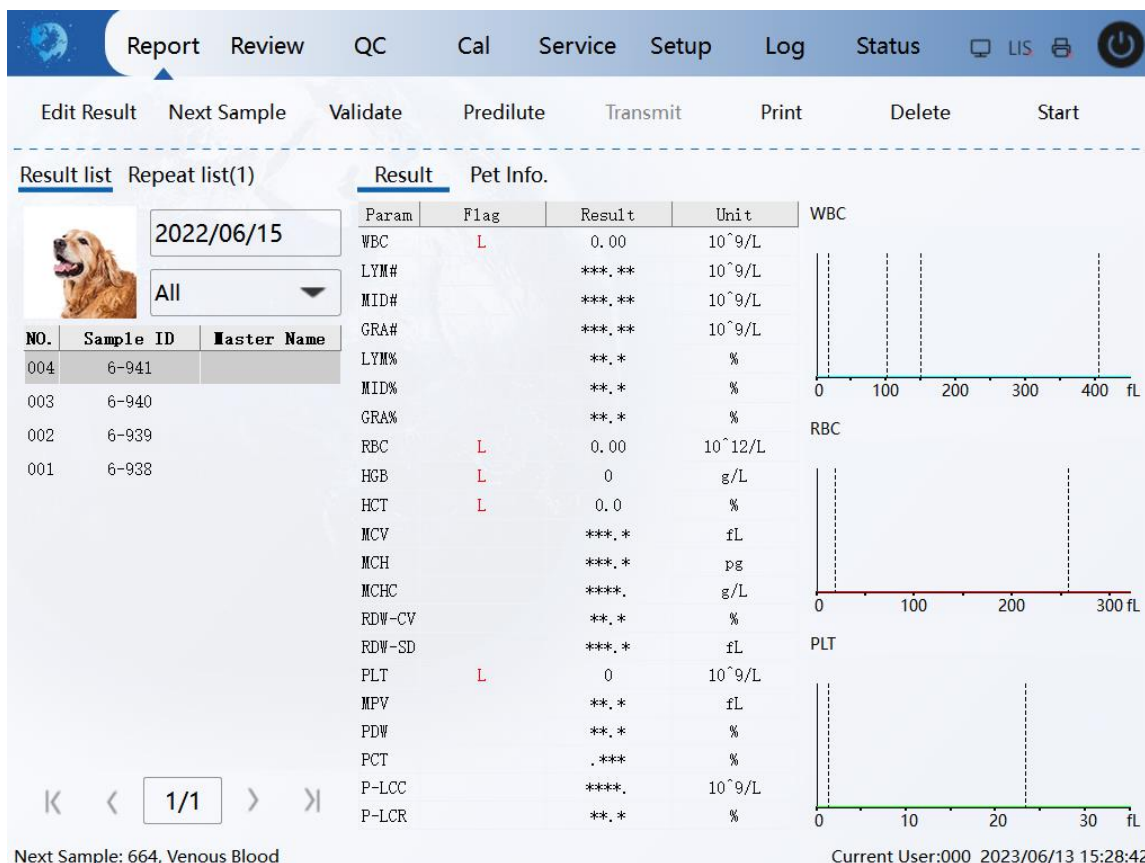


Figure 4-1 Report

The report interface can be divided into the following four parts:

- Result list area

Displays a list of sample of set date and condition. It would display the current result if not filter. Users can see all sample records and sample or animal names in this area.

- Pet information area

The user can see each sample record and its main sample/animal information. The user can input the information related to the sample or animal.

- Graph & results area

Users can view and edit test results and histograms, etc.

- Function button

Users can check, print, edit, and LIS transmission to the selected samples in the result list by clicking the function button.

## 4.3 Result List Area

### 4.3.1 Result List

The result list defaults to displaying all the sample results of the current day.

In the result list area, the user can filter and view the result list by selecting date and condition. In addition, the user can also edit, validate/cancel, print, and delete the sample results by clicking the function button. For details, please refer to "4.6 Function button".

#### 4.3.1.1 List of results for the specified condition

1. Click the "Run Date" to select the test date of the sample.
2. Click the "Conditions" to select the sample state.

The sample state is explained in the following table:

Table 4-1 Sample status options and records

| Options     | Records                                           |
|-------------|---------------------------------------------------|
| All         | Displays all sample records.                      |
| Not Checked | Displays sample records that are not checked.     |
| Not Printed | Displays sample records that are not printed.     |
| No uploaded | Displays sample records without LIS transmission. |

### 4.3.2 Repeat List

The "Repeat list" interface displays the results of the retested samples on the current day.

Select a sample in the Repeat list, and you can view its result on the right side of the interface, as shown in Figure 4-2.

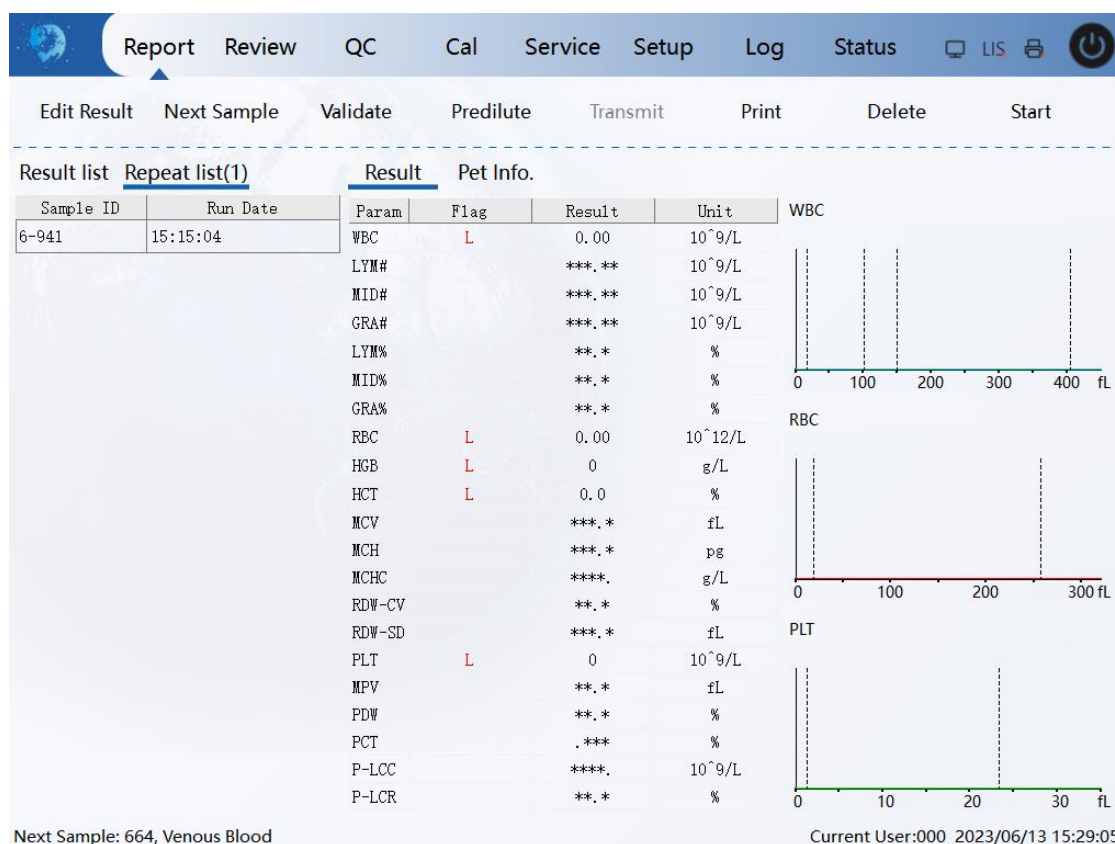


Figure 4-2 Repeated list

## 4.4 Pet Information Area

The user can edit the animal information corresponding to the sample before or after the test result.

## 4.5 Graph & Results Area

### 4.5.1 Result

The user selects a sample in the result list area to view the test result and histogram in the "Result" area, as shown in Figure 4-3.

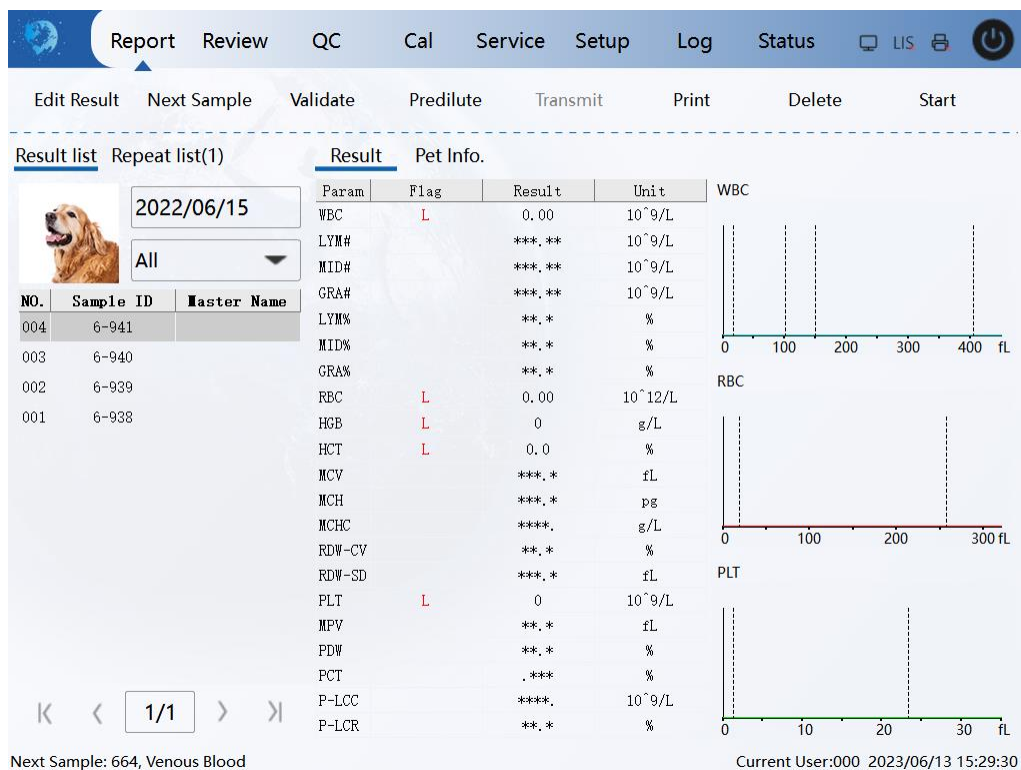


Figure 4-3 Results

## 4.6 Function Button

### 4.6.1 Validate

The user can select a sample in the result list to validate.

1. Select a sample.
2. Click "Validate".

The system would validate the selected sample.

If there is a sample the selected sample, the system would prompt the user that the sample with no test result cannot pass the audit after the review of the sample with the test result is completed.

The system would notify the user that the sample without result, if there is one, can not be validated after validation.

### NOTICE

- After validating, sample information, animal information and test results cannot be changed.
- For samples that have been validated, the "Validate" button becomes "Cancel Validate".

### 4.6.2 Print

In the result list, the user can click "Print" to print out the report of the selected single sample.

1. Click to select the sample to print.

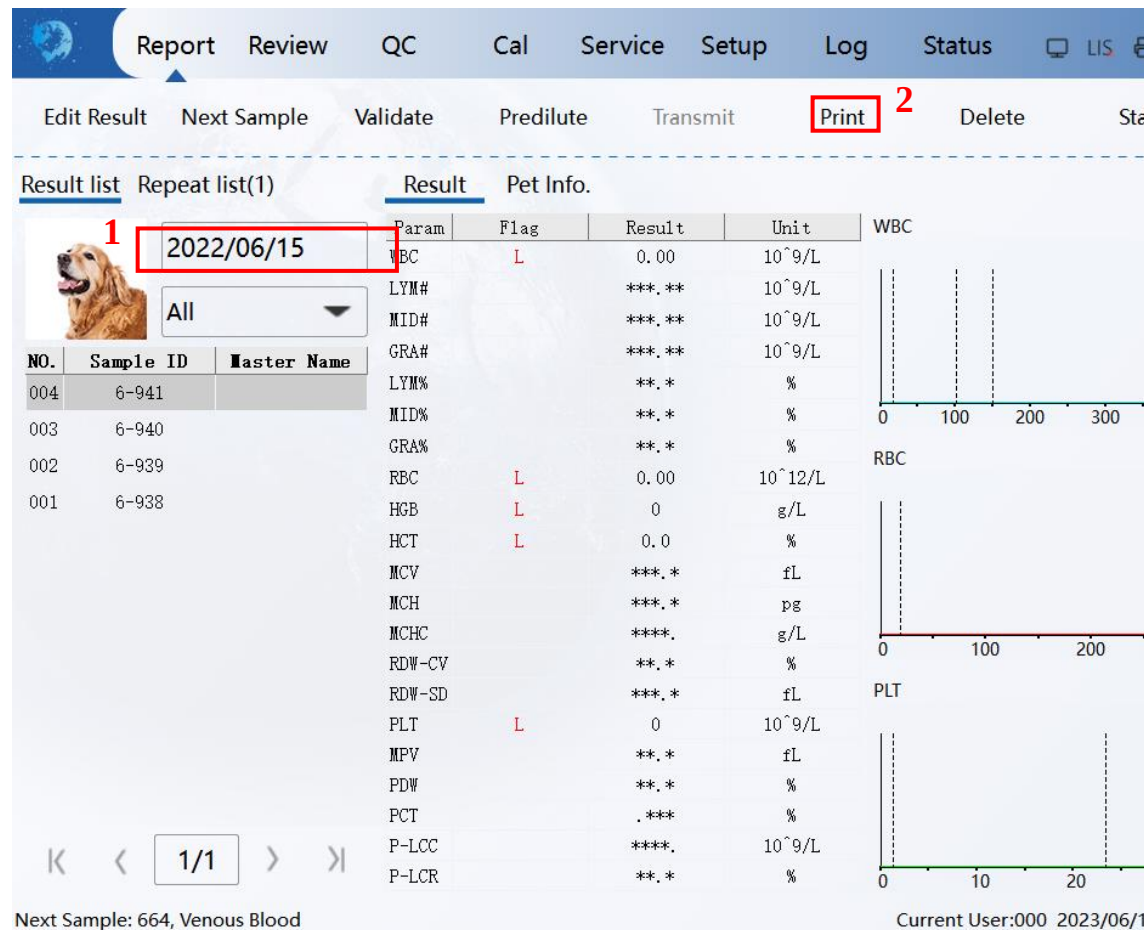


Figure 4-4 Print inspection report

2. Click "Print", the system pops up a window as shown in Figure 4-5.

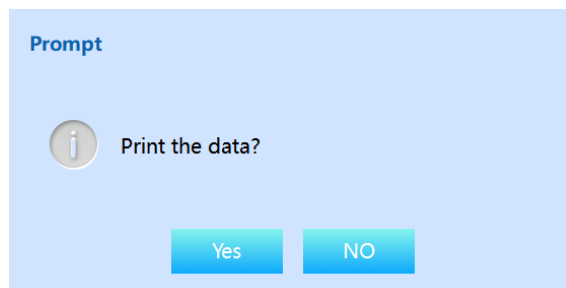


Figure 4-5 Printing

3. Click "Yes" to print.

### 4.6.3 Delete

#### NOTICE

- Validated samples can not be deleted.
- Only administrator can delete sample records.

1. Click to select the sample record to be deleted.
2. Click "Delete", the following pop-up window would show up.

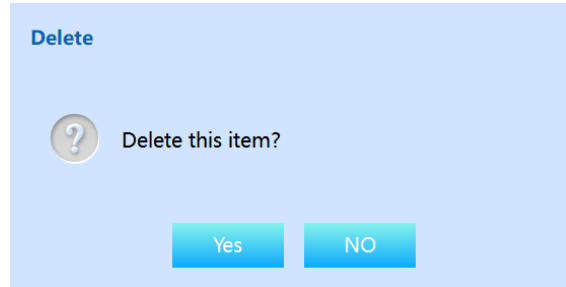


Figure 4-6 Delete sample record

3. Click "Yes" to delete the selected result record in the list.

## 4.6.4 Edit

The user can edit the sample results by following the steps below.

1. Select a sample in the result list, and click "Edit". The "Edit" pop-up window appear, as shown in Figure 4-7.

A light blue dialog box titled "Edit Result" in blue text. It contains two columns of input fields for various blood test results. The first column includes WBC (4.82), LYM% (42.1), MID% (7.6), GRA% (50.3), RBC (3.68), HGB (104), and MCV (98.1). The second column includes RDW-CV (11.4), RDW-SD (47.4), PLT (237), MPV (7.6), PDW (16.3), and P-LCR (21.7). Each input field has a unit next to it. At the bottom, there are two buttons: "OK" and "Cancel", both in blue with white text.

| Parameter | Value | Unit                |
|-----------|-------|---------------------|
| WBC       | 4.82  | 10 <sup>9</sup> /L  |
| LYM%      | 42.1  | %                   |
| MID%      | 7.6   | %                   |
| GRA%      | 50.3  | %                   |
| RBC       | 3.68  | 10 <sup>12</sup> /L |
| HGB       | 104   | g/L                 |
| MCV       | 98.1  | fL                  |
| RDW-CV    | 11.4  | %                   |
| RDW-SD    | 47.4  | fL                  |
| PLT       | 237   | 10 <sup>9</sup> /L  |
| MPV       | 7.6   | fL                  |
| PDW       | 16.3  | %                   |
| P-LCR     | 21.7  | %                   |

Figure 4-7 Edit result

2. Modify the test results and the results of the percentage of WBC classification parameters.
3. Click "OK" to save the results and exit.

If the sum of the percentages of the modified classification parameters is not equal to 100.00% or the WBC value is invalid, the system would note that the input is invalid, please confirm and try again.

After modifying the result data, the associated result values and information also change.

Corresponding result value and notification would change when the result data is changed.

### NOTICE

- Samples that have been validated can not be edited.
- The sample's background record can not be edited.

## 4.6.5 LIS Transmission

For details, refer to "8.1 General Settings > LIS Transmission"

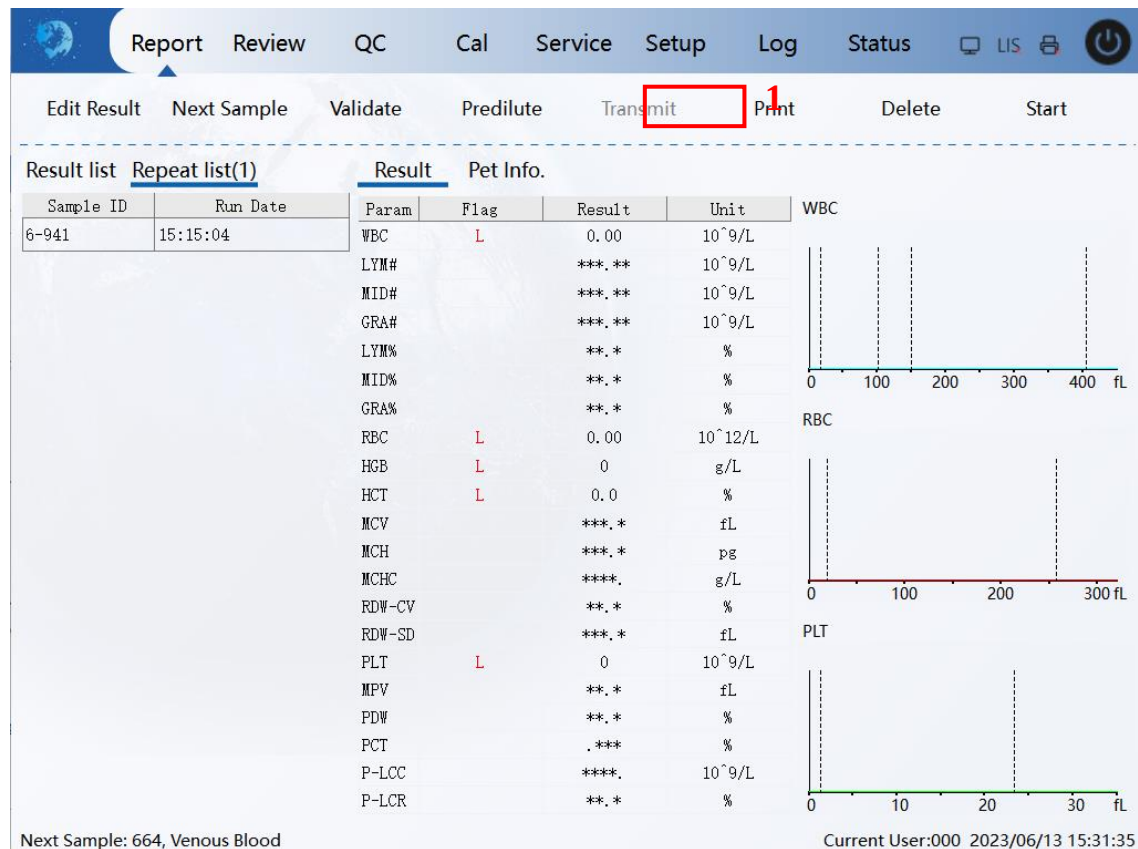


Figure 4-8 LIS transmission

## 4.6.6 Next Sample

The basic information of the sample needs to be entered before the sample analysis. The operation steps are as follows:

1. Click "Next Sample".
2. Select the blood sample mode in the window shown in Figure 4-9 below, and input the sample number and animal information.

The 'Next Sample' dialog box is shown. It has a 'Blood Mode' section with three radio buttons: 'Venous Blood' (selected), 'Capillary', and 'Prediluted'. Below this is a 'Sample' section with 'Sample Prefix' and 'Sample ID' fields. The 'Patient Info.' section contains several fields: Name, Gender (dropdown), Birthday, Age (dropdown with 'year' selected), Dept. (dropdown), Bed No., Ref.Group (dropdown with 'General' selected), Sam. Type (dropdown), Submitter (dropdown), and Medical NO. There is also a 'Remarks' text area. At the bottom are 'OK' and 'Cancel' buttons.

Figure 4-9 Next sample

If the blood sample is venous blood, select the "Venous Blood" mode. If the blood sample is collected peripheral blood ( $\geq 40\mu\text{L}$ ), please select the "Capillary" mode to test directly. If the blood sample is collected peripheral blood ( $20\mu\text{L}$ ) and needs to be prediluted before testing, please select the "Prediluted" mode.

1. After filling in the basic information of the sample, click "OK" to save.
2. Click "Start" or "Aspirate" to complete the count analysis.



## 4.6.7 Predilute

If the "Prediluted" mode is selected for counting in the "Next Sample" interface, sample prediluted is required.

The steps to prepare prediluted samples are as follows:

1. Click "Predilute" in the function button area.

The system pops up a window for adding diluent.

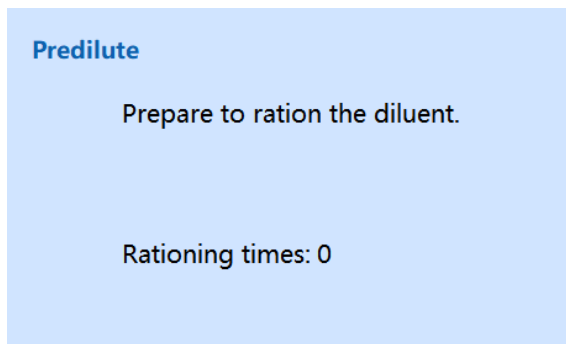


Figure 4-10 System prompts for adding diluent

2. Take a clean centrifuge tube, open the cap, and push the sampling probe vertically to the bottom of the centrifuge tube as shown in the figure below to avoid bubbles, adherent liquid or splashing when adding diluent.

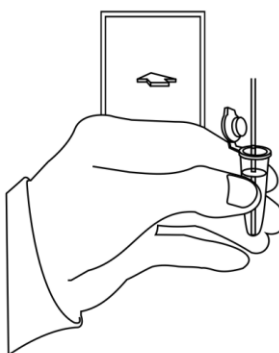


Figure 4-11 Method of adding diluent

3. Click "Start" or "Aspirate" to add the diluent. After adding the diluent (500 $\mu$ L), the user can remove the centrifuge tube after hearing beep.
4. Collect 20  $\mu$ L of peripheral blood and quickly pour it into a centrifuge tube containing diluent, cover and mix well.
5. When the preparation of the prediluted samples is complete, click "Exit". The system exits the dilution operation.
6. To prepare more dilutions, repeat step 3~4.

### NOTICE

- Users can also use a pipette to take 500  $\mu$ L of the diluent manually, and then mix thoroughly with 20  $\mu$ L of peripheral blood.
- The prepared diluent should avoid from falling dust, otherwise it would cause analysis deviation.
- After the peripheral blood and the diluent have fully reacted, they should be placed for 3 minutes, and then re-mixed before analysis.
- Be sure to perform the analysis within 30 minutes of the sample dilution, otherwise the analytical results obtained would be inaccurate.
- Samples that have been left for a period of time need to be remixed before analysis.
- Each laboratory should evaluate the stability of sample analysis results in prediluted mode according to their respective sample numbers, collection methods, and technical levels.



# 5 QC

---

## 5.1 Overview

The hematology analyzer may have deviation during long-term use, which may lead to erroneous or unreliable analysis results. The QC program provides an effective method for detecting possible errors. Only by being familiar with the theory of QC and mastering the actual operation method can the user effectively eliminate the influence of deviation on the analysis results.

In order to ensure the reliability of the sample analysis results, it is recommended that the user conduct quality control of the analyzer with three levels of QC products at low, medium and high levels each day. When it is necessary to use the QC product with new batch number, use the new QC product and the old one simultaneously for 5 days, twice a day, and the results should be within the reference range specified in the instructions for use of the QC product.

---

### NOTICE

- Users should use the QC products and reagents approved by our company, and store and use them in strict accordance with the instructions for use of QC products and reagents. QC products must be used before expiration date. QC products must be mixed thoroughly before use.
  - Ordinary users only have the right to browse and execute quality control analysis, but not to edit.
- 

## 5.2 L-J QC

### 5.2.1 QC Principle

In the L-J QC mode, the operator can perform quality control on 21 measurement parameters. Considering the different needs, only some parameters are supported for QC. The analyzer can provide 60 QC files for the operator to save QC parameters and results. Each QC file can be set to 1 batch number, corresponding to high, medium or low values. The QC file of each batch can save up to 500 QC results. When there are more than 500 QC results, the new QC results would sequentially cover the oldest results.

### 5.2.2 QC Setup

---



#### Biological risks

- All items (such as samples, QCs, calibrators, reagents, waste liquids, etc) and areas where these items are placed are potentially bioinfectious. When users touch or step into these areas in the laboratory, they should abide by the laboratory safety operation regulations and wear personal protective outfit (such as laboratory protective clothing, gloves, masks, etc).
- 

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### NOTICE

- Only administrators have permission to set QC settings.
  - For the QC file with results, if the reference value or deviation limit is changed after the reference value or deviation limit is changed and saved, the changed data would be marked yellow and recorded in the system log.
- 

Before analyzing a new batch of QC products, a QC file needs to be set for each batch of QC products. Users can set the QC settings in the QC file by any of the following methods.

#### 5.2.2.1 Manual entry

1. As shown in Figure 5-1, click "QC > QC Setup" to enter the "QC Setup" interface.

Report Review **QC** Cal Service Setup Log Status

L-J Delete Transmit Save

QC Setup QC Analysis QC Graph QC Table

| File NO. | In use                              |
|----------|-------------------------------------|
| 1        | <input type="checkbox"/>            |
| 2        | <input type="checkbox"/>            |
| 3        | <input type="checkbox"/>            |
| 4        | <input checked="" type="checkbox"/> |
| 5        | <input type="checkbox"/>            |
| 6        | <input type="checkbox"/>            |
| 7        | <input type="checkbox"/>            |
| 8        | <input type="checkbox"/>            |
| 9        | <input type="checkbox"/>            |
| 10       | <input type="checkbox"/>            |

Lot No.  Level  Exp. Date 2022/07/04

Sample ID  Mode Whole Blood Setter

| Param | Target | Limit(#) | Unit                | Param  | Target | Limit(#) | Unit               |
|-------|--------|----------|---------------------|--------|--------|----------|--------------------|
| WBC   |        |          | 10 <sup>9</sup> /L  | MCH    |        |          | pg                 |
| LYM#  |        |          | 10 <sup>9</sup> /L  | MCHC   |        |          | g/L                |
| MID#  |        |          | 10 <sup>9</sup> /L  | RDW-CV |        |          | %                  |
| GRA#  |        |          | 10 <sup>9</sup> /L  | RDW-SD |        |          | fL                 |
| LYM%  |        |          | %                   | PLT    |        |          | 10 <sup>9</sup> /L |
| MID%  |        |          | %                   | MPV    |        |          | fL                 |
| GRA%  |        |          | %                   | PDW    |        |          | %                  |
| RBC   |        |          | 10 <sup>12</sup> /L | PCT    |        |          | %                  |
| HGB   |        |          | g/L                 | P-LCC  |        |          | 10 <sup>9</sup> /L |
| HCT   |        |          | %                   | P-LCR  |        |          | %                  |
| MCV   |        |          | fL                  |        |        |          |                    |

Next Sample: 6, Venous Blood Current User:admin 2022/07/04 16:48:27

Figure 5-1 L-J QC

- Select a File No. with empty QC information (selection range: 1~60), refer to Table 5-1, and set the parameter information of the QC file, including QC Lot No., QC level, validity period, QC mode and sample ID, etc.

### NOTICE

The "Lot No." and "QC mode" of different QC files are not allowed to be repeated at the same time.

Table 5-1 QC file information

| Parameter | Meaning                                                                      | Instructions                                                                                                                                                                      |
|-----------|------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| File No.  | QC file number. The system provides a total of 60 QC files for users to set. | Not editable.                                                                                                                                                                     |
| Lot No.   | Lot number of QC products.                                                   | Manual input.<br><b>NOTICE</b><br>Lot No. is not allowed to be empty, 1-16 digits, including characters, numbers, letters and special characters, does not support Chinese input. |
| Level     | The level of QC substances, including high, medium and low.                  | Select from the drop-down list.                                                                                                                                                   |
| Exp. Date | The expire date of the QC product.                                           | Exp. Date defaults to the current date of the system, please adjust it to the actual exp. date of the QC product.                                                                 |
| QC Mode   | QC mode for QC products, including venous blood and prediluted.              | Select from the drop-down list.                                                                                                                                                   |

| Parameter                    | Meaning                                                                                                            | Instructions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sample ID                    | The number of the QC sample.                                                                                       | <p>It is allowed to be empty, not repeatedly enter the number of samples that have been tested.</p> <p><b>NOTICE</b></p> <ul style="list-style-type: none"> <li>• Sample ID can be edited with English letters, numbers and all special characters on the keyboard, but does not support Chinese or other language types (such as Japanese, Korean, etc).</li> <li>• The length of the input is in the range [1,25] and cannot be empty.</li> <li>• The end character of the Sample ID must be a number, but cannot be all numbers "0".</li> </ul> |
| Setter                       | The setter of the QC file, that is, the user who is currently logged in to its system.                             | Not editable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Existing data/total capacity | The total data and QC results already present in the current QC file. Each QC file can store up to 500 QC results. | Not editable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

1. Enter the Target value and deviation range of each parameter according to the QC product specification.
2. Click "Save" to save the QC information.

## 5.2.3 QC Analysis

After completing the QC setup, the user can choose one of the following methods to perform QC analysis according to the selected QC mode:

- Venous blood.
- Prediluted.

### 5.2.3.1 QC analysis (venous blood)



#### Biological risks

- All items (such as samples, QCs, calibrators, reagents, waste liquids, etc) and areas where those items are placed are potentially bioinfectious. When users touch or step into those areas in the laboratory, they should abide by the laboratory safety operation regulations and wear personal protective outfit (such as laboratory protective clothing, gloves, masks, etc).



## Warning

- The sampling probe is sharp and may be stained with biohazardous substances. Please be careful when operating the host machine and do not touch the sampling probe.
- It is possible for samples to spill out of the uncapped blood collection tube and create a biological risk. Be careful when handling the uncapped blood collection tube.
- A ruptured blood collection tube may cause personal injury or biological risk. Be careful not to damage the blood collection tube when loading or removing from its holder.
- Clothes, hair and hands must keep a certain distance to prevent from being pinched by moving parts.
- Reagents can irritate eyes, skin and mucous membranes. When users use reagents in the laboratory, they should follow the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc).
- Once the reagent splashes on the skin, rinse immediately with plenty of water and seek medical attention if necessary. When get into eyes, rinse immediately with plenty of water and see a doctor .



## Caution

- Do not reuse disposable items.

## NOTICE

- The user can only use disposable items approved by the company, such as vacuum blood collection tubes, centrifuge tubes, and capillaries.

The L-J QC analysis steps in venous blood mode are as follows:

1. Click "QC" to enter the QC interface.
2. Click "QC Analysis".
3. Select the File No. to perform the QC analysis. As shown in Figure 5-2, the interface displays the corresponding QC information.

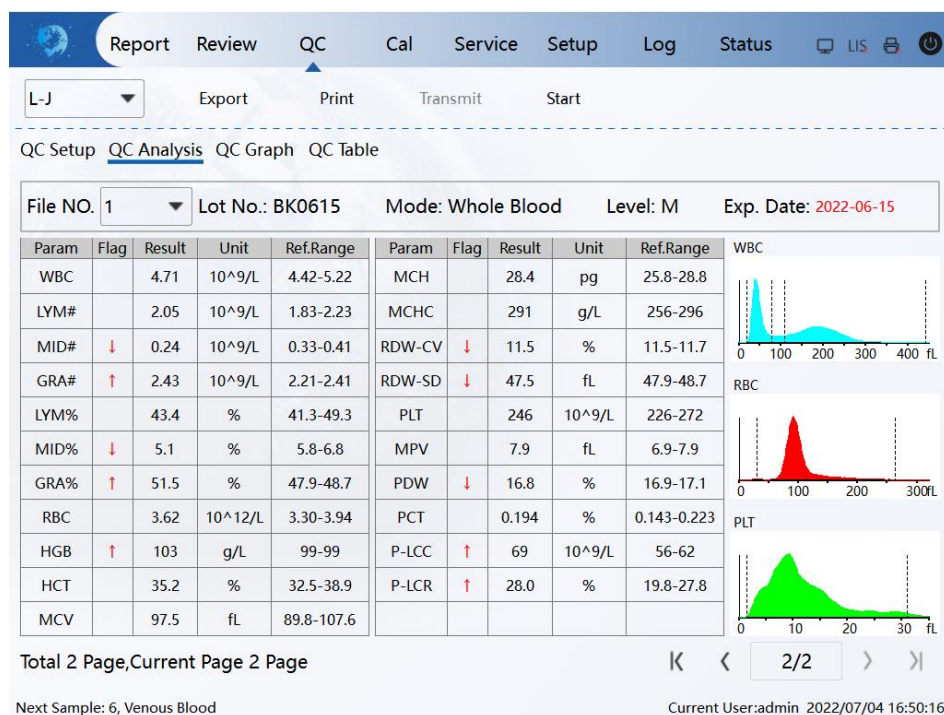


Figure 5-2 QC file information

4. Confirm that the level of the QC product to be analyzed is consistent with that shown in the current QC file and is not expired.
5. Prepare QC products according to the instructions for use of QC products.
6. Make sure the QC mode is "Venous Blood".
7. Shake the prepared QC product as shown in the figure below to mix thoroughly.

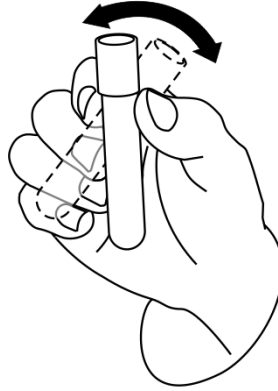


Figure 5-3 Mixing of QC products

8. Put the QC product under the sampling probe and suck the QC product after mixing.
9. Press the Aspirate button to start QC analysis.
10. The machine would beep after aspirating, then remove the QC product. After the analysis, the results would be displayed on the current interface (as shown in Figure 5-4) and automatically saved to the current QC file.

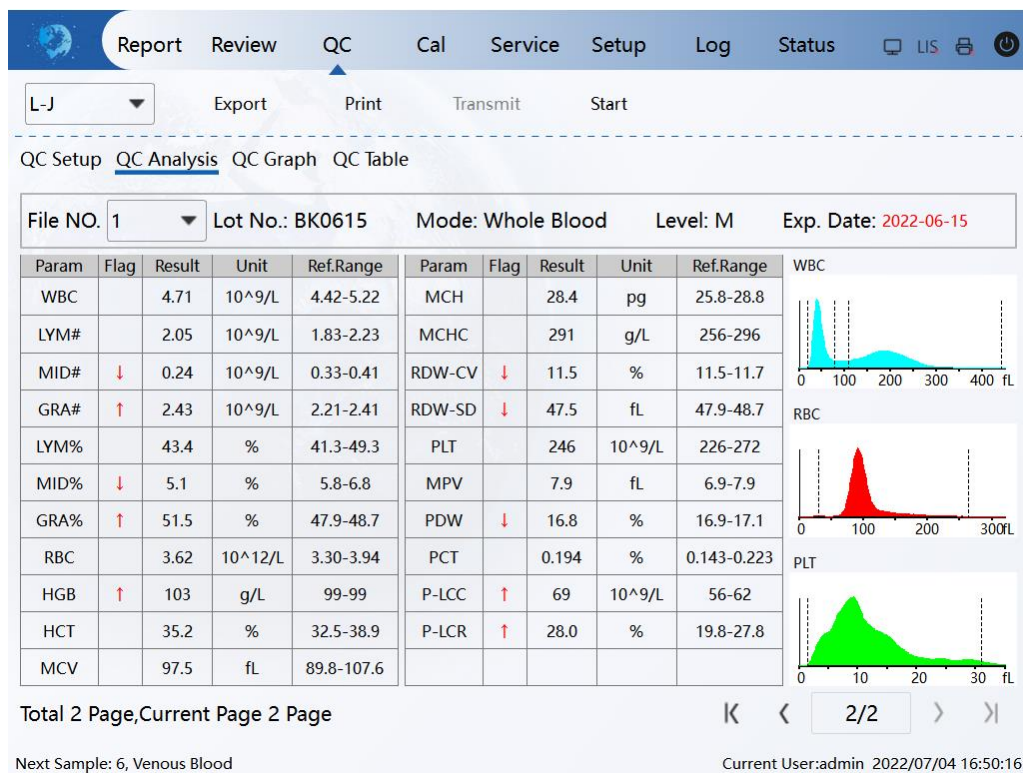


Figure 5-4 QC analysis results

11. If necessary, repeat the above steps to continue QC analysis.

### 5.2.3.2 QC analysis (prediluted)

---



#### **Biological risks**

- All items (such as samples, QCs, calibrators, reagents, wastes, etc) and areas where those items are placed are potentially infectious. When users contact related items and areas in the laboratory, they should abide by the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc).
- 



#### **Warning**

- The sampling probe is sharp and may be stained with biohazardous substances. Please be careful when operating the host machine and do not touch the sampling probe.
  - It is possible for samples to spill out of the uncapped blood collection tube and create a biological risk. Be careful when handling the uncapped blood collection tube.
  - A ruptured blood collection tube may cause personal injury or biological risk. Be careful not to damage the blood collection tube when loading or removing from its holder.
  - Clothes, hair and hands must keep a certain distance to prevent from being pinched by moving parts.
  - Reagents can irritate eyes, skin and mucous membranes. When users use reagents in the laboratory, they should follow the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc).
  - Once the reagent splashes on the skin, rinse immediately with plenty of water and seek medical attention if necessary. When get into eyes, rinse immediately with plenty of water and see a doctor.
- 



#### **Caution**

- Do not reuse disposable items.
- 

#### **NOTICE**

- The user can only use disposable items approved by the company, such as vacuum blood collection tubes, centrifuge tubes, and capillaries.
  - The user can also use a pipette to suck 500  $\mu$ L of the dilution.
  - The prepared diluent should prevent from falling dust, otherwise it would cause analysis error.
  - After the peripheral blood and the diluent have fully reacted, they should be placed for 3 minutes, and then re-mixed before analysis.
  - Be sure to perform the analysis within 30 minutes of the sample dilution, otherwise the analytical results obtained would be unreliable.
  - Samples that have been left for a period of time need to be remixed before analysis.
  - Each laboratory should evaluate the stability of sample analysis results in prediluted mode according to their respective sample numbers, sample collection methods, and technical levels.
- 

1. Click "QC" to enter the QC interface.
2. Select QC type "L-J".
3. Click "QC Analysis".
4. Select the File NO. to perform the QC analysis. As shown in Figure 5-5, the interface displays the corresponding QC information.



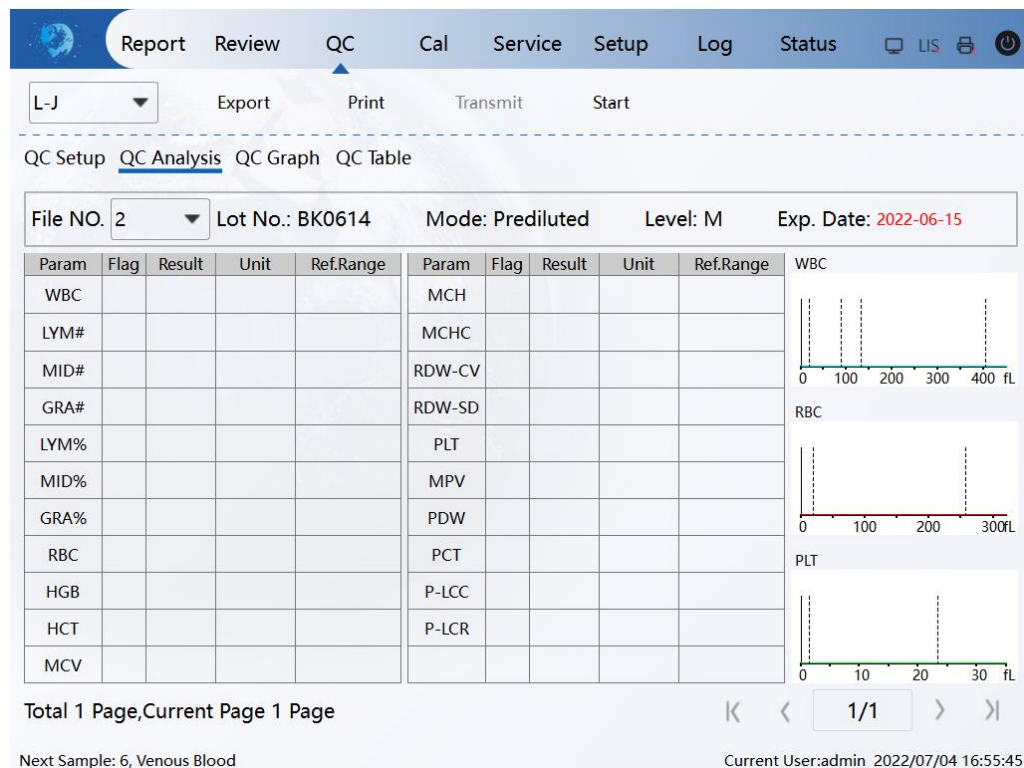


Figure 5-5 QC file information (prediluted mode)

- Confirm that the level of the QC product to be analyzed is consistent with that shown in the current QC file and is not expired.
- Prepare QC products according to the instructions for use of QC products.
- Make sure the QC mode is "Prediluted", the count status icon and the indicator on the host machine are green.
- Click "Start" in the function button area, the prompt information is as follows.

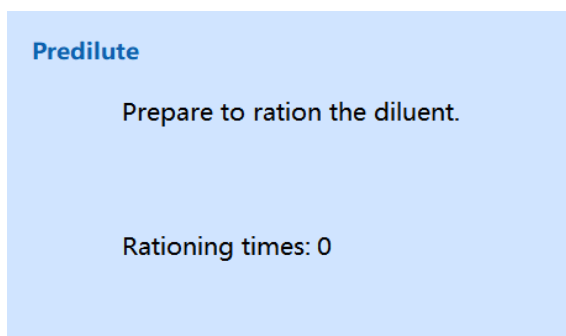


Figure 5-6 System prompt for adding diluent

- Take a clean centrifuge tube, open the cap, and insert the sampling probe vertically to the bottom of the centrifuge tube as shown in the figure below to avoid bubbles, adherent liquid or splashing when adding diluent.

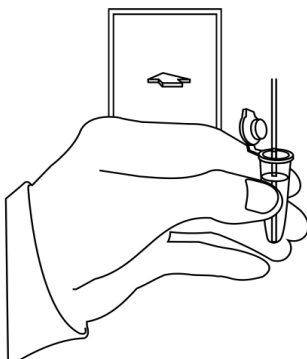


Figure 5-7 How to add diluent

10. Press the Aspirate button to start adding the diluent.
11. The machine would beep after aspirating, then remove the QC product.
12. Collect 20  $\mu$ L QC product and quickly pour it into a centrifuge tube containing diluent, cover the cap and mix well.
13. Open the cap of the centrifuge tube and place it under the sampling probe, and press the aspirate button.
14. After aspirating, the user can remove the centrifuge tube. After the analysis, the results would be displayed on the current interface (as shown in Figure 5-4) and automatically saved to the current QC file.
15. If necessary, repeat the above steps to continue QC analysis.

---

**NOTICE**

- If the QC file is expired, its Exp. date would be displayed in red.
  - There would be a note "↑", "↓" or "H", "L" before the result exceeds the preset limit.
- 

## 5.2.4 Review of QC Results

After completing the QC analysis, the user can review the QC results in two ways:

- QC Graph
- QC Table

### 5.2.4.1 QC graph

---



#### Biological risks

- All items (such as samples, QCs, calibrators, reagents, waste liquids, etc) and areas where these items are placed are potentially bioinfectious. When users touch these items or step into these areas in the laboratory, they should abide by the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc).
- 

1. Click "QC" to enter the QC interface.
2. Select QC type "L-J".
3. Click "QC Graph".
4. Select the File NO. that you want to review. As shown in Figure 5-8, the interface displays the corresponding QC information and QC graphs.



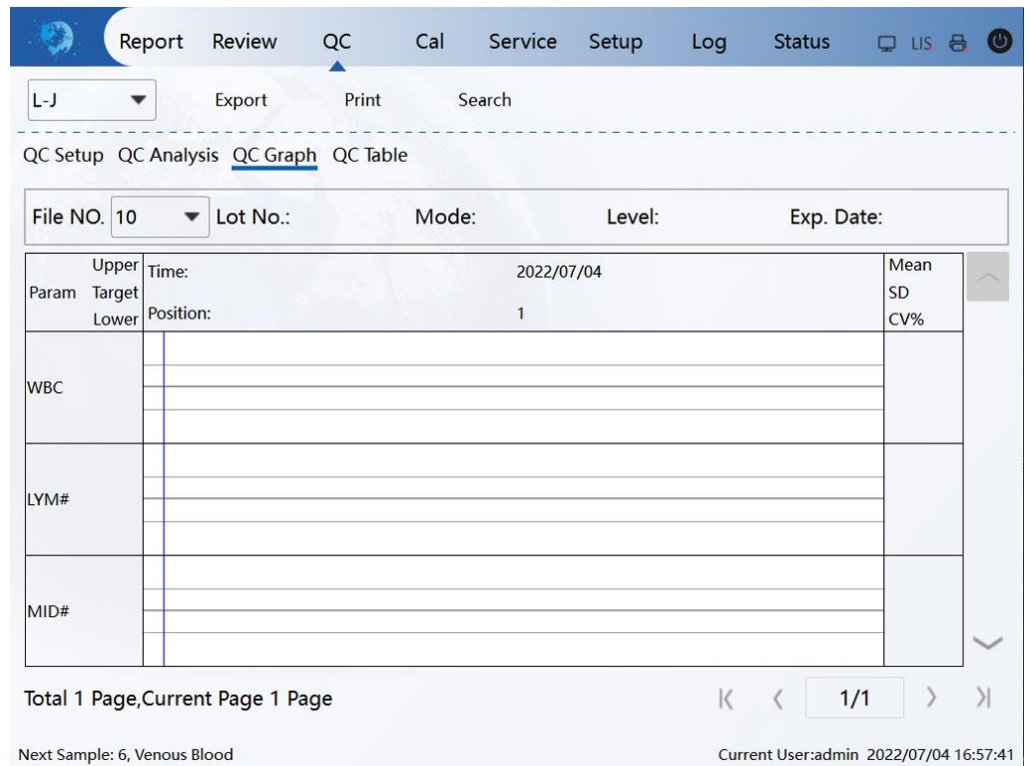


Figure 5-8 QC graph

5. Drag the scroll bar on the right side of the QC list to browse all results. Click "K <" and "> I" to browse all QC results.

#### 5.2.4.2 QC table



#### Biological risks

- All items (such as samples, QCs, calibrators, reagents, wastes, etc) and areas where those items are placed are potentially infectious. When users contact related items and areas in the laboratory, they should abide by the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc).
1. Click "QC" to enter the QC interface.
  2. Select QC type "L-J".
  3. Click "QC Table".
  4. Select the File NO. that you want to review, such as "10". As shown in Figure 5-9, the interface displays the corresponding QC information and QC graphs.

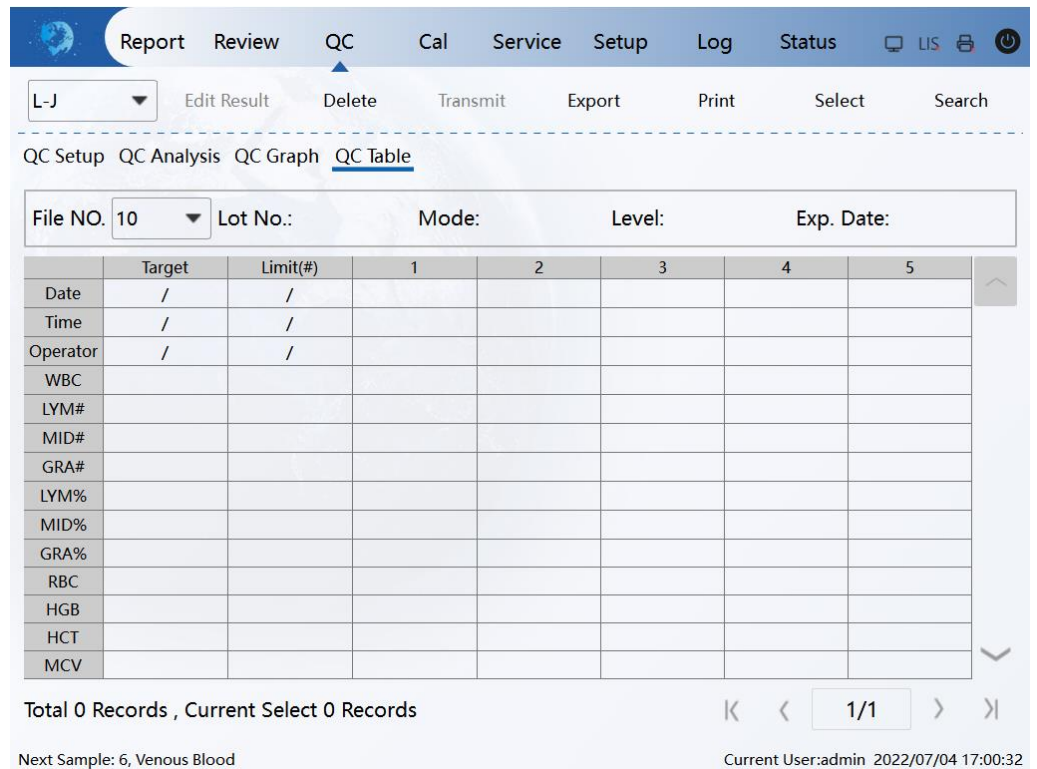


Figure 5-9 QC table

5. Drag the scroll bar on the right side of the QC list to browse the results of all parameters. Click "K <" and "> I" to browse all QC results.

### Delete

Only the administrator have the right to delete.

1. Select the QC result you want to delete and click "Delete".
2. Select "Yes" in the pop-up window, as shown in Figure 5-10.

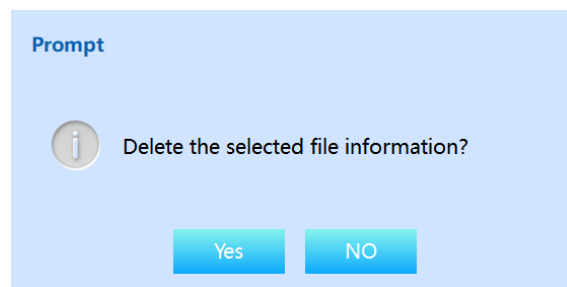


Figure 5-10 Delete current QC data (QC Table)

### Edit

Select a cell in the list and click "Edit" to edit the selected QC data.

### Save

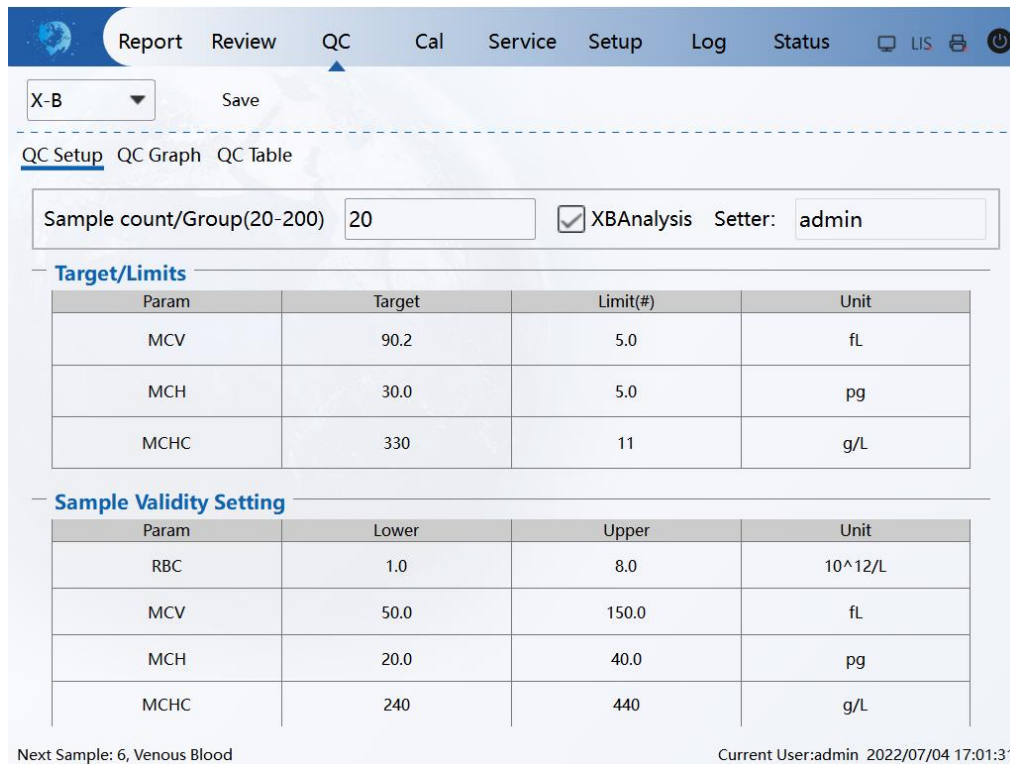
Click "Save" to save the edited parameters.

## 5.3 X-B QC

X-B QC does not have QC products, and is also the quality monitoring method of the product. The two can reflect the inspection quality of the machine from different aspects, and cannot replace each other. X-B QC data comes from random samples, not classified by disease type. A reference range is formed by a given value and upper and lower limits, and to observe the change trend of each batch of X-B values on the reference range.

The device performs X-B QC on all three parameters, and the number of samples for X-B numerical analysis in each batch is between 20 and 200, and the default value is 20.

## 5.3.1 QC Setup



Report Review **QC** Cal Service Setup Log Status

X-B Save

QC Setup QC Graph QC Table

Sample count/Group(20-200) 20 ☒ XBAAnalysis Setter: admin

**Target/Limits**

| Param | Target | Limit(#) | Unit |
|-------|--------|----------|------|
| MCV   | 90.2   | 5.0      | fL   |
| MCH   | 30.0   | 5.0      | pg   |
| MCHC  | 330    | 11       | g/L  |

**Sample Validity Setting**

| Param | Lower | Upper | Unit                |
|-------|-------|-------|---------------------|
| RBC   | 1.0   | 8.0   | 10 <sup>12</sup> /L |
| MCV   | 50.0  | 150.0 | fL                  |
| MCH   | 20.0  | 40.0  | pg                  |
| MCHC  | 240   | 440   | g/L                 |

Next Sample: 6, Venous Blood Current User: admin 2022/07/04 17:01:31

Figure 5-11 X-B QC setup

The "Sample Count" in each group can be set between 20 and 200, and the default value is 20. If XB analysis has been checked, the test sample would also be used as X-B QC analysis data. The "Target value" and "Limit value" of the parameter need to be set.

The Target value and Limit value of X-B QC are manually calculated and filled by the user. The parameter Target value is the average value after statistical calculation of the sample data after the test in the user's region. The sample should reach a certain number (recommended more than 1000) and confirm that the source of the sample is random (the data reference value in different regions would be different). The Limit value is recommended to be selected from 5% to 10%.

- Parameters: The user can choose to perform QC on all or part parameters.
- Delete: Delete X-B QC setup data.

## 5.3.2 QC Table

The device can store up to 2000 X-B QC data, open the X-B QC table, as shown below:

Report

Review

QC

Cal

Service

Setup

Log

Status

LIS

X-B

Delete

Export

Print

Select

QC Setup

QC Graph

QC Table

Group NO: 1

☒ Group Display

|          | Target | Limit(#) | 1          | 2          | 3          | 4          | 5          |
|----------|--------|----------|------------|------------|------------|------------|------------|
| Date     | /      | /        | 2022/06/15 | 2022/06/15 | 2022/06/15 | 2022/06/15 | 2022/06/15 |
| Time     | /      | /        | 18:14:09   | 18:16:35   | 18:24:55   | 18:27:10   | 18:28:21   |
| Operator | /      | /        | admin      | admin      | admin      | admin      | admin      |
| MCV      | 90.2   | 5.0      | 94.0       | 93.1       | 94.1       | 93.3       | 93.4       |
| MCH      | 30.0   | 5.0      | 28.0       | 28.1       | 28.3       | 28.0       | 28.8       |
| MCHC     | 330    | 11       | 298        | 302        | 301        | 300        | 309        |

Total 5 Records , Currently selected 0 Records

1/1

Next Sample: 6, Venous Blood

Current User:admin 2022/07/04 17:03:00

Figure 5-12 X-B QC table

The device displays the QC results of 3 parameters. If some parameters are not quality controlled, the corresponding cells are empty.

The X-B QC list can display up to 5 pieces of data at a time. If there are more than 5 pieces of data, you can click "⏪" and "⏩" to view.

Click "Delete" in the list form, and a delete note would pop up. After confirmation, part or all of the QC data would be deleted.

### 5.3.3 QC Graph

The system has the ability to display the X-B QC analysis data in the form of graphs. As shown below:

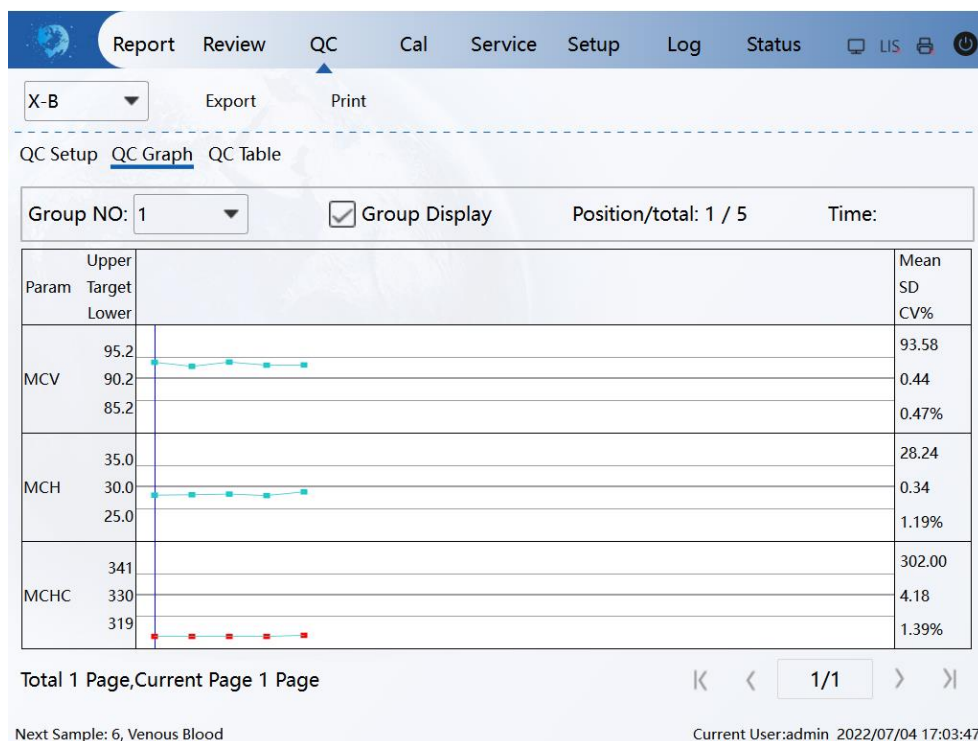


Figure 5-13 X-B QC graph

- Position/Total: Displays the current QC data point position and the total number of X-B QC analyses.

- Time: Test time for QC data.

Each screen displays the QC data distribution of three parameters. The three values on the left of the QC graph from top to bottom are: upper limit, target, and lower limit.

Click " ", " 

" to display the QC data of different "Group No."

Click "Print" to print out the QC data for the current group of parameters.

# 6 Calibration

---

## 6.1 Overview

Calibration is the bias correction factor for blood sample analysis under specified conditions to obtain accurate results. In order to obtain accurate blood sample analysis results, please regularly calibrate the analyzer according to the steps given in this chapter.

---

**NOTICE**

- Only administrator can calibrate.
  - Users should use the calibrators and reagents approved by the company, and store and use them in strict accordance with the instructions for use of the calibrators and reagents.
  - Only calibrator counts performed under the Cal. interface are effective.
  - Calculated repeatability should also be considered.
- 

## 6.2 Frequency of Calibration

Because the performance of the analyzer is stable, the analyzer has been calibrated before leaving the factory, and generally, it does not need frequent calibration. In the following four cases, the user needs to calibrate the analyzer:

- Before the first use (usually done by our company's engineers when installing the device).
  - After replacing the main parts.
  - When the host is not used for a long time, it would be restored to use.
  - QC data shows systematic error (bias) or when the data exceeds preset limits.
- 

**NOTICE**

- Only the analyzer is calibrated can it provide accurate data.
- 

## 6.3 Calibration Type

The analyzer owns two calibration types: Manual calibration and Calibrator calibration, which can calibrate part or all parameters of WBC, RBC, HGB, MCV, PLT and MPV.

Report Review QC **Cal** Service Setup Log Status LIS

Manual Calibrator History

User Service Factory

General Save Print

| Whole Blood |                |                     | Prediluted |                |                     |
|-------------|----------------|---------------------|------------|----------------|---------------------|
|             | Coefficient(%) | Cal. Date           |            | Coefficient(%) | Cal. Date           |
| WBC         | 100.00         | 2023-01-05 14:08:52 | WBC        | 100.00         | 2018-01-01 00:00:00 |
| RBC         | 100.00         | 2023-01-05 14:08:52 | RBC        | 100.00         | 2018-01-01 00:00:00 |
| HGB         | 100.00         | 2023-01-05 14:08:52 | HGB        | 100.00         | 2018-01-01 00:00:00 |
| MCV         | 100.00         | 2023-01-05 14:08:52 | MCV        | 100.00         | 2018-01-01 00:00:00 |
| PLT         | 100.00         | 2023-01-05 14:08:52 | PLT        | 100.00         | 2018-01-01 00:00:00 |
| MPV         | 100.00         | 2023-01-05 14:08:52 | MPV        | 100.00         | 2018-01-01 00:00:00 |

Next Sample: 664, Venous Blood Current User:000 2023/06/13 11:23:10

Figure 6-1 Manual calibration

Report Review QC **Cal** Service Setup Log Status LIS

Manual **Calibrator** History

Cal. Mode ☒ Whole Blood ☐ Prediluted

Calibrator Info. Lot No.  Exp. Date

Calibration Data Target Start Save Select Clear Print

|                                     | Parameter | WBC | RBC | HGB | MCV | PLT | MPV |
|-------------------------------------|-----------|-----|-----|-----|-----|-----|-----|
|                                     | Target    |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 1         |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 2         |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 3         |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 4         |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 5         |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 6         |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 7         |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 8         |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 9         |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 10        |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 11        |     |     |     |     |     |     |
| <input checked="" type="checkbox"/> | 12        |     |     |     |     |     |     |
|                                     | Mean      |     |     |     |     |     |     |
|                                     | CV(%)     |     |     |     |     |     |     |
|                                     | Factor(%) |     |     |     |     |     |     |

Next Sample: 664, Venous Blood Current User:000 2023/06/13 11:23:27

Figure 6-2 Calibrator calibration



## 6.3.1 Preparation



### Biological risks

- All items (such as samples, QCs, calibrators, reagents, wastes, etc) and areas where those items are placed are potentially infectious. When users contact related items and areas in the laboratory, they should abide by the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc).



### Warning

- The sampling probe is sharp, and the blood samples, QC products and calibrators that may be on the sampling probe are potentially biologically infectious. Please avoid touching the sampling probe.
- Reagents irritate eyes, skin and mucous membranes. When users touch reagent-related items in the laboratory, they should abide by the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc).
- Once the reagent touches the skin, rinse immediately with plenty of water and seek medical attention if necessary. When touching eyes, rinse immediately with plenty of water and seek medical attention.
- Clothes, hair and hands must keep a certain distance to prevent them from being pinched by moving parts.
- The user should abide by the relevant regulations of the region and country on the discharge and disposal of reagents, waste liquids, waste samples, consumables, etc.



### Caution

- Do not reuse disposable items.

### NOTICE

- Users should use the QC products and reagents approved by the company, and store and use them in strict accordance with the instructions for use of the QC products and reagents.
- The user can only use disposable items approved by the company, such as vacuum blood collection tubes, centrifuge tubes, and capillaries.

Check the following steps before calibration, and confirm that the background range, repeatability and carryover rate of the analyzer are within the range specified in the manual before calibration. Otherwise, it is necessary to find the reason, and then judge whether calibration is required after the problem is solved. If the problem cannot be solved, please contact the company service center.

1. Check the host and reagents to ensure that the reagents are sufficient to complete the entire calibration process. If the reagents are used up during the calibration process, re-calibration is required.
2. Conduct the background detection. If the bottom right of the screen prompts "Background Abnormal", refer to "14 Troubleshooting" for processing to ensure that the background detection results meet the requirements (see "Appendix A Specifications" for the background range).
3. Use the median QC product to count 11 times continuously in the whole blood-CBC+DIFF mode, take the count results from the 2nd to the 11th time, and check the repeatability of the count results from the 2nd to the 11th time in the "Review" interface, and ensure that it is in the next within the range specified in the table.

Table 6-1 Sample range and repeatability

| Parameter | Measurement range                         | Repeatability |
|-----------|-------------------------------------------|---------------|
| WBC       | $(3.5 \sim 9.5) \times 10^9/L \leq 6.0\%$ | $\leq 6.0\%$  |
| RBC       | $(3.8 \sim 5.8) \times 10^{12}/L$         | $\leq 3.0\%$  |



|     | Parameter                     | Measurement range | Repeatability |
|-----|-------------------------------|-------------------|---------------|
| HGB | (115~175) g/L                 | ≤ 2.5%            |               |
| PLT | (125~350) ×10 <sup>9</sup> /L | ≤ 10.0%           |               |
| HCT | 35%~50%                       | ≤ 3.0%            |               |

4. Count 3 times with the high-value QC product, and then immediately count 3 times with the matching diluent. Then calculate the carryover rate according to the following formula.

$$\text{Carry-over rate (\%)} = \frac{\text{1st low value sample result} - \text{3rd low value sample result}}{\text{3rd high value sample result} - \text{3rd low value sample result}} \times 100\%$$

The results should meet the requirements of the table below.

Table 6-2 Carry-over rate

| Parameter | Carry-over rate |
|-----------|-----------------|
| WBC       | ≤1.5%           |
| RBC       | ≤1.0%           |
| HGB       | ≤1.0%           |
| PLT       | ≤3.0%           |

5. It is recommended that the user establish a record file and make a record table for archiving. The content of the record table is recommended to include the following items: date, source of calibrator, batch number and its reference value, and background detection value.

## 6.3.2 Verify Calibration Factors

After calibration, it is recommended to verify the calibration coefficients as follows:

1. Analyze the calibrator at least 3 times, and check whether the analysis results are within the allowable range.
2. Analyze QC products with high, medium and low values, measure each concentration at least 3 times, and check whether the analysis results are within the allowable range.
3. Analyze at least 3 normal fresh blood samples with known reference values, each sample is measured at least 6 times, and check whether the analysis results are within the allowable range.

## 6.3.3 Calibration History

Click "Cal > History" to enter the calibration history interface. Users can view the calibration history list and detailed calibration data.

Report

Review

QC

Cal

Service

Setup

Log

Status

LIS

Manual

Calibrator

History

History List

| NO. | Cal. Date           | Verifier | Cal. Type  | Cal. Mode | Remarks |
|-----|---------------------|----------|------------|-----------|---------|
| 1   | 2023-05-18 18:26:46 | produce  | Manual Cal |           |         |
| 2   | 2023-05-18 17:13:38 | produce  | Manual Cal |           |         |
| 3   | 2023-05-18 17:13:37 | produce  | Manual Cal |           |         |
| 4   | 2023-05-18 16:55:32 | produce  | Manual Cal |           |         |
| 5   | 2023-05-18 16:55:32 | produce  | Manual Cal |           |         |
| 6   | 2023-05-18 16:54:16 | produce  | Manual Cal |           |         |
| 7   | 2023-05-18 16:54:15 | produce  | Manual Cal |           |         |
| 8   | 2023-05-18 16:53:06 | produce  | Manual Cal |           |         |
| 9   | 2023-05-18 16:53:05 | produce  | Manual Cal |           |         |
| 10  | 2023-05-18 16:53:01 | produce  | Manual Cal |           |         |
| 11  | 2023-05-18 16:53:00 | produce  | Manual Cal |           |         |
| 12  | 2023-05-18 16:52:55 | produce  | Manual Cal |           |         |

Detail Data

|                 | WBC | RBC | HGB | MCV | PLT | MPV | RDW-CV | RDW-SD |
|-----------------|-----|-----|-----|-----|-----|-----|--------|--------|
| Pre Coefficient |     |     |     |     |     |     |        |        |
| New Coefficient |     |     |     |     |     |     |        |        |

Next Sample: 664, Venous Blood

Current User:000 2023/06/13 11:23:44

Figure 6-3 Calibration history

- History list

The last 100 calibration histories are displayed in the list, including the following items:

- Cal. Date: The operating system date when the calibration coefficients were saved.
- Verifier: The performer of the calibration operation.
- Cal. Type: Includes manual calibration, calibrator calibration and fresh blood calibration.
- Cal. Mode: The mode taken during calibration, including "whole blood" and "Prediluted".
- Remarks: Supplementary notes for relevant calibration information.

- Detailed calibration data

Select any record in the "History List" to see details.

# 7 Review

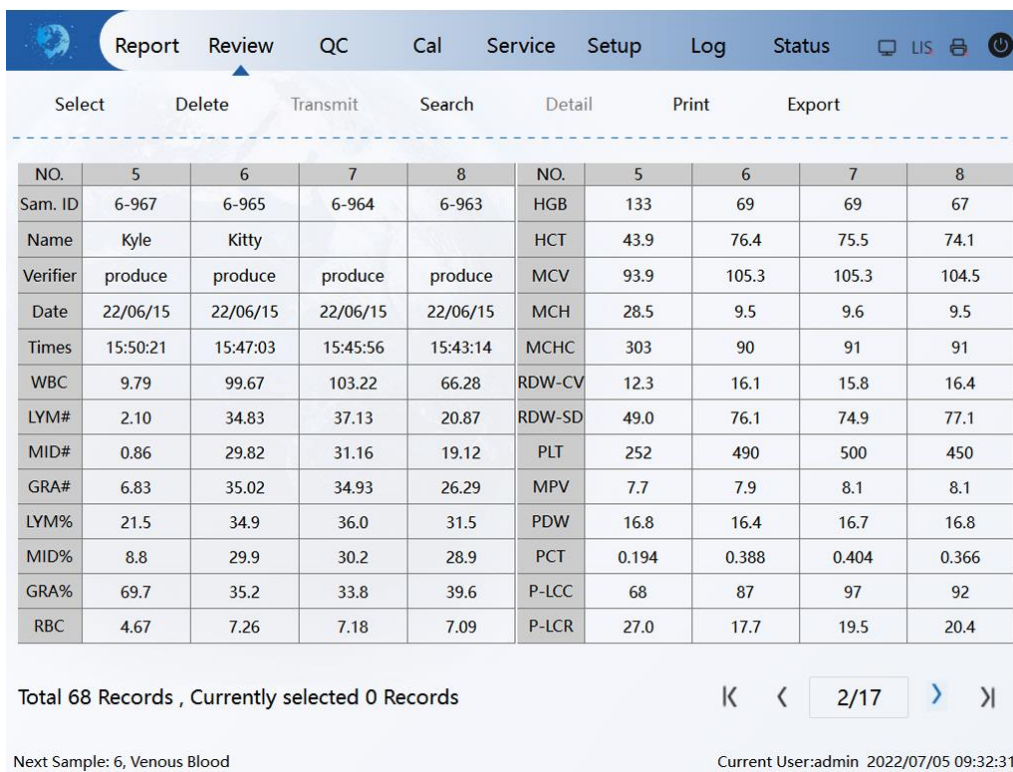
## 7.1 Overview

After each sample analysis is performed, the analyzer automatically stores the sample information, result data, Flag prompt information, histogram and its scatter plot in the review database. The sample library can store up to 300,000 sample records.

In the "Review" interface, users can look up the stored sample information, result, Flag prompt information, histogram and its scatter plot, and can also query, compare and export history samples.

## 7.2 Interface Introduction

Users can browse, query, compare, print and export previous results in the review interface. Click "Review" to enter the "Review" interface, as shown in Figure 7-1.



| <div>  <span>Report</span> <span>Review</span> <span>QC</span> <span>Cal</span> <span>Service</span> <span>Setup</span> <span>Log</span> <span>Status</span> <span>LIS</span> <span>Print</span> <span>Power</span> </div> |          |          |          |          |        |       |       |       |       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|----------|----------|--------|-------|-------|-------|-------|
| <div> <span>Select</span> <span>Delete</span> <span>Transmit</span> <span>Search</span> <span>Detail</span> <span>Print</span> <span>Export</span> </div>                                                                                                                                                   |          |          |          |          |        |       |       |       |       |
| NO.                                                                                                                                                                                                                                                                                                         | 5        | 6        | 7        | 8        | NO.    | 5     | 6     | 7     | 8     |
| Sam. ID                                                                                                                                                                                                                                                                                                     | 6-967    | 6-965    | 6-964    | 6-963    | HGB    | 133   | 69    | 69    | 67    |
| Name                                                                                                                                                                                                                                                                                                        | Kyle     | Kitty    |          |          | HCT    | 43.9  | 76.4  | 75.5  | 74.1  |
| Verifier                                                                                                                                                                                                                                                                                                    | produce  | produce  | produce  | produce  | MCV    | 93.9  | 105.3 | 105.3 | 104.5 |
| Date                                                                                                                                                                                                                                                                                                        | 22/06/15 | 22/06/15 | 22/06/15 | 22/06/15 | MCH    | 28.5  | 9.5   | 9.6   | 9.5   |
| Times                                                                                                                                                                                                                                                                                                       | 15:50:21 | 15:47:03 | 15:45:56 | 15:43:14 | MCHC   | 303   | 90    | 91    | 91    |
| WBC                                                                                                                                                                                                                                                                                                         | 9.79     | 99.67    | 103.22   | 66.28    | RDW-CV | 12.3  | 16.1  | 15.8  | 16.4  |
| LYM#                                                                                                                                                                                                                                                                                                        | 2.10     | 34.83    | 37.13    | 20.87    | RDW-SD | 49.0  | 76.1  | 74.9  | 77.1  |
| MID#                                                                                                                                                                                                                                                                                                        | 0.86     | 29.82    | 31.16    | 19.12    | PLT    | 252   | 490   | 500   | 450   |
| GRA#                                                                                                                                                                                                                                                                                                        | 6.83     | 35.02    | 34.93    | 26.29    | MPV    | 7.7   | 7.9   | 8.1   | 8.1   |
| LYM%                                                                                                                                                                                                                                                                                                        | 21.5     | 34.9     | 36.0     | 31.5     | PDW    | 16.8  | 16.4  | 16.7  | 16.8  |
| MID%                                                                                                                                                                                                                                                                                                        | 8.8      | 29.9     | 30.2     | 28.9     | PCT    | 0.194 | 0.388 | 0.404 | 0.366 |
| GRA%                                                                                                                                                                                                                                                                                                        | 69.7     | 35.2     | 33.8     | 39.6     | P-LCC  | 68    | 87    | 97    | 92    |
| RBC                                                                                                                                                                                                                                                                                                         | 4.67     | 7.26     | 7.18     | 7.09     | P-LCR  | 27.0  | 17.7  | 19.5  | 20.4  |

Total 68 Records , Currently selected 0 Records

K
<
2/17
>
|

Next Sample: 6, Venous Blood
Current User:admin 2022/07/05 09:32:31

Figure 7-1 Review interface

The review interface can be seen in two parts: the list area and the function buttons, among which:

- List area: You can browse each sample record and its main sample/animal information.
- Function buttons: You can select, delete, LIS transmission, search and print, export and other operations for samples.

## 7.3 List Area

The list area is located in the middle of the review interface, and displays a list of analyzed samples, which includes the basic information of the samples, such as Sample ID, Name, Verifier, Date and Times, etc, as shown in Figure 7-2.

| NO.      | 5        | 6        | 7        | 8        | NO.    | 5     | 6     | 7     |   |
|----------|----------|----------|----------|----------|--------|-------|-------|-------|---|
| Sam. ID  | 6-967    | 6-965    | 6-964    | 6-963    | HGB    | 133   | 69    | 69    |   |
| Name     | Kyle     | Kitty    |          |          | HCT    | 43.9  | 76.4  | 75.5  | 7 |
| Verifier | produce  | produce  | produce  | produce  | MCV    | 93.9  | 105.3 | 105.3 | 1 |
| Date     | 22/06/15 | 22/06/15 | 22/06/15 | 22/06/15 | MCH    | 28.5  | 9.5   | 9.6   |   |
| Times    | 15:50:21 | 15:47:03 | 15:45:56 | 15:43:14 | MCHC   | 303   | 90    | 91    |   |
| WBC      | 9.79     | 99.67    | 103.22   | 66.28    | RDW-CV | 12.3  | 16.1  | 15.8  | 1 |
| LYM#     | 2.10     | 34.83    | 37.13    | 20.87    | RDW-SD | 49.0  | 76.1  | 74.9  | 7 |
| MID#     | 0.86     | 29.82    | 31.16    | 19.12    | PLT    | 252   | 490   | 500   | 4 |
| GRA#     | 6.83     | 35.02    | 34.93    | 26.29    | MPV    | 7.7   | 7.9   | 8.1   |   |
| LYM%     | 21.5     | 34.9     | 36.0     | 31.5     | PDW    | 16.8  | 16.4  | 16.7  | 1 |
| MID%     | 8.8      | 29.9     | 30.2     | 28.9     | PCT    | 0.194 | 0.388 | 0.404 | 0 |
| GRA%     | 69.7     | 35.2     | 33.8     | 39.6     | P-LCC  | 68    | 87    | 97    |   |
| RBC      | 4.67     | 7.26     | 7.18     | 7.09     | P-LCR  | 27.0  | 17.7  | 19.5  | 2 |

Figure 7-2 List review

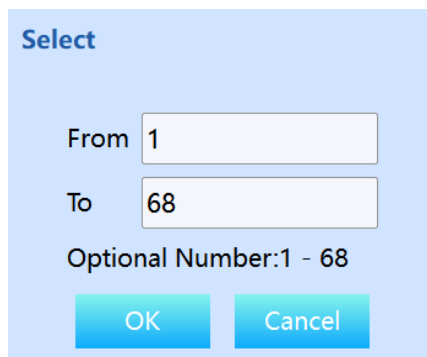
## NOTICE

- The list area displays the records of all analyzed samples by default. If you switch from the "Report" interface to the "Review" interface, the list area displays all the records of the analysis day of the last selected sample before the switch.

## 7.4 Function Buttons

- Select

Click "Select" to display the selection box, as shown in the following figure:



The image shows a 'Select' dialog box with a light blue background. It contains two input fields: 'From' with the value '1' and 'To' with the value '68'. Below these fields, it says 'Optional Number: 1 - 68'. At the bottom, there are two buttons: 'OK' and 'Cancel'.

Figure 7-3 Select

Enter the record No. to be selected in the "From" and "To" edit boxes, and click "OK". If the edit boxes entered same value, a single record would be selected.

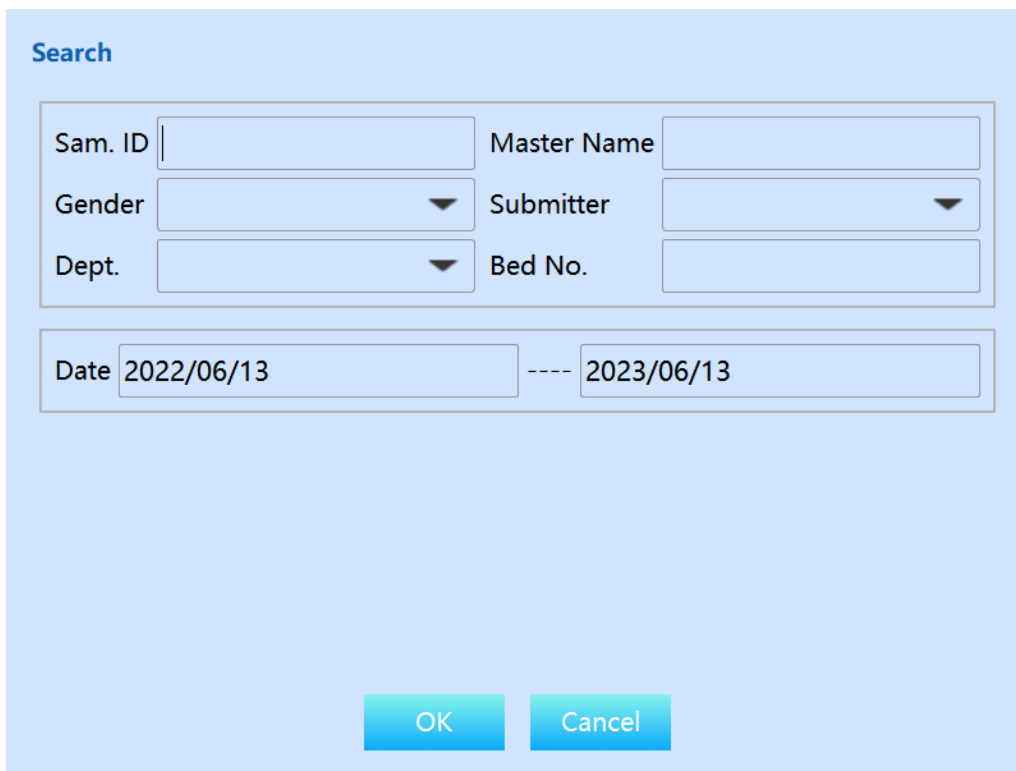
Click "Cancel", the system would not select any record items.

- LIS Transmit

LIS transmission provides data transmission function, and data can be selected in the following ways:

- Select.
  - Click a single column of the list and select a history data. If no data is selected, all data can be transmitted. Click "Transmit" to see the transmission box to select the data to be transmitted, and click "Start".
- Search

The search function allows users to search for the required records according to the specified conditions. Click "Search" to see the search dialog box, as shown in the following figure:



The image shows a 'Search' form with a light blue background. At the top left is the title 'Search'. Below it is a grid of input fields. The first row contains 'Sam. ID' (text input) and 'Master Name' (text input). The second row contains 'Gender' (dropdown menu) and 'Submitter' (dropdown menu). The third row contains 'Dept.' (dropdown menu) and 'Bed No.' (text input). Below this grid is a date range section with 'Date' followed by two text inputs: the first contains '2022/06/13' and the second contains '2023/06/13', separated by a dashed line '----'. At the bottom of the form are two blue buttons: 'OK' and 'Cancel'.

Figure 7-4 Search condition

Sam. ID is the unique identifier of the search history. If an ID is entered, other search conditions are invalid. The user can use one or more conditions to query, after entering the information, click "OK", if there are records that meet the conditions, it would be displayed in the review list. If there are no records that meet the conditions, the system would prompt no data.

- Delete

The delete function can be used to delete selected data and all history data. The methods for selecting data are:

- a) Use the selected function.
- b) Click the single column of the list and select an item of history data. If no data is selected, the system would prompt the user to select at least one sample.

- Print

The printing function prints the selected history data according to the printing method set by the system. For printing settings, please refer to "8.1 Common Setup".

- Detail

The "Detail" function is used to view the detailed data information of a sample. After selecting a record in the history list, click "Detail" to enter the sample detailed information review window, as shown in the following figure:

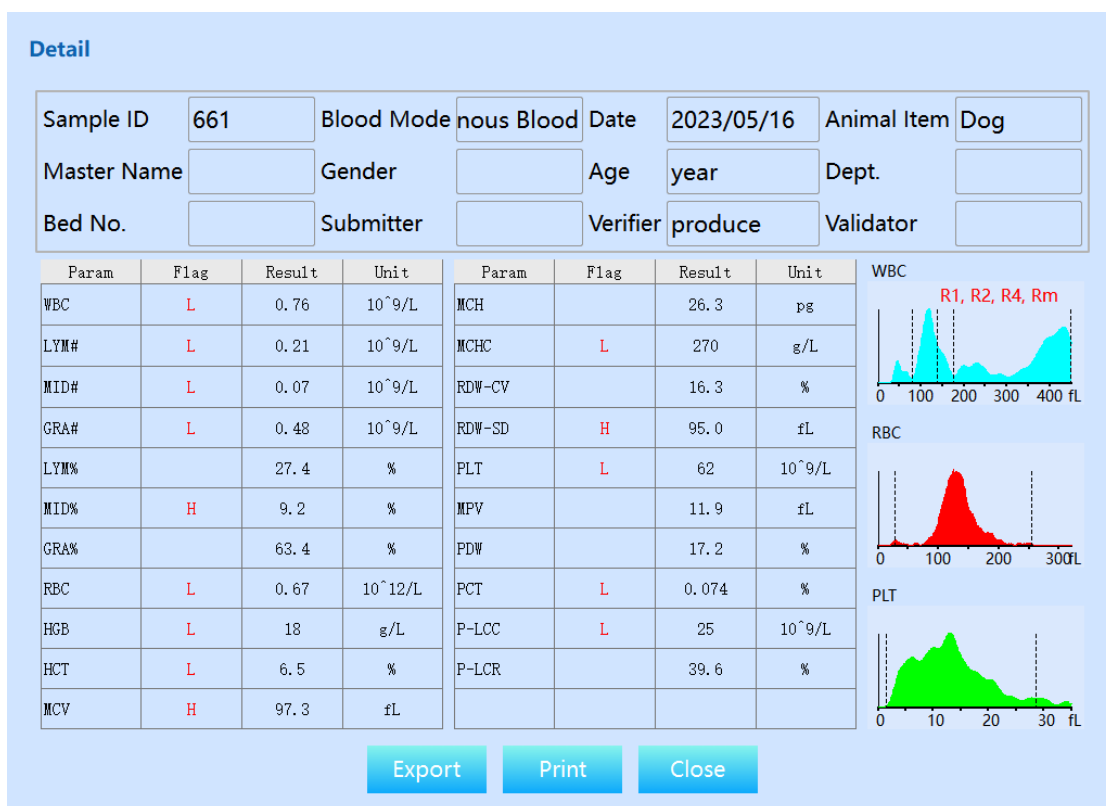


Figure 7-5 Sample history data

Basic information, results and histograms of the samples are shown in this interface.

# 8 Setup

## 8.1 Common Setups

Setup is used to set various parameters of the system, click "Setup" on the main interface to enter the setting window, click "Common", you can set auxiliary information, laboratory information, LIS setup, print setup, maintenance setup, and machine setup.

- **AUX INFO:** Users can set the sample ID entry method, select the sample prefix, select the prediluted test reminding, select the flag and virtual keyboard settings. As shown in the following figure:

The screenshot shows the KYNTEL Setup window with the 'Common' tab selected. The 'AUX INFO' section is active, displaying various configuration options. The 'Sample ID Entry Method' is set to 'Auto-increment'. The 'Sample Prefix' field is empty. The 'Next Sample ID after startup' is set to 'Following the sample ID before shutdown'. The 'Predilution test reminding' is set to 'Reminding'. The 'Flag' section has 'H/L' selected, and the 'Modify' checkbox is checked. The 'Other Settings' section has 'Virtual keyboard' and 'Auto refresh the result(report)' checked, and 'Startup background test' is also checked. There are buttons for 'Keyboard Language', 'Reset Waste', 'Save', and 'Cancel'. The status bar at the bottom shows 'Next Sample: , Venous Blood' and 'Current User:admin 2023/03/10 09:49:02'.

Figure 8-1 Auxiliary information

- **LAB INFO:** Record information such as hospitals and laboratories, as shown in the following figure:

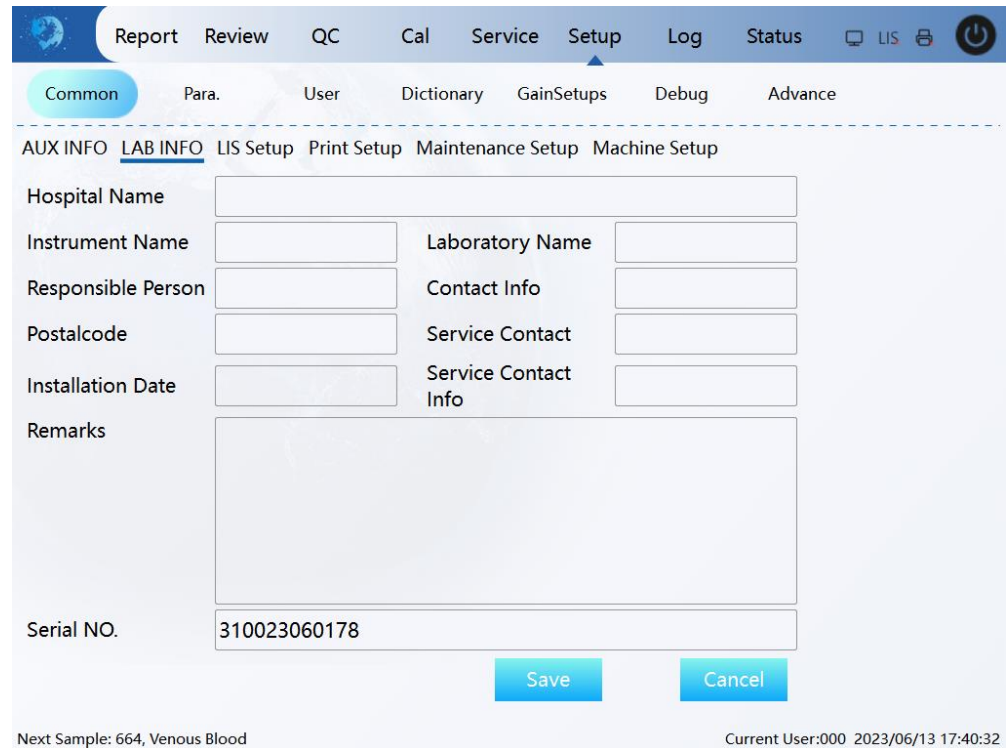


Figure 8-2 Laboratory information

- LIS Setup: Perform network settings and transmission mode settings.

**Note:** Before setting the LIS transmission, please check whether the hematology analyzer has been connected to the LIS server through a network cable.

1. Check and obtain LIS server IP address.
2. IP address setting of "LIS Setup" interface: If the IP address of LIS server is 10.0.0.20, the IP address of "LIS Setup" interface should be set to 10.0.0.20, and the port number 5000 by default. As shown in the Figure 8-3, click "Save" to complete the "LIS Setup".

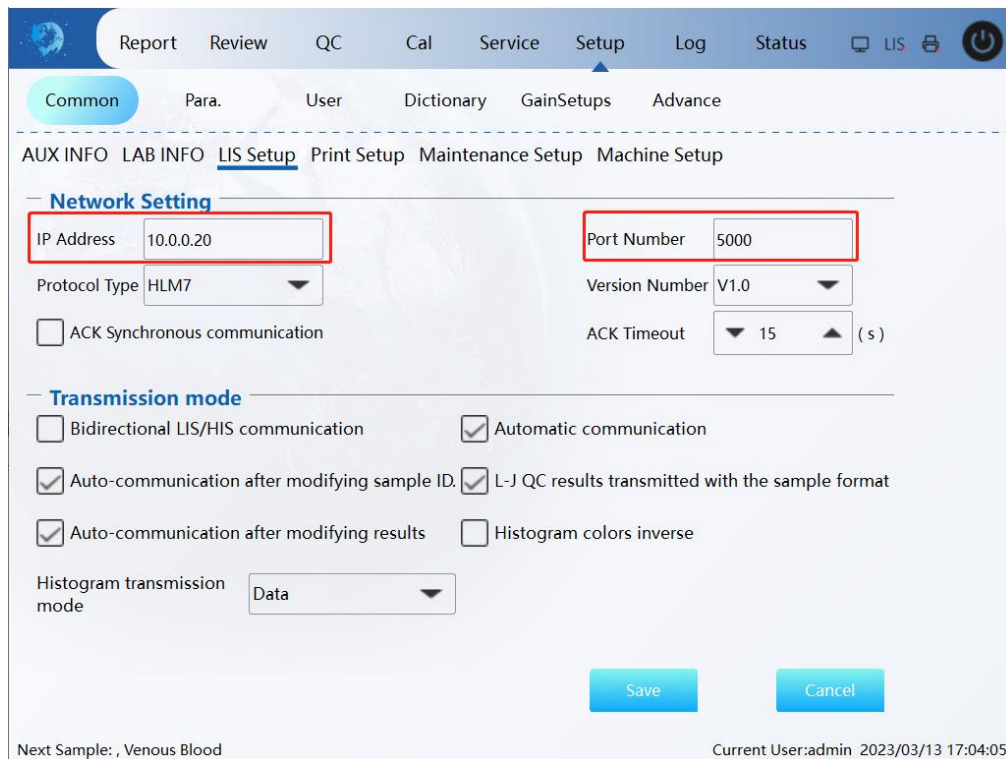


Figure 8-3 LIS setup

3. IP address settings in the "Machine Setup" interface: Set the IP address of the "Machine Setup" interface according to the IP address of LIS server to ensure that the IP address and the IP address



of the LIS server are in the same network segment. For example, the IP address of the LIS server is 10.0.0.20, and the IP address of the "Machine Setup" interface can be set to 10.0.0.10, as shown in the following figure. Click "save" to complete the "Machine Setup".

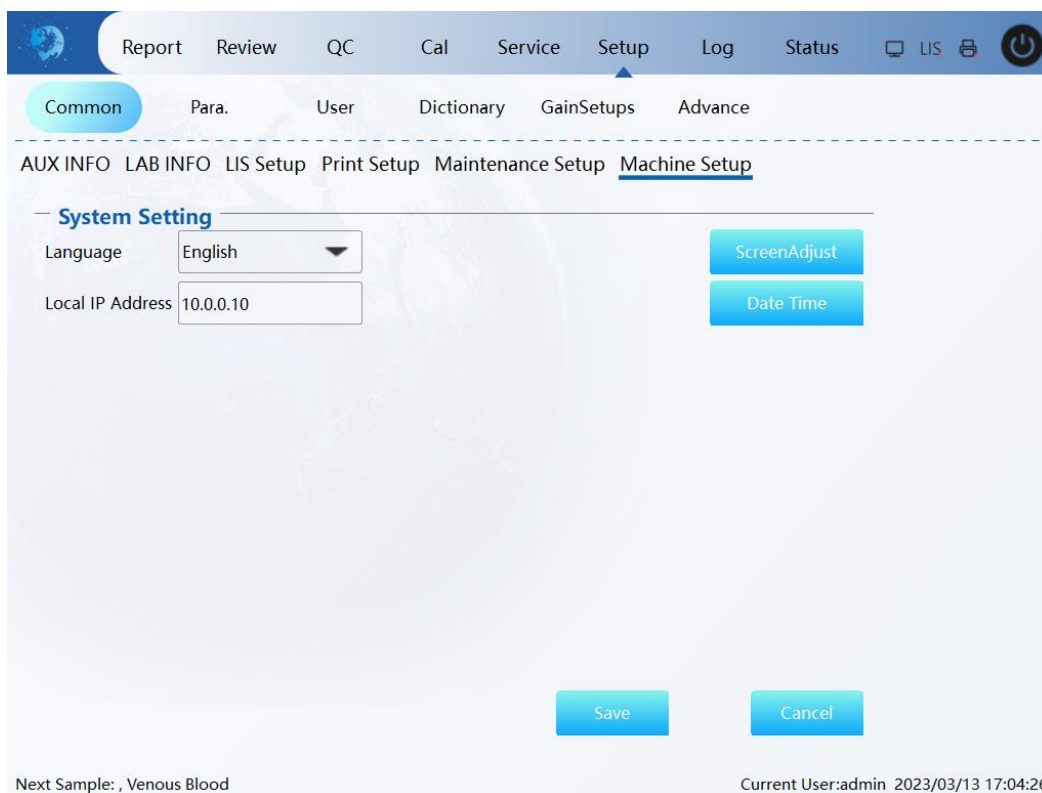


Figure 8-4 Machine setup

**Note:** If the LIS connection fails (as shown in the status bar ) , it can be changed according to the free port of LIS server to avoid connection failure due to port occupation; If changing the port number still fails to connect, check whether the firewall at the LIS server side remains off.

- **Print Setup:** You can choose to use a built-in printer or an external printer, as shown below:
  1. **Printer Name:** Click the drop-down arrow to select the printer to print from.
  2. **Copies:** Click the up and down arrows to select the number of copies to be printed.
  3. **Add Printer:** To add a new printer, click this button to add it.
  4. **Template Setup:** Click the drop-down arrow to select the desired print template.
  5. **Report Setup:** Edit the report title.

Figure 8-5 Print setup

➤ Maintenance Setup, you can set AutoFlush, Auto maintain frequency, etc, as shown in the following figure:

1. Auto flush: Set the time for automatic fluidics flush.
2. Auto maintain frequency: Set the number of samples for automatic cleaning.

Figure 8-6 Maintenance setup

➤ Machine setup: Users can set the system as shown below:

Language: Click the drop-down arrow to select the language displayed by the software.

Report Review QC Cal Service Setup Log Status

Common Para. User Dictionary GainSetups Advance

AUX INFO LAB INFO LIS Setup Print Setup Maintenance Setup Machine Setup

**System Setting**

Language English

Local IP Address 10.0.0.10

ScreenAdjust

Date Time

Save Cancel

Next Sample: , Venous Blood Current User:admin 2023/03/10 10:00:09

Figure 8-7 Machine setup

## 8.2 Parameter Setups

Click "Para.", the interface is as follows:

Report Review QC Cal Service Setup Log Status

Common Para. User Dictionary GainSetups Debug Advance

Param Unit Animal Item

Unit China

Restore

| Param | Unit                | Data Format | Param  | Unit               | Data Format |
|-------|---------------------|-------------|--------|--------------------|-------------|
| WBC   | 10 <sup>9</sup> /L  | ***, **     | MCH    | pg                 | ***, *      |
| LYM#  | 10 <sup>9</sup> /L  | ***, **     | MCHC   | g/L                | ****, .     |
| MID#  | 10 <sup>9</sup> /L  | ***, **     | RDW-CV | %                  | **, *       |
| GRA#  | 10 <sup>9</sup> /L  | ***, **     | RDW-SD | fL                 | ****, *     |
| LYM%  | %                   | **, *       | PLT    | 10 <sup>9</sup> /L | ****, .     |
| MID%  | %                   | **, *       | MPV    | fL                 | **, *       |
| GRA%  | %                   | **, *       | PDW    | %                  | **, *       |
| RBC   | 10 <sup>12</sup> /L | **, **      | PCT    | %                  | . ***       |
| HGB   | g/L                 | ***, .      | P-LCC  | 10 <sup>9</sup> /L | ****, .     |
| HCT   | %                   | **, *       | P-LCR  | %                  | **, *       |
| MCV   | fL                  | ***, *      |        |                    |             |

Save Cancel

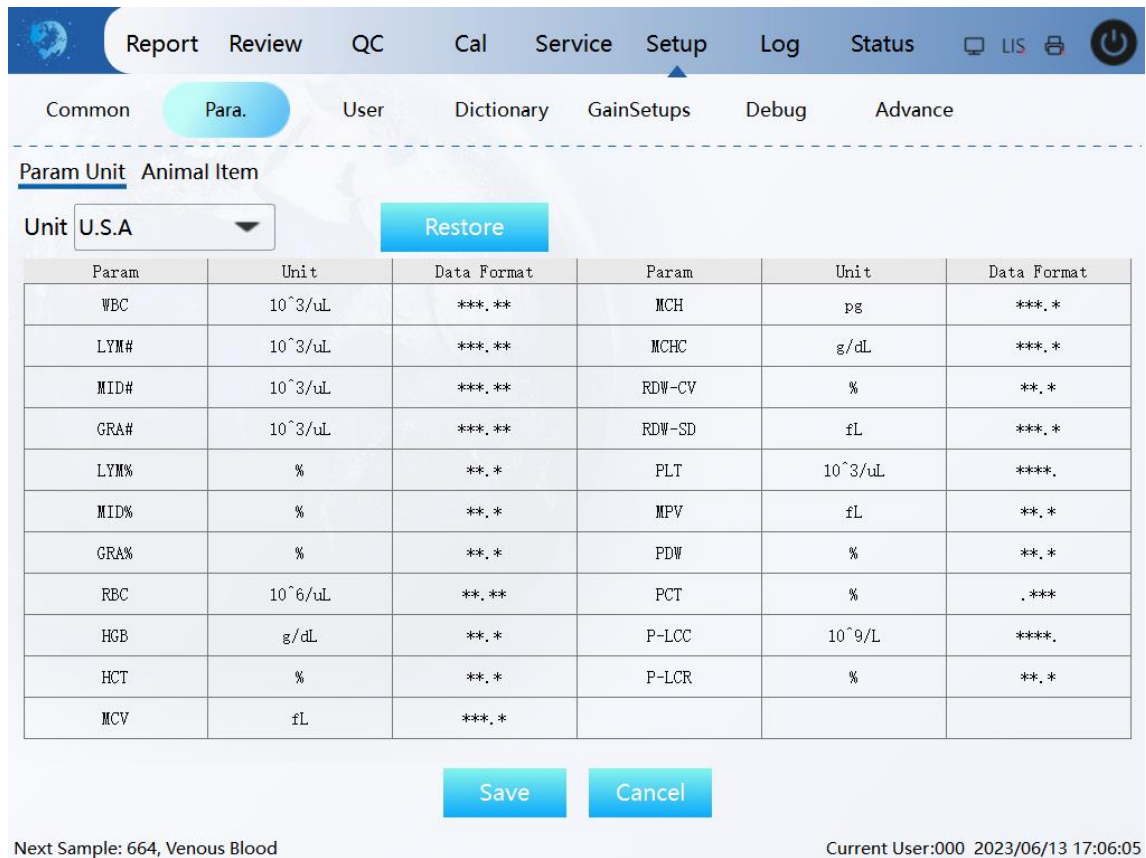
Next Sample: 664, Venous Blood Current User:000 2023/06/13 17:05:33

Figure 8-8 Parameter setup

The device has set the reference range of each parameter before leaving the factory. If the user needs to modify the reference range, select "Group" in the "Ref.Group" interface, fill in the values in the lower limit and upper limit, and click "Save".

## 8.2.1 Unit

If you want to change the unit of the parameter, click "Param Unit", as shown below:



Report Review QC Cal Service **Setup** Log Status LIS

Common **Para.** User Dictionary GainSetups Debug Advance

Param Unit Animal Item

Unit **U.S.A** **Restore**

| Param | Unit               | Data Format | Param  | Unit               | Data Format |
|-------|--------------------|-------------|--------|--------------------|-------------|
| WBC   | $10^3/\mu\text{L}$ | ***, **     | MCH    | pg                 | ***, *      |
| LYM#  | $10^3/\mu\text{L}$ | ***, **     | MCHC   | g/dL               | ***, *      |
| MID#  | $10^3/\mu\text{L}$ | ***, **     | RDW-CV | %                  | **, *       |
| GRA#  | $10^3/\mu\text{L}$ | ***, **     | RDW-SD | fL                 | ***, *      |
| LYM%  | %                  | **, *       | PLT    | $10^3/\mu\text{L}$ | ****, .     |
| MID%  | %                  | **, *       | MPV    | fL                 | **, *       |
| GRA%  | %                  | **, *       | PDW    | %                  | **, *       |
| RBC   | $10^6/\mu\text{L}$ | **, **      | PCT    | %                  | . ***       |
| HGB   | g/dL               | **, *       | P-LCC  | $10^9/\text{L}$    | ****, .     |
| HCT   | %                  | **, *       | P-LCR  | %                  | **, *       |
| MCV   | fL                 | ***, *      |        |                    |             |

**Save** **Cancel**

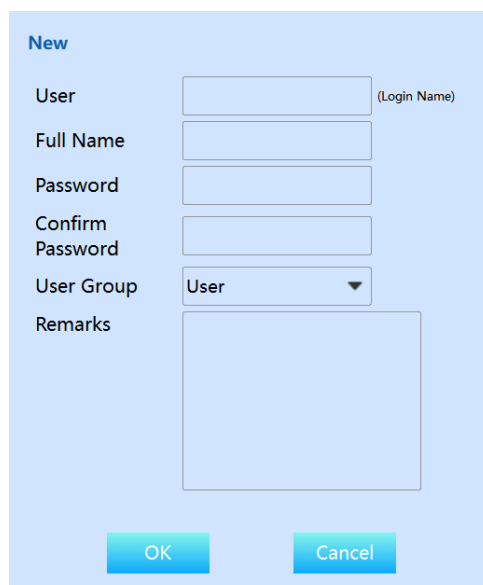
Next Sample: 664, Venous Blood Current User:000 2023/06/13 17:06:05

Figure 8-9 Parameter unit

There are a total of 6 units to choose from, and you can also choose custom settings, among which WBC, LYM#, MID#, GRA# use the same unit. After selecting the unit, remember to click "Save" to return. If you click "Cancel", the unit would not be changed.

## 8.3 User Setups

There are two user levels in the system: system administrator and user, each with different permissions. The default is a common user, and some settings are disabled at this time. To activate these settings, please click "New" to open a dialog box, as shown below:



**New**

User  (Login Name)

Full Name

Password

Confirm Password

User Group **User** ▼

Remarks

**OK** **Cancel**

Figure 8-10 Create a new user

Enter the user name and set the password, select the user group (admin or user), and click the "OK" button. If

you are an administrator, all functions in the other settings interface would be activated. If you are a user, other functions would be activated except that you do not have user management rights. The system default administrator user name is "admin", password is "admin".

## 8.4 Dictionary Setups

| Data dictionary items | NO. | Gender | Remark |
|-----------------------|-----|--------|--------|
| Gender                | 1   |        |        |
| Age Unit              | 2   | male   |        |
| Sample Type           | 3   | female |        |
| Dept.                 |     |        |        |
| Submitter             |     |        |        |

Next Sample: , Venous Blood

Current User:admin 2023/03/10 10:02:01

Figure 8-11 Data dictionary

Users can preset gender, age unit, sample type, department and other content in the program.

## 8.5 Gain Setups

| Item   | CurrentVal | AdjustRate(%) |
|--------|------------|---------------|
| WBC    | 100        | 100           |
| RBC    | 100        | 100           |
| WBC(P) | 100        | 100           |

**HGB Setting**

Blank Voltage: 0.00(V)

HGB Value: 100

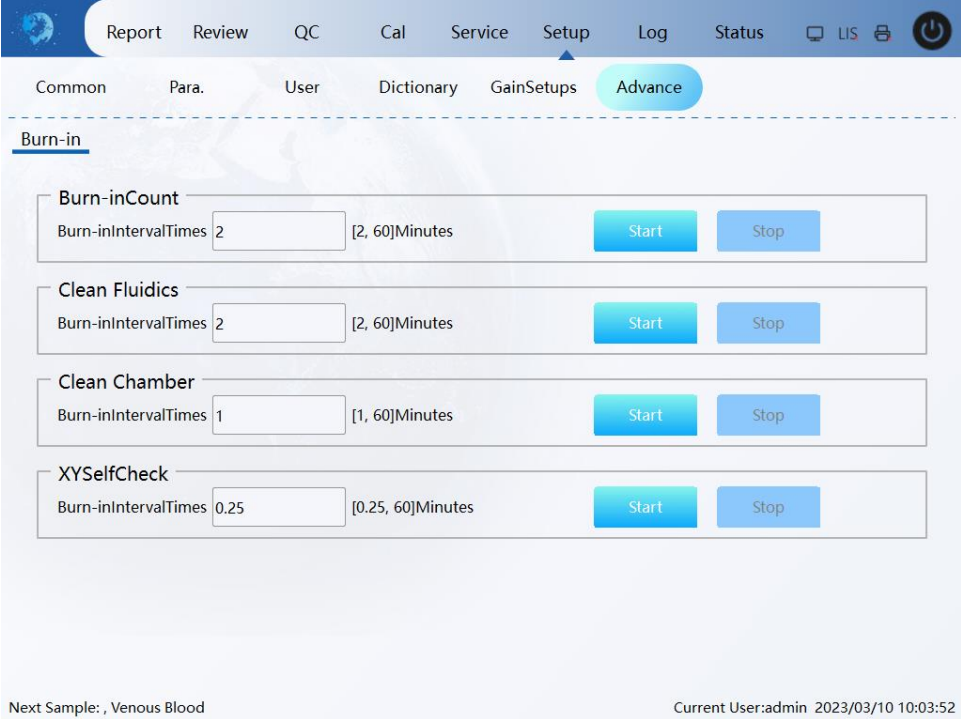
Next Sample: , Venous Blood

Current User:admin 2023/03/10 10:02:27

Figure 8-12 Gain setups

Users can set the gain of WBC, RBC, WBC(P) and related settings of HGB.

## 8.6 Advanced Setups



The screenshot displays the 'Advanced' setup page in the KYNTEL software. The top navigation bar includes 'Report', 'Review', 'QC', 'Cal', 'Service', 'Setup' (selected), 'Log', 'Status', and system icons. Below this, a sub-menu shows 'Common', 'Para.', 'User', 'Dictionary', 'GainSetups', and 'Advance' (selected). The main section is titled 'Burn-in' and contains four configuration blocks:

- Burn-inCount:** Burn-inIntervalTimes is set to 2, with a range of [2, 60] Minutes. It includes 'Start' and 'Stop' buttons.
- Clean Fluidics:** Burn-inIntervalTimes is set to 2, with a range of [2, 60] Minutes. It includes 'Start' and 'Stop' buttons.
- Clean Chamber:** Burn-inIntervalTimes is set to 1, with a range of [1, 60] Minutes. It includes 'Start' and 'Stop' buttons.
- XYSelfCheck:** Burn-inIntervalTimes is set to 0.25, with a range of [0.25, 60] Minutes. It includes 'Start' and 'Stop' buttons.

At the bottom of the interface, the status bar shows 'Next Sample: , Venous Blood' on the left and 'Current User:admin 2023/03/10 10:03:52' on the right.

Figure 8-13 Advanced setups

Set the burn-in interval of "Burn-inCount", "Clean Fluidics", "Clean Chamber" and "XY SelfCheck".

# 9 Service

---

## 9.1 Overview

In order to ensure the accurate and effective operation of the analyzer, the user needs to perform daily maintenance on the analyzer according to the requirements of this chapter. The analyzer provides a number of automatic maintenance services to facilitate the user to complete the maintenance work.

This chapter introduces the various maintenance service functions of the analyzer and some handling measures in case of failure.



### Biological risks

- The surfaces of all parts of the analyzer are potentially infectious and safety precautions should be taken during operation and maintenance.
- 



### Caution

- Improper maintenance may damage the analyzer, the user must follow the instructions in this manual for maintenance.
  - If you encounter any problems that do not appear in the manual, please contact the company service center, and the professionals of the company would give maintenance suggestions.
  - The analyzer must be serviced with company-supplied parts. If you have any questions, please contact the company's service center.
  - During maintenance, avoid touching the sharp tip of the sampling probe.
- 

## 9.2 Change Reagents

---



### Warning

- Reagents irritate eyes, skin and mucous membranes. When users touch reagent-related items in the laboratory, they should abide by the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc).
  - Once the reagent touches the skin, immediately rinse with plenty of water, and seek medical treatment if necessary. Once the reagent comes into the eyes, immediately rinse with plenty of water and see a doctor.
- 

### NOTICE

- The reagents should be left for a period of time to stabilize before use.
  - Users should perform background detection after replacing reagents such as diluent or lyse to ensure that the background value is within the normal range and prepare for sample analysis.
- 

The user needs to replace the reagent in the following cases:

- The system prompts that the reagent has been used up.
- The reagents in the tubing may be contaminated.
- The reagent has been confirmed to be contaminated or expired
- It is suspected that there are air bubbles in the pipeline.



Users can replace the following reagents by themselves:

- Diluent
- Lyse
- All reagents

The steps for changing reagents are as follows:

1. Click "Service > Replace Reagent" to enter the interface shown in Figure 9-1.

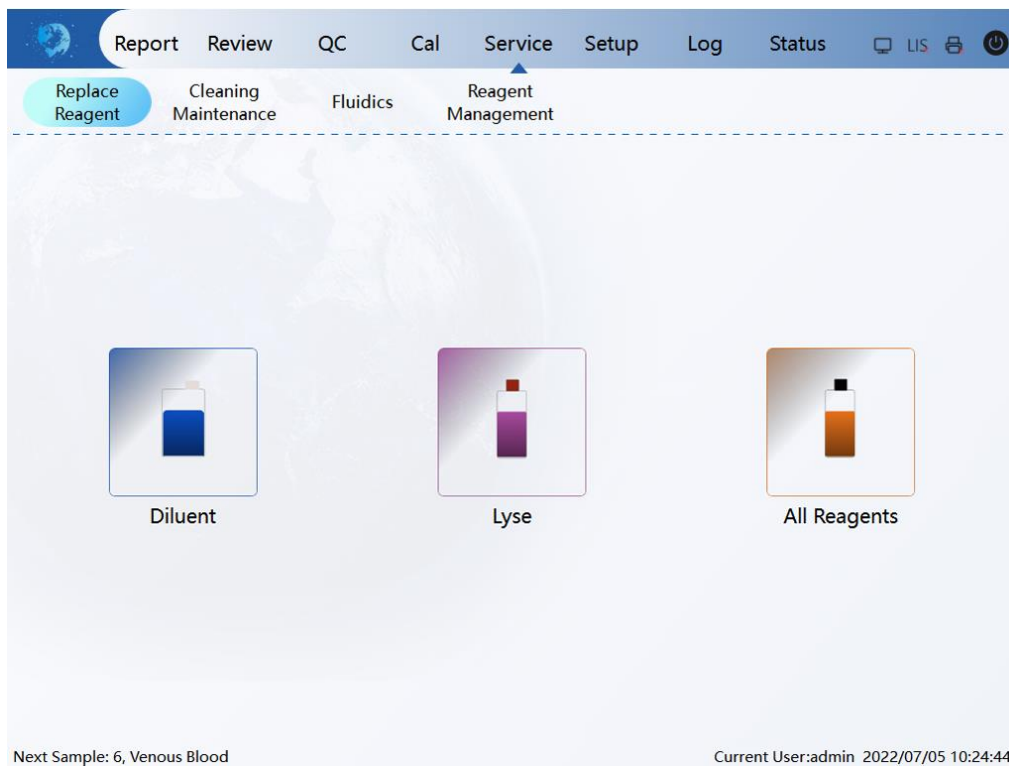


Figure 9-1 Replace reagent

2. Click the name of the reagent to be replaced, such as "Diluent".

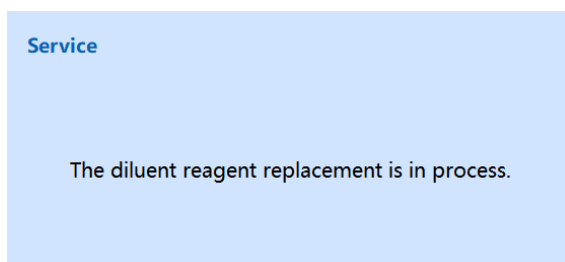


Figure 9-2 Replace the diluent

3. After the system has finished processing, a message box would pop up, indicating that the reagent replacement is complete.
4. Click "OK" to close the box. If necessary, continue to replace other reagents by following the above steps.

## 9.3 Cleaning Maintenance

### 9.3.1 Cleaning

The steps for cleaning and maintaining the components inside the device are as follows:

1. Click "Service > Cleaning Maintenance" to enter the interface shown in Figure 9-3.



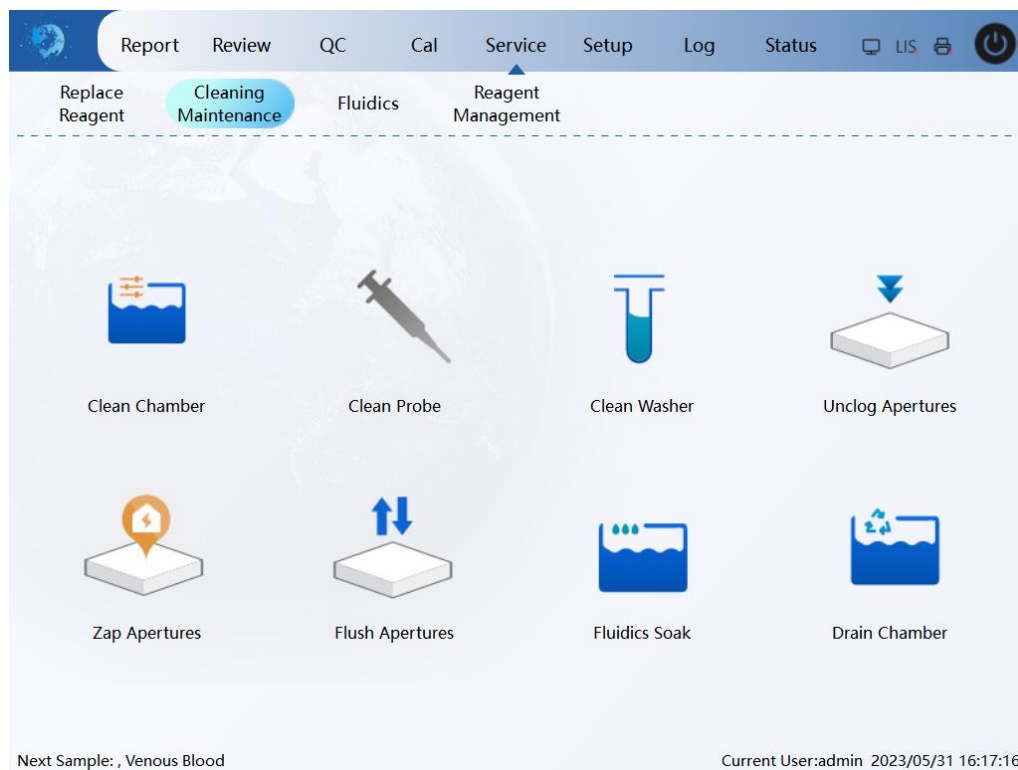


Figure 9-3 Cleaning maintenance

- Click on the icon for the part you wish to clean, such as "Clean Chamber".

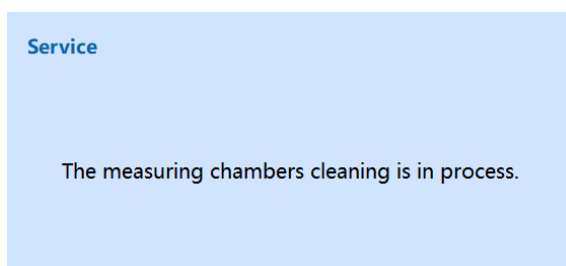


Figure 9-4 Clean chamber

- After the system cleaning is complete, a message box would pop up indicating that the cleaning is successful.
- Click "OK" to close the dialog. If necessary, continue cleaning other parts by following the steps above.

### 9.3.2 Blockage

If there is a blockage fault, or the counting result is found to be inaccurate, and it is suspected that the apertures are blocked, the blockage removal operation can be performed. The steps to remove the blockage are as follows:

- Click on the "Unclog Apertures" icon. The system starts cleaning, and the following prompt box pops up.

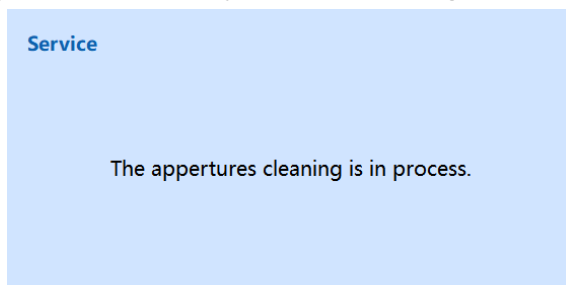


Figure 9-5 Unclog apertures

- After the blockage removal is completed, the system pops up a message box indicating that the blockage removal is complete.

3. Click "OK" to close the prompt box. If necessary, repeat the above steps to continue the blockage removal operation.

### 9.3.3 Fluidics Soak

The user should perform "Fluidics Soak" in the following situations.

- If the background result is out of the background range, the scatter plot classification effect is reduced, or the aperture is blocked, the problem is unable to be solved after performing other maintenance operations.
- If the sample size is small (less than 30 samples/day), the user should execute "Fluidics Soak" during daily shutdown to prevent the accumulation of contamination in the machine (because it would cause serious impact on the results and the machine itself after accumulation to a certain extent!), thus guaranteeing the accuracy of the results.
- The analyzer is powered on continuously for more than 24 hours.

The steps of soaking in the cleaning fluid are as follows:

1. Click on "Fluidics Soak". A prompt box would pop up on the interface, as shown in the following figure.

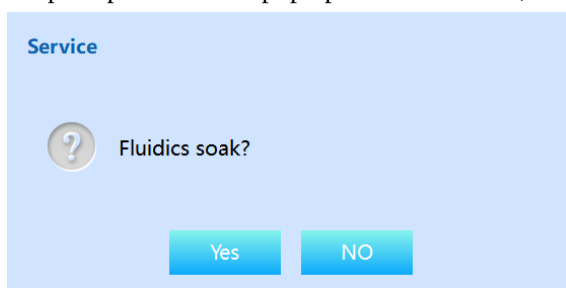


Figure 9-6 Tips for cleaning solution preparation

2. Click "Yes", the interface pops up a prompt box, as shown in the following figure.

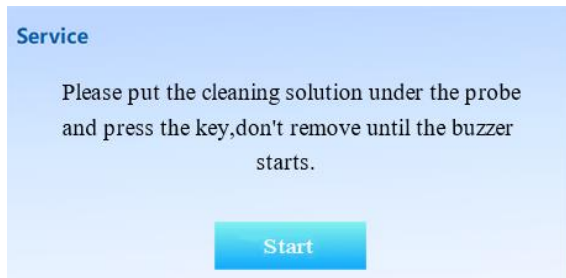


Figure 9-7 Tips for soaking

3. According to the interface prompt, put the cleaning solution under the sampling probe, and press the Aspirate button or click "Start" on the interface. The interface is displayed as shown in the following figure.

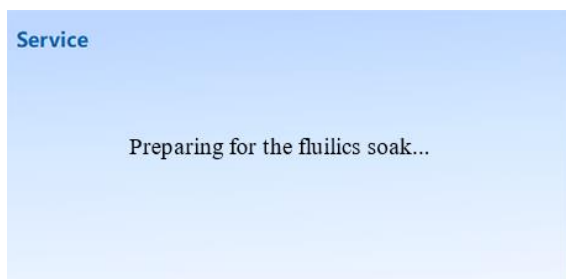


Figure 9-8 Tips for preparing to soak

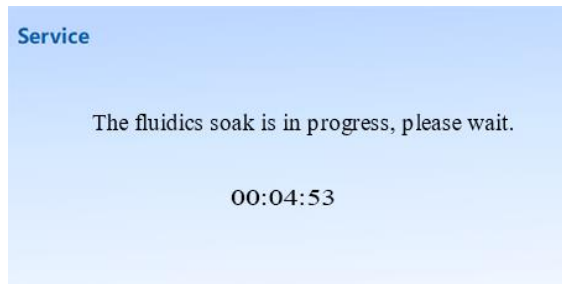


Figure 9-9 Tips for soaking

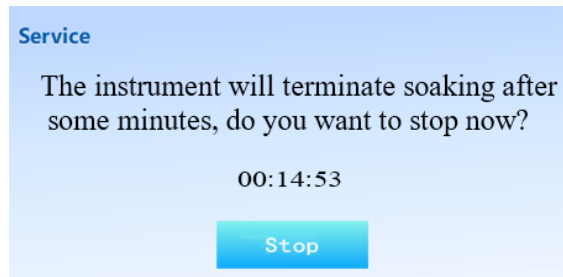


Figure 9-10 Tips for stopping soaking

4. After the device has been soaked for 5 minutes, the user can manually stop soaking.
5. Click "Stop" or wait for the device to automatically soak for 15 minutes, and after the device performs post-immersion cleaning, the operation is completed.

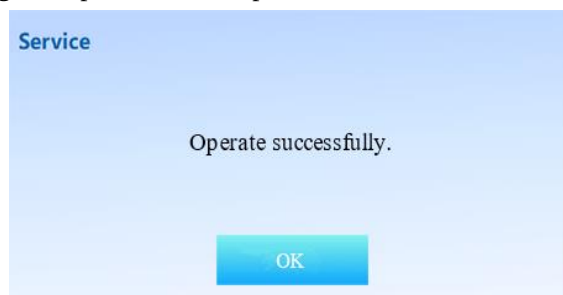


Figure 9-11 Tips for successful operation

6. Click "OK" to complete the operation. If necessary, repeat the above steps to continue soaking in the cleaning solution.

## 9.4 Fluidics

Fluidics functions include "Fluidics Init", "Clean Fluidics", "Perfuse Fluidics", "Drain Fluidics" and "Prepare to Ship".

### 9.4.1 Fluidics Init

If major components have been replaced or the fluidics system has been repaired to the analyzer, "Fluidics Init" should be performed as follows:

1. Select the "Service > Fluidics" tab to enter the Fluidics interface.

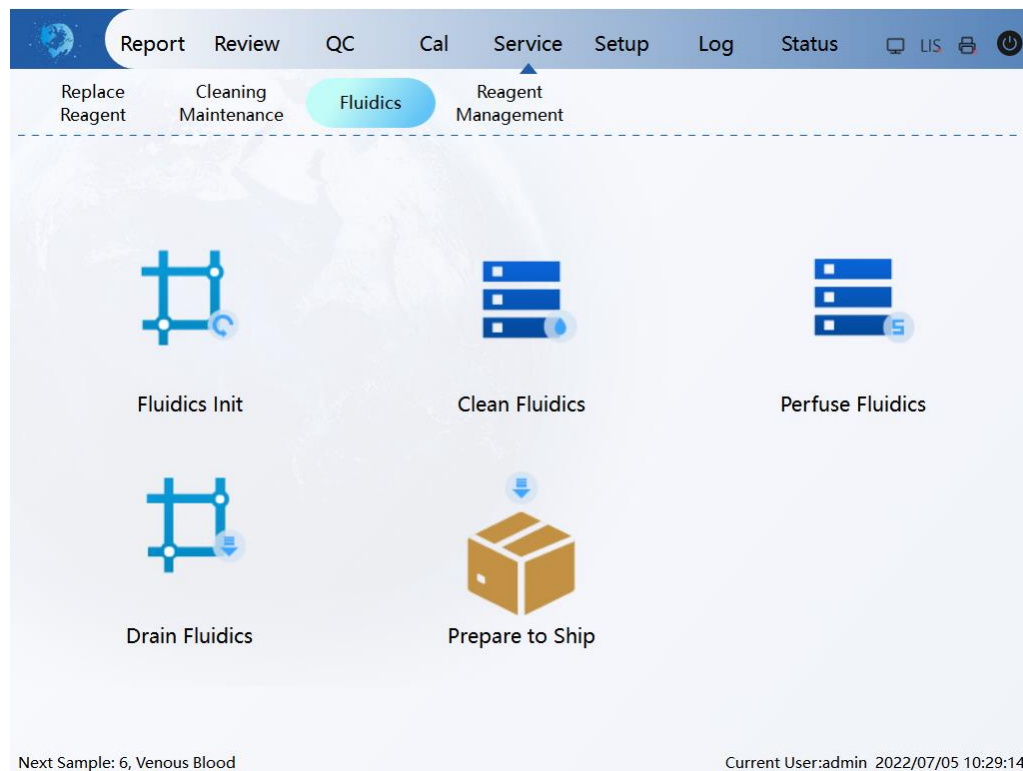


Figure 9-12 Fluidics

- Click "Fluidics Init", the interface prompts as shown below.

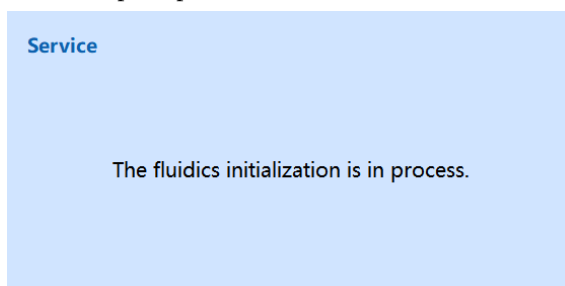


Figure 9-13 Tips for fluidics initialization

- After the initialization is completed, a pop-up box on the interface prompts that the initialization of the fluid circuit is completed. Click OK to complete the operation.

## 9.4.2 Clean Fluidics

If the background result of each parameter exceeds the background range, the user should perform "Clean Fluidics" according to the following steps:

- Select the "Service > Clean Fluidics" to enter the Clean Fluidics interface.
- Click the "Clean Fluidics" icon, the interface prompts as follows.

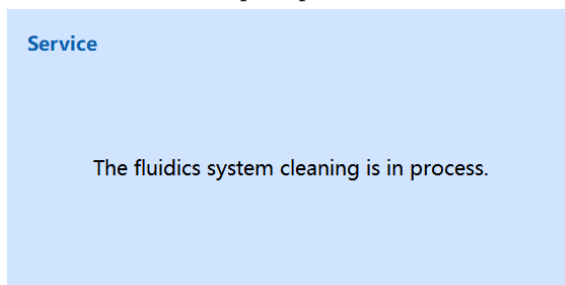


Figure 9-14 Tips for fluidics system cleaning

- After the cleaning is completed, a pop-up box on the interface prompts that the cleaning is completed. Click "OK" to complete the operation.

## 9.4.3 Drain Fluidics

When the device has not been used for more than a week, this function can be used to drain the fluidic system to prevent crystallization and ensure the performance of the device. The operation steps are as follows:

1. Click on the "Drain Fluidics" icon. The system pops up the following dialog box. Follow the prompts to remove the tubes from diluent and lyse and click "OK".

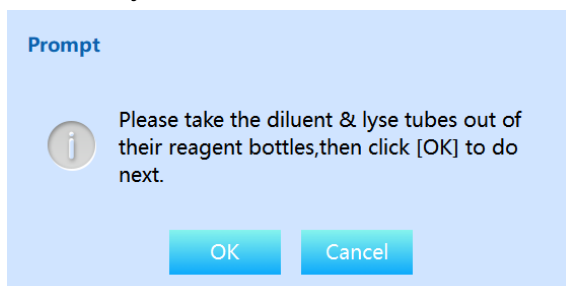


Figure 9-15 Tips for operation

2. The system performs "Drain Fluidics", and the interface is shown in the figure below.

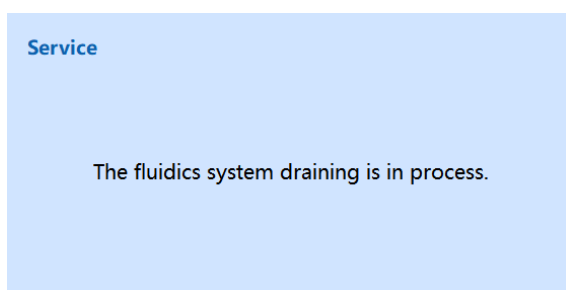


Figure 9-16 System draining

3. After Draining is completed, a pop-up box on the interface prompts you to select perfuse fluidics or shutdown.



### Warning

- Users should abide by the relevant regulations of the region and country on the discharge and disposal of reagents, waste liquids, waste samples, consumables, etc.

## 9.4.4 Prepare to Ship

The analyzer should be packed before being unused for more than two weeks or before long-distance transportation. The packaging steps are as follows:

1. Click "Prepare to Ship", the following dialog box would pop up.

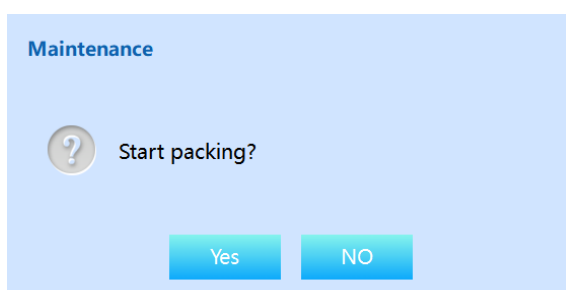


Figure 9-17 Tips for starting packaging

2. Click "Yes" and the following dialog box would pop up.

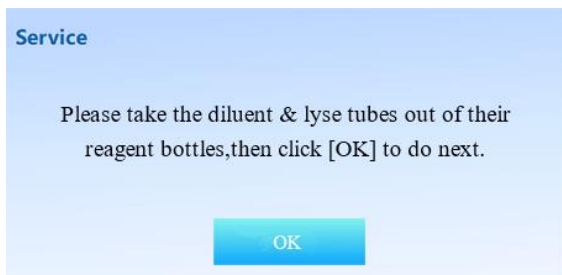


Figure 9-18 Tips for packaging

3. Take out the tubes in diluent and lyse, click "OK", the system would prepare for packaging and the following dialog box would pop up.

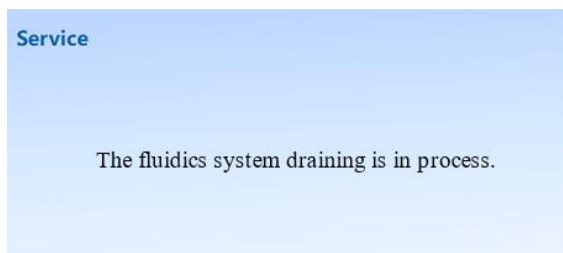


Figure 9-19 Tips for draining

4. Insert tubes of diluent and lyse into distilled water, click "OK".

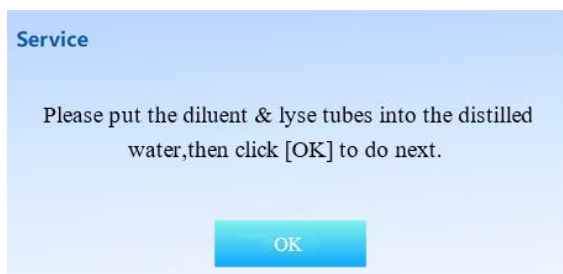


Figure 9-20 Tips for preparing distilled water

5. The system starts to perform the next step and the following dialog box pops up.

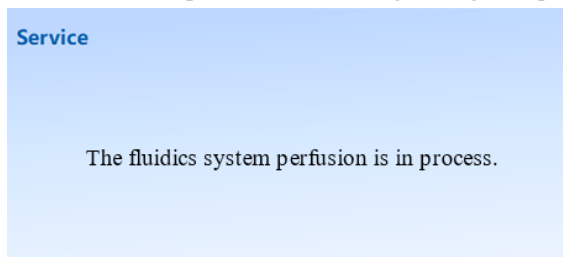


Figure 9-21 Tips for perfusion

6. Take out the tubes in distilled water, click "OK".

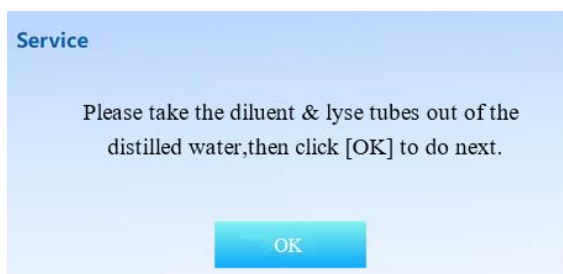


Figure 9-22 Tips for removing tubes

7. The system starts to perform the next operation and the following dialog box pops up.

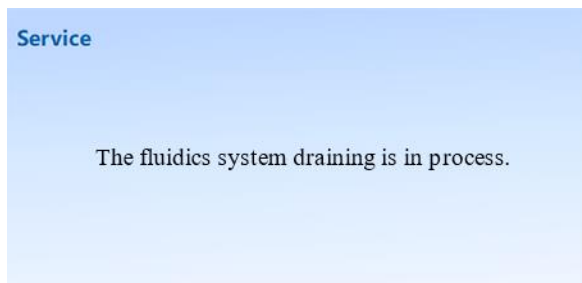


Figure 9-23 Tips for draining

8. After the system operation is completed, it would prompt to turn off the power switch. After shutting down, clean the waste liquid chamber and properly dispose of the waste liquid.



### Warning

- Users are obliged to abide by the relevant regulations of the region and country on the discharge and disposal of reagents, waste liquids, waste samples, consumables, etc.

## 9.5 Reagent Management

After connecting a new reagent, the user can set the reagent information on the reagent management interface, including expiration date, bottle opening date and remaining amount. After completing the reagent setup, the reagent replacement operation can be performed.

Click "Service > Reagent Management" to enter the reagent management interface, as shown in Figure 9-24.

| Report          | Review               | QC         | Cal                 | Service           | Setup   | Log      | Status | LIS | Print | Power |
|-----------------|----------------------|------------|---------------------|-------------------|---------|----------|--------|-----|-------|-------|
| Replace Reagent | Cleaning Maintenance | Fluidics   | Reagent Management  |                   |         |          |        |     |       |       |
| Reagent         | Exp. Date            | Decap date | Decap validity days | Decap expiry date | Volume  | Remarks  |        |     |       |       |
| Diluent         | ---                  | 2022/07/05 | ---                 | ---               | 5000 mL | 00010000 |        |     |       |       |
| Lyse            | ---                  | 2022/07/05 | ---                 | ---               | 500 mL  | 00010000 |        |     |       |       |
|                 |                      |            |                     |                   |         | Edit     |        |     |       |       |

Next Sample: 6, Venous Blood

Current User: produce 2022/07/08 16:23:07

Figure 9-24 Reagent management

### 9.5.1 Set Reagent Information

The user can set the reagent information through the following steps.

1. Select a reagent (such as "Lyse"), then click "Edit" to enter the reagent information setting page, as shown in Figure 9-25.

Figure 9-25 Reagent information

2. Enter the remaining amount of the reagent in the volume edit box, the unit of lyse is mL, and the unit of diluent is L.
3. Click "Apply" to save the settings.

## 9.6 Printing Paper Replacement

1. Press the area in the box shown in Figure 9-26 to open the cover of the printing paper box.



Figure 9-26 Open the cover

2. Take out the waste paper tube and ensure that there is no waste printing paper.
3. As shown in Figure 9-27, put the printing paper under the middle of the rolling shaft and insert it as deep as possible into the gap behind the rolling shaft, as shown in Figure 9-28.

Note: If the printing paper is not placed in the direction shown in the figure 9-27, the device would not print.



Figure 9-27 Paper placing direction



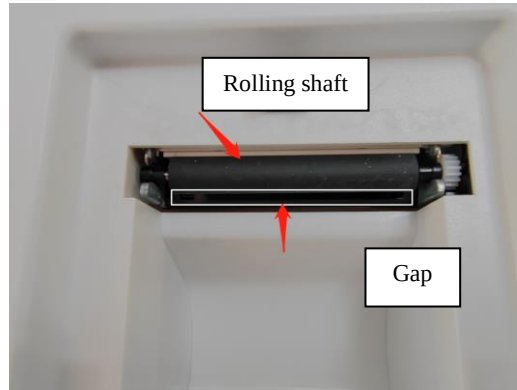


Figure 9-28 The gap behind the rolling shaft

4. The printer automatically rolls the paper, as shown in Figure 9-29.



Figure 9-29 Roll out the paper

5. Check whether the printing paper position is centered. If not, move the printing paper to the centre.  
Note:
  - a) Check whether the printing paper is properly installed and centered by observing the distance between the printer paper and both sides, as shown in Figure 9-30, to ensure the paper ejected from the device straightly.
  - b) After adjusting the printing paper, check whether the rolling shaft is firmly fixed in its original position.
6. If the paper is not ejected properly, repeat Step 3-5 until the paper is properly installed.  
Note: Ensure that the printing paper is inserted as deep as possible under the rolling shaft.
7. Close the cover after threading the printing paper through the slot, as shown in the Figure 9-31.



Figure 9-30 Place the paper in the centre



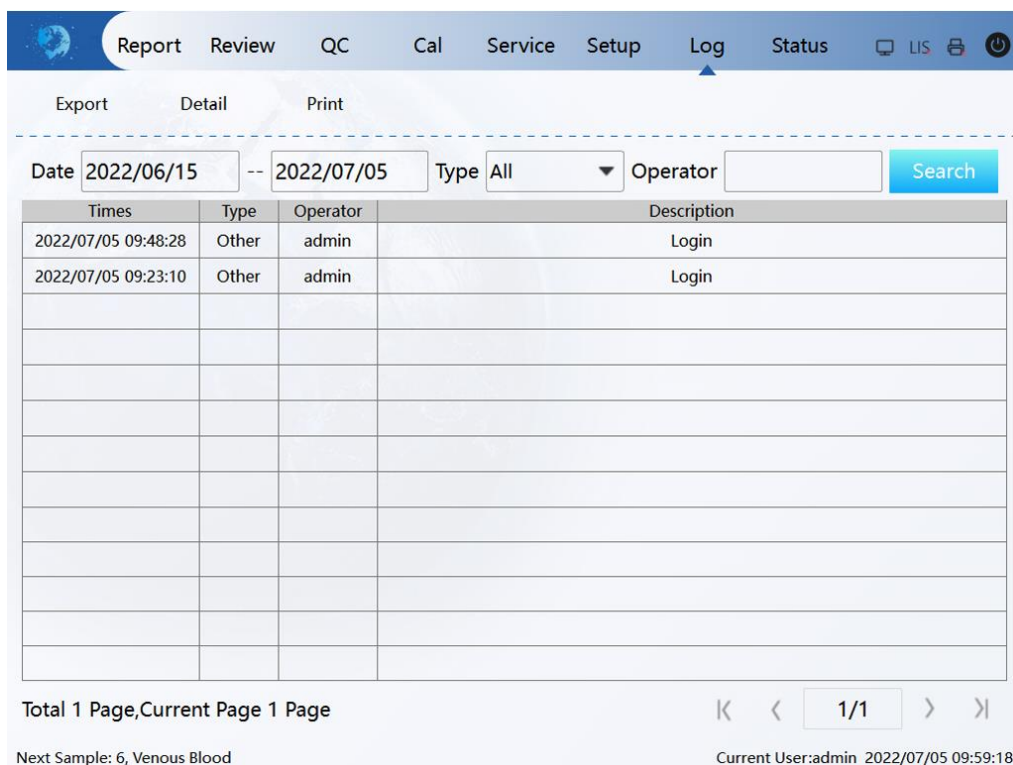
Figure 9-31 Installation completes

# 10 Log

In the "Log" interface, users can look up parameter modification, other logs, fault information and records of all logs. The system can store log records for up to 5 years.

## NOTICE

- If the storage is full when a new record is added, the system would automatically cover the oldest history record.
- Administrators can view all operation records of themselves and ordinary users, while ordinary users can only view their own operation records.



| Times               | Type  | Operator | Description |
|---------------------|-------|----------|-------------|
| 2022/07/05 09:48:28 | Other | admin    | Login       |
| 2022/07/05 09:23:10 | Other | admin    | Login       |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |
|                     |       |          |             |

Figure10-1 Log

# 11 Status

The user can view the current device status information of the analyzer in the status interface, including "Voltage", "Version", "Self Check" and "Counter".

## 11.1 Voltage

Click "Status > Voltage" to enter the voltage status interface.

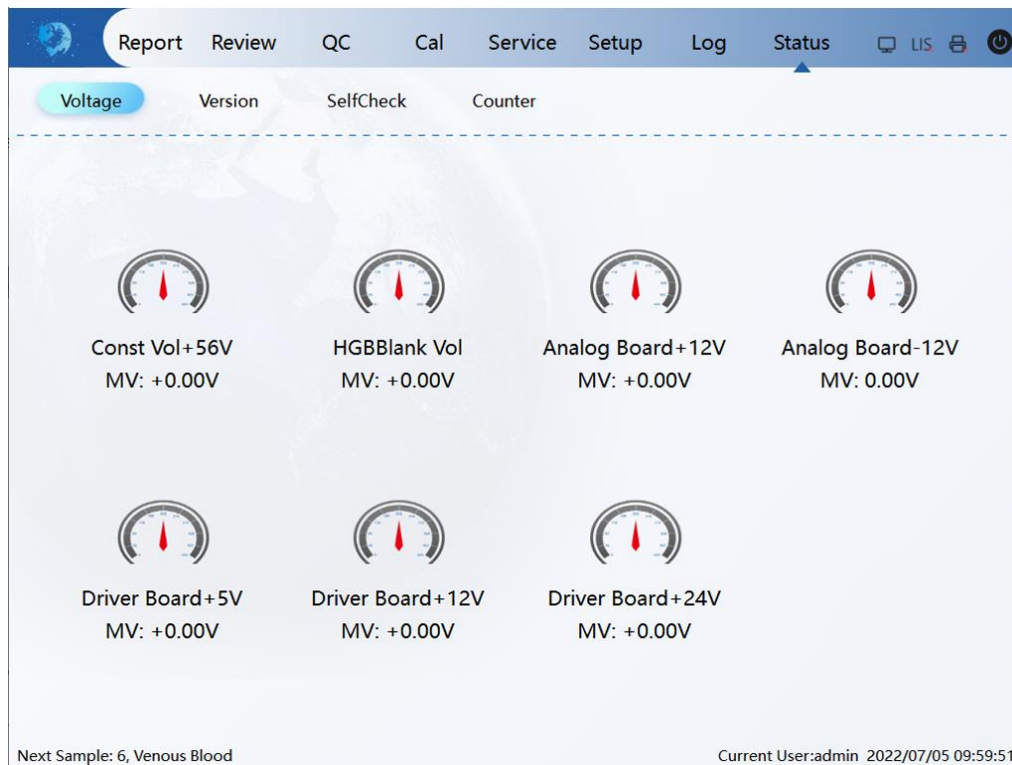


Figure 11-1 Voltage

The user can look up the voltage information of the analyzer, and the icon of the voltage value outside the normal range would display a red prompt.

## 11.2 Version

Click "Status > Version" to enter the version information interface, as shown in Figure 11-2.

| Report          |             | Review           |           | QC        |  | Cal     |  | Service |  | Setup |  | Log |  | Status |  |
|-----------------|-------------|------------------|-----------|-----------|--|---------|--|---------|--|-------|--|-----|--|--------|--|
| Voltage         |             | Version          |           | SelfCheck |  | Counter |  |         |  |       |  |     |  |        |  |
| Machine Version | V1.0.0.0VET | Drive Board FPGA |           |           |  |         |  |         |  |       |  |     |  |        |  |
| Core Bord MCU   |             | Linux Kernal     |           |           |  |         |  |         |  |       |  |     |  |        |  |
| AD Board FPGA   |             | Lqd Rd Seq       |           |           |  |         |  |         |  |       |  |     |  |        |  |
| Drive Board MCU |             | ALG Lib          |           |           |  |         |  |         |  |       |  |     |  |        |  |
| Data Base       | 1.2.1       | Print Lib        | 1.0.10605 |           |  |         |  |         |  |       |  |     |  |        |  |
| LIS Lib         | 1.0.9972    | Reagent MGT      | 1.2.10878 |           |  |         |  |         |  |       |  |     |  |        |  |
| Soft Keyboard   | 0.1.10213   |                  |           |           |  |         |  |         |  |       |  |     |  |        |  |

Next Sample: 664, Venous Blood

Current User:000 2023/06/13 17:11:49

Figure 11-2 Version information

Users can view the version information of each part of the analyzer.

## 11.3 Counter

Click "Status > Counter" to enter the counter interface, as shown in Figure 11-3. Users can view count times for samples, backgrounds and QC.

| Report                 |   | Review  |  | QC        |  | Cal     |  | Service |  | Setup |  | Log |  | Status |  |
|------------------------|---|---------|--|-----------|--|---------|--|---------|--|-------|--|-----|--|--------|--|
| Voltage                |   | Version |  | SelfCheck |  | Counter |  |         |  |       |  |     |  |        |  |
| Sample count times     | 0 |         |  |           |  |         |  |         |  |       |  |     |  |        |  |
| Background count times | 0 |         |  |           |  |         |  |         |  |       |  |     |  |        |  |
| QC count times         | 0 |         |  |           |  |         |  |         |  |       |  |     |  |        |  |

Next Sample: 6, Venous Blood

Current User:admin 2022/07/05 10:01:35

Figure 11-3 Counter

## 11.4 Motor

Users can test the performance of each syringe and sampler. The self-test steps are as follows:

1. Click "SelfCheck > Motor" to enter the motor self-check interface. As shown in Figure 11-4.



Figure 11-4 Motor

2. Click the component to be checked, such as "Vacuum Syringe", and wait for the system to report the self-check result.
3. Click "OK" to close the dialog.

## 11.5 Valve

When controlling the switch of each valve (pump), you can judge whether the valve (pump) is normal according to whether the corresponding valve (pump) makes a sound of opening and closing, or touches the corresponding valve (pump) with his hand to check whether the device performs the action.

The steps for valve self-test are as follows:

1. Select "SelfCheck > Valve" to enter the valve self-check interface, as shown in Figure 11-5.

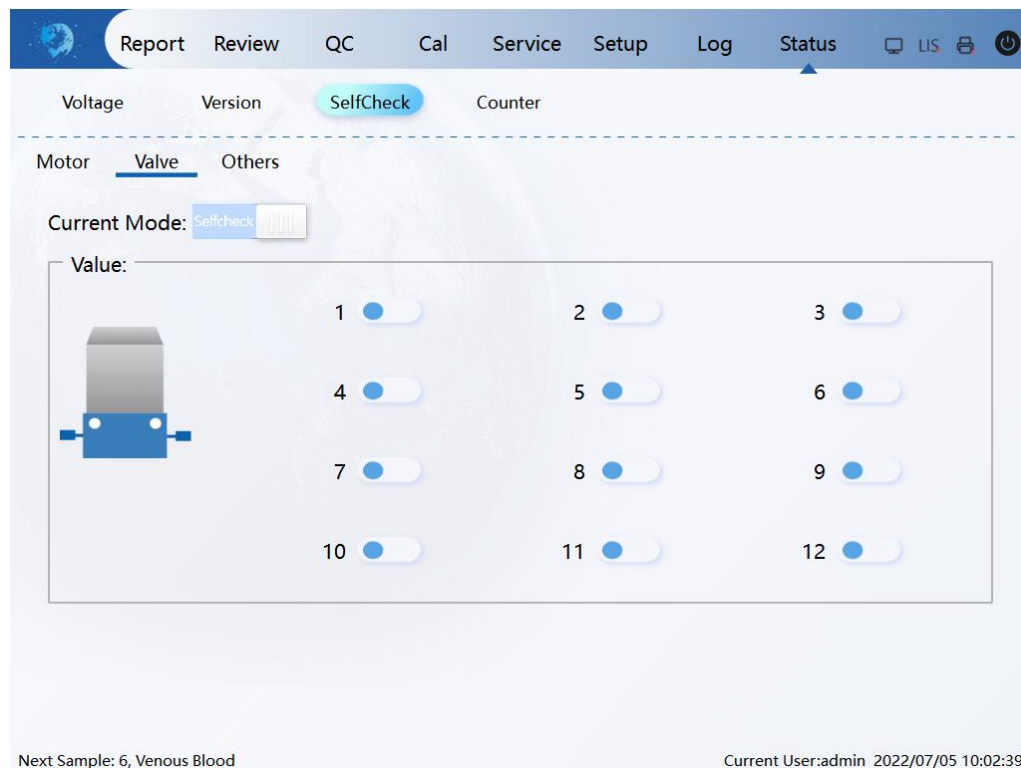


Figure 11-5 Valve

2. Click the corresponding number (such as "1") of the valve to be detected, and judge whether the valve is normal according its sound when closing and opening.

## 11.6 Others

Users can also perform self-checks on the following:

- WBC Aperture Voltage
- RBC Aperture Voltage

The operation steps are as follows:

1. Click "Self-Check > Others" to enter the interface shown in Figure 11-6.

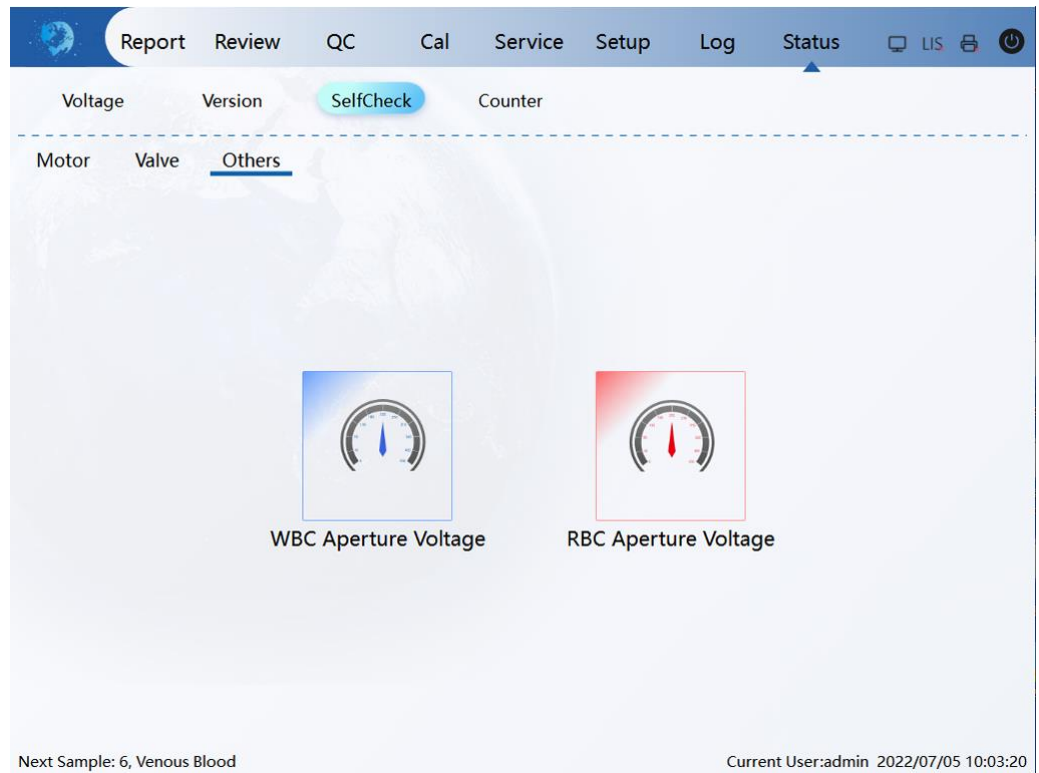


Figure 11-6 Others

2. Click on the targeted icon, such as "WBC Aperture Voltage", to start the self-test. The system performs the corresponding self-check operation. After the self-check is completed, the interface pops up the self-check result.

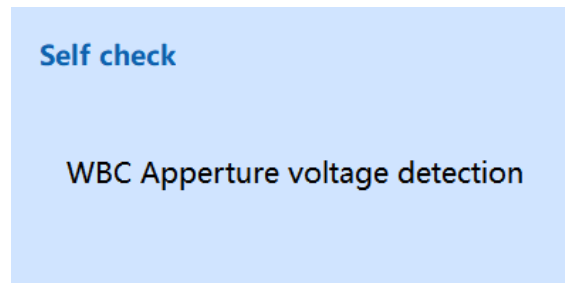


Figure 11-7 WBC aperture voltage detection

# 12 Shutdown

---

## 12.1 Shutdown

Shutdown procedures must be performed every day before completing work. During the shutdown process, the device would perform daily maintenance and cleaning of the measuring line. Click "Shutdown" in the main interface, and the system would pop up the icon dialog box:

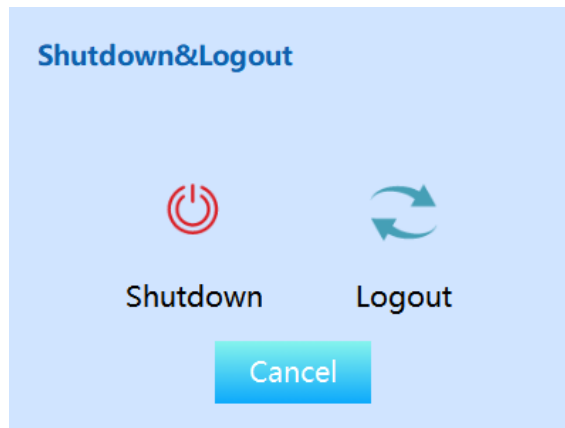


Figure 12-1 Shutdown & Logout

After clicking "Shutdown", the system executes the shutdown procedure. After the execution is completed, the device can be powered off at this time.

---

### NOTICE

- It is forbidden to directly turn off the power without executing the shutdown procedure.
-



# 13 Maintenance

---

As a precision device, the routine maintenance of the hematology analyzer is of great significance to the normal use of the device, the accuracy of the results, and the clinical diagnosis. Please strictly follow the instructions of this chapter.

## 13.1 Daily Maintenance

1. Before shutting down, wipe the area 2cm above the tip of the sampling needle with a soft cloth or dust-free paper dipped in a little cleaning solution, and wipe from top to bottom. After wiping, please perform the "Flush Apertures" operation on the "Services" interface.
2. If there is dust on the device, please wipe the dust off with a clean cloth.
3. If the test is abnormal, perform a background test to observe whether the bank is too high. If it continues to be high, please refer to the common troubleshooting.

## 13.2 Weekly Maintenance

1. Actively perform "Fluidics Soak" at least twice a week. Operation: On the Service-Cleaning Maintenance interface, select "Fluidics Soak" and follow the prompts. The soaking times can be increased according to the actual situation.
2. Shut down normally at least once a week for at least one hour.
3. If the device is not expected to be idle for more than a week, perform the "Drain Fluidics" function in "Service - Fluidics".

## 13.3 Monthly Maintenance

If there is dirt on the outside of the counter chamber shield and the sampler, please wipe it with a clean damp cloth to prevent the sundries from falling into the counter chamber and blocking the aperture, thus causing the device to not work properly.

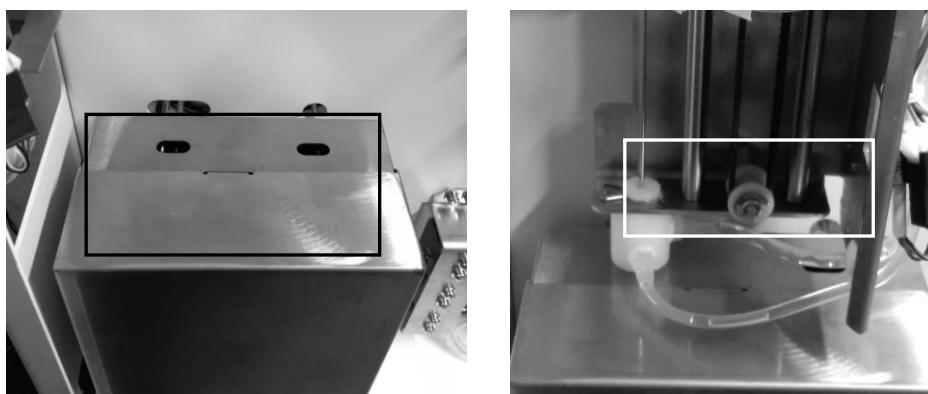


Figure 13-1 Cleaning of the counter chamber shield and sampler

# 14 Troubleshooting

Common faults and solutions of the device:

| Problem                             | Solution                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device can not start.               | Check that the device is powered on. Check if the power plug is loose. Check voltage. Check whether the internal SD card is loose, turn off the power, and restart.                                                                                                                                                                                                                                                                                                              |
| No diluent.                         | To replace the diluent, select "Diluent" in the Service-Reagent Replacement interface or the reagent management interface and perform corresponding operations to replace it.                                                                                                                                                                                                                                                                                                    |
| No lyse.                            | To replace lyse, select "Lyse" in the Service Reagent Replacement interface or reagent management interface to perform corresponding operations to replace.                                                                                                                                                                                                                                                                                                                      |
| Waste fluid is full.                | Drain the waste barrel.                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Blank count value repeated too high | <p>Whether the reagent is used up. If the reagent is deteriorated or contaminated, replace it with a new reagent.</p> <p>Select "Flush Apertures" in the service interface. If the problem cannot be solved, "Fluidics Soak" can be performed.</p> <p>Check whether the temperature or pressure of the working environment of the device is normal. Check whether there are high-power electrical appliances around the device and whether there is a strong magnetic field.</p> |
| Blocking                            | <p>Select "Zap Apertures" in the "Cleaning Maintenance" interface to unblock. Then select "Clean Fluidics" to clean the whole machine after unblocking.</p> <p>Check whether the tightness of the syringe in the device is normal.</p>                                                                                                                                                                                                                                           |
| Bubbles                             | <p>Select "Clean Chamber" in the service interface to check whether the solenoid valve works normally.</p> <p>Confirm whether the connection of the reagent pipeline is normal, and refill the reagent.</p>                                                                                                                                                                                                                                                                      |
| Printer cannot print                | Check whether the printing paper is enough, check whether it is connected normally, and check the printer settings in the system settings.                                                                                                                                                                                                                                                                                                                                       |
| Mechanical noise                    | <p>Open the right door of the analyzer and check whether there is any foreign matter stuck in the moving parts.</p> <p>Check whether the piston of the vacuum syringe is out of the cavity, if so, align the piston with the cavity, and then perform the reset action to let the piston enter the negative pressure cavity.</p>                                                                                                                                                 |

# Appendix A Specifications

| BK-3100VET Auto Animal Hematology Analyzer |                            |                                                                                                                                                     |
|--------------------------------------------|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Item                                       |                            | Descriptions                                                                                                                                        |
| General                                    | Throughput                 | 60 samples/hour                                                                                                                                     |
|                                            | Principle                  | Impedance for WBC differentiation and WBC/RBC/PLT count; Colorimetric method for HGB                                                                |
|                                            | Channels                   | 2                                                                                                                                                   |
|                                            | Parameters                 | 21 parameters(including WBC, Mid#, Lym#, Gran#, Mid%, Lym%, Gran%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, MPV, PDW, PCT, P-LCR, P-LCC) |
|                                            | Histograms                 | 3 histograms(including WBC, RBC, PLT histograms)                                                                                                    |
|                                            | Sample volume              | Normal: 10μL, Prediluted: 20μL                                                                                                                      |
| Software                                   | Calibration                | Manual, auto and fresh blood calibration                                                                                                            |
|                                            | Counting modes             | Venous, capillary, prediluted                                                                                                                       |
|                                            | Print                      | Auto print, manual print                                                                                                                            |
|                                            | LIS                        | Support Bi-directional LIS                                                                                                                          |
|                                            | Language                   | Chinese, English, Spanish, French, Russian, Ukrainian                                                                                               |
| Reagent                                    | Reagent                    | Diluent 20L, Hemolytic agent 500mL                                                                                                                  |
|                                            | Cleanser                   | Standard: Probe cleanser: 50mL                                                                                                                      |
| Specifications                             | Input                      | 9.7-inch touch screen, mouse, keyboard (optional)                                                                                                   |
|                                            | Output                     | Internal printer, support external printer                                                                                                          |
|                                            | Printer paper              | 57mm×30mm                                                                                                                                           |
|                                            | Interface                  | 4 USB ports, 1 network port, 1 RS232 serial port                                                                                                    |
|                                            | Storage                    | 100,000 results with histogram                                                                                                                      |
|                                            | Dimension                  | 295mm×418mm×467mm                                                                                                                                   |
|                                            | Clogging removal technique | Reverse flush, high voltage burning                                                                                                                 |
|                                            | Net weight                 | 19kg                                                                                                                                                |
|                                            | Gross weight               | 31kg                                                                                                                                                |
| Working environment                        | Work temperature           | 10°C~40°C                                                                                                                                           |
|                                            | Power requirement          | AC100V~240V, input power≤150VA, 50/60HZ                                                                                                             |
|                                            | Relative humidity          | ≤80%                                                                                                                                                |
|                                            | Atmospheric pressure       | 86.0kPa~106.0kPa                                                                                                                                    |
| Storage environment                        | Work temperature           | -10°C~40°C                                                                                                                                          |
|                                            | Relative humidity          | 30% ~85%                                                                                                                                            |
|                                            | Atmospheric pressure       | 70.0kPa~110.0kPa                                                                                                                                    |

| BK-3100VET Auto Animal Hematology Analyzer |                 |              |                                     |                                   |
|--------------------------------------------|-----------------|--------------|-------------------------------------|-----------------------------------|
| Item                                       |                 | Descriptions |                                     |                                   |
| Performance                                | Carry-over rate | Parameter    | CV                                  |                                   |
|                                            |                 | WBC          | $\leq 1.5\%$                        |                                   |
|                                            |                 | RBC          | $\leq 1.0\%$                        |                                   |
|                                            |                 | HGB          | $\leq 1.0\%$                        |                                   |
|                                            |                 | PLT          | $\leq 3.0\%$                        |                                   |
|                                            | Background      | Parameter    | Background                          |                                   |
|                                            |                 | WBC          | $\leq 0.5 \times 10^9/L$            |                                   |
|                                            |                 | RBC          | $\leq 0.05 \times 10^{12}/L$        |                                   |
|                                            |                 | HGB          | $\leq 2g/L$                         |                                   |
|                                            |                 | HCT          | $\leq 0.5\%$                        |                                   |
|                                            |                 | PLT          | $\leq 10 \times 10^9/L$             |                                   |
|                                            | Linearity       | Parameter    | Measurement range                   | Allowable error                   |
|                                            |                 | WBC          | $(1.0 \sim 10.0) \times 10^9/L$     | $\pm 0.5 \times 10^9/L$           |
|                                            |                 |              | $(10.1 \sim 99.9) \times 10^9/L$    | $\pm 5\%$                         |
|                                            |                 | RBC          | $(0.3 \sim 1.00) \times 10^{12}/L$  | $\pm 0.05 \times 10^{12}/L$       |
|                                            |                 |              | $(1.01 \sim 7.00) \times 10^{12}/L$ | $\pm 5\%$                         |
|                                            |                 | HGB          | $(20 \sim 70) g/L$                  | $\pm 2g/L$                        |
|                                            |                 |              | $(71 \sim 200) g/L$                 | $\pm 3\%$                         |
|                                            |                 | PLT          | $(20 \sim 100) \times 10^9/L$       | $\pm 10.0 \times 10^9/L$          |
|                                            |                 |              | $(101 \sim 999) \times 10^9/L$      | $\pm 10\%$                        |
|                                            | Precision       | Parameter    | Repeatability                       | Measurement range                 |
|                                            |                 | WBC          | $\leq 6.0\%$                        | $(3.5 \sim 9.5) \times 10^9/L$    |
|                                            |                 | RBC          | $\leq 3.0\%$                        | $(3.8 \sim 5.8) \times 10^{12}/L$ |
|                                            |                 | HGB          | $\leq 2.5\%$                        | $(115 \sim 175) g/L$              |
|                                            |                 | PLT          | $\leq 10.0\%$                       | $(125 \sim 350) \times 10^9/L$    |
|                                            |                 | HCT          | $\leq 3.0\%$                        | $35\% \sim 50\%$                  |