

Chapter 5 Operation Principles

5.1 Overview

The Vcheck H6 operates using laser-based flow cytometry combined with nucleic acid-specific fluorescent dyes for the precise identification and differentiation of white blood cells. It employs the sheath flow impedance method to measure the count and volume distribution of RBCs and PLTs. PLT analysis is performed using both sheath flow impedance and nucleic acid fluorescence staining methods. HGB is measured using a cyanide-free spectrophotometric method. RET is analyzed through laser flow cytometry combined with nucleic acid fluorescent staining. Based on these measurements, the Analyzer calculates additional parameter results.

5.2 Sample preparation and intake volume

To ensure the accuracy of analysis results, the sample size must meet the following requirements:

Table 23 Sample volume requirements

Mode	Minimum sample size
Whole blood	≥0.25mL

The Vcheck H6 Analyzer supports single-sample (manual sampling) mode. The sample volume requirements are as follows:

For venous whole blood in CD mode: ≤ 28 µL

For venous whole blood in CDR mode: ≤ 34 µL

Sample volume per pre-dilution test: 20µL.

5.3 WBC test principle

5.3.1 Nucleic acid fluorescent staining technology

The DIFF/WNR channel of the Analyzer utilizes nucleic acid fluorescent staining technology.

On the one hand, red blood cells (RBCs) in the sample are lysed by special reagent components, allowing white blood cells (WBCs) to be processed differently so that various cell types exhibit distinct differences in volume and complexity.

On the other hand, nucleic acid-containing substances within WBCs are labeled with a novel asymmetric cyanine fluorescent dye in the presence of reagents. Since different cell types, maturation stages, and abnormal developmental states contain varying amounts of nucleic acid, the degree of fluorescence labeling also varies.

Cellular characteristics are measured as follows:

- (1) Forward scattering signal characterizes differences in cell volume.
- (2) Lateral scattered light reflects the complexity of intracellular structures.
- (3) Fluorescence signal intensity indicates the degree of nucleic acid staining.

The DIFF channel enables differentiation of the major WBC subsets (lymphocytes [LYM], monocytes [MON], neutrophils [NEU], eosinophils [EOS], and basophils [BASO]) by detecting signal variations in three-dimensional space after reagent treatment. Additionally, it identifies and alerts for immature granulocytes (IMG) while simultaneously counting WBCs.

Cellular characteristics and differentiation:

- (1) Lymphocytes are relatively small, with most of their internal space occupied by the nucleus, resulting in a high nucleus-to-cytoplasm ratio and low nucleic acid content. Consequently, they exhibit lower fluorescence and lateral scatter signals.
- (2) Monocytes are larger in size, have a high nucleus-to-cytoplasm ratio but lower intracellular complexity, and contain more nucleic acids, leading to higher fluorescence intensity and slightly stronger lateral scatter than lymphocytes.
- (3) Neutrophils are larger, with a medium nucleus-to-cytoplasm ratio, dispersed nuclear distribution, and lower nucleic acid content. They have weaker fluorescence signals but stronger lateral scatter signals.
- (4) Eosinophils and basophils share similar size and nucleus-to-cytoplasm ratios with neutrophils but have lower nucleic acid content in their nuclei. However, they contain varying amounts of granules that differ in size, quantity, shape, and nucleic acid content, leading to variations in fluorescence and side scatter signals among different animal species.
- (5) Immature granulocytes have higher intracellular nucleic acid content, resulting in stronger fluorescence signals on the scatter plot.

The principle of fluorescence staining detection technology is illustrated in Figure 19.

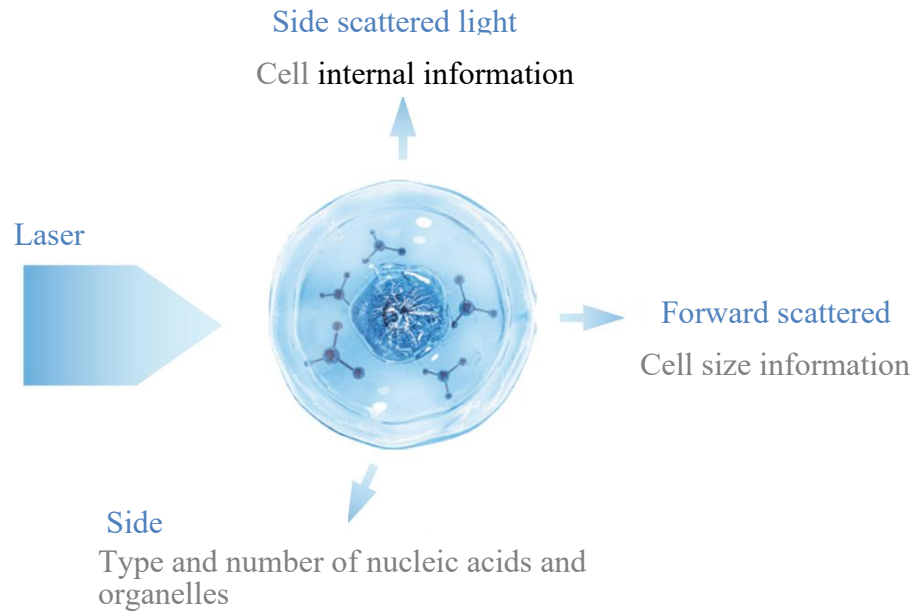


Figure 19 Fluorescence detection principle

5.3.2 WBC parameters

As shown in Figure 20:

1. Shadow cell area – Represents RBC fragments after lysis, as seen on the scatter diagram.
2. Basophil (BASO) population
3. Neutrophil (NEU) population
4. Eosinophil (EOS) population
5. Monocyte (MON) population
6. Lymphocytes (LYM) population

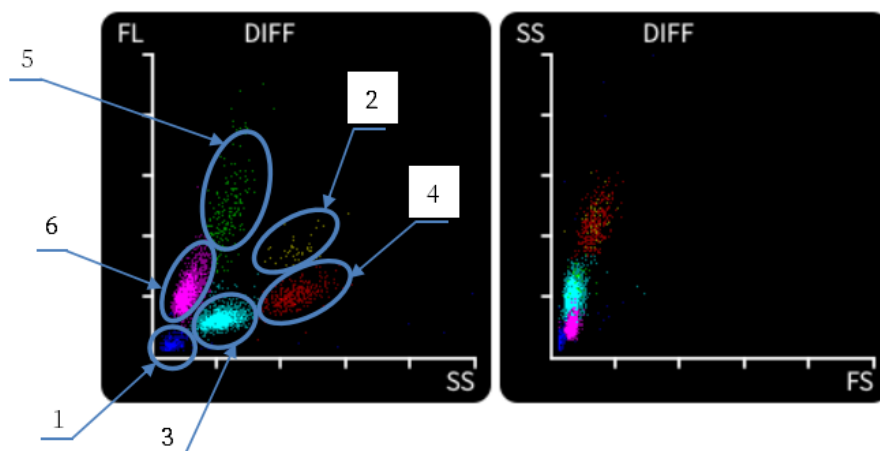


Figure 20 Differential scatter diagram

Table 24 WBC parameter data calculation method

SN	Full name	Abbreviation	Formula/method	Unit
1	White blood cell	WBC	Sum of particles of DIFF channel falling in WBC area	10 ⁹ /L
2	Lymphocyte percentage	LYM%	$LYM\% = \frac{\text{Number of granules falling in LYM area of DIFF channel}}{\text{Total counts of WBC granules of DIFF channel}} \times 100\%$	%
3	Lymphocyte counts	LYM#	LYM# = WBC×LYM%	10 ⁹ /L
4	Monocyte percentage	MON%	$MON\% = \frac{\text{Number of granules falling in MON area of DIFF channel}}{\text{Total counts of WBC granules of DIFF channel}} \times 100\%$	%
5	Monocyte counts	MON#	MON# = WBC×MON%	10 ⁹ /L
6	Neutrophil percentage	NEU%	$NEU\% = \frac{\text{Number of granules falling in NEU area of DIFF channel}}{\text{Total counts of WBC granules of DIFF channel}} \times 100\%$	%
7	Neutrophil counts	NEU#	NEU# = WBC×NEU%	10 ⁹ /L
8	Eosinophil percentage	EOS%	$EOS\% = \frac{\text{Number of granules falling in EOS area of DIFF channel}}{\text{Total counts of WBC granules of DIFF channel}} \times 100\%$	%
9	Eosinophil counts	EOS#	EOS# = WBC×EOS%	10 ⁹ /L
10	Basophil percentage	BASO%	$BASO\% = \frac{BASO\#}{WBC} \times 100\%$	%
11	Basophil counts	BASO#	BASO# = Sum of particles of WNR channel falling in BASO area	10 ⁹ /L
12	Immature granulocyte percentage	IMG%	$IMG\% = \frac{\text{Number of granules falling in IMG area of DIFF channel}}{\text{Total counts of WBC granules of DIFF channel}} \times 100\%$	%
13	Immature granulocyte counts	IMG#	IMG# = WBC×IMG%	10 ⁹ /L

5.4 Principle of HGB concentration detection

5.4.1. Principle of colorimetry

In the HGB sample cup, after the lyse is added to the diluted sample, the RBCs are lysed, releasing HGB, which then forms an HGB complex by combining with the lyse. At one end of the HGB sample cup, an LED emits monochromatic light at a wavelength of 540 nm to irradiate the HGB complex solution. At the other end, a photoelectric tube receives the transmitted light. The light intensity signal is amplified and converted into a voltage signal, which is then compared with the voltage generated by the blank transmitted light (measured before the sample is added to the colorimetry chamber, when only diluent is present). Based on this

comparison, the HGB concentration of the sample is determined. The HGB concentration is proportional to the absorbance of the sample at 540 nm. The measurement and calculation are performed automatically by the Analyzer, and the results are displayed in the analysis result.

5.4.2 HGB concentration parameters

The HGB concentration is calculated according to the following formula:

$$\text{HGB} = \text{Constant} \times \text{Ln} \left(\frac{\text{Background transmission light intensity}}{\text{Sample transmission light intensity}} \right)$$

5.5 Principle of RBC/PLT detection

5.5.1 Principle of sheath flow impedance method

The Analyzer uses the sheath flow impedance method to measure and count cells. As shown in Figure 21, within the conductive liquid (primarily a diluent), a constant current source is applied to the electrodes, forming a closed circuit with stable impedance. When cells pass through the micropores, they displace the conductive liquid, causing a change in the circuit's resistance and generating electrical pulses. The amplitude of each pulse varies depending on the volume of the passing cell, allowing the Analyzer to determine both the number and size of the cells based on the pulse count and amplitude.

Since the number of pulses corresponds to the number of cells passing through the micropores, and the pulse amplitude corresponds to their volume, the Analyzer measures each individual cell and classifies it accordingly. The system automatically groups cells into RBCs, PLTs, and other categories based on a volume classification algorithm preset in the software.

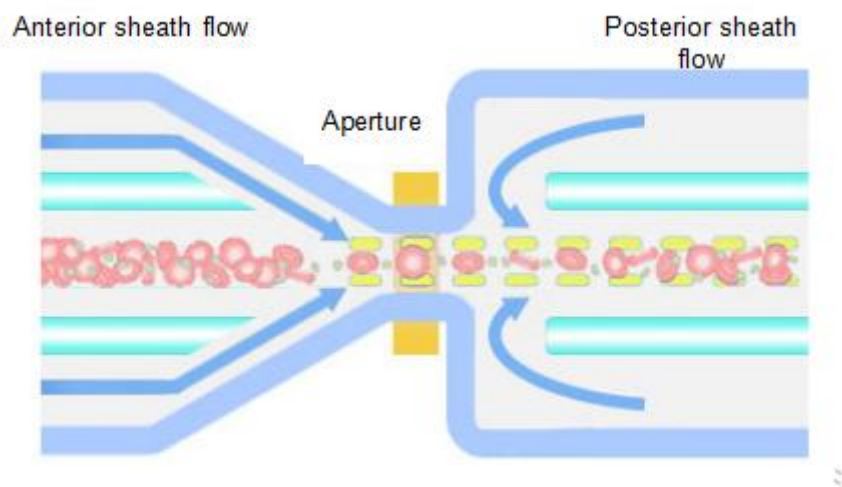


Figure 21 Sheath flow impedance method

5.5.2 Nucleic acid fluorescent staining test technology

The principle of the RET channel is similar to that of the DIFF/WNR channel. The key difference is that in the RET channel, RBCs are not hemolyzed but instead sphered by the DR diluent. Then, the nucleic acids of RBCs and PLTs are stained with a fluorescent dye.

5.5.3 RBC parameters

Table 25 RBC parameter data calculation method

SN	Full name	Abbreviation	Formula/method	Unit
1	Red blood cell	RBC	The number of RBCs is obtained by directly measuring the number of electric pulses corresponding to the RBCs.	$10^{12}/L$
2	Hematocrit	HCT	$HCT = RBC \times MCV / 10$ The ratio of RBCs to plasma, expressed as the percentage of whole blood solvent.	%
3	Mean corpuscular volume	MCV	Obtained from the RBC size distribution data	fL
4	Mean corpuscular hemoglobin	MCH	$MCH = \frac{HGB}{RBC}$ The average number of HGB contained in RBCs	pg
5	Mean corpuscular hemoglobin concentration	MCHC	$MCHC = \frac{HGB}{HCT} \times 100$ The ratio of HGB weight to average RBC volume	g/L
6	Coefficient of variation of red blood cell distribution width	RDW_CV	Obtained from the RBC histogram	%
7	Red blood cell distribution width standard deviation	RDW_SD	The width of the histogram at 20% of the peak value of the relative RBC histogram	fL

Note: RBC Distribution Width - Standard Deviation (RDW-SD) represents the width of the histogram at 20% of the peak value in the relative RBC histogram, as shown in Figure 22.

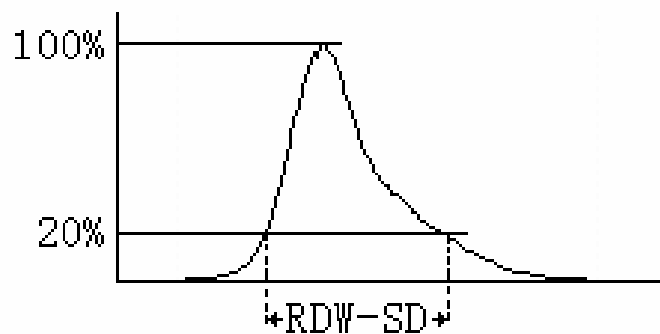


Figure 22 Figure of standard deviation

5.5.4 PLT parameters

Table 26 PLT parameter data calculation method

SN	Full name	Abbreviation	Formula/method	Unit
1	Platelet	PLT	The number of PLTs is obtained by directly measuring the number of electric pulses corresponding to the PLTs.	10 ⁹ /L
2	Mean platelet volume	MPV	The mean PLT volume (MPV) is calculated according to the PLT histogram.	fL
3	Platelet distribution width	PDW	Obtained from the PLT histogram. It is the geometric standard deviation (10 GSD) of PLT volume distribution.	fL
4	Plateletcrit	PCT	PCT=PLT×MPV/10000	%
5	Platelet - larger cell ratio	P_LCR	Obtained from the PLT histogram. It is the ratio of the number of PLTs with a volume of more than 12fL to the total number of PLTs.	%
6	Platelet - larger cell counts	P_LCC	P_LCC=PLT×P_LCR	10 ⁹ /L
7	Immature platelet fraction	IPF	Obtained from PLT optical scatter diagram. $IPF = \frac{\text{Number of immature optical platelet granules}}{\text{Total number of optical platelet granules}} \times 100\%$	%

5.6

RET parameters

Table 27 RET parameter data calculation method

SN	Full name	Abbreviation	Formula/method	Unit
1	Reticulocyte percentage	RET%	$RET\% = \frac{\text{Cell counts in reticulocyte area}}{\text{Cell counts in mature RBC area} + \text{cell counts in reticulocyte area}} \times 100\%$	%
2	Reticulocyte counts	RET#	RET# = RBC×RET%	10 ⁹ /L
3	Immature reticulocyte fraction	IRF	IRF=MFR+HFR	%
4	High fluorescent reticulocyte fraction	HFR	$HFR = \frac{\text{Cell counts in HFR area}}{\text{Cell counts in reticulocyte area}} \times 100\%$	%
5	Medium fluorescent reticulocyte fraction	MFR	$MFR = \frac{\text{Cell counts in MFR area}}{\text{Cell counts in reticulocyte area}} \times 100\%$	%
6	Low fluorescent reticulocyte fraction	LFR	LFR=100%-HFR-MFR	%
7	Reticulocyte hemoglobin expression	RHE	Calculated according to the data of RET scattered light.	pg

Chapter 6 Introduction of Analyzer Menu

6.1 Overview

The Analyzer is pre-initialized before delivery, and upon first boot, all interfaces are set to system defaults. To accommodate various application needs, certain parameters in the menu can be reconfigured as needed.

6.2 Menu

Click “Menu” to open the drop-down menu, as shown in Figure 23:

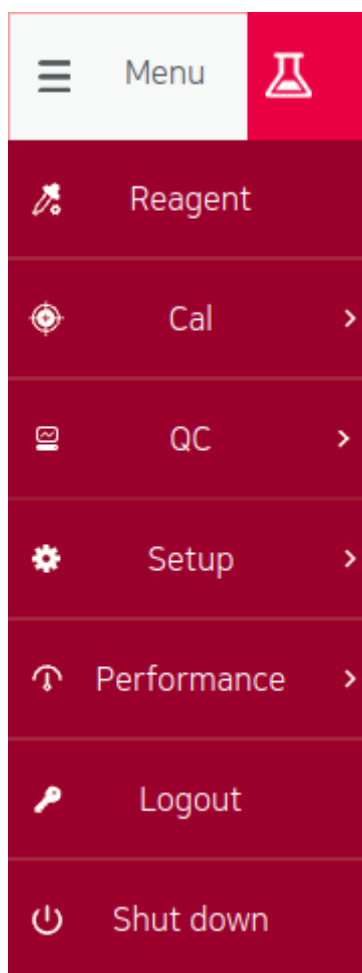


Figure 23 Menu interface

6.3 Reagent management



- As all clinical samples, control materials, and calibrators are potentially infectious, it is essential to follow established laboratory or clinical procedures. Wear appropriate protective equipment, including lab coats, medical gloves, and safety glasses, when handling these items.

⚠ CAUTION

- To ensure accurate test results, do not mix fresh reagents with any remaining reagents.
- If a reagent comes into contact with your skin, rinse the area immediately with plenty of clean water. If it comes into contact with your eyes, rinse thoroughly with clean water and seek medical attention promptly.

Click “Menu”→”Reagent” to access the reagent management interface, as shown in Figure 24.

Reagent						
Reagent	Validity date	Open date	Expiry date	Residual (%)	Remaining test	Remaining test
DS diluent	2025-09-13 19:22:09	2025-07-15 19:22:09	2025-09-13 19:22:09	90.20%	18,039079L	601
LD lyse	2027-07-14 08:00:00	2025-07-15 22:28:42	2025-09-13 22:28:42	58.00%	0.116000L	77
LH lyse	2025-08-17 00:19:59	2025-06-18 00:19:59	2025-08-17 00:19:59	26.95%	0.269500L	539
FD dye	2025-10-06 01:10:33	2025-07-08 01:10:33	2025-10-06 01:10:33	76.40%	0.019100L	955
DR diluent	2025-09-13 01:01:57	2025-07-15 01:01:57	2025-09-13 01:01:57	59.80%	0.299000L	199
FR dye	2025-10-09 17:46:05	2025-07-11 17:46:05	2025-10-09 17:46:05	73.67%	0.008840L	442

Details
Replace
Set Threshold
Non-Retic Kit

Next sample ID:25
Lis status:Disconnected
2025-07-16 09:08:16

Figure 24 Reagent management interface

Upon entering the interface, information of the reagents is displayed, including: Reagent name, validity date, open date, expiry date, residual(%) and remaining test of each reagent.

Click on a specific reagent, then click “Details” to open a popup window displaying detailed information about the selected reagent, as shown in Figure 25.

Details	
Reagent batch No.	00000000
Reagent	DS diluent
Production date	2025-07-15 19:22:09
Shelf life	60
Open date	2025-07-15 19:22:09
Valid days	60
Expiry date	2025-09-13 19:22:09
Total	20.000000L
Residual	18.039079L

[Return](#)

Figure 25 Reagent details

Reagent activation is required under the following conditions:

- (1) When the reagent quantity reaches 0.
- (2) When the reagent has expired.

If an “Insufficient Reagent” or “Expired Reagent” alarm appears, double-click the fault prompt text to open the Reagent Management popup. Click “Resolve” to navigate to the Reagent Management interface.

Before placing the reagent card onto the card reader, replace the expired or empty reagent with a new one. For details on the reagent replacement process and precautions, refer to Chapter 10: Maintenance.

Select the corresponding reagent and click the “Replace” button on the Reagent Management screen to begin the replacement process. When the Activate popup appears, as shown in Figure 26, click “Activate” to start the 15-second countdown.

Activate
Click the [Activate] button to activate LD lyse
Activate Cancel

Figure 26 Reagent Activation

During the countdown, place the reagent card that comes with the new reagent onto the card reader located on the left side of the Analyzer.

For FR dye and FD dye reagents, a separate reagent card is not provided. Instead, an RFID chip is embedded beneath the label on the reagent bottle. During the countdown, simply place the bottle itself on the card reader to complete activation.

Once the reagent card (or the reagent bottle for FR and FD dyes) is successfully recognized, a confirmation popup will appear. Click “OK” to allow the Analyzer to automatically complete the

replacement procedure.

When the replacement process is complete, the corresponding reagent information on the Reagent Management screen will be automatically reset.

For example, when replacing the LH lyse: After the reagent card is successfully recognized, a popup window (Figure 27) will appear. Clicking “OK” will initiate the LH lyse replacement, and the software will reset the remaining volume accordingly.

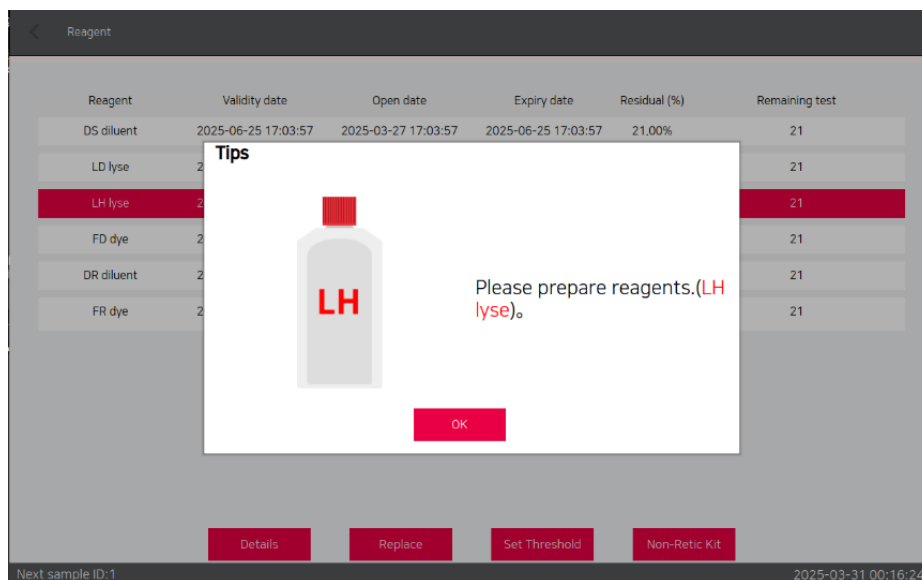


Figure 27 Confirm LH lyse priming

For using the H6 Reagent Pack (Non-Retic):

After replacing all reagents included in the H6 Reagent Pack (Non-Retic), click “Non-Retic Kit” on the Reagent Management interface — there’s no need to manually select individual reagents.

When the Activate popup appears, click “Activate” to start the 15-second countdown. During the countdown, place the reagent card that comes with the new H6 Reagent Pack (Non-Retic) onto the card reader located on the left side of the Analyzer.

Once the reagent card is successfully recognized, a confirmation popup will appear. Click “OK” to initiate the replacement of all reagents in the H6 Reagent Pack (Non-Retic). The software will automatically reset the remaining volumes accordingly.

6.4 Calibration

For instructions on calibration operations, refer to Chapter 9 Calibration.

6.5 QC

For instructions on QC operations, refer to Chapter 8 QC.

6.6

Settings

Click “Menu” → “Setup” to access the Setup menu, which contains the following sub-menus, as shown in Figure 28.

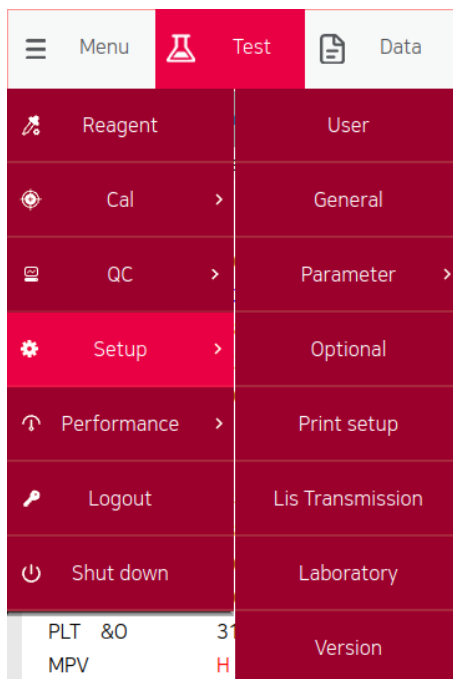


Figure 28 Settings menu

6.6.1 User management

Click “Menu” → “Setup” → “User” to access the user management interface, as shown in Figure 29.

To perform daily inspections, the inspection doctor (or operator) must log in to the system using their credentials. Therefore, user information should be archived in advance, and only the administrator has permission to configure user accounts.

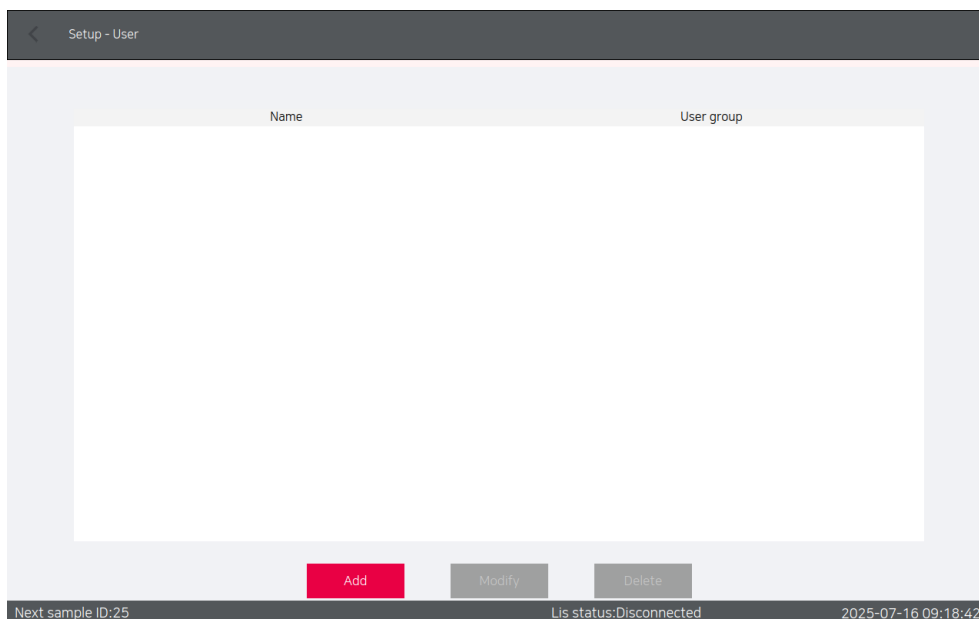


Figure 29 User management interface

Click “Add” to add a user, as shown in Figure 30.

Figure 30 Add a user

When adding a user, you can configure the following settings: Username, password, confirm password, and user group.

After setting the desired user information, click “OK” to save.

Click “Cancel” to return to the user management interface without saving.

1) User authentication method: The username and password is used for user authentication.

2) User group: There are two user groups, Regular User (Normal User), Administrator (Admin)

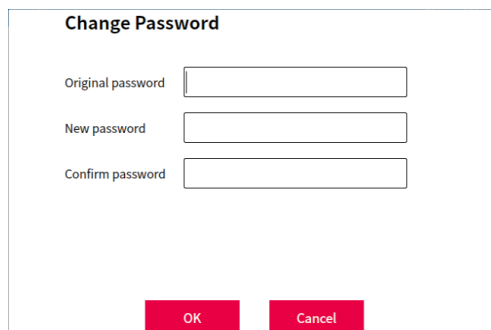
* Regular users can perform routine operations in submenus, including performance, maintenance, settings, statistics, quality control, logout, and shutdown.

* Administrators have all the permissions of a regular user plus access to: Calibration and Service. Additionally, administrators can add and delete usernames under user management in the settings menu.

Click “Modify” to change the password for the selected username, as shown in Figure 31.

Enter the original password, new password, and confirm the new password.

Click “OK” to successfully change the password or click “Cancel” to cancel the modification.



The image shows a 'Change Password' dialog box. It contains three input fields: 'Original password', 'New password', and 'Confirm password'. At the bottom, there are two buttons: 'OK' and 'Cancel'.

Figure 31 Password modification

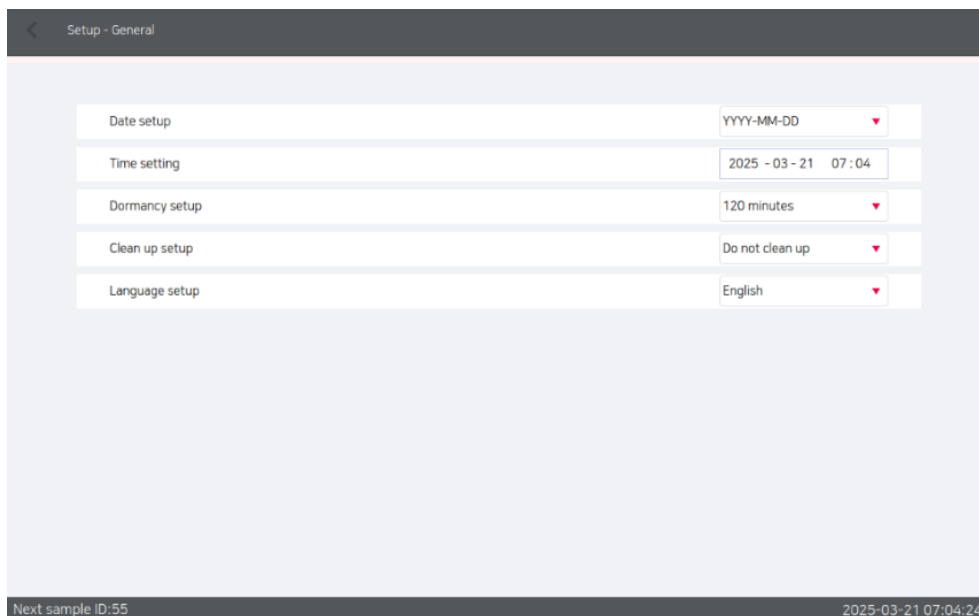
Click “Delete” to delete the password for the selected username.

NOTE

- The username and password cannot be empty.

6.6.2 General settings

Click “Menu” → “Setup” → “General” to access the general settings interface, as shown in Figure 32.



The image shows the 'Setup - General' interface. It has a dark header bar with a back arrow and the text 'Setup - General'. Below the header, there is a table of settings:

Date setup	YYYY-MM-DD ▼
Time setting	2025 - 03 - 21 07:04
Dormancy setup	120 minutes ▼
Clean up setup	Do not clean up ▼
Language setup	English ▼

At the bottom of the interface, there is a status bar with the text 'Next sample ID:55' on the left and '2025-03-21 07:04:24' on the right.

Figure 32 General settings

- Date setup: Configure the date and time and select a date display format.
- Time setting: Set the current time.
- Sleep mode setup: Set the system to “No sleep” or specify a sleep time.
- Clean-up setup: Choose “No cleaning” or specify a cleaning interval (number of days) to automatically delete stored results, preventing Analyzer memory overflow.
- Language setup: Select the desired system language.

6.6.3 Parameters

Click “Menu” → “Setup” → “Parameter” to access the parameter settings menu, as shown in Figure 33.

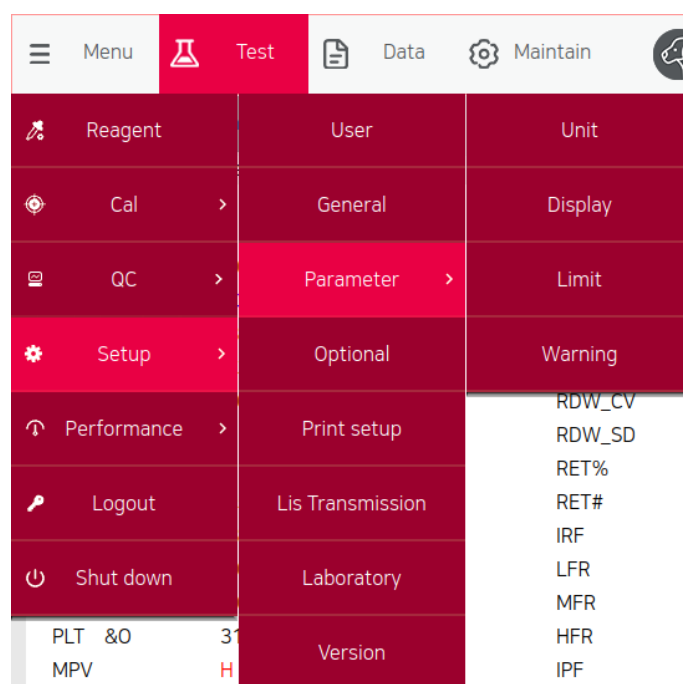


Figure 33 Parameters

6.6.3.1 Parameter units

Click “Menu” → “Setup” → “Parameter” → “Unit” to enter the parameter unit interface, as shown in Figure 34.

Setup - Unit

WBC RBC PLT RET Research RET research

WBC	10 ⁹ /L
LYM%	%
MON%	%
NEU%	%
EOS%	%
BASO%	%
IMG%	%
LYM#	10 ⁹ /L
MON#	10 ⁹ /L
NEU#	10 ⁹ /L

Animal Save Reset

Next sample ID:25 Lis status:Disconnected 2025-07-16 09:21:29

Figure 34 Parameter units

The system categorizes parameters into WBC, RBC, PLT, RET research parameters and RET research parameters. Once a category is selected, the related parameters will be displayed.

The optional units for each parameter are shown in the figure. Operators can change the parameter units based on regional requirements. For example, after clicking “WBC,” various unit options will appear on the right. You can click parameters on the left to select and adjust other units.

Click “Animal” to switch the animal species and configure customized parameter units. Then click “Save” to apply the settings. To restore factory defaults, click “Reset.”

6.6.3.2 Parameter display

Click “Menu” → “Setup” → “Parameter” → “Display” to access the parameter display interface, as shown in Figure 35.

Setup - Display

WBC RBC PLT RET Research RET research

WBC	☒
LYM%	☒
MON%	☒
NEU%	☒
EOS%	☒
BASO%	☒
IMG%	☒
LYM#	☒
MON#	☒
NEU#	☒

Animal Save Reset

Next sample ID:25 Lis status:Disconnected 2025-07-16 09:37:11

Figure 35 Parameter display

The operator can select which parameters to display. By default, all parameters are selected. To hide a parameter, uncheck it and click “Save”.

Click “Animal” to select the animal category and configure the corresponding parameter display settings. To restore the factory default settings, click “Reset.”

6.6.3.3 Parameter limits

Click “Menu” → “Setup” → “Parameter” → “Limit” to access the parameter limits interface, as shown in Figure 36.

The screenshot shows the 'Setup - Limit' interface. At the top, there are tabs for 'WBC', 'RBC', 'PLT', and 'RET', with 'WBC' selected. Below the tabs is a table with columns: 'Parameter', 'Lower limit', 'Upper limit', and 'Unit'. The table contains the following data:

Parameter	Lower limit	Upper limit	Unit
WBC	6.00	17.00	10 ⁹ /L
LYM%	6.00	40.00	%
MON%	2.00	13.00	%
NEU%	42.00	84.00	%
EOS%	0.50	10.00	%
BASO%	0.00	1.30	%
IMG%	0.00	999.99	%
LYM#	0.830	4.690	10 ⁹ /L
MON#	0.140	1.970	10 ⁹ /L

At the bottom of the table, there are three buttons: 'Animal', 'Save', and 'Reset'. Below the buttons, there is a status bar with the following information: 'Next sample ID:25', 'Lis status:Disconnected', and '2025-07-16 09:40:01'.

Figure 36 Parameter limits

The operator can adjust the parameter limits based on the selected animal category. Click the input boxes under “Lower limit” and “Upper limit” to modify the values. Click “Animal” to choose an animal category, then configure the corresponding parameter limits. Click “Save” to apply the changes. Click “Reset” to restore the factory default settings.

6.6.3.4 Alarm limit

Click “Menu” → “Setup” → “Parameter” → “Warning” to access the alarm limits interface, as shown in Figure 37.

When a parameter result falls within the alarm limit, the Analyzer will trigger the corresponding alert. Each parameter value can be modified as needed. After making changes, click “Save”.

To configure settings by animal type, click “Animal” to select the appropriate category. Click “Reset” to restore factory default settings.

Information	Number	Parameter	Symbol	Value	Unit	Remarks
Low-value WBC multiplication counting	0	WBC	<	1.00	10 ⁹ /L	
Low-value PLT-O multiplication counting	1	PLT-O	<	50	10 ⁹ /L	
Leukocytopenia	2	WBC	>	20.00	%	
Leukocytosis	3	WBC	<	3.00	10 ⁹ /L	
Neutrophilia	4	NEU#	>	20.00	%	
Neutropenia	5	NEU#	<	20.00	%	
Monocytosis	6	MON#	>	40.00	%	
Lymphocytosis	7	LYM#	>	25.00	%	
Lymphopenia	8	LYM#	<	25.00	%	
Eosinophilia	9	EOS#	>	40.00	%	

Next sample ID:25 Lis status:Disconnected 2025-07-16 09:42:32

Figure 37 Alarm limits

6.6.4 Optional parameters

Click “Menu” → “Setup” → “Optional” to access the optional parameter settings interface, as shown in Figure 38.

Setup - Optional

- Waste full: ☐
- Display WBC multiplication: ☐
- Display PLT-O multiplication: ☐
- Dilution reminder: ☒
- Quality control algorithm: CBC-XN
- Calibration algorithm: Calibrator
- Message and graphics selection: Diff
- QC Message and graphics selection: Alarm info
- Reset sample number at 0:00:
- Reset sample No after autoblack: ☐

Next sample ID:25 Lis status:Disconnected 2025-07-16 09:45:10

Figure 38 Optional parameters

(1) Waste full

If set to “X”, no alarm will be triggered when the waste liquid tank is full.

If set to “√”, an alarm will be triggered when the waste liquid tank is full.

(2) Display WBC multiplication:

When enabled, the WBC count time is automatically extended for more accurate results when

WBC is below $1.00 \times 10^9/L$ (default value, adjustable in “Alarm Limits”).

(3) Display PLT-O multiplication

When enabled, the PLT-O count time is automatically extended for more accurate results when PLT-O is below $1.00 \times 10^9/L$ (default value, adjustable in the alarm limits interface).

(4) Dilution reminder

When enabled, a drainage alert will pop up during the pre-dilution testing.

(5) Quality control algorithm

Optional algorithms HQ-60, 5-DIFF, CBC-XN, and CBC-X/HQ-6D: Quality control testing shall be classified according to the selected algorithm.

(6) Calibration algorithm: Select either the animal blood sample algorithm or the calibrator algorithm for calibration.

(7) Message and graphics selection: After a sample test is completed, the top section of the information and graph display area provides the following selectable options: “Alarm Info,” “Diff,” and “Ret.”

(8) QC Message and graphics selection: After a QC sample test is completed, the top section of the information and graph display area provides the following selectable options: “Alarm Info” and “Diff.”

(9) Zero the sample number:

If set to “X”, the sample ID will reset to 1 at the beginning of each day.

If set to “√”, the sample ID will continue sequentially across the day (e.g., if 10 samples were tested today, tomorrow’s first sample ID will start at 11).

(10) Reset sample number at 0:00:

After startup, the daily starting sample ID can be set and it will reset at 00:00.

(11) Reset sample No after autoblack.

After startup, the sample ID will be automatically reset upon completion of the blank test.

(12) Close the quality control record switch.

After startup, disable the quality control log.

6.6.5 Print setting

Click “Menu” → “Setup” → “Print Setup” to access the print settings interface, as shown in Figure 39.

The printer type can be set to:

- USB Printer (A4)
- USB Printer (A5 - Landscape)

- USB Printer (A5 - Portrait)
- PDF

The color settings can be adjusted to:

- Grayscale
- Color

Figure 39 Print setting

Click “Confirm” to save the settings.

Click “Cancel Print” to stop the current print job.

Click “Printer Settings” to search for available printers or switch to a different one.

Click “Reset printer” to reset the printer settings.

Click “Export PDF Files” to save the print content as a PDF file.

6.6.6 LIS transmission Settings

Click “Menu” → “Setup” → “LIS Transmission” to access the transmission settings. Here, you can configure the LIS communication IP address and set up both automatic and manual data transmission, as shown in Figure 40.

Figure 40 Transmission settings interface

6.6.7 Laboratory

Click “Menu” → “Setup” → “Laboratory” to open the laboratory settings interface, as shown in Figure 41. Here, you can enter the hospital name, laboratory name, after-sales contact information, and other relevant details.

Figure 41 Laboratory

6.6.8 Version information

Click “Menu” → “Setup” → “Version” to access the version information interface, as shown in Figure 42.

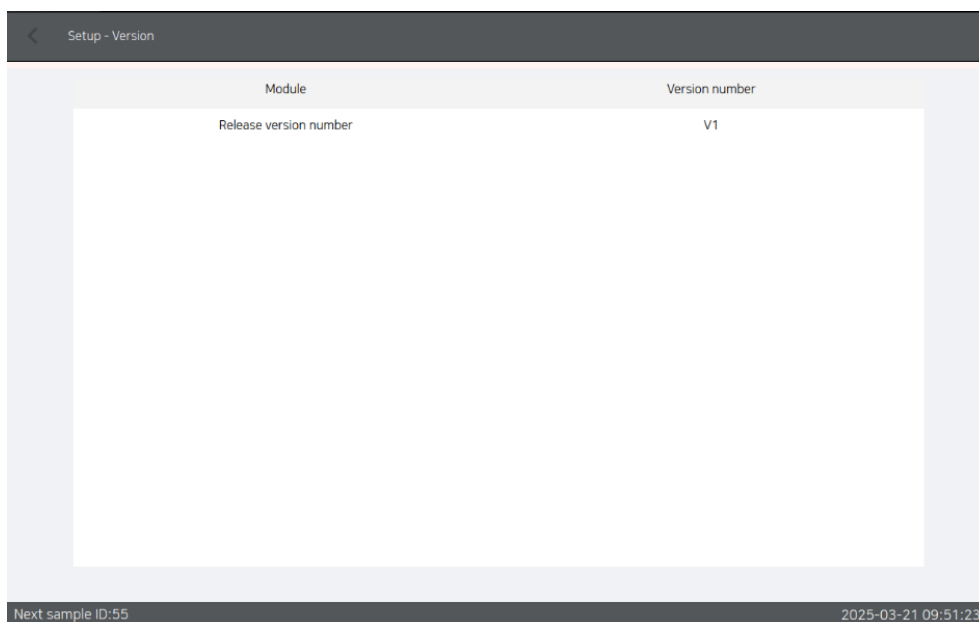


Figure 42 Version information

NOTE

- Users should perform system upgrades and maintenance as needed based on the Analyzer version information.

6.7**Performance**

Click "Menu" → "Performance" to access the performance menu, as shown in Figure 43.

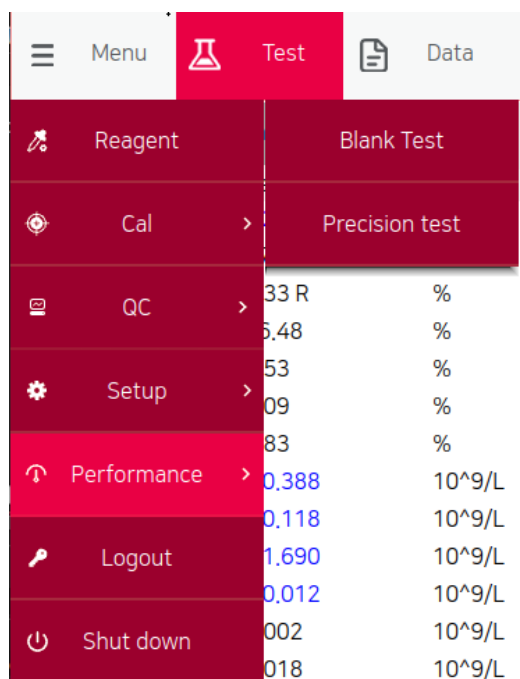


Figure 43 Performance menu

6.7.1 Blank test

Click “Menu” → “Performance” → “Blank test” to open the blank test interface, as shown in Figure 44.

Performance - Blank Test

Mode information: Blood+whole blood+CD

Date	Time	WBC	RBC	HGB	PLT
2025-04-24	18:59:09	4.79	2.25	47	86
2025-04-21	17:53:04	0.00	0.00	0	0
2025-04-21	17:49:25	0.00	0.00	0	0
2025-04-21	17:43:52	0.00	0.00	0	0
2025-04-21	17:27:58	0.00	0.00	0	0
2025-04-21	16:35:51	0.00	0.00	0	0

Parameter	WBC(10 ⁹ /L)	RBC(10 ¹² /L)	HGB(g/L)	PLT(10 ⁹ /L)
Limit	0.2	0.02	1	10
Result				

Animal Export Export limit Import limit Test mode Delete Clear Blank option

Next sample ID:25 Lis status:Disconnected 2025-07-16 09:53:05

Figure 44 Blank test

The date, time, parameter results, and other information for each blank test will be recorded on this interface. If the results are within acceptable limits, “Pass” will be displayed.

- Click “Animal” to select the animal category.
- Click “Export” to save blank test results to a USB drive.
- Click “Export Limit” to export the current threshold parameters to a USB drive.
- Click “Import Limit” to load limit configuration files from the connected USB drive, replacing all existing system limit parameters.
- Click “Test Mode” to select the desired test mode, as shown in Figure 45.

Mode information

Test mode
Blood

Type of blood sample
Whole blood Pre-diluted

Analytical model
CBC DIFF RET

OK Cancel

Figure 45 Mode

After selecting a test record, click “Delete” to remove the selected entries.

Click “Clear” to delete all blank test data.

Click “Blank Option” to set automatic blank testing at startup, as shown in Figure 46. When

enabled, the system will perform a non-sampling test based on the configured number of cycles each time the device is powered on. If the blank test passes, normal daily testing will proceed automatically.

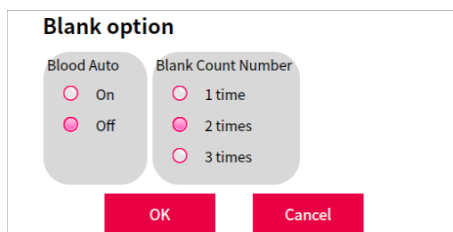


Figure 46 Set automatic blank test at startup

6.7.2 Precision test

Click “Menu” → “Performance” → “Precision test” to access the precision test interface, as shown in Figure 47.

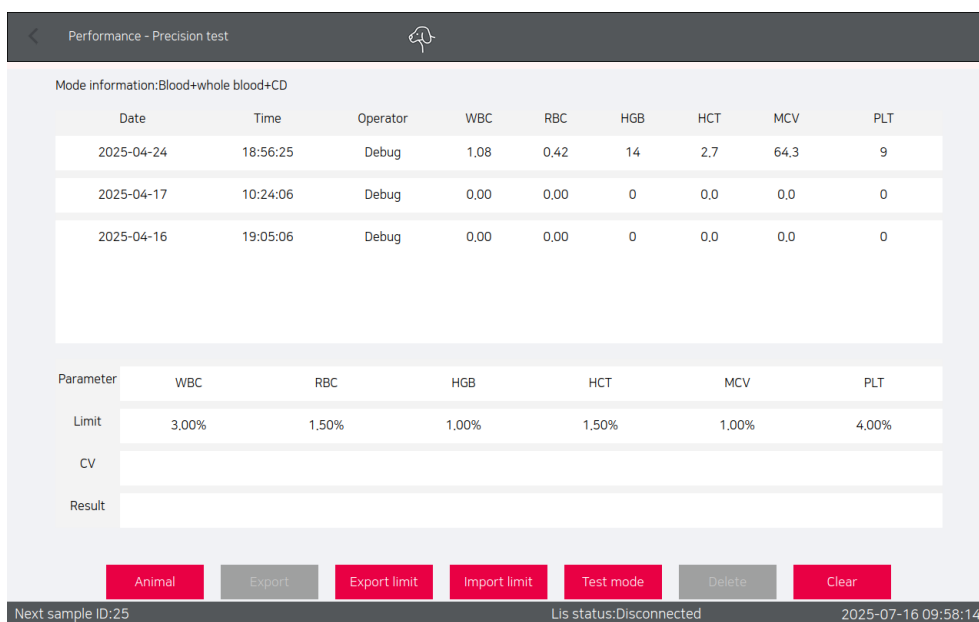
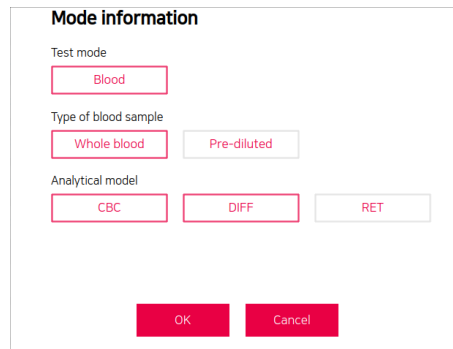


Figure 47 Precision test interface

The interface records information such as the date, time, and results for each test sample. If the CV (coefficient of variation) value is within the specified range, “Pass” will be displayed.

- Click “Animal” to select the animal category.
- Click “Export” to save test results to a USB drive.
- Click “Export Limit” to save the CV threshold values to a USB drive.
- Click “Import Limit” to load CV threshold values from a USB drive into the Analyzer.
- Click “Test Mode” to select the desired test mode, as shown in Figure 48.



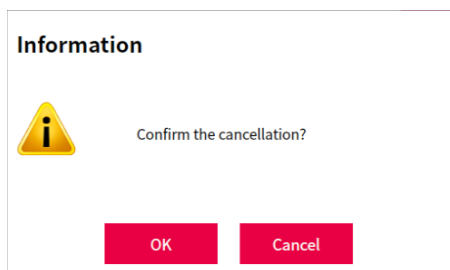
The dialog box is titled "Mode information". It contains three sections: "Test mode" with a button labeled "Blood"; "Type of blood sample" with two buttons labeled "Whole blood" and "Pre-diluted"; and "Analytical model" with three buttons labeled "CBC", "DIFF", and "RET". At the bottom, there are two buttons labeled "OK" and "Cancel".

Figure 48 Mode

Click "Delete" to remove the selected test results.
Click "Clear" to delete all test results.

6.8 Logout

Click "Menu" → "Logout" to open the logout dialog box, as shown in Figure 49.

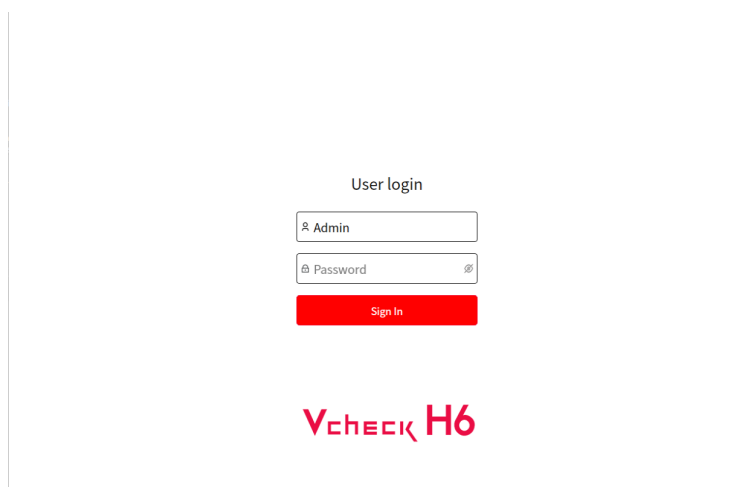


The dialog box is titled "Information". It features a yellow warning icon with an exclamation mark. To the right of the icon, the text "Confirm the cancellation?" is displayed. At the bottom, there are two buttons labeled "OK" and "Cancel".

Figure 49 Logout

(1) Click "OK" to log out of the current user account.

(2) The system will return to the login interface, allowing another user to log in, as shown in Figure 50.



The login interface is titled "User login". It contains two input fields: "Admin" and "Password". Below these fields is a red button labeled "Sign In". At the bottom of the interface, the logo "Vcheck H6" is displayed.

Figure 50 Login interface

6.9 Shutdown and soak

(1) Click “Menu” → “Shut down” to open the shutdown dialog box, as shown in Figure 51.

Information



Confirm shutdown and click OK to perform the shutdown soak process

OK

Cancel

Figure 51 Shutdown

(2) After clicking “OK” a reminder box will pop up prompting to insert the probe cleaner, as shown in Figure 52.

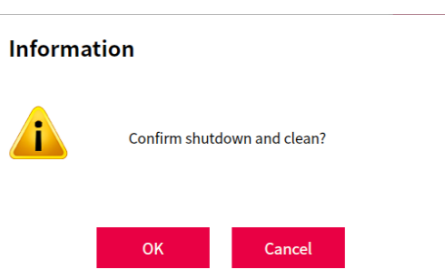


Figure 52 Reminder box

(3) After placing the probe cleaner under the sample probe, click “OK” to start the shutdown and soaking process. The probe cleaner will be aspirated only once, so ensure that the sample probe’s bottom is fully immersed in the probe cleaner throughout the soaking process.

(4) Once cleaning is complete, turn off the Analyzer’s power switch.

(5) If you click “Cancel” in Figure 51, the Analyzer will perform a shutdown cleaning cycle using diluent instead of the probe cleaning solution. Once the cleaning is complete, the system will prompt you to turn off the power.

NOTE

- Turn off the power switch only when prompted to turn off the power.

6.10 Test

Clicking “Test” allows you to view the selected test results as shown in Figure 53. If no test is selected, the system will display the latest test results.

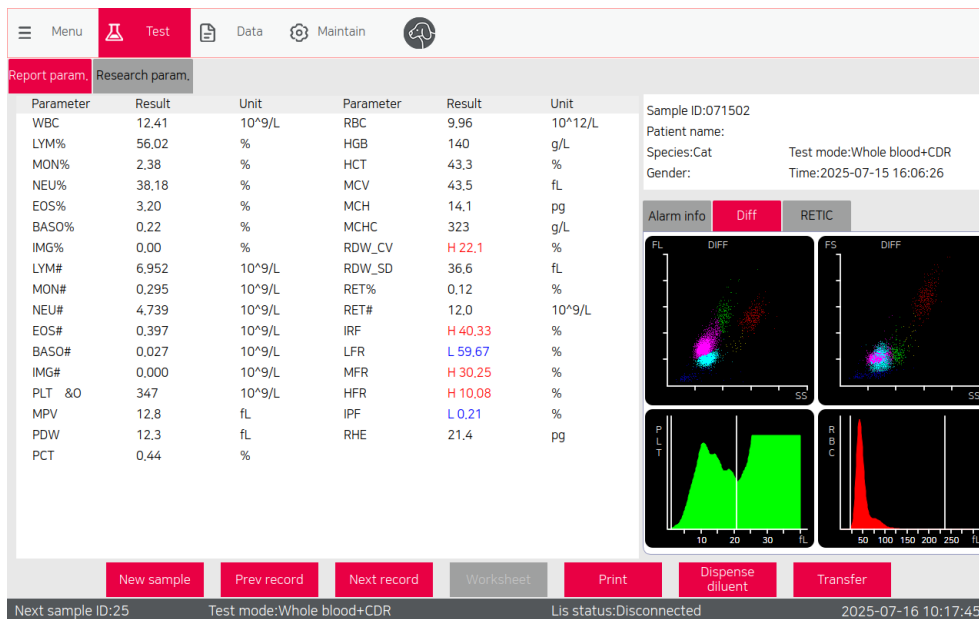


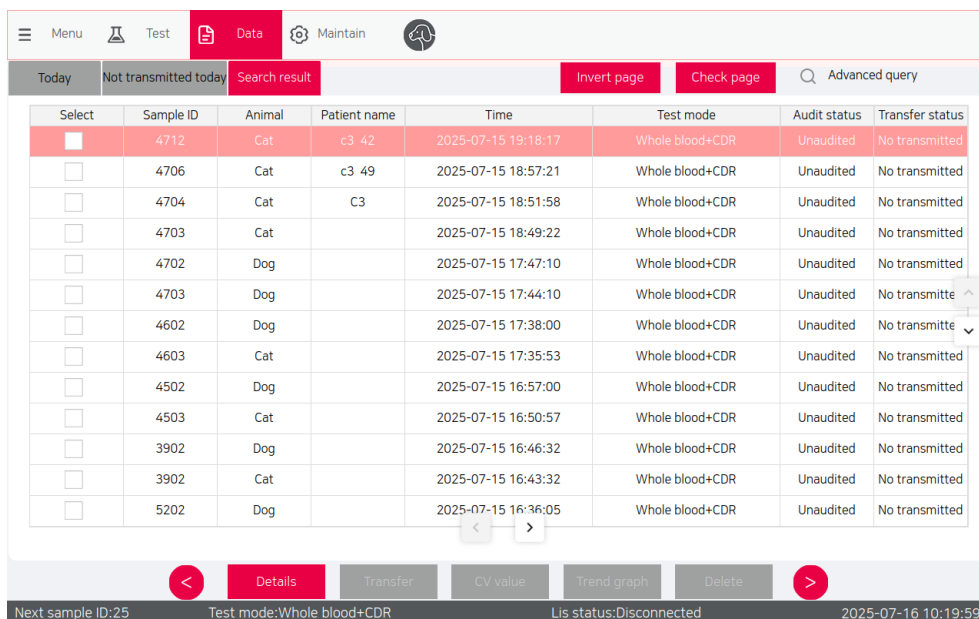
Figure 53 Test interface

6.11 Data

Clicking on “Data” will take you to the data interface, as shown in Figure 54.

By clicking the buttons below the interface, you can perform the following actions on selected samples: (To view additional buttons, click the left or right arrows (< / >).)

- “Details”: View detailed information
- “Transfer”: Transfer data
- “CV value”: Calculate CV values for multiple selected samples
- “Trend graph”: Generate trend charts for multiple samples
- “Delete”: Delete selected samples
- “Audit”: Review samples
- “Cancel audit”: Cancel sample review
- “Edit”: Edit sample information
- “Export data”: Export sample information



Select	Sample ID	Animal	Patient name	Time	Test mode	Audit status	Transfer status
☒	4712	Cat	c3 42	2025-07-15 19:18:17	Whole blood+CDR	Unaudited	No transmitted
☐	4706	Cat	c3 49	2025-07-15 18:57:21	Whole blood+CDR	Unaudited	No transmitted
☐	4704	Cat	C3	2025-07-15 18:51:58	Whole blood+CDR	Unaudited	No transmitted
☐	4703	Cat		2025-07-15 18:49:22	Whole blood+CDR	Unaudited	No transmitted
☐	4702	Dog		2025-07-15 17:47:10	Whole blood+CDR	Unaudited	No transmitted
☐	4703	Dog		2025-07-15 17:44:10	Whole blood+CDR	Unaudited	No transmitted
☐	4602	Dog		2025-07-15 17:38:00	Whole blood+CDR	Unaudited	No transmitted
☐	4603	Cat		2025-07-15 17:35:53	Whole blood+CDR	Unaudited	No transmitted
☐	4502	Dog		2025-07-15 16:57:00	Whole blood+CDR	Unaudited	No transmitted
☐	4503	Cat		2025-07-15 16:50:57	Whole blood+CDR	Unaudited	No transmitted
☐	3902	Dog		2025-07-15 16:46:32	Whole blood+CDR	Unaudited	No transmitted
☐	3902	Cat		2025-07-15 16:43:32	Whole blood+CDR	Unaudited	No transmitted
☐	5202	Dog		2025-07-15 16:36:05	Whole blood+CDR	Unaudited	No transmitted

Next sample ID:25 Test mode:Whole blood+CDR Lis status:Disconnected 2025-07-16 10:19:59

Figure 54 Data interface

6.12 Maintenance

Click “Maintain” to access the maintenance interface, which displays maintenance operations and part usage statistics, as shown in Figure 55.

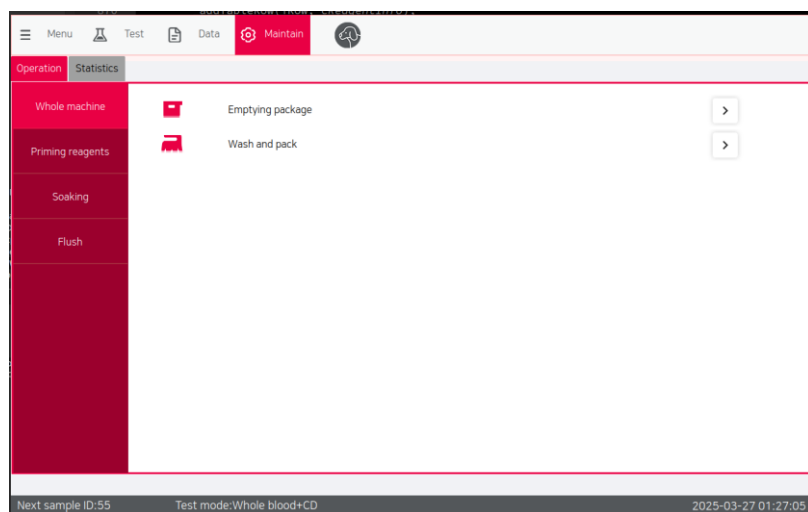


Figure 55 Maintenance interface

6.12.1 Complete maintenance

Click “Whole machine” to enter the complete maintenance interface, as shown in Figure 56.

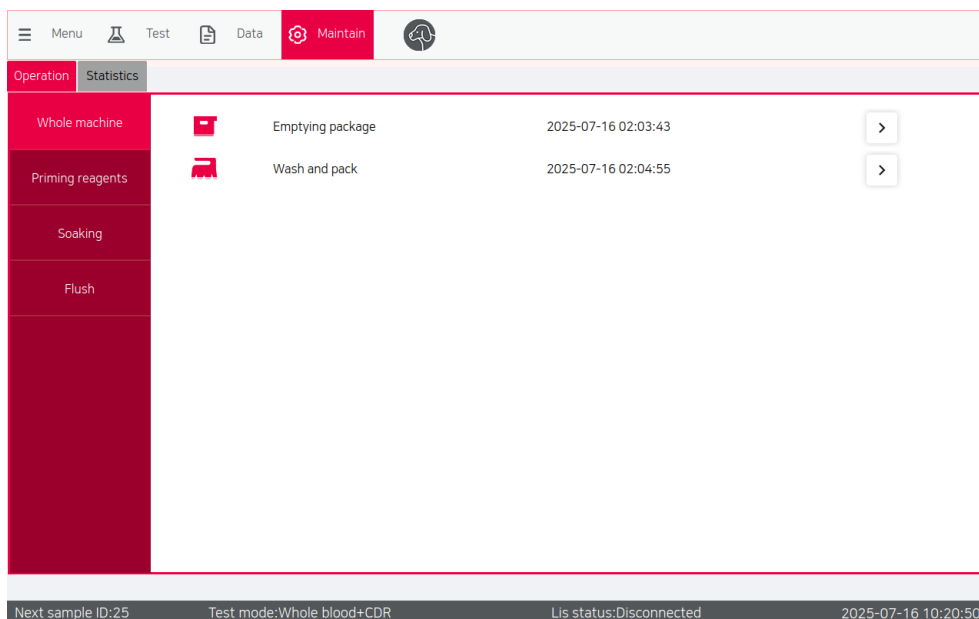


Figure 56 Complete maintenance

(1) Empty Package

Perform the “Empty Package” procedure when the Analyzer will not be used for an extended period (more than 10 days) or needs to be transported. This process involves draining all internal fluids from the Analyzer. Refer to Section 10.3, “Soaking and Complete Maintenance,” for detailed instructions.

Before starting this process, thoroughly rinse the entire analyzer with deionized or distilled water by performing the “Wash and Pack” procedure.

(2) Wash and pack

Perform the “Wash and Pack” procedure when it is necessary to thoroughly rinse all internal pipelines and testing components of the Analyzer.

Note: Deionized or distilled water must be used for this procedure.

Perform the “Wash and Pack” procedure when need to Thoroughly rinse all internal pipelines and testing components of the Analyzer.

Note: Deionized or distilled water must be used for this procedure.

6.12.2 Maintain and prime reagent

Click “Priming Reagents” to access the maintain and prime reagent interface, as shown in Figure 57.

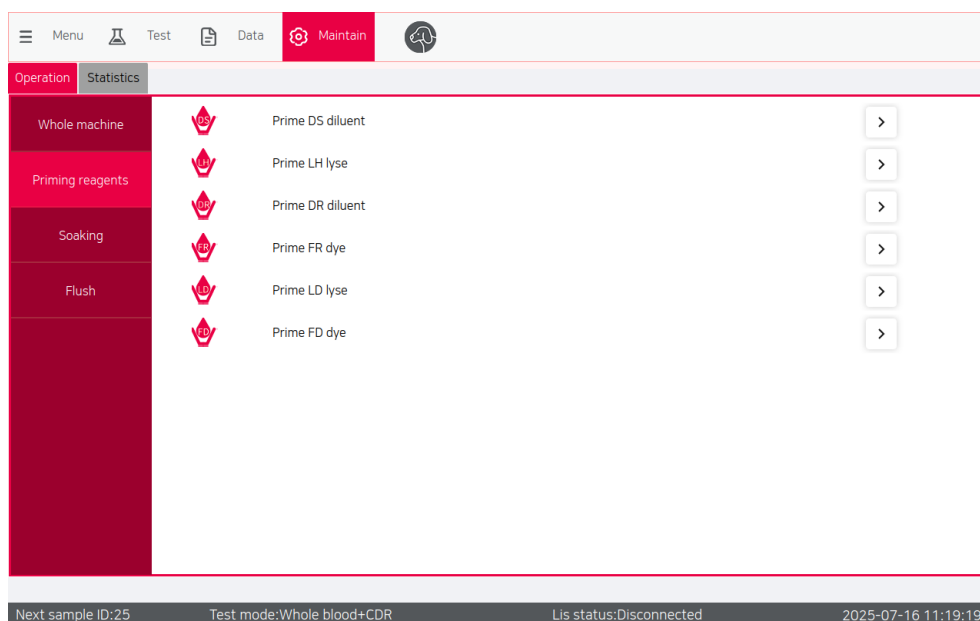


Figure 57 Maintain and prime reagent

➤ Prime DS diluent

The operator can prime the DS diluent under the following two conditions:

- (1) Presence of bubbles in the diluent pipeline.
- (2) Insufficient diluent requiring replacement of the entire DS diluent.

➤ Prime LH lyse

The operator can prime the LH lyse under the following two conditions:

- (1) Presence of bubbles in the LH lyse pipeline.
- (2) Insufficient LH lyse requiring replacement of the entire LH lyse.

➤ Prime DR diluent

The operator can prime the DR diluent under the following two conditions:

- (1) Presence of bubbles in the diluent pipeline.
- (2) Insufficient diluent requiring replacement of the entire DR diluent.

➤ Prime FR dye

The operator can prime the FR dye under the following condition:

- (1) Insufficient FR fluorescent dye requiring replacement of the entire FR fluorescent dye.

➤ Prime LD lyse

The operator can prime the LD lyse under the following condition:

- (1) Insufficient LD lyse requiring replacement of the entire LD lyse.

➤ Prime FD dye

The operator can prime the FD fluorescent dye under the following condition:

(1) Insufficient FD fluorescent dye requiring replacement of the entire FD fluorescent dye.

NOTE

- To ensure test accuracy, do not mix fresh reagents with remaining reagents.
- When replacing reagents, ensure they are of the same type and correctly connected.
- After replacing a reagent container or bag, check that the reagent pipe is not twisted.
- When changing the dye, hold the bottle by the top or a sturdy side to prevent accidental squeezing, which could cause spills or sprays.

6.12.3 Soaking

Click “Soaking” to access the soak interface, as shown in Figure 58.

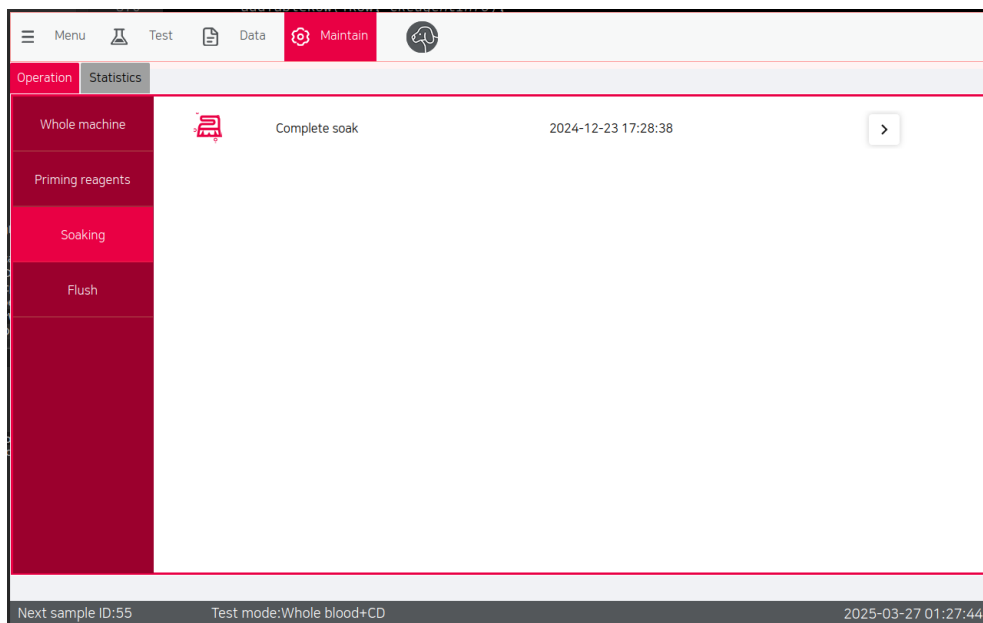


Figure 58 Soaking

➤ Complete soak

Perform the “Complete Soak” procedure to soak the Analyzer using probe cleaner and follow the on-screen prompts.

6.12.4 Flush

Click “Flush” to access the flush interface, as shown in Figure 59.

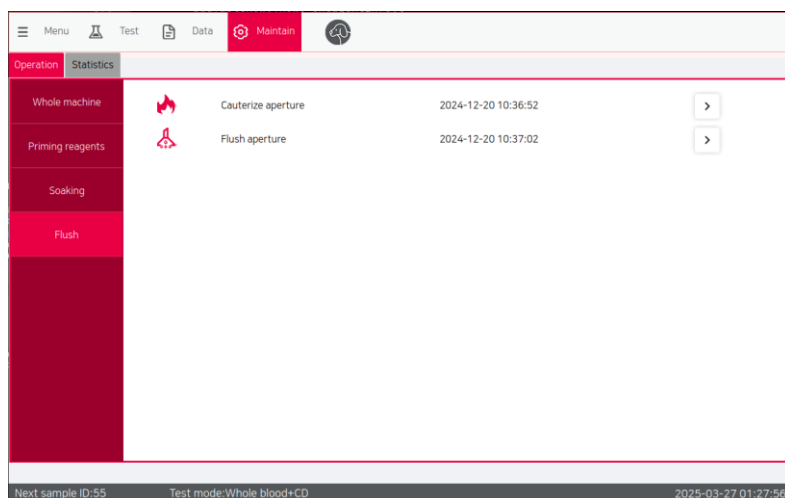


Figure 59 Flush

(1) Cauterize aperture

If the aperture is clogged, perform the “Cauterize aperture” procedure to perform cauterization to clear the blockage.

(2) Flush aperture

If the aperture is clogged, perform the “Flush aperture” procedure to flush the obstruction.

6.12.5 Part usage statistics

The “Statistics” section records information about parts requiring maintenance. The table displays the remaining maintenance time/times and the progress of different components.

When maintenance is due, the system will display a prompt for the required parts. After completing maintenance, click “Reset” to update the maintenance time/times, as shown in Figure 60.

Label	Maintenance mode	Usage information	Setup
MM001	Maintain optical sheath flow syringe	24% 0/30000times, Remaining time: 275 Days	Reset
MM002	Maintain impedance sheath flow syringe	59% 0/30000times, Remaining time: 149 Days	Reset
MM003	Maintain sample aspiration syringe	59% 0/30000times, Remaining time: 149 Days	Reset
MM006	Replace waste liquid filter of HGB reaction pool	59% 0/30000times, Remaining time: 149 Days	Reset
MM008	Replace waste liquid filter of WDF reaction pool	59% 0/30000times, Remaining time: 149 Days	Reset
MM0010	Replace waste liquid filter of RET reaction pool	59% 0/30000times, Remaining time: 149 Days	Reset
MM0011	Maintain probe wiper and filter	100% 0/30000times, Remaining time: 0 Days	Reset
MM0012	Maintain sample probe	100% 0/30000times, Remaining time: 0 Days	Reset
CM001	Replace optical sheath flow syringe	30% 0/60000times, Remaining time: 514 Days	Reset
CM002	Replace impedance sheath flow syringe	30% 0/60000times, Remaining time: 514 Days	Reset
CM003	Replace sample aspiration syringe	30% 0/60000times, Remaining time: 514 Days	Reset

Next sample ID:25 Test mode:Whole blood+CD Lis status:Disconnected 2025-07-16 11:26:15

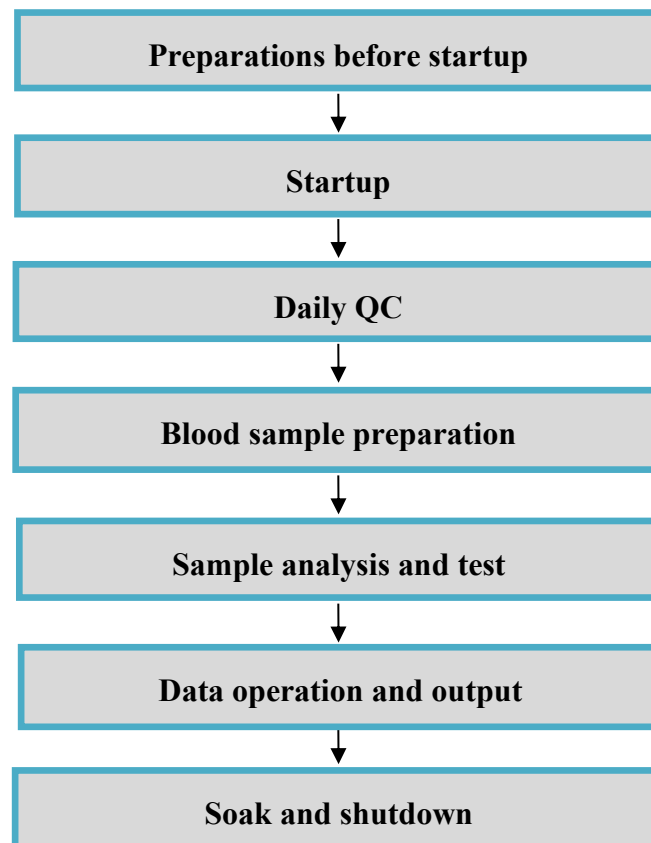
Figure 60 Part usage statistics

Chapter 7 Daily Operation

7.1 Overview

This chapter provides a detailed overview of the daily operation process for the Analyzer, covering all steps from startup to shutdown. It also explains the sample analysis operation process across different operating modes.

The daily operation processes are as shown below:



NOTE

- The Analyzer must be operated by a veterinary medical laboratory professional.
- Before using the Analyzer, ensure that all reagents are correctly placed.
- Use only company-specified reagents and follow the storage and usage guidelines in the User Manual.
- If reagents have been transported at sub-zero temperatures, allow them to reach room temperature for at least 24 hours before use.

7.2 Preparations before startup

Before turning on the Analyzer, perform the following pre-startup checks to ensure the system is ready for operation:

(1) Check the waste container

Dispose of waste liquid properly every day.

Empty the waste container before starting the Analyzer.

(2) Check the reagents, pipelines, and power supply

Ensure that all necessary reagents are available for testing.

Verify that the reagent and waste liquid pipelines are properly connected and not bent.

Check that the power plug is securely inserted into the power outlet.



- Samples, control materials, calibrators, waste liquid, etc. may pose a potential biological infection risk. Operators must follow laboratory safety protocols and wear appropriate personal protective equipment (e.g., lab coats, gloves) when handling these materials.
- Operators are responsible for complying with applicable regional and national regulations regarding the disposal of reagents, waste liquids, waste samples, and related materials.

7.3 Startup

Follow these steps to start the Analyzer:

(1) Turn on the power switch located at the back of the Analyzer. The status indicator will turn blue.

(2) The Analyzer will automatically initialize and perform a self-test. During this process, the status indicator will turn green.

(3) Once initialization is complete, the status indicator remains green, and the login interface is displayed, as shown in Figure 61.



Figure 61 Login interface

(4) Click the input box to bring up the soft keyboard, as shown in Figure 62. Use it to enter your username and password.

* Initial usernames and passwords are as follows: The administrator username is "Admin", and the password is "admin." The operator username is "User", and the password is "User."

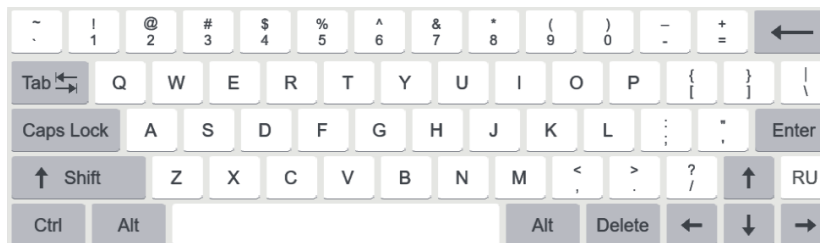


Figure 62 Soft keyboard

(5) After entering the username and password, the system will display the test interface, as shown in Figure 63.

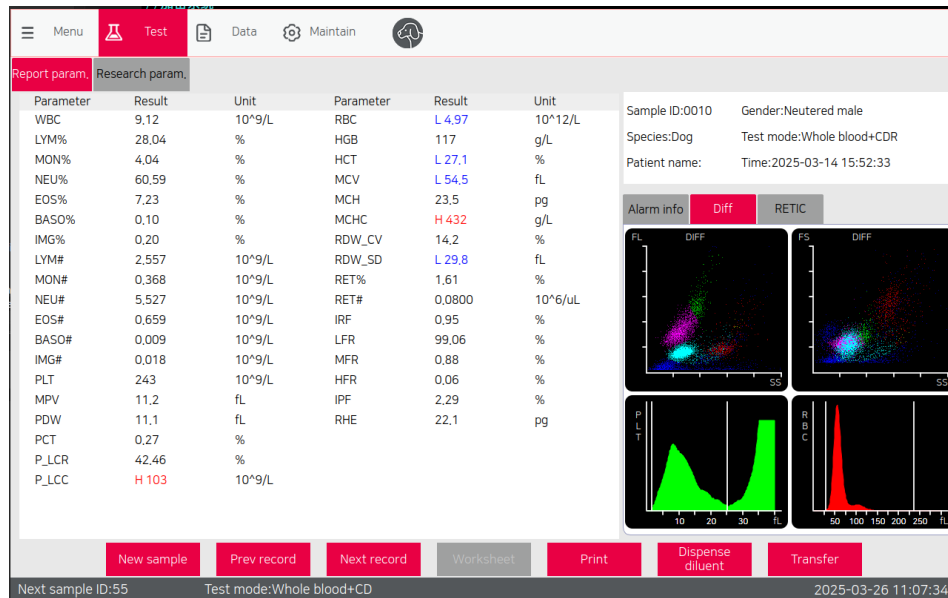


Figure 63 Test interface

(6) A blank test must be performed after the Analyzer has started normally and before testing any blood samples. Please refer to 6.7.1 “Blank Count” in Chapter 6 “Introduction of Analyzer Menu” of the User Manual for detailed instructions.

The acceptable range for blank test data can be found in Appendix A.6.5.

If any of the blank test values fall outside the acceptable range, the test steps above can be repeated. If the results still do not meet the specified requirements after five attempts, please refer to Chapter 11, “Troubleshooting” in the User Manual for further guidance.

7.4 Daily QC

Before performing sample analysis, daily QC analysis must be conducted to ensure reliable results from the Analyzer. For details, please refer to Chapter 8, “Quality Control,” of the User Manual.

7.5 Sample preparation



- Since all clinical samples, control materials, and calibrators may contain blood or serum, they are considered potentially infectious. It is essential to follow established laboratory or clinical procedures and wear appropriate personal protective equipment, such as lab coats, medical gloves, and safety goggles, when handling these materials.
- Avoid direct contact with blood samples, control materials, and calibrators. Always handle them strictly in accordance with relevant safety protocols.

NOTE

- Blood samples must be collected and handled in accordance with the relevant standards established by the local government or laboratory.
- The blood collection process must be clean and free from contamination, and an appropriate anticoagulant must be used. EDTA dipotassium (EDTA-K₂·2H₂O) is recommended.
- Do not shake the blood collection tube vigorously.
- Venous blood can be stored at room temperature for up to 8 hours. If immediate testing is not possible, the sample should be stored at 2–8°C, and the storage period should not exceed 24 hours.
- Samples stored at 2–8°C must be brought to room temperature for at least 15 minutes before analysis.
- Samples that have been stored for a period of time should be gently re-mixed prior to testing.
- Do not reuse disposable items.
- If vacuum blood collection tubes are used, ensure that the cap is clean before use.

7.5.1 Test tube specification

The Vcheck H6 Analyzer is designed for open sample aspiration, making it compatible with various EDTA blood collection tubes. Follow the sample volume filling guidelines provided by the tube manufacturer to avoid:

- (1) Insufficient sample volume, which may prevent the Analyzer from aspirating enough blood.
- (2) Excess sample volume, which may cause clot formation or platelet aggregation.

7.5.2 Preparation of venous blood (whole blood) samples

Venous blood should be collected using a vacuum blood collection tube containing dipotassium EDTA (1.5 – 2.2 mg/mL). Dipotassium EDTA (EDTA-K₂) helps maintain the morphology of RBCs and WBCs while preventing PLT aggregation. After blood collection, gently invert the test tube 5–10 times to ensure proper mixing.

The following anticoagulants are commonly used in collection of whole blood:

- (1) Heparin: Increases cell agglutination (WBC & PLT) and alters cytoplasm color in Romanowsky staining (blue blank). High concentrations (>7.5 µL/capillary) may elevate HCT and MCV.
- (2) Sodium citrate: Dilutes blood to ~10/11 of its original volume. Used for coagulation testing and in cases of suspected pseudothrombocytopenia caused by EDTA.

(3) Acid citrate dextrose (ACD) and citrate phosphate dextrose adenine (CPDA) containing adenine: Widely used for cell concentration (especially PLT concentration) but not recommended for cell counting.

(4) EDTA:

- EDTA-K₂ is common in the USA and Japan.
- EDTA-K₃ is used in the USA and Europe.
- Na₂EDTA is occasionally used.
- ISCH (1993) recommends EDTA-K₂ and EDTA-K₃ as the preferred anticoagulants for hematology. However, other EDTA salts can also be used.
- EDTA may cause pseudothrombocytopenia (due to PLT aggregation) in rare cases (1 in 800 probability).

(5) Fluoride: Used prior to EDTA. No known side effects have been reported.

7.5.3 Preparation of RET samples

Refer to Section 7.5.2: “Preparation of Venous Blood (Whole Blood) Samples” for RET sample preparation. Both whole blood and peripheral blood can be used for the RET test.

7.5.4 Sample stability and accuracy requirements

Fresh whole blood samples are recommended for analysis. According to the ICSH (International Council for Standardization in Haematology), a fresh blood sample is defined as one that is tested within 4 hours of collection.

If properly mixed and stored in an EDTA tube, the sample remains highly accurate for up to 8 hours.

Note: For accurate WBC volume distribution results, test the sample 5–20 minutes after collection and within 8 hours.

If immediate testing is not possible, store the sample at 2–8°C. The storage period should not exceed 24 hours. Before analysis, samples stored at 2–8°C must be brought to room temperature for at least 15 minutes and gently re-mixed.

To ensure accurate test results, the blood volume in vacuum collection tubes must be greater than 0.25 mL.

7.6 Sample analysis

7.6.1 Sample analysis operation flow

7.6.1.1 Blood test



- All clinical samples, control materials, and calibrators may contain animal blood or serum and should be treated as potentially infectious. Operators must follow established laboratory or clinical protocols and wear personal protective equipment (PPE), including: Lab coats or protective clothing, Medical gloves, Safety glasses, etc.

⚠ WARNING

- Keep clothing, hair, and hands at a safe distance from moving parts to prevent injury.
- The sample probe has a sharp needle tip and can easily cause injury. It may also carry infectious agents after contact with blood samples. Avoid any contact with the sample probe.

⚠ CAUTION

- Do not reuse test tubes.
- As this is an open test, you must manually remove the tube cap. Always wear gloves to protect yourself and prevent potential infection.
- Ensure that the selected test mode matches the sample being tested.
- If the room temperature exceeds the Analyzer's specified operating range, test results may be unreliable, and a temperature error will appear in the fault message area.

NOTE

- Before analyzing the sample, check for any clots in the blood that could lead to inaccurate results.
- Do not open the front cover of the Analyzer once the counting process has started.

The operation process is as follows:

(1) On the Test Interface, click "New Sample" to open the new sample entry interface, as shown in Figure 64.

New sample

Sample ID: 55 Hospital:

Patient name: Doctor:

Owner: Breed:

Weight: Species: Dog ▼

Gender: Male ▼ Sample type: Whole blood ▼

Age: 0 ▼ Y 0 ▼ M Test mode: CBC+DIFF ▼

Remark:

OK Cancel

Figure 64 New sample entry

(2) Enter the patient's information (sample ID, patient name, owner, etc.). You may also use the default sample number as the Sample ID.

(3) Under Species, select the appropriate animal category from the dropdown menu.

(4) Select Sample Type. Choose Whole Blood if testing whole blood samples.

(5) Under Test Mode, select the appropriate analysis mode. The default mode for whole blood testing is CD (CBC+DIFF).

The available blood test modes and their corresponding functions are as shown in Table 28.

Table 28 Blood sample test mode

Type	Selectable test modules
Venous whole blood	CD, CDR

Table 29 Explanation of analysis modes

Abbreviation	Explanation
CBC+DIFF (CD)	Blood cell counting and classification of WBC
CBC+DIFF+RET (CDR)	Blood cell counting, WBC classification, and RET testing

(5) Click "OK" to finalize the mode selection. The entered Sample ID and selected Test Mode will appear at the bottom of the screen.

(6) Thoroughly mix the blood sample. Remove the cap from the vacuum collection tube and place the tube under the sample probe. Ensure that the sample is fully immersed in the probe both before and after aspiration, as shown in Figure 65.

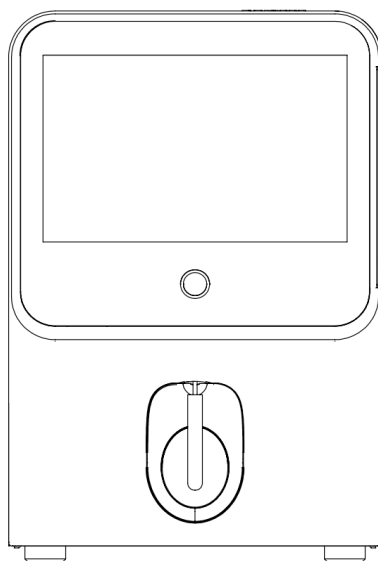


Figure 65 Sample tube position

(7) Press the “Count” button on the front of the Analyzer to begin sample aspiration.

(8) When the system beeps, sample aspiration is complete, and the sample tube can be removed.

NOTE

- The test results of each sample will be automatically saved in the “Data” interface.
- If a sample ID is not entered, the system will assign one incrementally by default.

7.6.2 Treatment of alarm prompt in testing process

If errors occur during the testing process due to insufficient reagent volume, expired reagent, or missing reagent, the working status indicator will flash red. Replace the reagent with a new one and prime it. Once properly set up, the Analyzer can resume analysis.

If issues such as clogging or bubbles occur: Click on the status indicator to troubleshoot and resolve the issue. Once resolved, the Analyzer can continue testing.

NOTE

- For information on reagent priming, refer to Section 6.12.2, “Maintain and Prime Reagent”.

7.6.3 Confirmation of test data

After testing, the sample data is displayed on the screen, as shown in Figure 66.

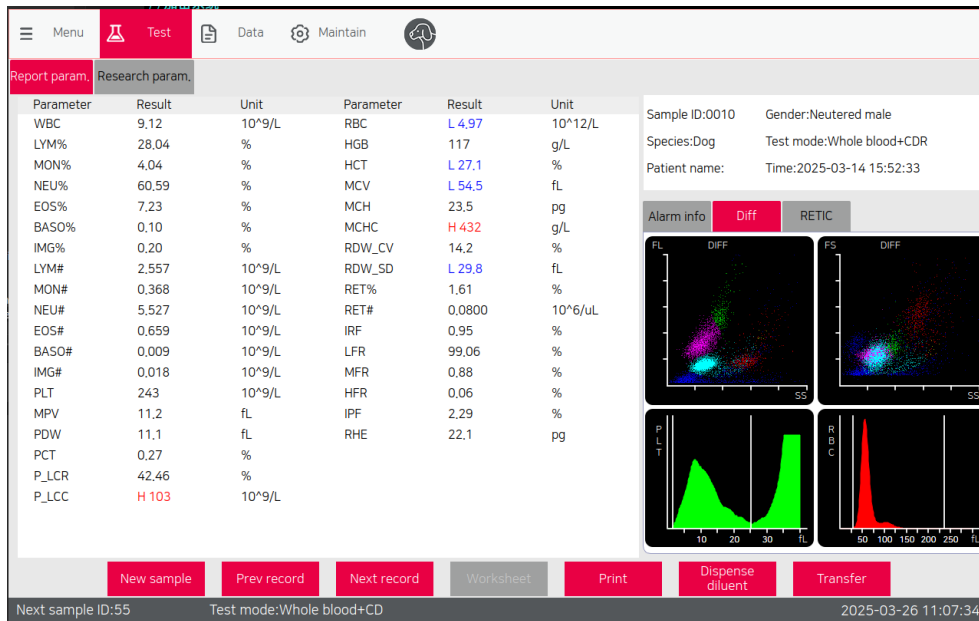


Figure 66 Test data

On the left side of the screen, test parameter results are displayed along with any parameter alarms.

- A blue result or a value prefixed with “L” indicates that the test result is lower than the reference range.
- A red result or a value prefixed with “H” indicates that the test result is higher than the reference range.
- A black result indicates that the test result is within the reference range.
- A result displayed as “****” means the test result is invalid or exceeds the display limit for that parameter.

On the right side of the screen, additional sample information is displayed, including the current sample ID, gender, species, patient name, test time and test mode.

On the Information and graphic display area

- Click “Alarm info” to display WBC, RBC and PLT parameter information.
- Click “Diff” to view the optical classification chart of blood routine.
- Click “RETIC” to display RET pattern.

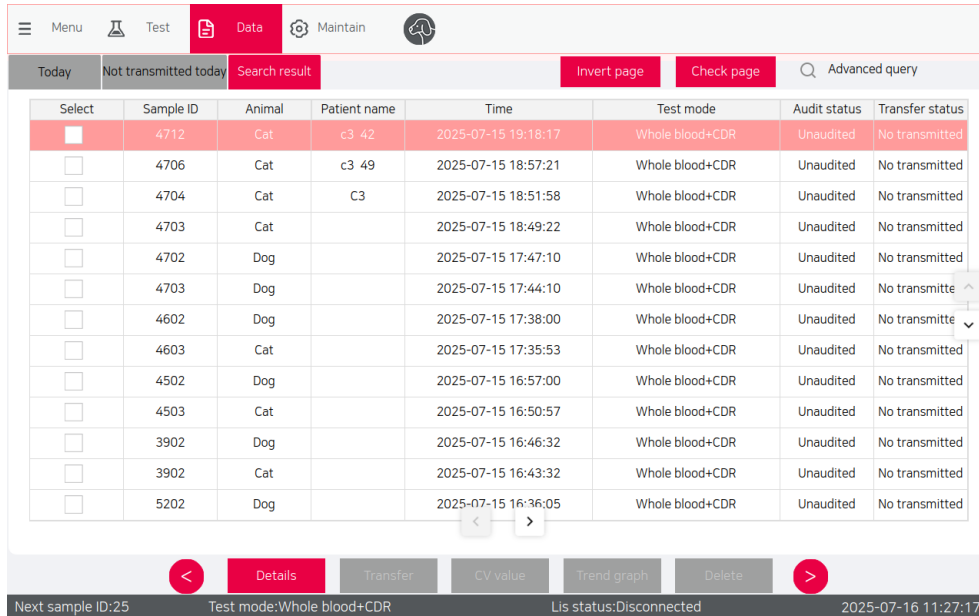
7.7 Data operation and output

After each sample is analyzed, the Analyzer automatically saves the results to the database. Operators can view and review all stored parameter results, scatter plots, and histograms. Additional features are available to support comprehensive data queries and management.

7.7.1 Data query

Click “Data” to enter the data query interface, as shown in Figure 67.

The interface displays: Select, Sample No (Sample ID), Animal (Species), Pat. Name (Patient name), Time, Test mode, Audit status, Transfer status



Select	Sample ID	Animal	Patient name	Time	Test mode	Audit status	Transfer status
☒	4712	Cat	c3 42	2025-07-15 19:18:17	Whole blood+CDR	Unaudited	No transmitted
☐	4706	Cat	c3 49	2025-07-15 18:57:21	Whole blood+CDR	Unaudited	No transmitted
☐	4704	Cat	C3	2025-07-15 18:51:58	Whole blood+CDR	Unaudited	No transmitted
☐	4703	Cat		2025-07-15 18:49:22	Whole blood+CDR	Unaudited	No transmitted
☐	4702	Dog		2025-07-15 17:47:10	Whole blood+CDR	Unaudited	No transmitted
☐	4703	Dog		2025-07-15 17:44:10	Whole blood+CDR	Unaudited	No transmitted
☐	4602	Dog		2025-07-15 17:38:00	Whole blood+CDR	Unaudited	No transmitted
☐	4603	Cat		2025-07-15 17:35:53	Whole blood+CDR	Unaudited	No transmitted
☐	4502	Dog		2025-07-15 16:57:00	Whole blood+CDR	Unaudited	No transmitted
☐	4503	Cat		2025-07-15 16:50:57	Whole blood+CDR	Unaudited	No transmitted
☐	3902	Dog		2025-07-15 16:46:32	Whole blood+CDR	Unaudited	No transmitted
☐	3902	Cat		2025-07-15 16:43:32	Whole blood+CDR	Unaudited	No transmitted
☐	5202	Dog		2025-07-15 16:36:05	Whole blood+CDR	Unaudited	No transmitted

Navigation controls: < Details Transfer CV value Trend graph Delete >

Status bar: Next sample ID:25 Test mode:Whole blood+CDR Lis status:Disconnected 2025-07-16 11:27:17

Figure 67 Data interface

Use the navigation symbols on the right side of the screen to scroll through results, as shown in Figure 68.



Figure 68 Symbol

The functions of the data interface include:

(Click the left or right arrow (< / >) to scroll and view more buttons.)

- Advanced query: Filter results based on a specified date range and conditions.
- Details: View sample result data along with corresponding graphs.
- Transfer: Send sample data to the LIS.
- CV value: Calculate CV values for multiple test results.
- Trend graph: Display trend charts for multiple test results.
- Delete: Delete selected sample data.

- Audit: Review and approve sample results.
- Cancel audit: To remove the approved status, select the samples and click “Cancel Audit” in the audit menu.
- Edit info: Edit sample information.
- Export: Export selected sample data to a USB drive.

7.7.2 Data screening

To perform an advanced search, click on “Advanced query” at the top right of the data interface. This will open the data search input box, as shown in Figure 69. The system allows filtering of sample records based on one or multiple conditions. When multiple custom conditions are applied, the system will retrieve only the samples that meet all specified criteria.

- Select samples from a specific time period.
- Search for samples within a specific sample number (Sample ID) range.
- Search for specific samples by patient name.

The image shows a dialog box titled "Advanced query". It contains four input fields: "Start" with a date value "2025 -05 -23", "End" with a date value "2025 -07 -23", "Sample ID" with two empty boxes separated by a hyphen, and "Patient name" with a single empty box. At the bottom of the dialog are two red buttons labeled "OK" and "Cancel".

Figure 69 Advanced search interface

7.7.3 Delete data

As the number of tested blood samples increases, the Analyzer’s stored data may grow significantly. To manage storage efficiently, operators should regularly review and delete stored data as needed.

Additionally, automatic periodic deletion can be configured in “Setup” → “General” → “Clear up setup.”

To delete data manually, select the data to be deleted (either single or multiple records). Click “Delete” to remove the selected data.

NOTE

- Deleted data cannot be recovered from the Analyzer. Operators should carefully review and confirm before proceeding with deletion.

7.7.4 Detailed information

Click on a sample—the background color will turn pink, indicating that the sample is selected.

Click “Details” to open the detailed data view, as shown in Figure 70 below.

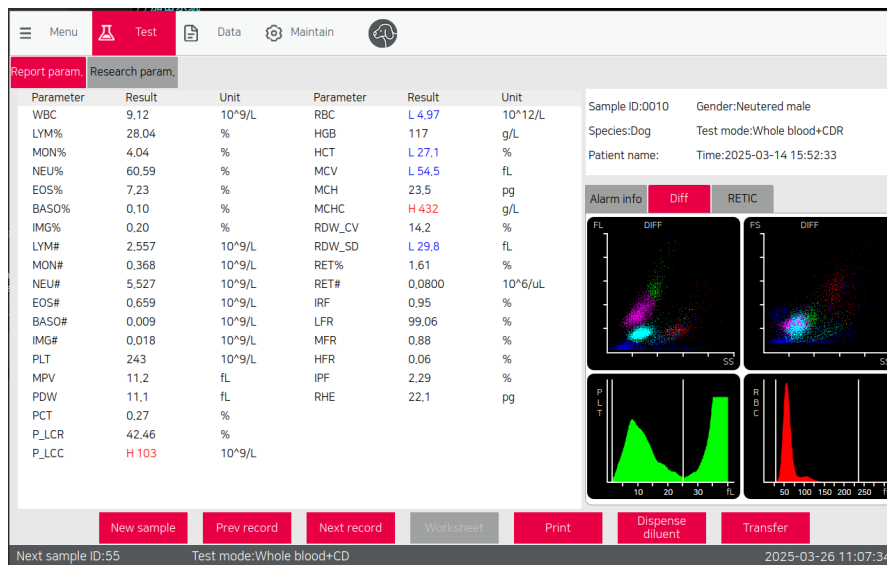


Figure 70 Details

Prev record: Displays the last recorded sample.

Next record: Displays the next recorded sample.

7.7.5 Data transmission

Before transmitting data, ensure that the Analyzer is properly connected to a computer.

To transmit a sample record:

- (1) Select the sample to be transmitted from the query interface.
- (2) Click “Transfer” to send the data.

7.7.6 Edit sample

You can edit the information of tested samples, including Sample ID, Name, Gender, Weight, Age, and other fields. You may also add comments.

7.7.7 CV value

Select multiple samples and click “CV Value” to view the mean, CV, and SD for each parameter.

7.7.8 Trend graph

After selecting multiple data points, click “Trend Graph” to view parameter fluctuation trends over time.

7.7.9 Audit, cancel audit

- 1) Audit: Approve the selected samples.
- 2) Cancel audit: To revoke the approved status of samples, select the target samples and click “Cancel Audit” on the audit menu.

7.7.10 Export

Export the selected sample data to a USB drive in CSV format.

7.8 Shutdown



- All clinical samples, control materials, and calibrators may contain animal blood or serum and should be treated as potentially infectious. Operators must follow established laboratory or clinical protocols and wear personal protective equipment (PPE), including: Lab coats or protective clothing, Medical gloves, Safety glasses, etc.

NOTE

- To maintain the stability of the Analyzer and ensure data accuracy, the Analyzer must be shut down properly after 24 hours of continuous operation.
- If the power is turned off directly without following the shutdown procedure, system data may be lost, preventing the Analyzer from starting normally.
- Operators must always follow the correct shutdown procedure to avoid system errors.
- After shutting down, wait at least 10 seconds before turning the Analyzer back on to prevent potential damage.

Before shutting down the Analyzer, ensure that all sample measurements are complete and follow the proper shutdown procedure. This process cleans the Analyzer’s sample cup and connected tubes.

- 1) Click “Menu” → “Shut down” to open the shutdown and soaking dialog box, as shown in Figure 71.

Information

Confirm shutdown and click OK to perform the shutdown soak process

OK

Cancel

Figure 71 Shutdown and soak

2) Click “OK”, and a reminder box will appear, prompting you to insert the probe cleaner, as shown in Figure 72.

Information

Confirm that probe cleaner has been put in?

OK

Figure 72 Probe cleaner dialog box

3) Place 4.5 mL of probe cleaner under the sample probe. Ensure the entire needle is immersed in the solution before and after aspiration. Once the soaking process is complete, the screen will display the “Please turn off the power” dialog box.

4) Turn off the Analyzer using the power switch on the back side.

5) Check the waste container and dispose of waste materials according to laboratory regulations.

Chapter 8 Quality Control

8.1 Overview

To ensure accurate counting and analysis, as well as to detect and eliminate systematic errors affecting the Analyzer's measurements in a timely manner, it is essential to maintain quality control of the Analyzer's measurement system. The Analyzer supports L-J, X-B, X-R, and X quality control modes.

BIONOTE recommends using BIONOTE-recommended control materials to run the QC program under the following conditions:

1. After starting the Analyzer each day and before testing blood samples
2. When the lot number of the reagents used in the Analyzer is changed
3. After the Analyzer is calibrated
4. After the Analyzer has been maintained, repaired, or had parts replaced
5. When following clinical or laboratory QC procedures
6. When there are concerns about the accuracy of analytical results

To obtain accurate QC results, operators must follow these precautions:

1. Check the condition of the control materials. Ensure they are stored in the required refrigerated environment and that the containers are free from cracks or damage.
2. Shake the control materials thoroughly according to the manufacturer's instructions.
3. Do not use control materials if the container has been opened longer than the period recommended by the manufacturer.
4. Do not heat or shake the control materials vigorously.
5. When using a new batch of high, medium, or low-level control materials, verify any value differences by comparing them to the control values of the previous batch.

Rules for out-of-control QC results:

1. 2S Rule: A warning is issued if a QC result exceeds ± 2 standard deviations (2S).
2. 3S Rule: An out-of-control alert is triggered if a QC result exceeds ± 3 standard deviations (3S).
3. Consecutive 2S Rule: An out-of-control condition occurs when two consecutive QC results exceed the $\pm 2S$ limit in the same direction.
4. 4SD Rule: An out-of-control condition is flagged if two consecutive QC values at the same level exceed ± 4 standard deviations.

5. 1S Rule: If four consecutive QC results for a single level fall outside the $\pm 1S$ range, an out-of-control status is indicated.

If the test data is out of control, the QC graph will turn red to indicate a failure. If quality control results fall outside acceptable limits, follow these recommended steps:

- (1) Identify the Cause of Failure: Refer to the list of possible causes in Table 30. Take appropriate corrective actions and verify each step to ensure the issue is resolved.
- (2) If corrective actions are ineffective, report the issue according to your laboratory's standard operating procedures.
- (3) Contact BIONOTE service personnel for further assistance and technical support.

Table 30 Analysis of control failure causes

Reason classification	Cause analysis	Corrective measures
Quality control materials	Use of non-analyzer-specific quality control materials	Check the Quality Control Material Label for compatibility
	Abnormal control material condition (e.g., clots, discoloration)	Invert and visually inspect the control material.
	Incorrect control material type, batch, or level	Verify the control material's label information
	Control materials exceeding their production validity period or open-bottle validity period	Check the expiry date before use.
	The Analyzer does not aspirate an adequate volume of the quality control material	Ensure the control material is fully immersed in the sample probe before and after aspiration.
Operation	Quality control material not at room temperature	Hand-shake or let the material sit until it reaches room temperature.
	Quality control material not well mixed	Thoroughly mix the material before use.
	Testing not performed according to instructions	Follow testing procedures strictly as per the Manual.
	Incorrect mode selection	Ensure the correct test mode is selected
Analyzer	Required maintenance not performed	Perform regular maintenance and cleaning or soak the probe with cleaner.
Reagent	Use of non-specific reagents	Verify reagent label compatibility before use.
	Reagents that have exceeded their expiration date or open-bottle validity period	Check the expiry date and replace expired reagents.
	Incorrect connections of reagent pipes.	Inspect pipe connections and match them by color coding.
Other	Target values, deviation limits, or QC chart rules do not match	Check that all QC parameters are consistent with the target value table



- All clinical samples, control materials, and calibrators may contain animal blood or serum and should be treated as potentially infectious. Operators must follow established laboratory or clinical protocols and wear personal protective equipment (PPE), including: Lab coats or protective clothing, Medical gloves, Safety glasses, etc.

8.2 Brief introduction of several basic QC methods

8.2.1 L-J QC

The Levey-Jennings (L-J) QC graph is used to visually represent the mean–standard deviation quality control method.

It is a simple and practical QC method in which each individual QC measurement can be plotted if the mean and standard deviation are known.

From this method, three key parameters—mean ($\bar{X}$), standard deviation (SD), and coefficient of variation (CV)—are used as references for quality control.

$$\bar{X} = \frac{\sum_{i=1}^n X_i}{n} \quad SD = \sqrt{\frac{1}{n-1} \sum_{i=1}^n (X_i - \bar{X})^2} \quad CV = \frac{SD}{\bar{X}} \times 100\%$$

8.2.2 X-B QC

The X-B QC method, developed in the 1970s for hematology quality control, is based on the principle that while the RBC count can vary significantly due to dilution, concentration, pathological, or technical factors, the volume of individual RBCs and the hemoglobin (HGB) content per RBC—such as MCV, MCH, and MCHC—remain relatively stable and are minimally affected by these factors.

Based on this principle, a QC method was established to monitor changes in average values, including mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).

8.2.3 X-R QC

The X-R QC method is used to visually represent the average value–standard deviation quality control method. The mean (X) control chart is primarily used to determine whether the average value of a process remains at the required level, while the range (R) control chart is used to assess whether the variability (standard deviation) of the process is within acceptable limits.

Two key parameters are required to describe the X-R QC graph: the average value ($\bar{X}$) and the range (R).