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KU-F50
Feces Analyzer

User Manual

KEYU

Zhuhai Keyu Biological Engineering Co., Ltd.

Copyright and Statement

Thank you for becoming a distinguished customer of Zhuhai Keyu Biological Engineering Co., Ltd. ("KEYU"), and congratulations on your purchase of KEYU's Feces Analyzer which will bring you convenience and a new experience.

This manual has been prepared based on the actual Feces Analyzer manufactured by KEYU and according to the applicable laws and regulations of China. This manual contains the information up to the time when it is printed. Zhuhai Keyu Biological Engineering Co., Ltd. reserves the rights for revision and interpretation of this manual, and may update the manual without prior notice. Pictures used in the manual are for reference only; if any picture is inconsistent with the actual product, the latter shall prevail.

The operator shall carefully read this manual before use and strictly follow the operating instructions described in the manual during operation. KEYU will assume no liability for any error or damage of the instrument caused by failure to follow the instructions herein.

Limited Warranty:

User Manual for Feces Analyzer defines the respective rights and obligations of KEYU and user in terms of quality assurance liability and after-sales services related to the product, and also provides for the generation and termination of such rights and obligations.

For an instrument sold by KEYU or its authorized agency, KEYU will provide one-year warranty services for defects in workmanship and materials from the date when the instrument is installed.

KEYU's inspection is not flawless.

KEYU's obligation under such warranty is limited to repair of the product, which does not cover any economic loss or consequential cost caused by downtime of the instrument, including but not limited to:

- Freight (including customs fees);
- Economic and time losses arising from failure to use the instrument;
- Accommodation, meals or other traveling expenses;
- Losses arising from inconvenience;
- Other costs.

KEYU will not be responsible for any direct, indirect or consequential damage caused by the following circumstances; and in such cases, KEYU shall no longer be held liable for the safety, reliability and running condition of the instrument. Meanwhile, the rights and obligations in terms of quality assurance liability and after-sales services related to the product and the generation and termination of such rights and obligations as agreed in the manual, as well as all free service rights, will be deemed as having been unconditionally and permanently waived.

- Abnormal use of the instrument, or use of the unmaintained or damaged instrument;
- Use of any reagent or accessory not provided or accepted by KEYU;
- Damage of the instrument caused by misoperation or negligence due to failure to follow the User Manual for Feces Analyzer;
- Use of parts not accepted by KEYU for replacement, or maintenance, repair or modification of the instrument by persons without the authorization of KEYU;
- Disassembly, assembly stretching or re-commissioning of components without permission.

NOTE: KEYU does not provide any implied warranties of merchantability and fitness of the instrument for a particular purpose.

You are welcome to contact us when encountering any technical problem during use. KEYU's After-sales Service Department has opened a service hotline to provide users with technical support and solutions.

In case of any fault of the instrument, keep relevant sample and immediately notify your local authorized agency of Zhuhai Keyu Biological Engineering Co., Ltd.

【Manufacturer】

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【Manual Version】
V1.1 (CEN)
【Approval and revision date of the instruction】
May 15, 2024

In Vitro Diagnostic medical device
For professional use only

Foreword

1. Safety Precautions

- This instrument is a valuable precision electronic medical analyzer. In order to avoid damage to the instrument and personal injury caused by electric shock, cut off the main power supply before moving the instrument.
- Use a regulated power supply with a power of 400VA or above.
- Before you connect a new hardware device to the instrument, disconnect all power cords; first connect the data cable of the device, and then connect the power cords.
- If you use a plug-and-play device in this instrument, we remind you that such operation could interrupt the running of the instrument or result in crash, and we will not guarantee the safety of the instrument and the plug-and-play device you use.
- Before installing or using the instrument, carefully read relevant information provided in this manual.
- Strong light, dust, high temperature, dampness, violent vibration and shaking will affect the precision and service life of the instrument. Therefore, care should be taken to avoid such conditions.
- During routine maintenance of the instrument, note that biological contaminants may exist in the auto sample loading unit, sampling probe, internal pipeline, optical slide assembly (OSA), waste pipe and waste tank due to frequent contact with feces samples; when cleaning and replacing these parts, wear disposable gloves or other protection equipment.

2. About the User Manual

This manual provides the general information about the use of the instrument. This is the best information guide for new users to use the instrument. Many users read the whole of this manual before using the instrument for the first time. If you read this manual, you will understand the features and operating steps of the instrument. During your daily use, you can quickly find the information you need in "Contents".

All persons who use, maintain or move the instrument shall read this manual.

Conventions used in this manual.

Safety Compliance Information

1. Symbol definition

⚠ NOTE

Information on how to avoid injury of the operator or other persons.

For WARNING symbols on the instrument, please read the corresponding instructions provided herein before operating the instrument.

2. Safety specifications

2.1 The power plugs of the instrument and the power plugs of the external devices must be connected to the power sockets on the wall, and the sockets must meet the requirements on the rated power label.

In addition, please use the wire provided by the instrument. If any other wire is used, it may cause an electric shock.

2.2 Equipotential conductor must be connected before the power plug of the instrument is inserted into the socket. The instrument must be unplugged before unplugging the equipotential conductor. To avoid an electric shock.

2.3 When the instrument is running, ensure that the ground wire of the instrument is connected to the earth. Please connect the ground wire when the instrument is shut down; otherwise, an electric shock may occur. Please connect the power supply to the ground in the correct way according to the user manual.

2.4 Before cleaning the instrument, remove the power wire. If the instrument fails, an electric shock may occur.

2.5 This instrument does not have any waterproof device, do not use this instrument in the place where water may enter the instrument. Do not spill any liquid into the instrument, otherwise, there will be an electric shock hazard.

2.6 Do not open the shell or rear cover unless authorized by the company, otherwise it will cause short circuit or electric shock.

3. Safety precautions

3.1 Electric damage Prevention

⚠ NOTE

The instrument must be used in a well-grounded environment, using independent power supply, voltage should meet the requirements of the instrument.

Do not step on, twist or pull the wires and cables. If the wires and cables break, they may cause fire.

Do not touch the power supply with wet hands.

If the liquid enter the instrument or the liquid in the instrument leak out, please disconnect the power supply in time.

3.2 Instrument Operating Condition

⚠ NOTE

Please don’t touch the moving parts of the instrument directly with your hands to avoid personal injury.

3.3 Sample

⚠ NOTE

Please do not touch the sample directly to avoid bacteria and other injuries to personnel.

If the sample stick to the instrument, please wipe it off as soon as possible.

3.4 Waste Liquid

⚠ NOTE

Please comply with the discharge and disposal regulations of reagent, waste liquid and waste sample in your country or region.

3. About Package

When you receive the packaging boxes shipped by KEYU or its agency, please open each packaging box together with engineering technicians of or authorized by the manufacturer to check whether the standard accessories are consistent with those shown in the *Packing List* supplied with the instrument and whether there is any serious mechanical damage.

4. Finding More Information

You can get more information about KEYU’s products as well as upgrade information related to this instrument by the following approaches.

1. Website:

You can get the latest information about the KU Series Feces Analyzer from our website: http://www.keyubio.com/

2. Other documents:

The packaging box of your product may contain other documents such as the latest product catalog, and product warranty documents provided by the agency.

Contents

Chapter 1 Introduction of Instrument

1.1 Overview of Instrument

The Feces Analyzer (hereinafter referred to as "instrument") is the latest testing instrument developed and manufactured by Zhuhai Keyu Biological Engineering Co., Ltd. ("KEYU") integrating multi-disciplinary fields and modern high and new technology.To ensure the accuracy of sample volume, a sample collection cup is specially designed to collect sample, which has the function of filtering feces residue.

The instrument can perform automatic deep cleaning of pipeline and inner and outer walls of sampling probe, which minimizes sample cross-contamination. In order to ensure the accuracy and repeatability of test results, the instrument uses a precision plunger pump to accurately control the aspiration of a minute amount of sample, and uses an independent mixing system for feces analysis.

To ensure fast, clear and stable images capturing, the instrument is equipped with a micrometer using a precision screw for adjustment of focal length, greatly improving the control accuracy of focal length of the micrometer. Automatically-controlled motion axes work together with the HD image acquisition system to get high quality images in the instrument, ensuring the reliability of test results.

The instrument uses a multi-channel counting cell; both ends of each channel have the forced cutoff function. The sample becomes still rapidly; with the auxiliary sedimentation function, formed elements can realize rapid sedimentation.

The instrument has 20 colloidal gold card reaction frame, allowing test of 6 colloidal gold items at the same time. Photos of test results will be taken to provide assistance in identification.

The instrument features high degree of automation and simple operation procedure; it is equipped with an auto sample loading unit and a pipeline alarm unit. After the operator puts the sample in the sample rack, the instrument will automatically finish sample loading, dilution, mixing, sample dispensing, image acquisition and washing. The counting result will be reported in the form of XX /HP or XX /LP or + sign. The doctor only needs to enter patient information and review the result to print the report. The instrument can store the patient's clinical data,formed element result, characters, colloidal gold items and other items. Data are stored by classification to facilitate quick browsing, query, editing, printing and transfer of data. All data are managed by database with a common interface provided to facilitate networking with the hospital's HIS and LIS. In all, the instrument is very useful for physical and chemical testing of feces in clinical use.

Fig. 1-1 Schematic diagram of the front of the instrument

⚠ NOTE

- To avoid electric shock, do not open the cover of the instrument during work.
- To avoid electric shock, ensure that the instrument is well grounded.
- When the instrument is running, the operator should not touch any moving part, and take care to protect his/her hands from being pricked or crushed.
- Be careful of pinching when you open the cover of the instrument.
- The sampling probe is sharp enough to cause the risk of piercing.

1.1.1 Main Components and Their Functions

The analyzer consists of PC, system software, optical slide assembly (OSA), sample aspiration probe, connecting pipe, pump, solenoid valve, fully automatic bio-microscope, CMOS image processor. System software mainly completes such working processes as auto dilution, mixing, sample aspiration, washing and image shooting. The PC with a display provides user-friendly human machine interfaces and also fulfill data analysis, display and storage of images shot. The pipeline mainly realizes injection and discharge of liquid throughout the test process. The functions of the entire system can be realized only with the effective cooperation of the mechanical structure.

1.1.1.1 Electronic Control Unit

1) Control the opening and closing of solenoid valve for the on-off control the

opening and closing of pipeline;

2) Control the opening and closing of pump to provide power for the pipeline;

3) Control the operation of sample loading stepper motor to provide power for the auto sample loading system;

4) Control the operation of microscope stepper motor to provide power for auto running of the microscope;

5) Control the light source of microscope;

6) Control the camera, automatically set relevant camera parameters and acquire images;

7) Control the operation of all lights and electric switches.

1.1.1.2 Imaging Unit of Microscope

The imaging unit of microscope mainly consists of microscope, camera and OSA.

1) The OSA provides a carrier for the sample.

2) The microscope magnifies the formed elements in the sample.

3) The camera acquires images after microscopic magnification.

1.1.1.3 System Control Unit

The system control unit consists of PC mainboard, storage media (e.g., hard disk drive, memory) and monitor. The instrument is installed with system control software, database, etc.

1) Communicate with the electronic control unit to control the operation of the instrument;

2) Acquire images and save the results;

3) Receive test results from other medical devices and communicate with the LIS;

4) Realize human-machine interaction.

1.1.1.4 Pipe Unit

The pipe unit mainly consists of solenoid valve, plunger pump and sampling probe, providing a channel and carrier for samples, reagents and liquid waste.

1.2 Intended Use

The Feces analyzer is used for the microscopic examination of the formed components of the feces sample and the qualitative detection of colloidal gold method for the immune items of the feces sample.

1.3 Reagent System

In order to maintain the best performance of the instrument, KEYU has developed special reagents for the Feces Analyzer. All the reagents have been inspected and confirmed OK. Use of reagents not supplied by KEYU will affect the performance of the instrument and lead to serious measurement errors, and could result in the occurrence of accidents. All reagents must be stored under room temperature to maintain the ideal chemical performance.The environment for reagent storage should not be too cold/hot and should not be exposed to direct sunlight; when the temperature is below 0℃, freezing of reagents could be caused easily, resulting in changes in the chemical performance and conductivity of reagents.

During use, in order to minimize reagent evaporation and reduce reagent contamination by external factors to the maximum extent possible, the reagent container shall be tightly closed with the container cover, and the pipe should enter the reagent through the container cover. Note: The quality of reagents changes over time, so all reagents must be used within the shelf-life.

1.3.1 Diluent

The diluent is a type of stable isotonic solution used for:

- Dilute the sample.
- Maintaining the cell morphology during measurement.
- Provide the background image.
- Routine cleaning of the instrument (i.e., rinsing the inner and outer walls of sampling probe, the counting cell and the pipeline) to prevent cross-contamination.

1.3.2 Cleaning Solution

- It is used for maintenance of the instrument in power-off state, which means the instrument will automatically fill all counting channels with cleaning solution before exiting the program every day. Upon restart next day, the instrument will automatically discharge cleaning solution out of the pipe and wash the pipe with diluent.

1.3.3 Concentrated Cleaning Solution

- Concentrated cleaning solution contains high-efficiency oxidant for deep cleaning of the instrument. It is used only when the counting cell or pipe system is seriously contaminated, for example, when there is a large number of spots in the microscopic image or plenty of viscous substance that cannot be washed off or removed by cleaning solution.

⚠ NOTE

- All reagents are used for in vitro tests; in case of contact with your eyes or skin, rinse with plenty of running water.

⚠ NOTE

- Please store or use the reagent kit according to relevant environmental requirements, and do not freeze or heat it; also keep the reagent kit away from any open power supply device, and use it within the shelf-life.

1.4 Reagent Dosage

Diluent: Approx.14～20mL/sample

Cleaning solution: Approx. 46-48 mL/shutdown

1.5 Storage and Application Environment

1.5.1 Power Supply

Voltage: AC 100-240V.

Frequency: 50/60 Hz.

Power consumption: ≤200VA.

Overvoltage categoryII

Intended environment pollution degree: 2

IP Degree: IPX0

1.5.2 Storage and Transport Environment

Ambient temperature: -10℃~40℃.

Relative humidity: ≤93%RH.

1.5.3 Environmental Conditions for Operation

- Optimum ambient temperature: 10~30℃.
- Relative humidity: ≤70%.
- Atmospheric pressure: 76kPa~106kPa.

- A good grounding environment should be available.
- The instrument should be placed on a fixed and stable workbench (having an area of at least 2000mm×800mm) that can bear >150KG weight; the distance between the rear of main unit and the wall should not be less than 40cm.
- Keep away from sources of strong electromagnetic interference.
- Avoid direct sunlight.
- Keep away from sources of vibration and interference.
- The power socket should conform to the electrical code, and reliable grounding must be available.

1.6 Software Operating Environment

1.6.1 Hardware Configuration

- RAM: 4GB (DDR3L 1600MHz) or higher
- CPU: Intel Pentium 4 or AMD Athlon 64 processor or higher
- Hard disk drive: 500GB (7200RPM) or higher

1.6.2 Software Environment

- System software: Windows 10 64-bit
- Antivirus software: N/A
- Network condition: Network connection is required to communicate with the LIS or HIS
- Supported software: Lazarus, Opencv, Caffe
- Application software: None

1.6.3 Security Software Update Requirements

N/A.

1.7 Data Ports

RJ45 network port, HL7 communication protocol.

1.8 User Access Control

The dongle must be inserted to start the software; account and password are required for login.

1.9 User Permission Control

There are two types of user account: Advanced User and General User. Advanced User can modify and set the printing, communication and formed element item modules, while General User can only view these modules.

1.10 Service Life

The optimum service life of the instrument is 5 years; see the accompanying Certificate of Conformity for the manufacturing date of the instrument.

1.11 Weight and Dimension

- Dimension of main unit: 820mm×680mm×640mm;

  Dimension of extended tray: 1620mm×680mm×640mm.

- Weight of main unit: Approx. 85kg.

- Weight of extended tray: Approx. 19kg.

Chapter 2 Operating Principle of Instrument

2.1 Basic Operating Principle

The instrument is intended to analyze images from formed elements of feces. After auto dilution, mixing, colloidal gold dispensing and sedimentation of the feces sample, the camera will take photos of formed elements in the feces; photos of colloidal gold test cards will be taken and stored, and colloidal gold items will be interpreted automatically; the result will be reported after manual review.

2.2 Operation Process of Instrument

The program controls the auto sample loading unit to convey the sample to the specified sampling position. The plunger pump and the sampling probe work together to dilute and mix the sample, aspirate certain amount of sample to be tested to the OSA, and dispense sample on the colloidal gold card. After sedimentation of sample in the OSA for certain time, the microscope magnifies the elements in the OSA, and the PC controls the camera to acquire and save images of sample distributed within the view; a standard feces analysis report will be formed according to the image processing result.

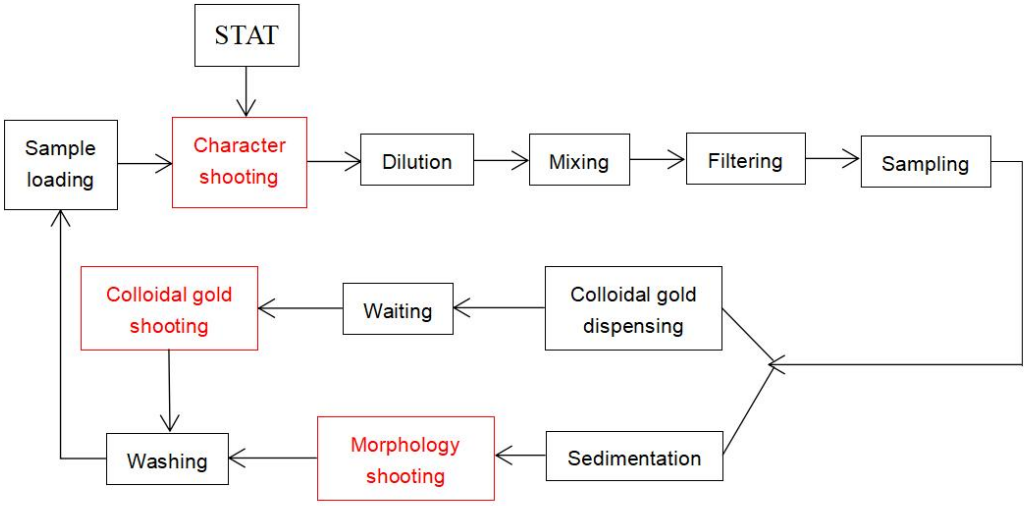

Fig. 2-1 Test Process

2.3 Technical Indicators of the Instrument

2.3.1 Appearance and Structure

1) It shall be smooth and clear with uniform color, without any obvious scratches, unevenness, sharp edge and burr.

2) The control key shall be able to be operated flexibly and reliably, and the fasteners shall be firm, while the connecting pipeline shall be free of leakage.

3) Words and marks shall be clear, accurate and firm.

4) Plastic parts shall be free of foaming, cracking, deforming and overflowing of infusion material.

5) The specimen collection cup shall be free of cracks and scratches.

2.3.2 Functions

2.3.2.1 Basic Functions

1) It shall have functions such as automatic injecting , automatic cleaning, automatic mixing, automatic filtering and automatic sampling.

2) Sample collection cup will exit and be pretended automatically after injection, available for rechecking.

3) It shall be able to shoot the appearance of specimen and save the image.

4) It shall have the ability to test multiple fecal colloidal gold test items simultaneously, and shoot the results.

5) There shall be 20 test channels for colloidal gold items.

6) The counting cell shall have more than 2 (including 2) channels.

7) It shall have the function that the colloidal gold test reagent can be loaded and exit automatically.

8) It shall have the function for emergency treatment and allowing on-call test for samples from emergency treatment.

9) It shall be able to carry out automatic batch testing, and at least 50 (or more) samples can be tested per batch.

10) It shall be able to shoot the formed components of the feces and identify automatically the category of each component or allow manual marking.

11) It shall be able to print reports with graphics and texts and report the formed component results in the form of xx pcs/HP or xx pcs/LP or the qualitative (-, +, ++, +++, ++++).

12) It shall be able to query the original data.

13) There shall be a data interface for connection with Lis and His.

14) It shall have the function of automatic interpretation of images shot for colloidal gold detection items.

15) It shall have the built-in barcode scanning function.

16) The KU-F50 has a detection speed of up to 85 samples per hour.

2.3.2.2 Sample Preprocessing Function

Instrument filtration and recovery method: add diluent into the specimen, mix well, filter

out large impurities in the feces by filter screen, and then recover the pathological formed components in the feces.

2.3.2.3 Analysis Function

1) Indicators of Science

It shall be able to identify the color and appearance of feces automatically or with manual assistance;

2) Formed component

It shall apply the microscopic examination method to analyze the pathological formed components in feces and have the functions of automatic identification, manual review and confirmation.

3) Fecal Occult Blood

It shall be able to automatically analyze the occult blood indicators in feces.

4) Extended items

It shall have the ability to test multiple fecal colloidal gold test items simultaneously and the function to shoot the results for automatic interpretation.

2.3.2.4 Self-test Function

The instrument shall have Power on Self-Test (POST) function.

2.3.2.5 Fault Alarm Function

The instrument shall have corresponding alarm prompts for operation errors, mechanical and circuit faults, etc.

2.3.3 Instrument performance indicators

2.3.3.1 Repeatability

The repeatability of formed components is shown in Table 1:

Table 1 Repeatability of formed components

Concentration (pcs/μL)	50～200	>200
CV(%)	≤20	≤15

2.3.3.2 Carry-over contamination

Carry-over contamination rate of the analyzer shall be ≤0.05%.

2.3.3.3 Performance indicators of colloidal gold

The coincidence rate of automatic interpretation results of colloidal gold test items shall be more than 90%.

2.3.3.4 Clinical application indicators-detection coincidence rate

Compared to the manual wet mount examination, the coincidence rate of testing fresh stool samples with machine can be more than 80%.

2.4 Scope of Application

The product is intended for formed elements in feces samples and qualitative test of feces samples by immune colloidal gold method.

2.5 Limitation

1) As the number of images acquired is limited, when there are few parasite eggs, the images acquired may not show the parasite eggs.
2) The formed element result is related to the reviewer's knowledge of formed elements and accumulation of experience.
3) The automatic identification function does not cover all the forms of formed component in the real world and misidentification may occur.
4) In the identification process, if the target is at the edge of the image, it will lead to the lack of extraction of the target features, and when multiple targets are close, the extraction of the target features will be disturbed, leading to inaccurate.

⚠ NOTE

- Better results can be achieved only when colloidal gold test reagent cards accepted by KEYU are used.
- Risk group 2 Light

CAUTION Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamp. May be harmful to the eyes.

Chapter 3 Installation of Instrument

To achieve the optimum operation performance of the instrument and obtain satisfactory clinical effects, initial installation and commissioning of the instrument must be performed by engineers with KEYU's authorization; if the instrument is moved or used in another place, it must be installed and used according to the following installation procedure.

⚠ NOTE

Installation of the instrument by any unauthorized or untrained person could result in damage of the instrument, and such damage is not covered by KEYU's free warranty. Without KEYU's authorization, no one shall install the instrument or use it.

3.1 Unpacking and Checking

Carefully take the instrument and its accessories out of the packaging box; properly keep the packaging materials for future transport or storage.

1) Check the accessories according to the Packing List;
2) Check whether there is any sign of water soaking;
3) Check whether there is any mechanical damage;
4) Check all exposed lead wires and inserted parts and accessories.

Please take the instrument and its accessories out of the packaging box together with the engineer authorized by the manufacturer or its agency.

In case of any problem, please contact KEYU's After-sales Service Department or agency immediately.

3.2 Installation Requirements

1) When handling the instrument, put your hands in the gap at the bottom of the instrument and lift it up.

   Note: When handling the equipment, pay attention to safety and be careful with your hands.

2) Selection and connection of power supply: Select an independent power supply as required; where necessary, an uninterruptible power supply (UPS) of ≥400VA should be equipped to ensure normal working.

3) Power-on check: Turn on all power switches to ensure normal data transfer and check whether each component of the instrument runs normally. Abnormalities

should be handled by engineering technicians in the field.

4) When placing the instrument, do not place the instrument at a position where it is difficult to operate the disconnecting unit.

5) Connection of communication cables: Monitor, keyboard, mouse and printer.

⚠ WARNING

- The instrument is not intended for home use.
- The instrument is not a therapeutic device.

⚠ NOTE

- The instrument should be protected from direct sunlight.
- The operating environment of the instrument should not be too cold/hot; if the air humidity is too high, water stain will exist on the surface of counting cell.
- Keep centrifuges and X-ray machines away from the instrument.
- Do not use mobile phones, radiophones or other devices generating strong radiation fields near the instrument, which may disturb normal working of the instrument.

3.3 Check of Power Supply

Before installing the instrument, check whether the power supply on the installation site meets the following requirements for the instrument:

Voltage: AC 100-240V.

⚠ NOTE

- The power input jack on the rear panel of the instrument should be grounded, and thus should be connected to a three-wire power socket with protective grounding through the power cord. User has the obligation to ensure the reliability of the protective grounding of

power supply.

- Appliance coupler and plug used as disconnecting device, Do not put the equipment in places where it is difficult to disconnect.
- Before connecting the instrument to power supply, check to ensure that each electrical plug is connected correctly and securely.
- Do not use under-rated detachable power cords.

⚠ NOTE

- Frequent voltage fluctuation will result in degradation of the performance and reliability of the instrument; user shall solve this problem before use of the instrument, for example, by installing an additional AC voltage stabilizer.
- Frequent power interruption will result in serious degradation of the performance and reliability of the instrument; user shall solve this problem before use of the instrument, for example, by installing an uninterruptible power supply (UPS) (equipped by user).

3.4 Connection of Reagent System

3.4.1 Connection of Diluent Pipe

Take the pipe with joint out of the reagent packaging box; connect the joint to the pipeline connector of the same color on the rear panel of main unit; insert the other end of the pipe into the sample diluent bottle, and tightly close the cap of diluent bottle. The diluent bottle must be placed on the same level as the instrument.

3.4.2 Connection of Cleaning Solution Pipe

Take the cleaning solution pipe with joint out of the reagent packaging box; connect the joint to the pipeline connector of the same color on the rear panel of main unit; insert the other end of the pipe into the cleaning solution bottle, and tightly close the cap of cleaning solution bottle. The cleaning solution bottle must be placed on the same level as the instrument.

3.4.3 Connection of Liquid Waste Pipe

Take the liquid waste pipe with joint out of the reagent packaging box; connect the joint to the pipeline connector of the same color on the rear panel of main unit; clockwise tighten the bottle cap on the liquid waste pipe to the opening of liquid waste bottle. The position where the liquid waste bottle is placed should be at least 50cm below the plane where the instrument is placed.

3.4.4 Treatment of Liquid Waste

Liquid waste produced by the instrument is the mixture of feces sample and reagent; strong odor will be produced if liquid waste is placed for a long period of time, so liquid waste should be treated in time. Any organization using the instrument is suggested to strictly observe the national and local laws and regulations for treatment of medical wastes and strictly follow the methods specified in the medical waste disposal procedure of the organization.

3.4.5 Connection of iodine solution tube

Take the iodine solution kit out of the package; link the joint with the corresponding iodine port on the rear panel; insert the other end of the tube into the iodine staining solution bottle, and fasten the cap of iodine solution bottle. The iodine solution bottle must be placed on the same level as the instrument.

⚠ NOTE 

- To prevent environmental pollution caused by liquid waste, it is forbidden to directly pour liquid waste to the drain; liquid waste must be biologically or chemically treated before discharge to the drain. Hospitals and laboratories have the obligation to observe the applicable regulations of the Environmental Protection Department of local government.

⚠ NOTE

- The special-purpose concentrated cleaning solution is used for

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deep cleaning and should not fed to the instrument through pipe.

⚠ NOTE

- After installation of all pipes, leave the pipes in a natural and relaxed state without forced distortion, bending or turning.
- All pipe joints should be installed manually without using any tool.
- If damage or leakage of the reagent bottle, expiry of shelf-life or other abnormalities are found during installation, the reagent should not be used on the instrument; please contact your local office or supplier for replacement.

3.5 Connection of Monitor, Mouse and Keyboard

Use the video cable to connect the monitor with the instrument;

Connect the power cord of the monitor;

Connect the mouse and keyboard to the instrument. If wireless keyboard and mouse are used, insert the wireless receiver into the USB port at the rear of the instrument, and install the driver.

⚠ NOTE

- The Monitor, PC and Printer are meet the safety requirements of standards IEC 61010-1, IEC 60590-1 or IEC 62368-1.

3.6 Connection of Main Unit Power Cord

Insert one end of the power cord into the power input socket of main unit, and the other end to a grounded three-phase power outlet.

⚠ NOTE

- The power adapter should be connected to a special socket.

3.7 Start of Instrument

1) Turn on the UPS switch (if any);
2) Turn on the switch of special power strip connected with the main unit system;
3) Power on the peripheral device (e.g., printer, monitor);
4) Press the Power button on the right panel/cover to turn on the instrument and start the operating system.

3.8 Connection of External Printer

1) Choose a proper position for placing the printer; it is suggested to place the printer on the right side of the instrument and keep a distance of at least 30cm from the instrument.
2) Install the accessories of the printer according to the Instruction Manual for the printer.
3) Connect the plug of printer cable to the corresponding socket on the rear panel of the instrument, and the other end to the printer.
4) Confirm that the power switch of printer is in OFF position; connect one end of the power cord to the printer, and the other end to the power outlet.
5) Install the communication cable; see the Instruction Manual for the printer for details.
6) Load printing paper according to the Instruction Manual for the printer.
7) Connect the power supply to initiate self-check of the printer.

⚠ NOTE

- On the first use, run the self-check program to test whether the printer is working normally; during subsequent use of the printer, the printing function of the printer can also be verified by running this program.

Chapter 4 Routine Operations

The operator is suggested to read this section carefully in order to properly operate the instrument.

4.1 Precautions

1) Ensure that the "Environmental Conditions for Operation" listed in 1.4.3 are met when the instrument is used.
2) Prior to startup, check the condition of reagent and waste tank condition; carry out replacement in time.
3) Make sure the sample rack holding sample collection cups is placed correctly.
4) When the instrument is under operating state, do not take out the sample collection cup and sample rack to avoid injury or damage of the instrument.
5) When turning off the instrument, also turn off the printer and the monitor.

⚠ NOTE

- Do not force shutdown to avoid data loss and fault of the instrument.
- Use of the instrument without following the methods specified by the manufacturer could compromise the protections provided for the instrument.

4.2 Startup of Instrument

1) Check the waste tank to see if replacement is necessary. If yes, replace the waste tank.
2) Test whether reagent is available; if not, change the reagent in time.
3) Check whether the printer, monitor, mouse and keyboard are reliably connected to the instrument.
4) Check whether the printer is ready and whether printing paper is available. See the Instruction Manual for the printer for details.

5) Check whether the instrument is connected to power supply.

6) Check whether the AC power cord of the monitor is connected.

7) Press the Power button on the right cover to turn on the instrument.

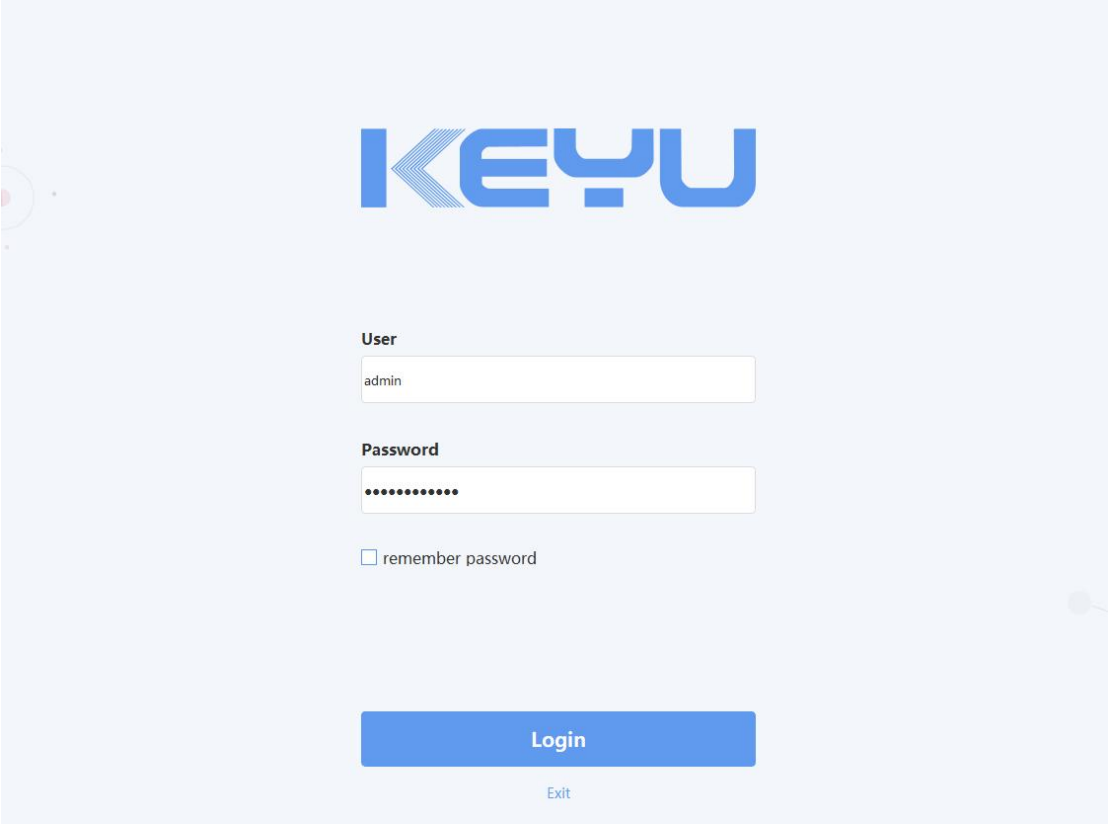


Fig. 4-1 Login

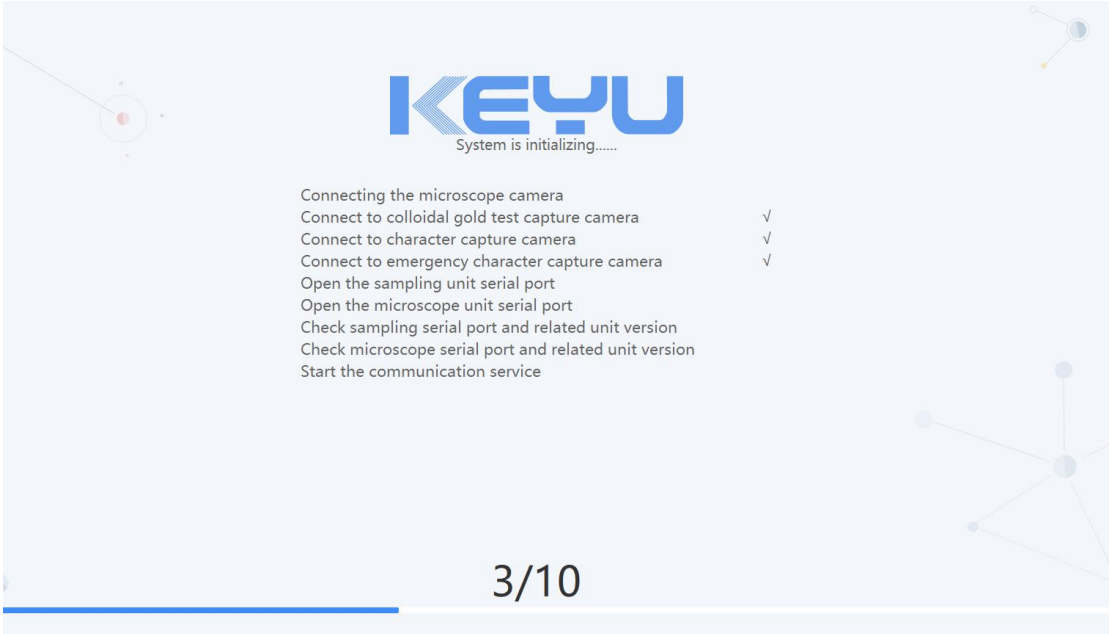


Fig. 4-2 Initialization Interface

⚠ NOTE

- During system login, the instrument will execute the washing process;You can choose to perform automatic focusing and background detection according to *Section 5.1 Focus* and *Section 5.3 Background* if necessary.

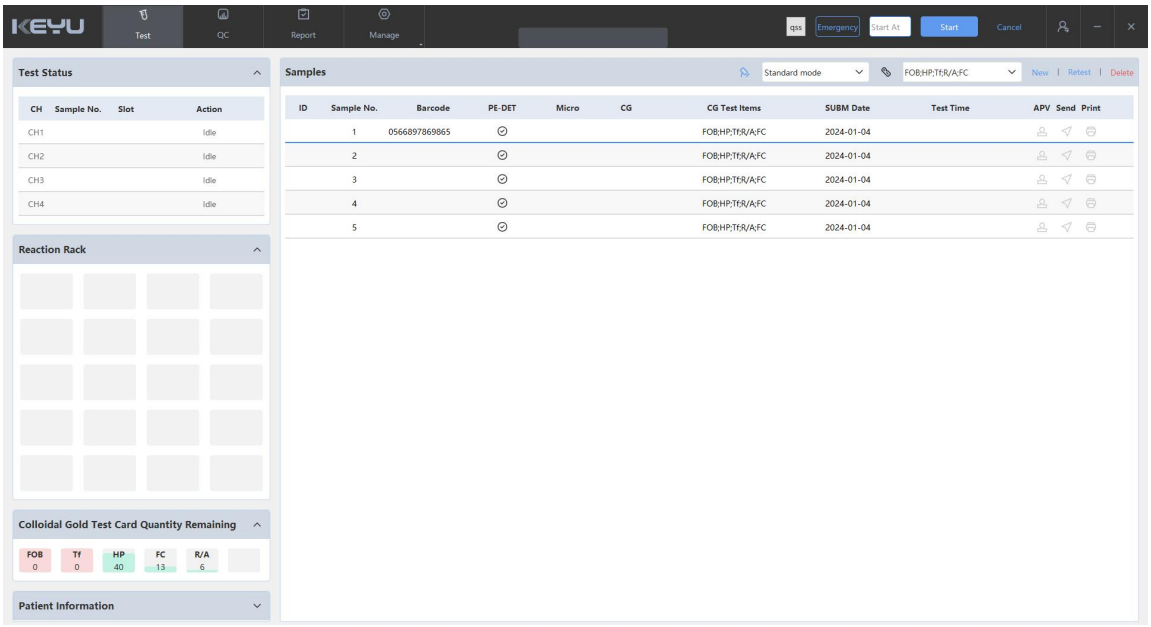


Fig. 4-3 Sample Test Interface

4.3 Introduction of Software

4.3.1 Routine Operation Process

1) Turning on the instrument — Turn on the instrument according to the process described in 4.2.

2) Starting the operation software of the instrument — Double click the < KU-F50> icon on the PC desktop.

3) Login interface — Enter <User> and <Password> as shown in Fig. 4-1; the instrument will display the system initialization interface as shown in Fig. 4-2.

4) Sample placement — Place the sample collection cups containing collected sample in the sample rack; put the sample rack in the sample loading tray.

5) Set colloidal gold items according to 6.2; the test reagent card in each colloidal gold card box position should be consistent with the item added (for example, if FOB is added to No. 1 card position, FOB card should be placed in No. 1 card position).

6) Starting test — Click <Start>; the instrument will start test. See Fig. 4-3.

7) Canceling test —— Click <Cancel> in the upper right corner to cancel the test.

8) Entry of patient information — Select the sample to be edited on the left side of the <Test> interface to enter information; patient information can be entered at any time.

9) Reviewing report —— At the end of the test, you can view and review the sample results in Review Report interface.

10) Printing report — When the sample result has been reviewed, the report can be printed at any time.

11) Switching user —— Click <User> in the upper right corner and then enter the new user in the login box to log into the system again.

12) Turning off the instrument — Click  ; the instrument will automatically perform maintenance and cleaning and exit the software.

⚠ NOTE

- The sample rack should be placed in the correct direction.
- When test is finished, take the sample rack out of the tray on the left.
- A sample having finished test can be taken out to receive test of other items.
- Do not exit the software during testing of samples, or the test result data may be lost.

4.3.2 Display of Test Status

During the test, the system will display the sample status, channel status, quantity of test

cards and reaction status of test cards. See. Fig. 4-3.

4.3.3 Display of Review Report

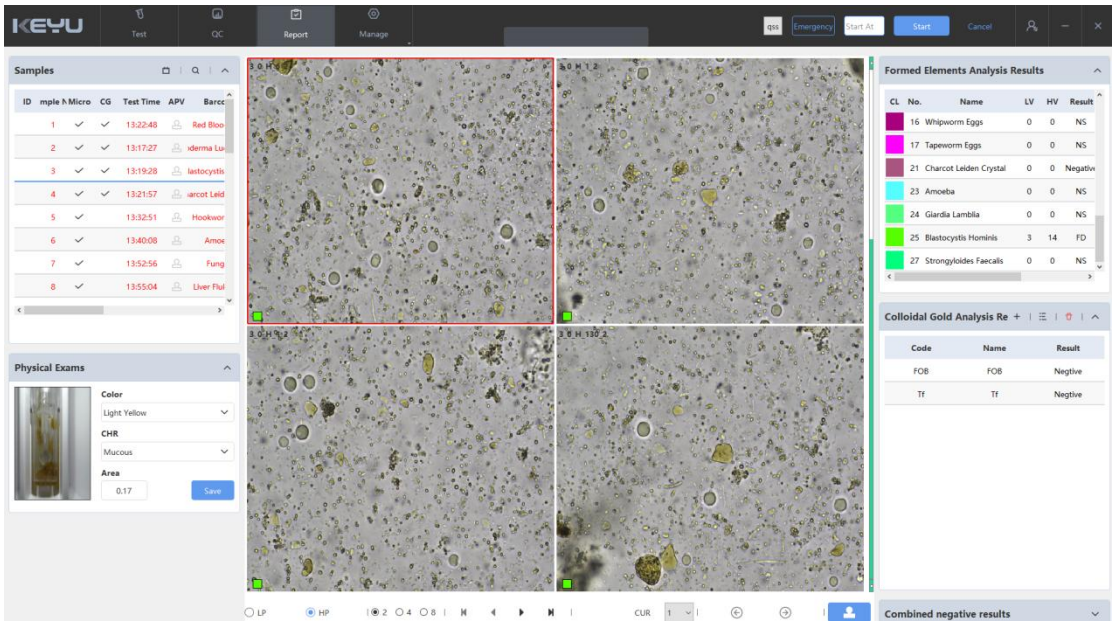


Fig. 4-4 Display of Review Report

In the Review Report interface as shown in Fig. 4-4, the formed element result, colloidal gold result, character result and color result of the sample are displayed.

4.4 Inspection modes

The analyzer currently uses two types of sample collection cups for sample detection, as shown in Fig. 4-5 and Fig. 4-6 below. The sample collection cup with the blue lid on the left of the picture is used for normal mode detection and with parasite eggs detection. The green lid sample collection cup on the right of the picture is used for special mode(flotation-precipitation).

Fig. 4-5 Sample Collection Cup

Fig. 4-6 Sample Collection Cup

4.4.1 Single way communication mode

4.4.1.1 Standard mode

Before testing, you can click <New> on the <Test> interface to create new samples to be tested in standard mode, don't tick on any special mode, as shown in Fig. 4-7.

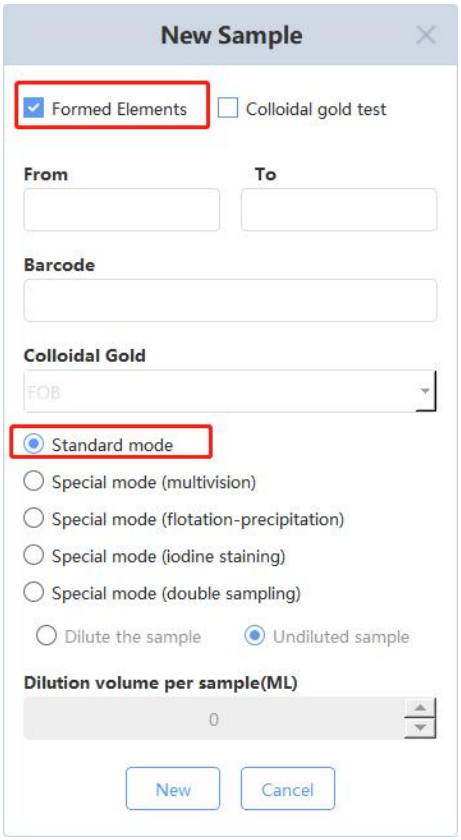


Fig. 4-7 Create standard mode sample

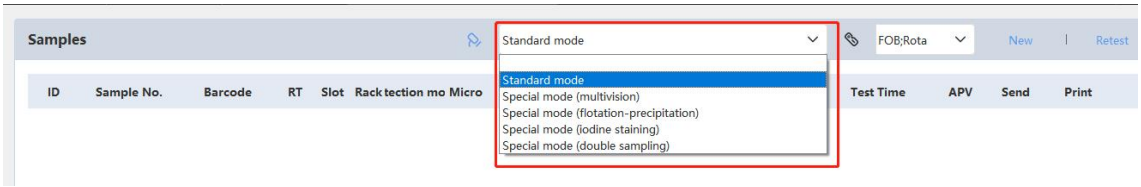


Fig. 4-8 Standard mode sample

After the detection, the detectiom mode status will indicate by an icon  and the microscopic inspection status will indicate by an icon ,as shown in Fig. 4-9.

Fig. 4-9 Finish standard mode detection

4.4.1.2 Special mode

4.4.1.2.1 Special mode(multivison)

In order to enhance the detection rate of parasite eggs and protozoa, special

mode(multivison) can be use. With the special mode(multivison) detection, the number of photos taken and the number of photo layers are different from those in standard mode. More photos can be taken the special mode(multivison) detection to better help the inspection of parasitic eggs and protozoa.

Before inspection, tick <special mode(multivison)> on the <Test> interface and create new samples for inspection, as shown in Fig. 4-10 and Fig. 4-11. Click "Start" to begin the inspection.

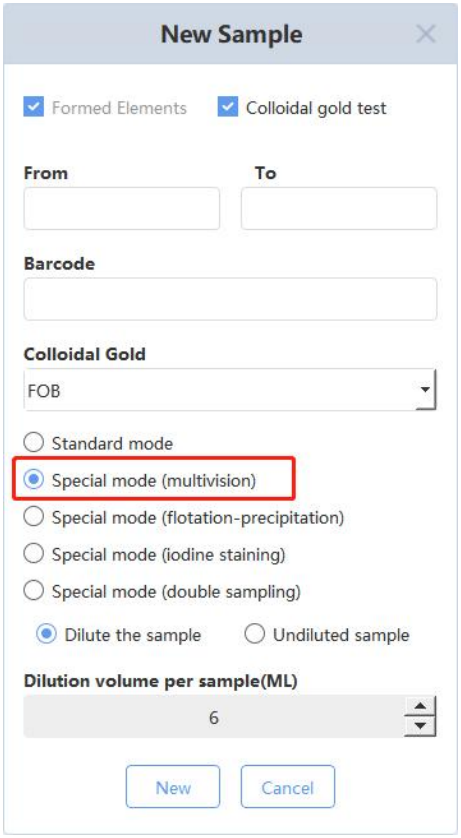


Fig. 4-10 Tick on special mode(multivison)

Fig. 4-11 Special mode(multivison) detection sample

After the detection, the detectiom mode status will indicate by an icon ⊙ and the microscopic inspection status will indicate by an icon ✓, as shown in Fig. 4-12.

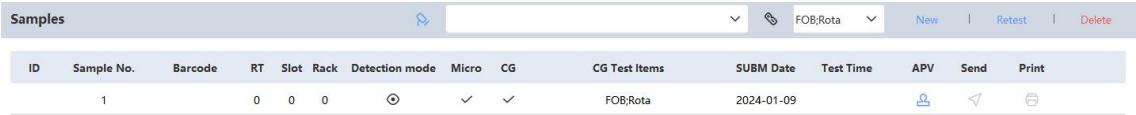


Fig. 4-12 Finish Special mode(multivison) test

4.4.1.2.2 Special mode(flotation-precipitation)

The flotation-precipitation mode combines the flotation and the precipitation method to enhance the detection rate of parasite eggs. So the whole flotation solution test was divided into a flotation sample and a precipitation sample. The number of photos taken and the number of photo layers are different from those in common mode. More photos were taken in general egg mode and flotation-precipitation solution to better help the inspection of parasite eggs.

Before testing, place the sample collection cup in the specimen holder on the instrument injection tray. In the <Test> interface, click <New>, tick on <Special mode(flotation-precipitation)>, and then click <Create> to create samples of floating method mode and precipitation mode at the same time, as shown in Fig. 4-13 and 4-14.

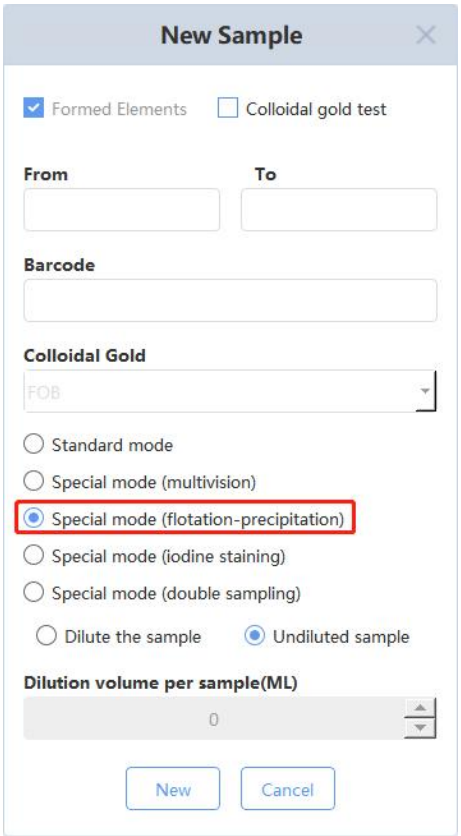


Fig. 4-13 Tick on Special mode(flotation-precipitation)

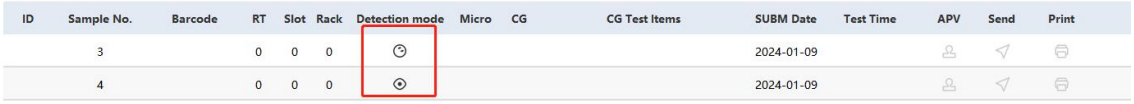


Fig. 4-14 Flotation sample and precipitation sample

After creating the sample, click "Start" to begin the inspection.

In flotation solution mode, the system will perform the flotation test first. The sampling probe will extract specimen from the top of the liquid. After finishing the flotation test, the instrument will execute the second precipitation test automatically. The sampling probe will down to the bottom of the same test tube in a specific depth and extract some specimen from the bottom. The specimen from the top and the bottom of the liquid will better help the inspection of parasite eggs.

Attention: There are two sample numbers in the flotation-precipitation detection mode. Actually the both results of flotation test and precipitation test are from a same specimen. The flotation test and precipitation test can be of help the inspection of different types of parasite eggs.

After the completion of sample detection, the results of floating method and precipitation method will be combined into one sample information and result report, which the detectiom mode status will indicate by an icon and the microscopic inspection status will indicate by an icon , as shown in Fig. 4-15.

Fig. 4-15 Finish Special mode(flotation-precipitation) test

4.4.1.2.3 Special mode(iodine staining)

We all know that feces contains many substances such as starch, bacteria, parasite eggs, protozoa, etc, thus we can using iodine staining solution to dyeing feces that make more easier to observe these substances. For example, the amoeba which subdivided into Entamoeba Hostolytical, Entamoeba Coli, Endolimax Nana, Iodamoeba Butschli, Entamoeba Hartmani, etc. The life cycle process includes two stages which are cystic and trophozoite. It is difficult to distinguish cystic, trophozoite and amoeba subdivision types under injecting diluent microscopic examination. In order to distinguish these types of

amoeba, iodine staining become more necessary.

When the instrument performs iodine staining mode, the concentration of staining solution is generally as follows: add 2.0g of iodine and 4.0g of potassium iodide into 100ml of distilled water and mix thoroughly, or directly use the staining solution of Gram staining.When using the solution above, it is generally diluted according to the ratio of staining solution and diluent 1:20. The default factory volume of diluent is 6ml, and the default volume of iodine solution is 0.3ml.

There might be different concentration between different bottles of iodine solution. And the iodine solution will degrade in bottle after being used gradually, which caused the concentration changed in different period. Therefore,the user should increase /decrease the volume of iodine solution according to the actual concentration in different period. For more details about these parameters, please refer to 5.2.4 PE-DET and 5.2.6 Use iodine staining.

Our instrument uses the iodine staining mode for detection. Put the specimen collection cup in the sample position, click <Start>, and the instrument will automatically add staining solution into the specimen collection cup according to the volume setting in the system, then add the diluent and mix the sample. The instrument will perform sampling after precipitation at the bottom of the sample cup. Sample staining need approximate 2 minutes before go to microscopic examination.

If you need to perform iodine staining on the samples that already have been diluted by diluent and tested in egg mode, you can click <New> and click <Special mode(iodine staining)>, and add an appropriate amount of diluent depending on the remaining amount of the sample (for example, if the original sample diluent is 6ml, and there is about 4.7ml left in the sample collection cup after one sampling, then the iodine staining operation should be selected without dilution).

Before inspection, tick on <Special mode(iodine staining)> on the <Test> interface and create new job for inspection, as shown in Fig. 4-16 and Fig. 4-17. Click "Start" to begin the inspection.

Note: Because the iodine solution will influence the result of colloidal gold test, the colloidal gold items can't be tested in iodine staining mode.

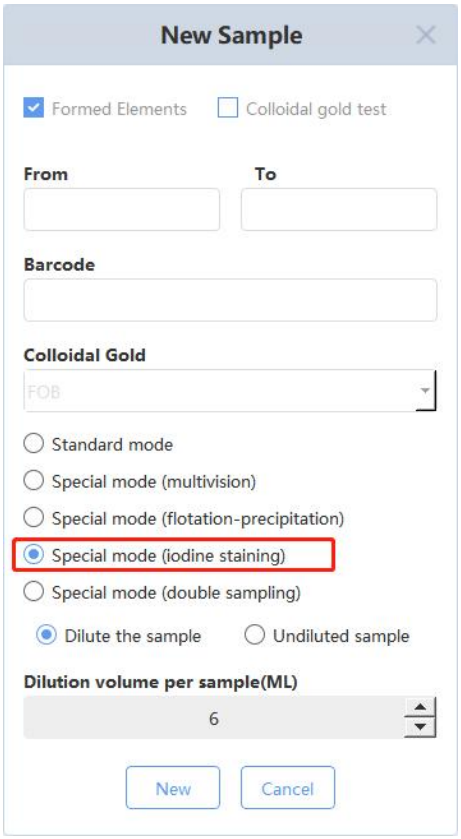


Fig. 4-16 Tick on special mode(iodine staining)

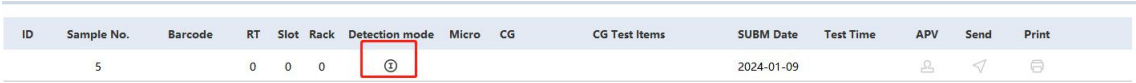


Fig. 4-17 Create iodine staining sample

After completing the detection,the detectiom mode status will indicate by an icon ⓘ and the microscopic inspection status will indicate by an icon ✓, as shown in Fig. 4-18.

Fig. 4-18 Finish iodine staining detection

4.4.1.2.4 Special mode(double sampling)

With the special mode(double sampling) detection, the number of photos taken and the number of photo layers are different from those in standard mode. More photos can be

taken the special mode(double sampling) detection to better help the inspection of parasitic eggs and protozoa. The instrument will analyze and test the same sample twice, sample the bottom of the same sample, and combine them into one sample information for reporting after the test is completed.

Before inspection, tick <special mode(double sampling)> on the <Test> interface and create new samples for inspection, as shown in Fig. 4-19 and Fig. 4-20 Click "Start" to begin the inspection.

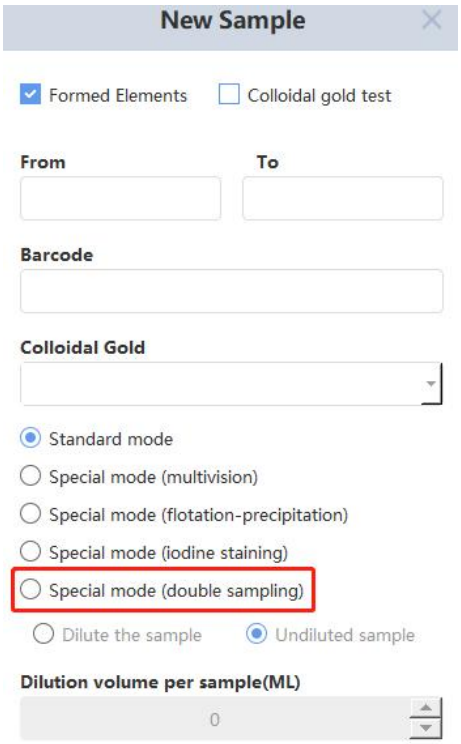


Fig. 4-19 Tick on special mode(double sampling)

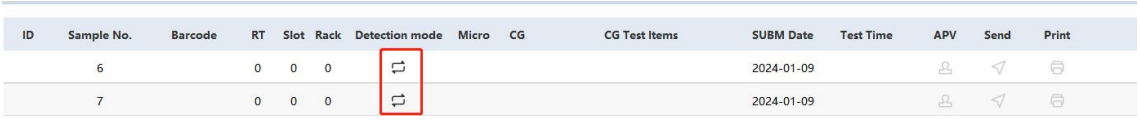


Fig. 4-20 Special mode(double sampling) detection sample

After completing the detection, the sample information from the two tests will be combined into a single sample information, which will be displayed under detectiom mode status will indicate by an icon, as shown in Fig. 4-21.the detectiom mode status will indicate by an icon and the microscopic inspection status will indicate by an icon ,as shown in Fig. 4-21.

Fig. 4-21 Finish Special mode(double sampling) test

4.4.1.3 Direct inspection

The default colloidal gold card inspection item is FOB，default detection mode is Standard mode. We can expand the drop down list to choose items that you needs to examine as shown in Fig. 4-22.

Before inspection start, we still can adjust the colloidal gold card test items. Double click the box <CG Test Items>, the drop down list will be expand on and you can add or remove the items that you need as shown in Fig. 4-23. Click <Start> to begin the inspection.

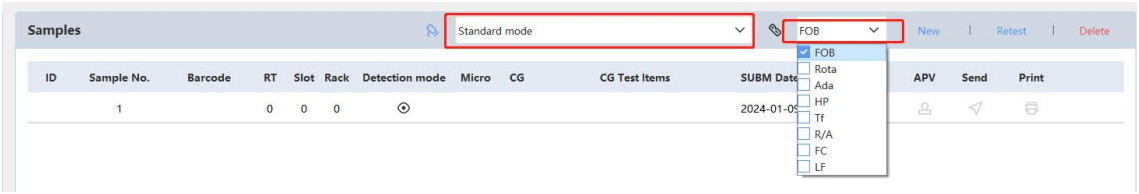


Fig. 4-22 Default item of colloidal gold and detection mode

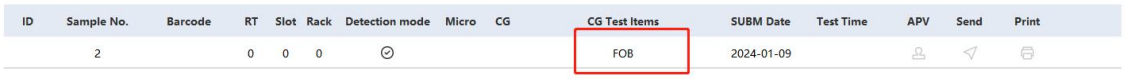


Fig. 4-23 Add or remove item

If no new sample for inspection is created, the default colloidal gold and formed elements items will be inspected.

You can also select the items to be detected by default, and click <Start> to detect directly according to the items selected by default, as shown in Fig. 4-22.

The red box on the left can drop down to select the colloidal gold items to be detected, and the red box on the right can drop down to select Standard mode, Special mode(multivision),Special mode(flotation-precipitation),Special mode(iodine staining)and Special mode(double sampling).

4.4.2 Two-way communication

For the inspection under two-way communication, the operations are as per Feces Analyzer LIS Connection Manual. The feces analyzer sends query request to LIS server to obtain the sample information, patient information and inspection item information by

the sample bar code, then it does the inspection. Three modes are available under bidirectional communication mode, including manually setting microscopy inspection items, automatically obtaining microscopy inspection items, and egg mode.

4.4.2.1 Standard mode

Place the sample collection cup affixed with bar code in the sample detection position and click <Start> to test the sample. After the instrument obtains the formed elements items to be tested from LIS, the instrument will automatically detect the relevant formed elements items.

For example, if the instrument asks LIS for testing information of a sample, the LIS sends the following information to the instrument:

DSP|7||0|||

.....

DSP|29||2^^^N|||

DSP|30||3^^^N|||

DSC||

Then LIS will send the information of formed elements items numbered 2 and 3 to the instrument, and the instrument will detect RBC and WBC items.

4.4.2.2 Special mode

4.4.2.2.1 Special mode(multivision)

Place the sample collection cup affixed with bar code in the sample detection position and click <Start> to test the sample. After the instrument obtains the formed elements items to be tested and the requirements for egg detection mode from LIS, and the instrument will automatically detect the relevant formed elements items.

For example, if the instrument asks LIS for testing information of a sample, the LIS sends the following information to the instrument:

DSP|7||1|||

.....

DSP|29||12^^^N|||

DSP|30||13^^^N|||

DSP|31||14^^^N|||

DSP|32||15^^^N|||

DSP|33||16^^^N|||

DSP|34||17^^^N|||

DSP|35||18^^^N|||

DSC||

Then, the mode sent by LIS to the instrument for testing is the egg model, and the instrument needs to test the visible component items with the serial number 12, 13, 14, 15, 16, 17 and 18, namely, liver fluke egg, ascaris egg, hook worm egg, pin worm egg, whip worm egg, tapeworm egg and ginger egg.

4.4.2.2.2 Special mode(flotation-precipitation)

Place the sample collection cup affixed with bar code in the sample detection position and click <Start> to test the sample. After the instrument obtains the formed elements items to be tested and the requirements for special mode(flotation-precipitation) from LIS, and the instrument will automatically detect the relevant formed elements items.

For example, if the instrument asks LIS for testing information of a sample, the LIS sends the following information to the instrument:

DSP|7||2|||

.....

DSP|29||12^^^N|||

DSP|30||13^^^N|||

DSP|31||14^^^N|||

DSP|32||15^^^N|||

DSP|33||16^^^N|||

DSP|34||17^^^N|||

DSP|35||18^^^N|||

DSC||

Then, the mode sent by LIS to the instrument for testing is Special mode(flotation-precipitation), and the instrument needs to test the visible component items with the serial number 12, 13, 14, 15, 16, 17 and 18, namely, liver fluke egg, ascaris egg, hook worm egg, pin worm egg, whip worm egg, tapeworm egg and ginger egg.

4.4.2.2.3 Special mode(iodine staining)

Place the sample collection cup affixed with bar code in the sample detection position and click <Start> to test the sample. After the instrument obtains the formed elements items to be tested and the requirements for Special mode(iodine staining) from LIS, and the instrument will automatically detect the relevant formed elements items.

For example, if the instrument asks LIS for testing information of a sample, the LIS sends the following information to the instrument:

DSP|7||3|||

.....

DSP|29||12^^^N|||

DSP|30||13^^^N|||

DSP|31||14^^^N|||

DSP|32||15^^^N|||

DSP|33||16^^^N|||

DSP|34||17^^^N|||

DSP|35||18^^^N|||

DSC||

Then, the mode sent by LIS to the instrument for testing is used FLOT-SED Mode, and the instrument needs to test the visible component items with the serial number 12, 13, 14, 15, 16, 17 and 18, namely, liver fluke egg, ascaris egg, hook worm egg, pin worm egg, whip worm egg, tapeworm egg and ginger egg.

4.5 Sample test

4.5.1 Sample Creation and Deletion

Sample IDs are differentiated by date. The everyday sample IDs start from "1" by default.

- Manual creation of sample

Before sample test, you can create new sample information at any time. In <Test> interface, click <New > at the top left corner; in the New Sample interface, enter the sample ID, select a colloidal gold item, tick <With parasite eggs detection>, and then click <New> to create new samples as shown in Fig. 4-24. After creation of a new sample, you can also change the colloidal gold items in the Colloidal Gold Items column; at most 6

items can be selected.

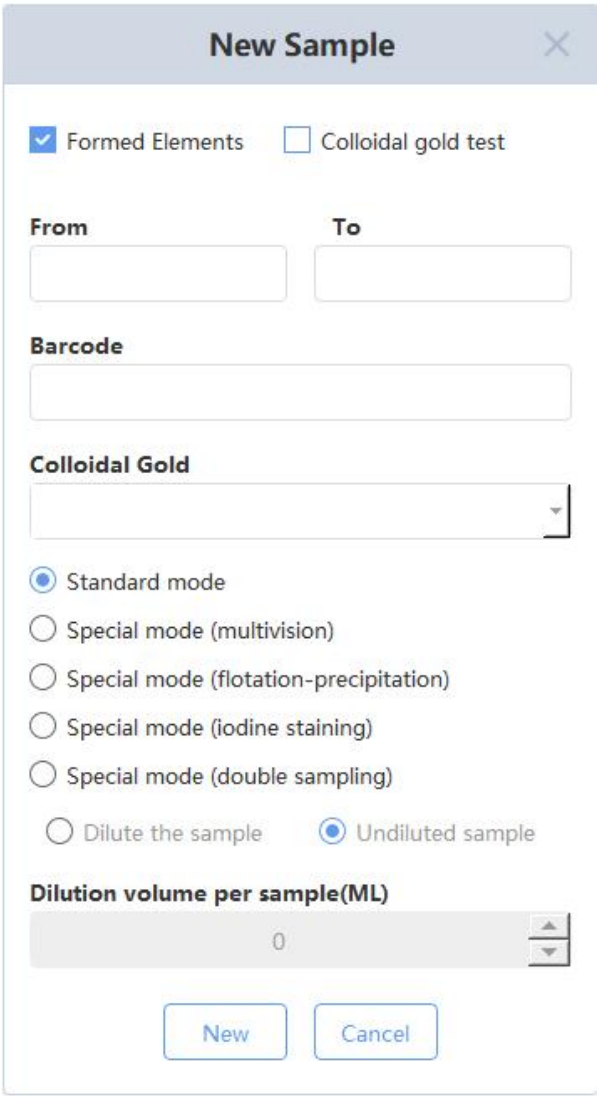


Fig. 4-24 Creation of New Sample

- Auto creation of new sample

During test, the instrument can add samples automatically; the system will apply auto numbering to sample IDs. The default colloidal gold test item is the colloidal gold item selected at the upper of the < Test> interface.

- Scanning sample barcode

  The instrument can scan the barcode of a new sample via the external barcode scanner; you can also enter the sample barcode after creation of a new sample.

- Sample deletion

  Deleting one sample: click a sample and then click the right mouse button to

delete the current sample.

Deleting a batch of samples: hold down the left mouse button to drag samples, or hold down the <Ctrl> button and click the left mouse button to select samples one by one, or hold down the <Shift> button and click the left mouse button to select a number of samples, and then click the right mouse button to display the Delete Sample dialog box, and finally click <Delete Sample> to delete the selected samples.

4.5.2 Entry and modification of Sample Information

In the <Test> interface, select the sample ID. You can enter relevant information of the sample on the left side, and then click <Save>.As shown in Fig. 4-25.

During or after test, you can edit sample information at any time.

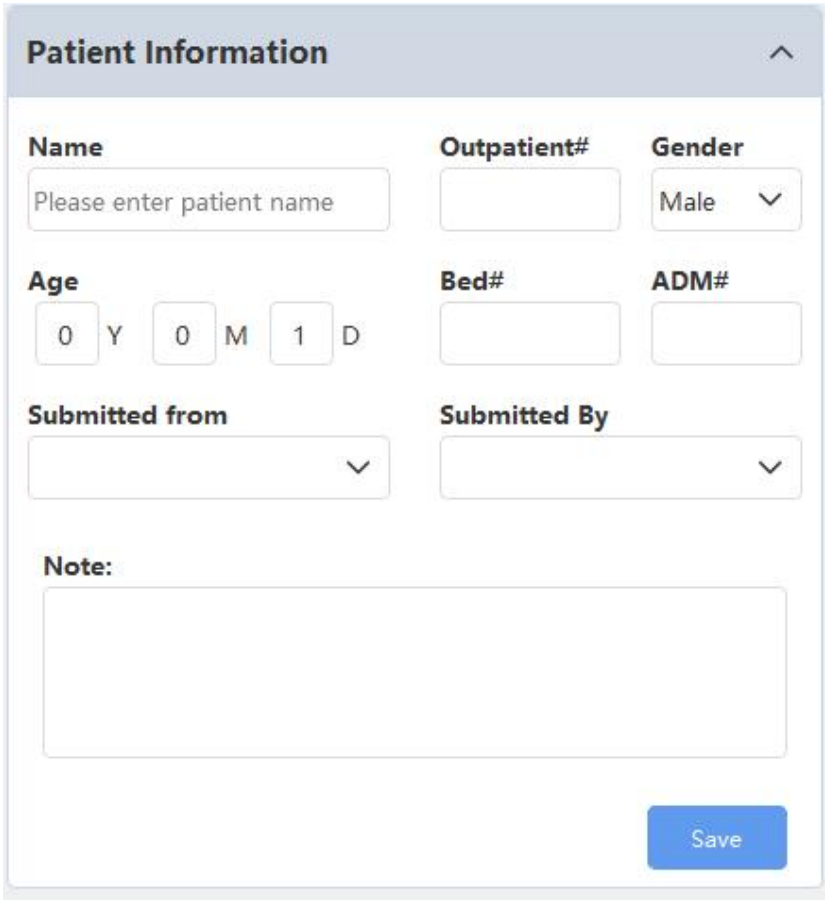


Fig. 4-25 Entry of Sample Information

Sample records for completed tests can be viewed on the left side of the <Report> interface. As shown in Fig. 4-26.

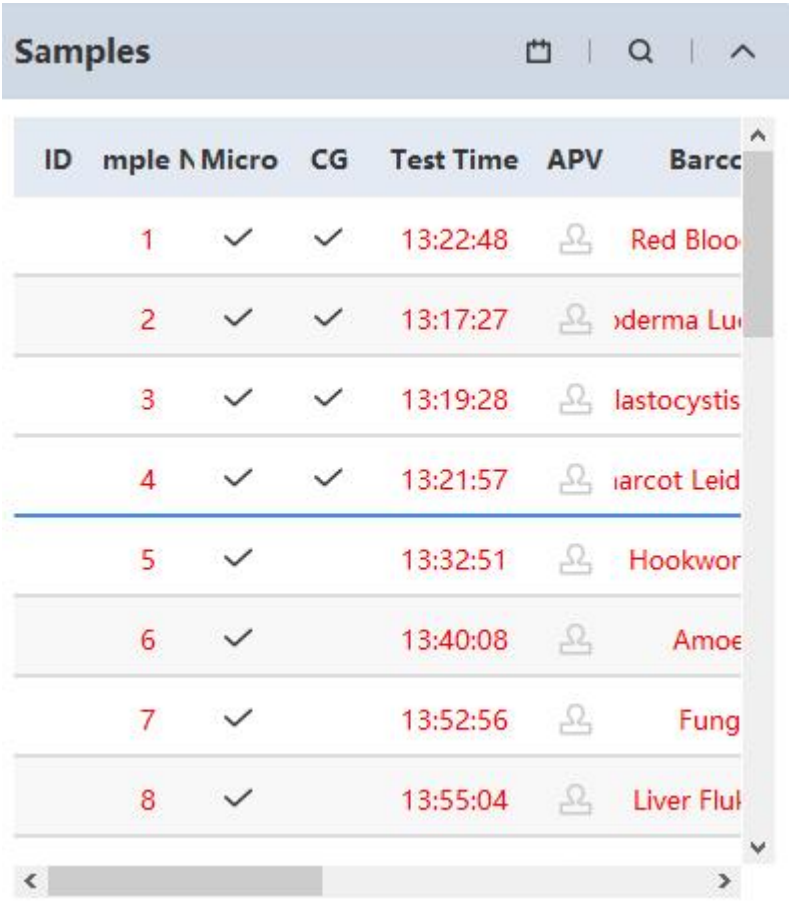


Fig. 4-26 Test Record

4.6 Review and Print

When test is finished, you can carry out sample review. Click a sample and then click the right mouse button to display such options as sample review and report printing,As shown in Fig. 4-27.

After selecting the sample to be reviewed in the <Report> interface, the information bar on the left side will display the sample information and patient information of this sample, and the result bar on the right side will show the results of formed element, colloidal gold test and physical of the sample.

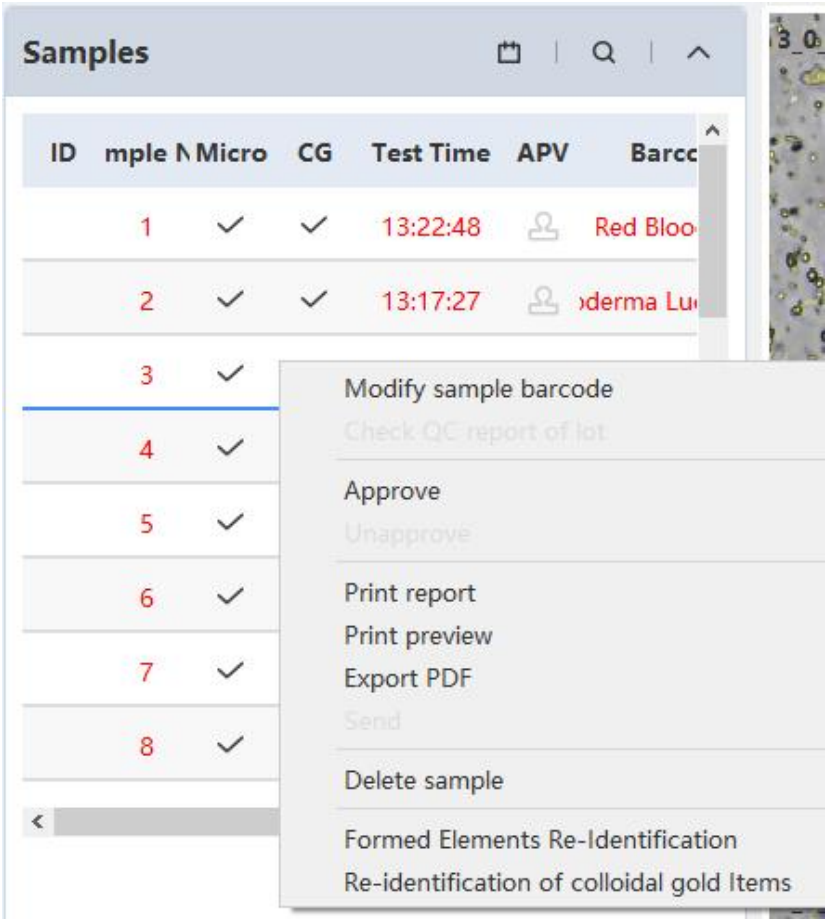


Fig. 4-27 Display of Review and Printing Function

4.6.1 Multi-view Combined Review Report

Click a sample in the Sample Info list to display a combination of multi-view images in the manner of 4 or 8 columns per row in Multi-view Combined Review Report interface, as shown in Fig. 4-28.

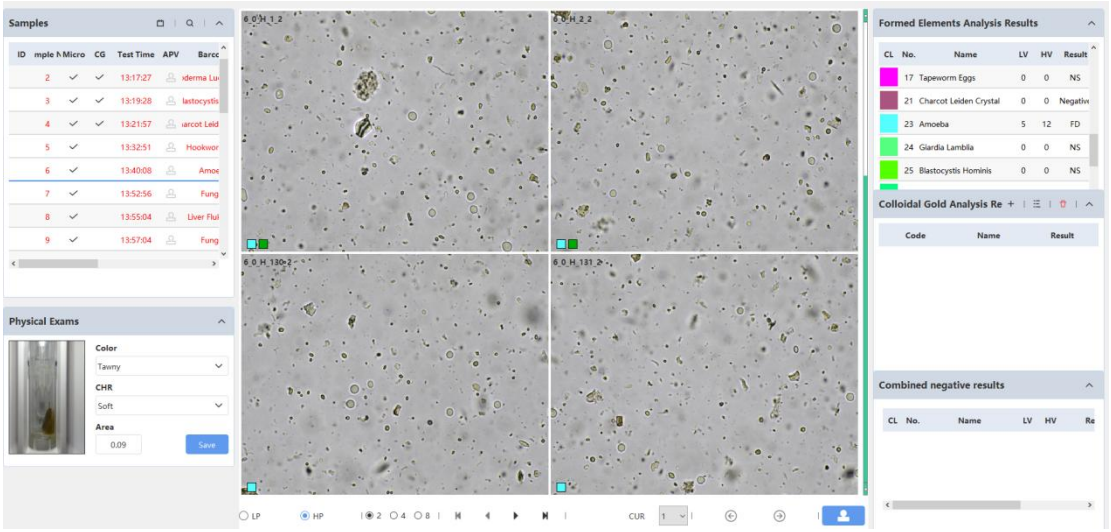


Fig. 4-28 Multi-view Combined Review Report Interface

In Multi-view Combined Review Report interface, the sample information, patient information, formed element result, colloidal gold result and photo, and physical indicator result are displayed respectively in the upper left area, lower left area, upper right area, middle right area and lower right area.

In this interface:

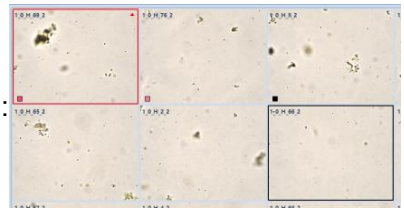
1) ⏮ ◀ ▶ ⏭ : you can click the arrows or the slider to switch among the images of different views;

2) You can click the right mouse button in the image to tick or cancel the display of annotations;

3) ○ LP ◉ HP : Switching between Magnification A and Magnification B during review;

4) : | ◉ 2 ○ 4 ○ 8 | you can choose to display 4 or 8 thumbnails in each row;

5) : ⊖ ⊕ Sample switching buttons;

6) :  red indicates the selected image; black indicates

unselected images;

7) You can directly modify the result in the Formed Element Result, as shown in Fig. 4-29.

No.	Name	LV	HV	Result	P
16	Whipworm Eggs	0	0	NS	
17	Tapeworm Eggs	0	0	NS	
21	Charcot Leiden Crystal	1	5	Postive	
23	Amoeba	0	0	NS	
24	Giardia Lamblia	0	0	NS	

Fig. 4-29 Modification of Results

With powerful functions of photography and AI recognition, our feces analyzer can take multi-layer pictures of fecal formed elements to obtain high definition images. Then the analyzer compares the captured pictures with the standard data in the database. After that, it marks and counts the special formed elements in the pictures, and gets the final results through its precise algorithm.

Up to now, our feces analyzers are able to identify the following relevant formed elements:

1. Red blood cells
2. Leukocyte
3. Fungus
4. Pus Ball
5. Fat globules
6. Epithelial Cell(rare)
7. Starch granule
8. Calcium oxalate crystal
9. Macrophage (rare)
10. Ganoderma lucidum spore
11. Liver fluke egg
12.Ascaris egg
13.Hookworm egg
14.Pinworm egg
15.Whipworm egg
16.Tapeworm egg
17.Spathocephala lata eggs
18.Charcot leiden crystal (rare)
19.Amoeba
20.Entamoeba Histolytical

21.Entamoeba Coli
22.Endolimax Nana
23.Giardia lamblia
24.Blastocystis hominis
25.Strongyloid faecalis (rare)
26.Blood
27.Plant Cell
28.Muscle Fiber
29.Egg of hymenolepis nana

By now, the followingformed elements are not recognizable by our analyzers:

1. Free fatty acids
2.Combined fatty acids
3.Egg of hymenolepis diminuta
4.Egg of dipylidium caninum
5.Ginger worm egg
6. Schistosoma japonicum egg
7.Egg of schistosoma mansoni
8.Egg of schistosoma haematobium
9.Egg of fasciola hepatica
10.Trichomona
11.Dientamoeba fragilis
12.Chilomastix mesnili
13.Paragonimus egg
14.Iodamoeba Butschli
15.Entamoeba hartmani
16.Giardia lamblia cyst
17.Giardia lamblia trophozoite
18.Cryptosporidium
19.Cryptosporidium parvum
20.Isospora belli
21.Cyclospora cayetanensis
22.Encephalitozoon intestinalis
23.Enterocytozoon bieneusi
24.Connective tissue
25.Balantidium coli
26.Mucous strand

Reasons for identification failure: The analyzer databank has no model similar to the formed element picture. The other possible reason is because the fecal formed elements are very complicated, the pictures are easily mixed up. As a consequence, not all types of elements could be identified.

Reporting principle: Due to the instrument identification failure or error, the laboratory physicians need to manually review all images one by one and make corrections accordingly by adding or removing the unrecognized and misrecognized elements.

Formed element inspection is a vital part in feces inspection, which serves as the foundation for determining many pathological diseases. Therefore, an accurate test result

is crucial. In this regard, we require clinicians to manually review the test results of the formed elements to ensure the accuracy of the results.

4.6.2 Big Image Review

In Multi-view Combined Review Report interface, click a thumbnail to display the big image for your review, as shown in Fig. 4-30.

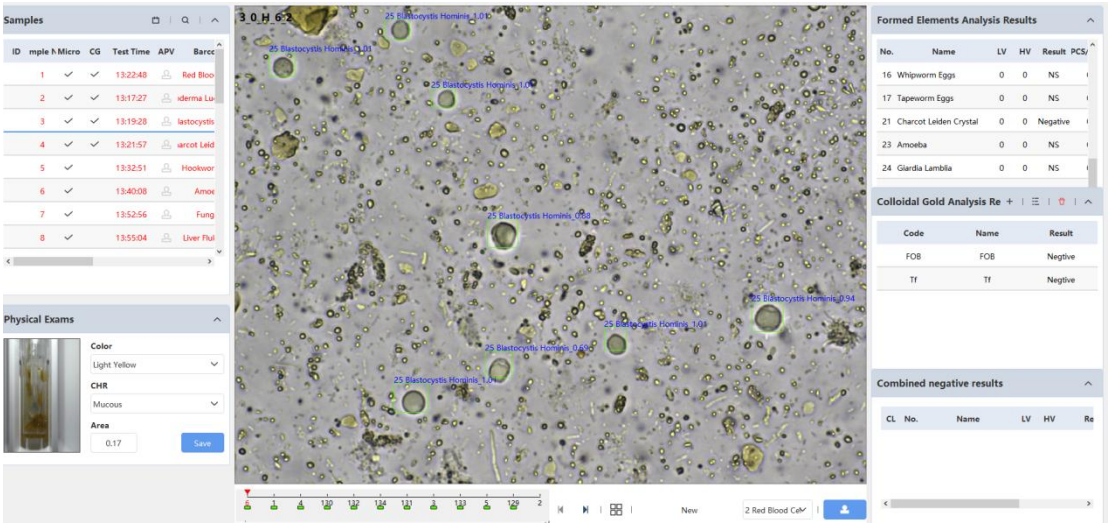
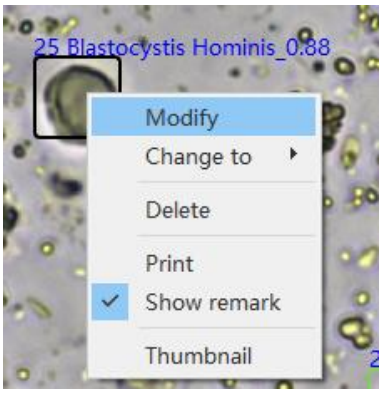
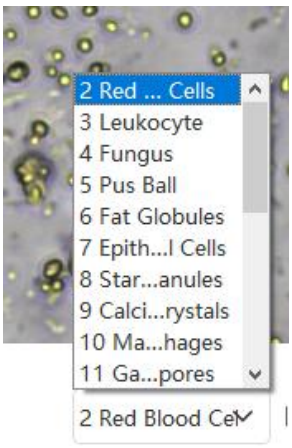


Fig. 4-30 Big Image Review Interface

1) : click the arrows to switch to different images.

2) 

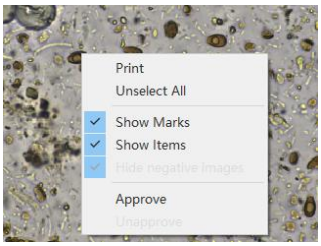
: red indicates unselected items; black indicates the selected item, where you can click the right mouse button to change the item name.

3) 

: click "New" to select an additional item to be marked.

4)  : Confirm Review button and Cancel Review button. When review is ended, click <Approve> to finish the review; in the Sample Info List, the review status will change to  . If you have set data output, the test result will be output.

5)  : click "Thumbnail" to return to the Multi-view Combined Review Report interface where 4 or 8 thumbnails are displayed in each row.

6) 

: Select images for printing -- You can click the right mouse button in the image to select or cancel printing of the image; the image selected will show the "P" letter. If the number of images selected exceeds the maximum allowed number, the images that are at the top of the list will be printed by default.

⚠ NOTE

- This interface allows layer switching of view images by rotating the mouse wheel.

4.6.3 Merging Item Result Function

In order to review and report the results of formed elements visually and conveniently, the KU-F50 can be turned on with the merging item result function for parasite eggs and protozoa. When the merging item result function is enabled, parasites and eggs that are set to be combined will be reported together in a single project (set as Eggs and Protozoa),

and the name of the project and the items that need to be combined can be modified by the after-sales service engineer. For example, the combined items of parasite eggs and protozoa include Liver Fluke egg, Ascaris egg, Whipworm egg, Hookworm egg, Entamoeba Histolytical, Entamoeba Coli, Giardia Lamblia, and Blastocystis Hominis, etc.
If the results of the above items are negative, the parasite eggs and protozoa are reported: negative.If Liver Fluke eggs and Hookworm eggs are found in the above items, the parasite eggs and protozoa are reported: liver fluke eggs are found, hookworm eggs are found.
When “Auto send” or “Send after approve” is enabled, the machine will send the results of the merged parasite eggs and protozoa to the LIS system in code as shown below,

OBX|2|ST||Red Blood Cells|Negative|/HP|Negative||||F||||||U|||
OBX|3|ST||Leukocyte|Negative|/HP|Negative||||F||||||U|||
OBX|4|ST||Fungus|Negative|/HP|Negative||||F||||||U|||
OBX|5|ST||Pus Ball|Negative|/HP|Negative||||F||||||U|||
OBX|6|ST||Fat Globules|Negative|/HP|Negative||||F||||||U|||
OBX|7|ST||Epithelial Cell|Negative|/HP|Negative||||F||||||U|||
OBX|8|ST||Starch Granule|Negative|/HP|Negative||||F||||||U|||
OBX|9|ST||Calcium Qxalate Crystal|Negative|/HP|Negative||||F||||||U|||
OBX|10|ST||Macrophage|Negative|/HP|Negative||||F||||||U|||
OBX|11|ST||Ganoderma Lucidum Spore|Negative|/HP|No Found||||F||||||U|||
OBX|21|ST||Charcot Leiden Crystal|Negative|/HP|Negative||||F||||||U|||
OBX|23|ST||Amoeba|NS|/HP|NS||||F||||||U|||
OBX|27|ST||Strongyloid Faecalis|NS|/LP|No Found||||F||||||U|||
OBX|1000|ST||Eggs and Protozoa|Liver Fluke Egg Found,Hookworm Egg Found|||No Found||||F||||||U|||
OBX|201|ST|Color|Color|Dark brown||Yellow||||F||||||P|||
OBX|202|ST|Trait|Characteristics|Watery||Soft Feces||||F||||||P|||

4.6.4 Reminder function for Entamoeba histolytical and Entamoeba coli

The subclass of Amoeba recognized by the AI includes Entamoeba Histolytical, Entamoeba Coli, Endolimax Nana and Amoeba (Other subclasses of Amoeba will be marked as mainclass of Amoeba except Entamoeba Histolytical, Entamoeba Coli and Endolimax Nana)
It is difficult to distinguish the subclass of Amoeba by smearing slide manually or microscopy of feces analyzer, because they are too similar to be distinguished and confirmed by AI. The user can distinguish the specific subclass of Amoeba by staining the sample with iodine solution.
Therefore, if Entamoeba Histolytical or Entamoeba Coli was detected during the microscopy, the instrument will make a reminder at the time of audit, when transmitting the results, to alert the user to confirm if it is Entamoeba Histolytical or Entamoeba Coli. It will prompt “Sample No. X found Entamoeba Histolytical, please perform automatic iodine staining review to confirm.” or “Sample No. X found Entamoeba Coli, please perform automatic iodine staining review to confirm.”.

4.6.5 Cancel Review

For a sample having been reviewed, you can click <Unapprove> to cancel review. Review can be canceled in the < Report>/Big Image Review interface.

⚠ NOTE

- The instrument cannot identify abnormality of feces samples; sample collection personnel should collect samples according to the requirements for clinical sample collection.
- Laboratory physicians are strongly suggested to review the samples in detail before submitting reports.
- If the feces sample is bright red or tarry black in color and the colloidal gold test result is negative, it is recommended that this feces sample be retested.

⚠ NOTE

- If the sample has been reviewed, change is impossible.
- "Low value" and "High value" in the Result List respectively represent the minimum total number and maximum total number of a component in the images of all groups in the sample.

4.6.6 Quick Review

In the <Report> interface, click <Approve> to quickly perform review and click <Unapprove> to quickly perform cancel review; this operation supports multi-choice.

4.6.7 Print

You can print the result of a reviewed sample. In the <Report> interface, select the sample for printing, and click <Print>. You can also click <Preview> to preview the report or click <Save as PDF> to output the PDF report.

The instrument supports multiple report formats; you can select the report format in the <System Manage> interface. See Section 7.5.

4.6.8 Send

Send the test results to other terminal devices, such as LIS and HIS servers.

In the <Report> interface, select the record, and then click <Send>.See Section 7.4 for Send settings.

4.7 Query History

In the Review Report interface, you can inquire the information of all samples in the upper left corner. Sample information can be inquired by date. "QTY" indicates the number of matching samples, as shown in Fig. 4-31.

Click the sample to be viewed; the Sample Info bar and the Result bar will show the information and result of this sample. Also, you can enter, modify, review and print sample information.

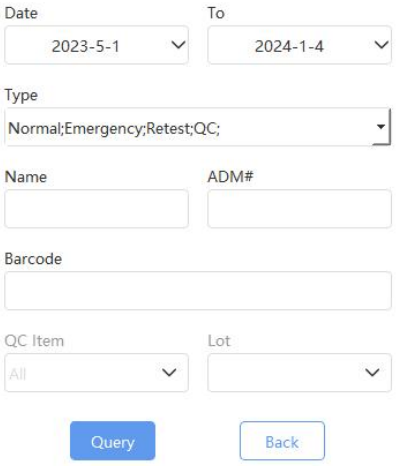


Fig. 4-31 Sample Info Query

4.8 QC Test

4.8.1 New QC Sample

Click <New> in QC interface to display the QC information editing window.

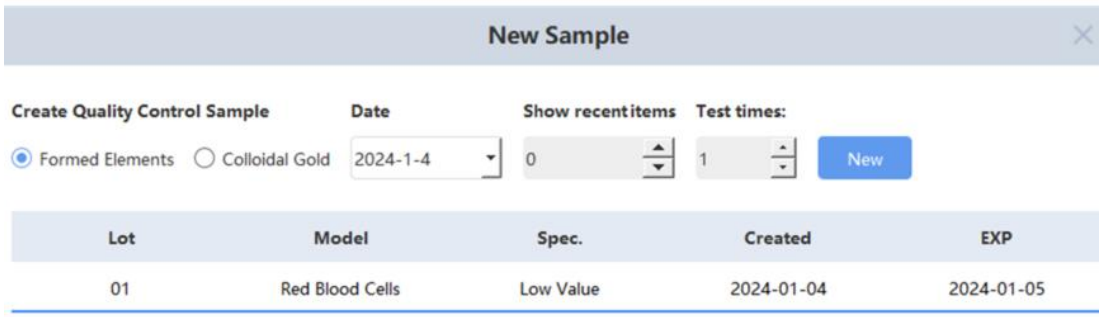


Fig. 4-32 Editing of QC Test Information

You can select Formed Element or Colloidal Gold QC samples.

4.8.2 QC Settings

Click <Settings> in QC interface to go to the QC Settings interface.

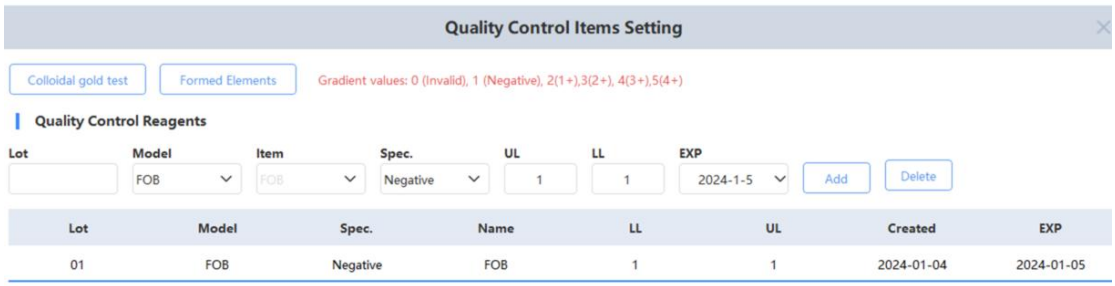


Fig. 4-33 Colloidal Gold QC Settings

1) Click <Colloidal Gold> to add colloidal gold QC samples.

2) Click <Add> in QC interface to create the QC samples to be tested; the batch No. of created QC samples starts from 20000, and can be changed.

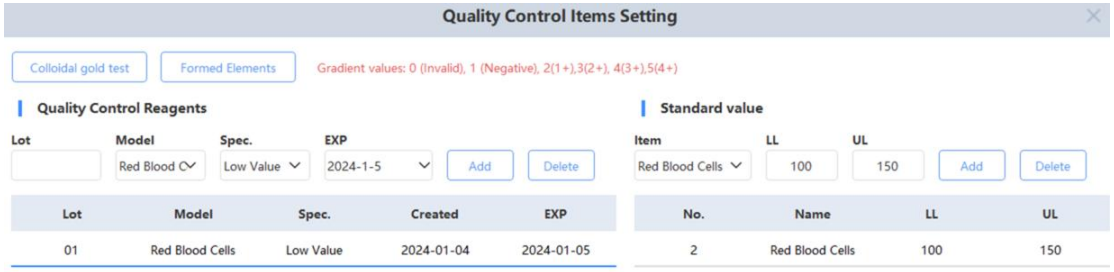


Fig. 4-34 Formed Element QC Settings

3) Click <Formed Elements> to add formed element QC samples.

4) Click <Add> in QC interface to create the QC samples to be tested; the created QC sample ID starts from 20000.

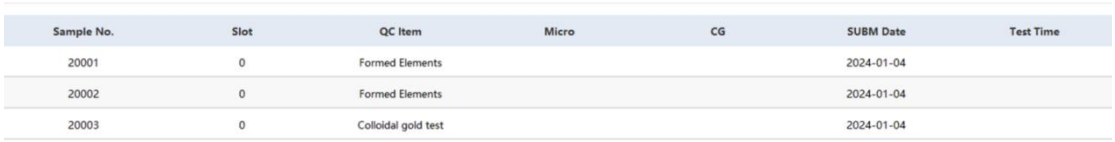


Fig. 4-35 List of QC to Be Tested

5) You can select Date and QC Type, and click <Query> to query historical QC results.

6) In the Sample List, click the QC sample; on the left side of the "Home" interface will display the QC information.

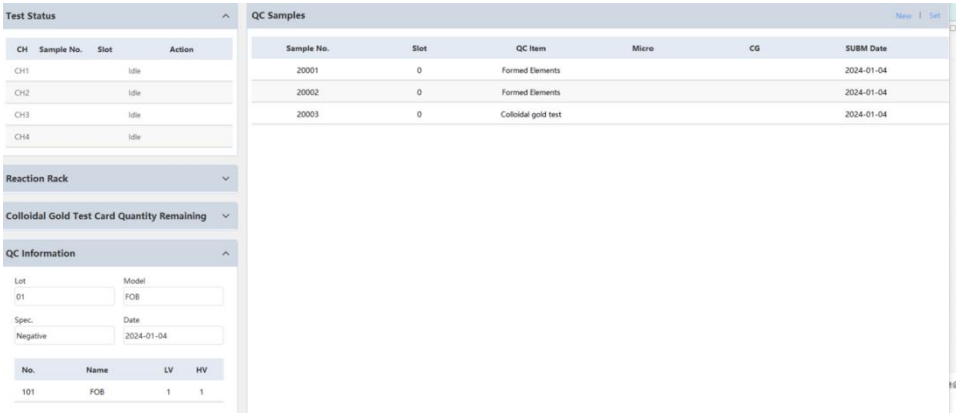


Fig. 4-36 Display of QC Information

⚠ NOTE

If the QC information is deleted, the QC information displayed will be empty. If tracing is needed, do not delete the QC information.

4.8.3 QC Operation

1) QC Preparation

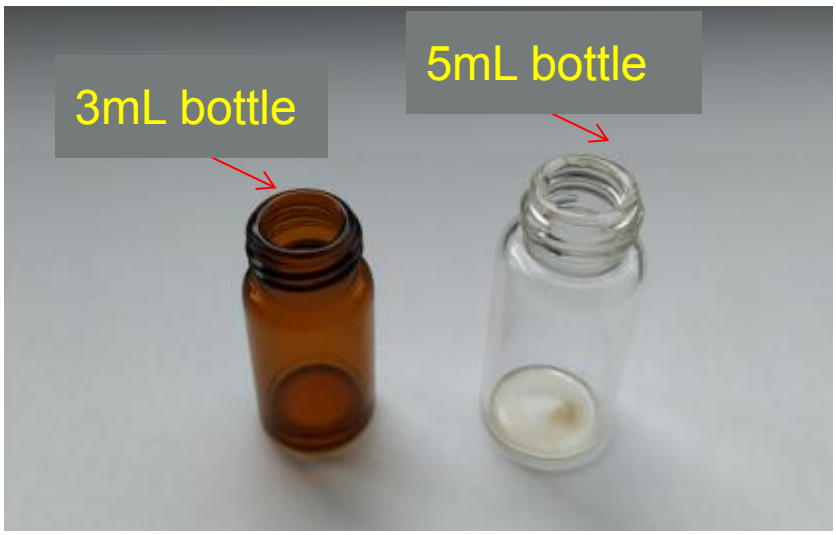


Fig. 4-37 QC Bottles

3mL or 5mL bottles are used for QC and colloidal gold used on the Feces Analyzer; 5mL bottles are used for formed elements (red blood cells and white blood cells). The specific size is subject to the QC.

2) Preparation of Bottle Sleeve Fitting QC Package

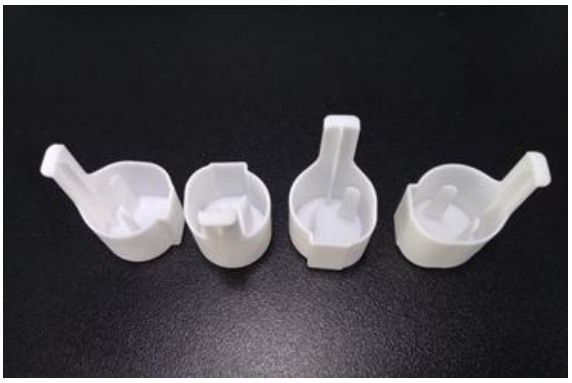


Fig. 4-38 QC Bottle Sleeves

Bottle sleeves should be placed on the blue QC sample rack of KU-F50.

Fig. 4-39 Placement of QC Bottle Sleeves

3) Creation of new QC sample to be tested

Add QC information according to Section 4.8.2; create a new QC sample to be tested according to Section 4.8.1.

4) Placement of QC

After pre-dilution, mixing and other treatment of QC according to the QC manual, place the QC to be tested on the sample rack in the sequence of new QC samples to be tested. For example, if two QC samples including No. 20001 fecal occult blood Low and No. 20002 fecal occult blood High are created, No. 1 and No. 2 QC samples placed on the sample rack will be fecal occult blood Low and fecal occult blood High, respectively.

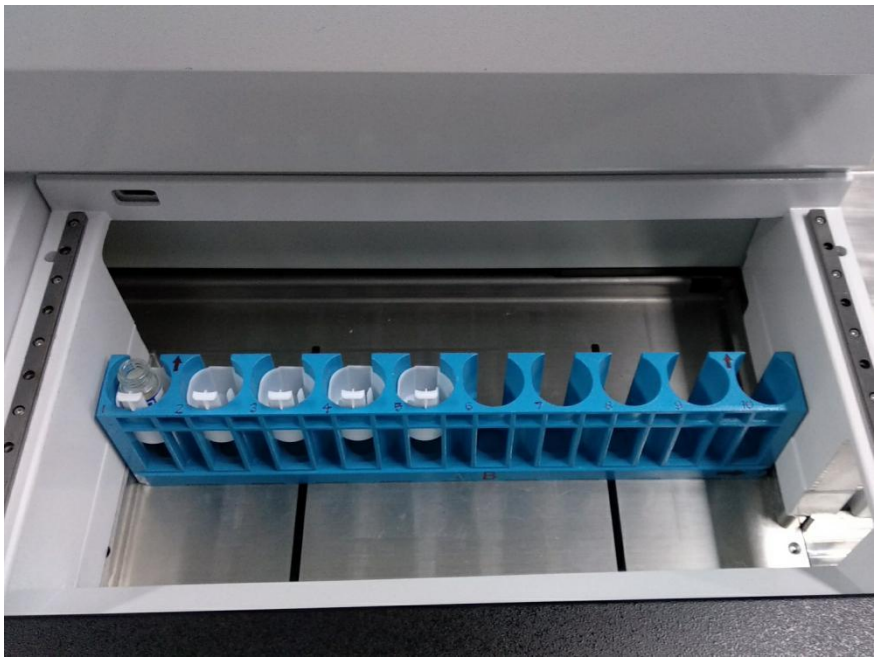


Fig. 4-40 QC on board

5) QC test

Click <Start> at the upper right of the interface, and the instrument will automatically recognize the blue QC sample rack and complete the QC test.

⚠ NOTE

Bottle sleeves should be placed only on the blue QC sample rack, or the test cannot be performed.

4.9 Retest

4.9.1 Create retest sample manually

Click the Retest in the <Test> interface,enter preset retest items interface as shown in Fig. 4-41：

1）Retest by matching the barcode

Input the intraday retest sample's barcode,colloidal gold item,diluent volume information(Maximum 10 samples can be retested each time)in the corresponding input field as shown in Fig. 4-41;

Put the retested sample on the right tray within the green sample rack. When the instrument is in idle status, please tick Match with barcode, then click the Start

button to start the retest.

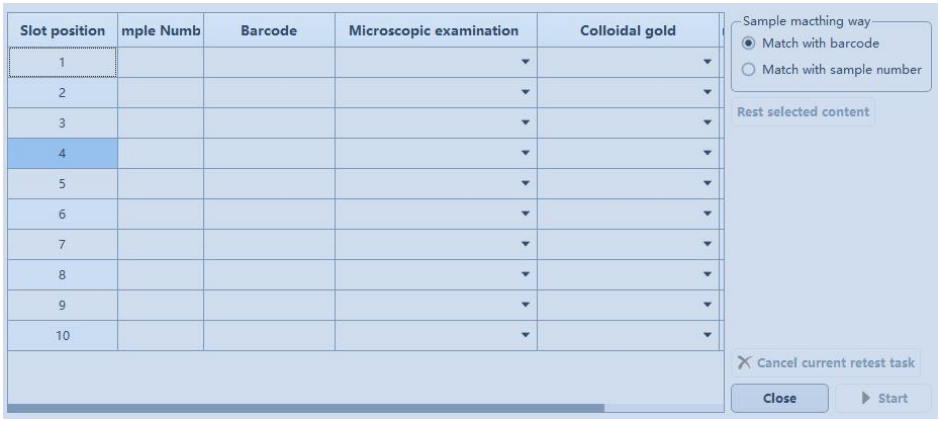


Fig. 4-41 Interface for items to be retest

2）Retest by matching sample number.

Input the intraday retest sample's number,colloidal gold item,diluent volume information (Maximum 10 samples can be retested each time)in the corresponding input field as shown in Fig. 4-41;

Put the retested samples on the right tray within a green sample rack, When the machine is in idle status, please tick 

, then click the 

button to start the retest.

⚠ WARNING

- Please make sure the corresponding relationship between the position of sample rack and the samples to be retested, the instrument will conduct the retest by the sample order.
- The color of retest sample rack is green. Placing samples in other kinds of sample rack will make the retest not to be done as expectation.
- Manual retest must be done during the spare time of the instrument.

4.9.2 Create retest sample automatically

When the samples with barcodes need to be retested, put the retested samples on the right tray within the green sample rack and click <start>. The machine will creat a sample

number which is same as the barcode number and then finish the retest.

4.10 STAT Function-Emergcy Slot

During the detection process, if there are emergency samples that require priority testing, you can follow the steps below for emergency testing.

1) Place the emergency sample to be tested correctly in the emergency position of the instrument.

2) On the <Sample Testing> interface, click on <Emergency> to open the new emergency sample window: as shown in Figure 4-42 below, select the corresponding testing mode and colloidal gold project, then click on <Create>.

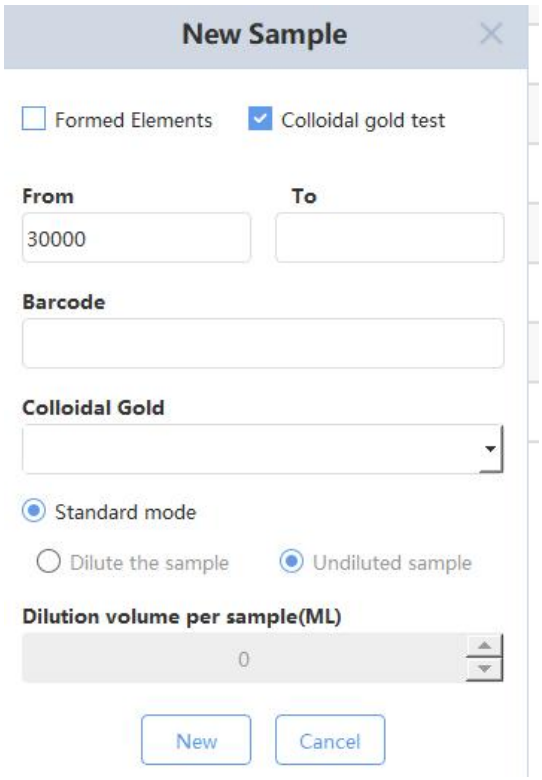


Figure 4-42 Create a new emergency sample test

3) After creating an emergency sample, the instrument will immediately perform sample testing. If there are batch samples currently being tested, the testing of emergency samples will be prioritized and performed immediately after the completion of the current sample testing.

4.11 Formed element analysis calibration

4.11.1 Summary

In order to obtain accurate test result, we need to do the formed element analysis calibration, ensure the deviation correction factor under the specified conditions. To obtain accurate sample analysis results, the instrument should be calibrated when needed according to the steps.

Our instrument only support manual calibration method.

⚠ NOTE

Only the administrator can do the calibration operation.

The operator should use our company's calibrator and regent, and store and use the calibrators and reagents in strict accordance with the using instructions.

4.11.2 Calibration frequency

The instruments have been calibrated before they out of factory and do not require frequent calibration, instruments should only be calibrated in the following cases:

Major components related to the analysis of formed elements have been replaced.

When the instrument has not been used for a long time.

The quality control data have a huge deviation.

⚠ NOTE

The test result can be used as a available data only after the calibration.

4.11.3 Calibration method

Calibration step:

（1）Place the calibration on the cup and test normally Start. Measure at least 5 times and record the results.

（2）Use calibration formula to calculate the new calibration coefficient. The calibration formula is as follows:

$$\text{New calibration factor} = \frac{\text{current calibration factor} * \text{reference value}}{\text{average value of measurement}}$$

For example: If the calibration reference value is 1114.4, the reference range is 687.5-1541.3, the current calibration factor is 110%.

Measure the calibration 6 times (n=6), and the results are 1035, 998, 1112, 1108, 1016, 983.

Index of repeatability CV=15%, meet the requirements, the average value of measurement is valid, if the measured value is outside the reference range, the result is invalid and cannot be used.

New calibration factor= $\frac{\text{current calibration factor} * \text{reference value}}{\text{average value of measurement}}$ =117.6%

If the calculated calibration factor outside the valid range (75%-125%), the calibration factor is invalid. In this situation, the operator need to look for the cause, then recalibrate and calculatethe calibration factor.

（3）After obtaining the new calibration factor, enter the new calibration factor in the calibration factor box.

（4）After entering the new calibration coefficient, click the "Save" button. If the message "Save successfully" is displayed and the calibration date is updated to the current system date, the current calibration factor is valid. Otherwise, the current calibration factor is invalid.

Chapter 5 Maintenance

To keep the instrument in good conditions over a long time, reduce the frequency of occurrence of faults and extend its service life, routine and periodic maintenance must be carried out carefully for the instrument. This chapter describes the methods and steps for maintenance of the instrument.

5.1 Focus

Click <Manage> → <Camera> to go to the Camera interface, and then click <Maintain> → <Focus> to go to the Focus interface.

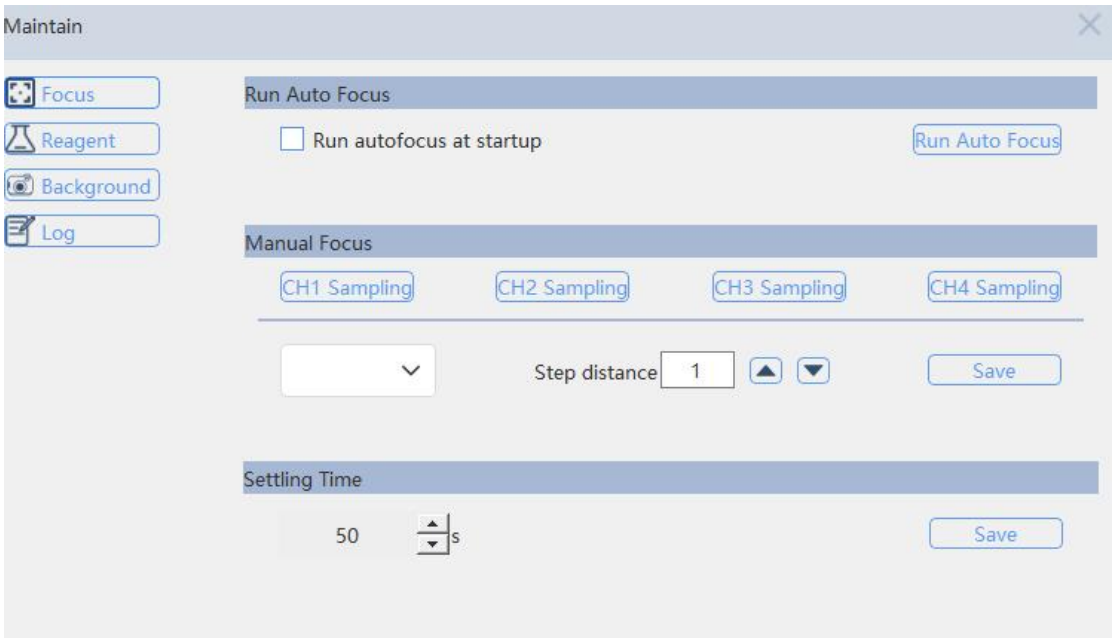


Fig. 5-1 Focus Interface

5.1.1 Focusing

Auto Focus or Manual Focus can be selected.

5.1.1.1 Auto Focus

1) Click <Run Auto Focus>; when <Focus successfully> is displayed, other operations can be performed.

2) When <Run autofocus at startup> is ticked, Auto Focus will be performed every time user logs into the software.

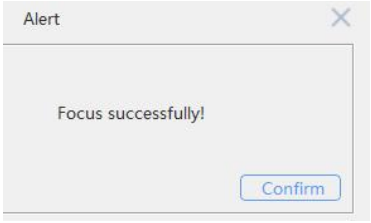


Fig. 5-2 "Focused successfully!" Prompt

5.1.1.2 Manual Focus

1) Use the sample collection cup to prepare about 8~10mL red blood cell suspension at the ratio of 2:1000μL (blood: diluent).

2) Place the sample collection cup containing red blood cell suspension on the sample rack, and then place the sample rack at the sample loading position of the tray.

3) Click each channel to load sample.

4) When red blood cell sedimentation becomes stable (in about 60s), view the Camera interface and observe whether red blood cells are clear; the red blood cell image should be adjusted to a pie shape, as shown in Fig. 5-2.

5) Select the focusing channel.

6) Click <▲> or <▼> to adjust the focal length until the image is clear. <Step Distance> is the number of steps for adjusting the focal length; it is suggested to set it to 1.

7) Close the <Focus > window; the instrument will automatically wash the channel.

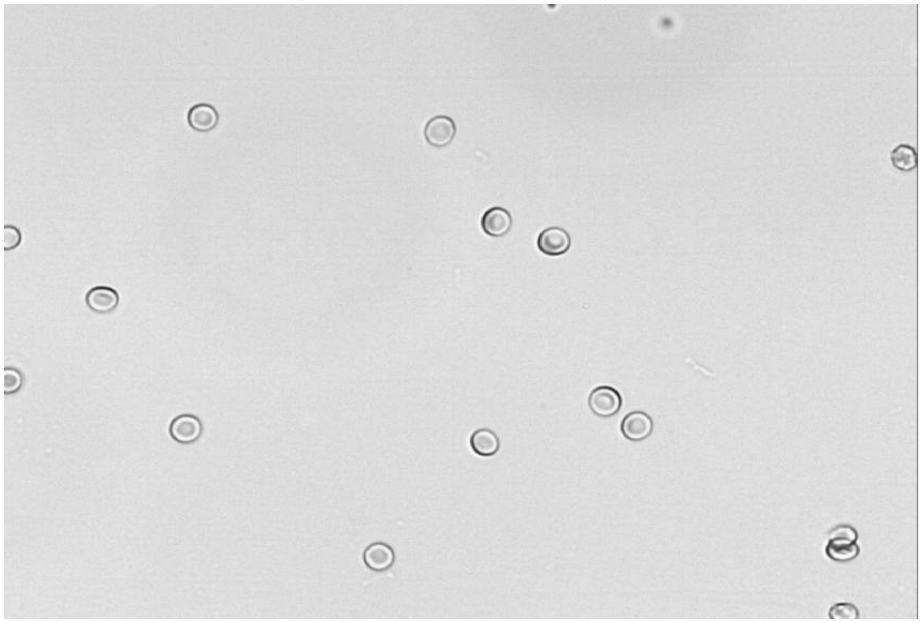


Fig. 5-3 Clear Erythrocyte Image

⚠ NOTE

- Manual Focusing is suggested at least once a week. When images become unclear, focusing should be carried out immediately.

5.2 Reagent

Click <Manage> → <Maintain> → <Reagent> to enter the Reagent interface.

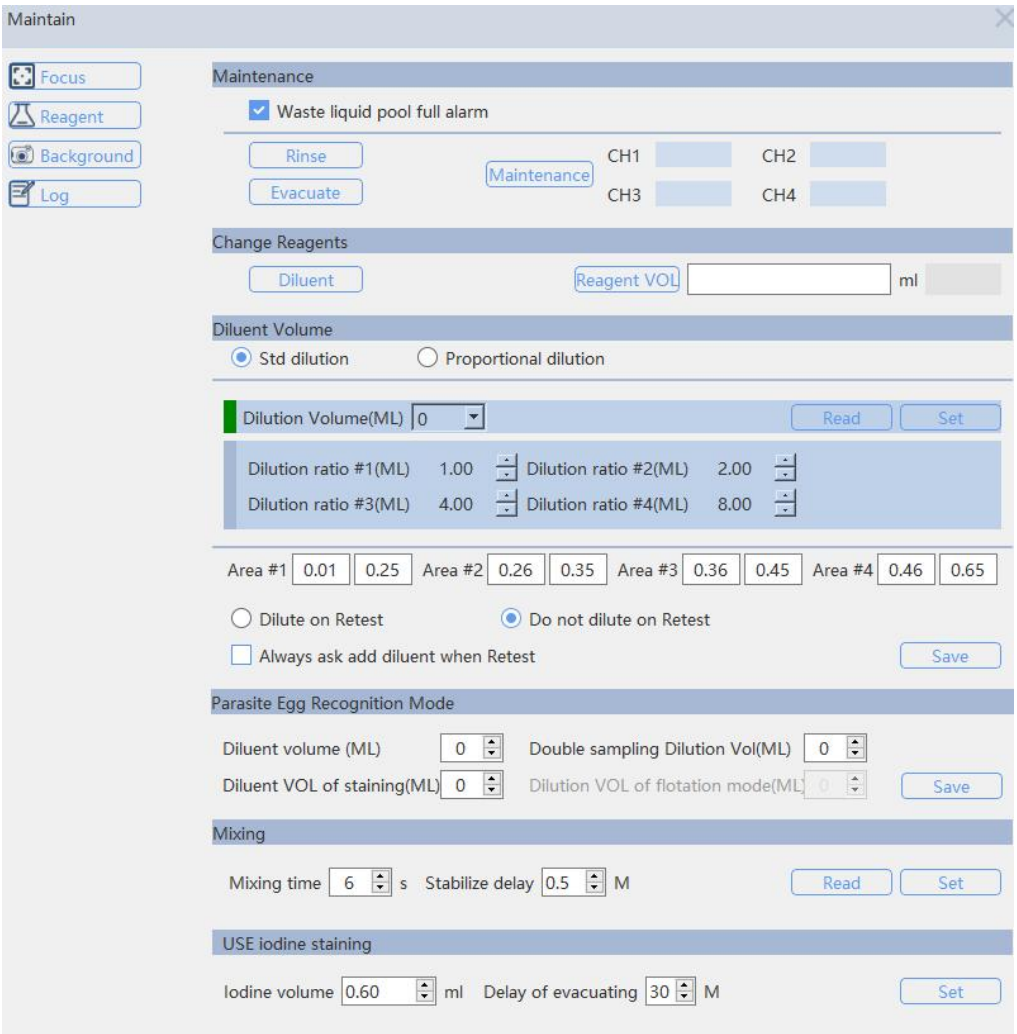


Fig. 5-4 Reagent

5.2.1 Maintenance

- Waste Liquid pool full alarm

When the waste liquid bottle is full, the instrument will display the "Waste Tank Full!"

message to remind you. If the liquid waste alarm is enabled, the instrument will also beep.

- Rinse

Click <Rinse>; Cleaning solution will be used to wash the pipe and channel.

- Evacuate

Before transport or when the instrument is to be left unused for a long period of time, unplug the reagent pipelines (not including the liquid waste pipe); click <Evacuate>; the instrument will discharge the reagent in the pipelines out of the instrument.

- maintenance

When there are lots of spots within the view which cannot be eliminated by washing, channel maintenance can be carried out. We suggest to perform maintenance once a week.

Operation steps:

1) Pour the concentrated cleaning solution (at least 11mL) into a clean sample collection cup.

2) Place the sample collection cup which containing concentrated cleaning solution on the sample rack, and place the sample rack at the sample loading position of the tray.

3）Click <Maintenance>.

4) Place it soak for about 5min.

5) Channel washing: at the end of channel maintenance, the instrument will automatically wash the channel.

5.2.2 Change Reagents

- Diluent

Each time we renew the diluent or cleaning solution, we need to click “Diluent” to prime new liquid into pipe and eliminate bubbles.

- Read reagent vol

The instrument contains a reagent card alarm device. When the reagent volume reading is too low, the instrument will display the "Change reagent card!" message. Please replace the sample diluent and reagent card, and click <Reagent VOL>.

5.2.3 Diluent volume

- Standard diluent volume

The instrument can set the diluent volume when sample is diluted; the diluent volume must be between 3-6mL.

- Dilution ratio

The instrument can add diluent based on the proportion of sample volume.

- Diluent volume for retest

In case of a retest, the instrument can decide to or not to add diluent, depending on the sample status.

If you tick <Always Prompt Add or Not Add Dilution>, the instrument will give the "Diluted" or "Not diluted" prompt during a retest.

5.2.4 Parasite Egg Recognition Mode

“Diluent volume(ML)” is showing the default volume of diluent when perform parasite egg mode.

“Diluent VOL of staining(ML)”is showing the default volume of diluent when perform iodine staining mode.

5.2.5 Mixing

- Set mixing time

The instrument can set the sample mixing time; the mixing time should not be less than 15s.

- Stabilize delay

When perform floatation and precipitation mode, we need to stabilize sample after mixing. The stabilize time should not be less than 1.5 minute.

5.2.6 Iodine Staining

- Iodine volume

“Iodine volume” is showing injecting volume of iodine into sample collection cup when perform iodine staining mode.As shown in Fig. 5-9.

- Delay of evacuating

When iodine liquid stay in the pipe for a long time, it will damaging the pipe. Therefore, we

need to evacuate the iodine liquid when instrument not doing iodine staining mode for a long time.

Note:

If lack of staining solution when performing Egg mode(staining), the instrument will prompt out the message ”Lack of staining solution, please click “Confirm” after reloading staining solution, or click “Cancel” to skip this examination ” as below.

You need to reload the staining solution and then click “Confirm” to continue the examination. Or you can click “Cancel” to skip the examination. If you click ”Cancel”, instrument will prompt out the message “Are you sure you don’t add staining solution?”. as below.

If you confirm not to reload the staining solution, you can click “Confirm”, and then the instrument will terminate this examination. If you still want to perform this examination, after you reloading the staining solution, you click “Cancel”, the instrument will perform the examination again. If there is not enough staining solution, the warning message will prompt out again.

The instrument is using peristaltic pump for adding iodine staining, and there have an deviation about 10% to 20% in the volume of iodine solution adding. Due to there is no precise requirement for the volume of staining solution, it depends on the effect of the sample result. Several factors that affect the effect of staining are as follows:

1. If the doctor finds that the staining effect is poor when they are using the iodine staining mode, check whether the staining solution has been opened for too long. Because the iodine solution itself may volatilize. In this case, you can replace it with a new iodine staining solution;
2. Check whether the peristaltic pump has been used for a long time, it causing the peristaltic pump to be deform and lose its elasticity, and this deformation will significantly reduced the adding amount volume of staining solution. We can replace the peristaltic pump for problem solved. For how to judge the insufficient staining solution and replace the peristaltic pump for detailed operations. It refer to 5.7.3 Monthly maintenance .
3. Manually modified the amount volume of staining solution, will affect the effective of staining.

5.3 Background

Click <Manage> → <Maintain> → <Background> to enter the Background interface.

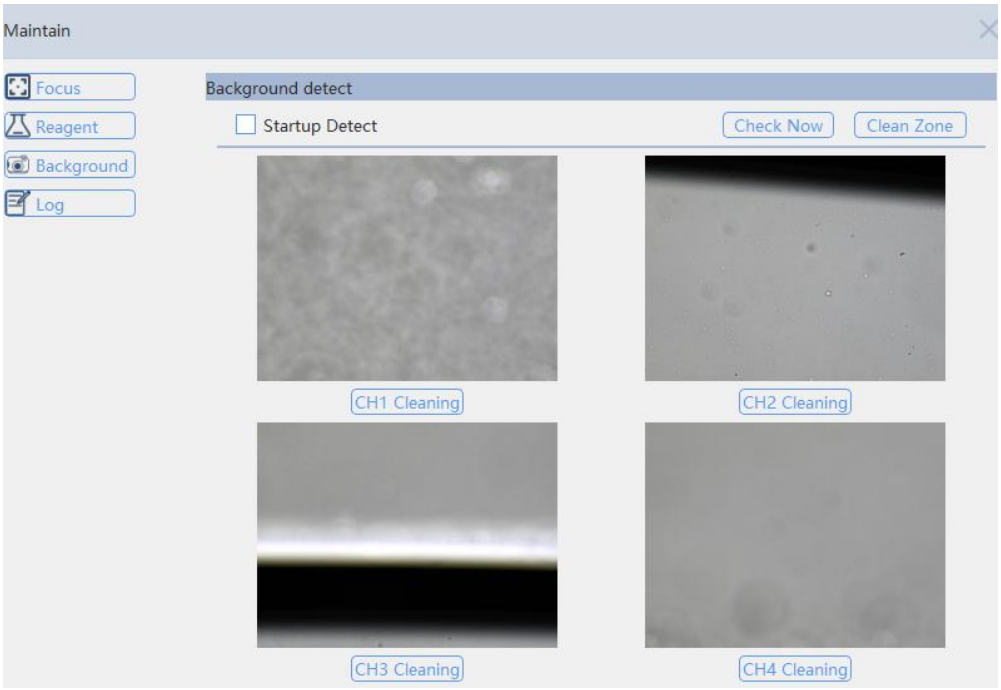


Fig. 5-3 Background

5.3.1 Background Detection

Background detection help user detect whether spots exist within the view, which affects the result when shooting images. When <Run background detect at startup> is ticked, background detection will be carried out automatically upon startup.

Click <Run background detect at startup> to take a background shot and identify whether the channels are clean. If the "Dirty channel" prompt pops up, please click "Channel cleaning" manually.

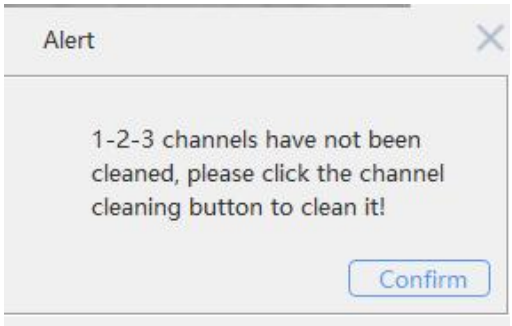


Fig. 5-3-1 "Dirty channel" Prompt

5.3.2 Counting Cell Wiping

When the surface of counting cell is dirty, it is need to wipe it clean. Click <Clean Zone>;

the objective will turn to the wiping position. Then use cotton swabs to wipe off the stains on the surface of counting cell. Close the Maintain window; the objective will reset automatically.

5.4 Record

Click <Manage> → <Maintain> → <Log> to enter the Reagent interface.

Errors and prompts appearing during running of the instrument are recorded to facilitate maintenance and timely troubleshooting of the instrument.

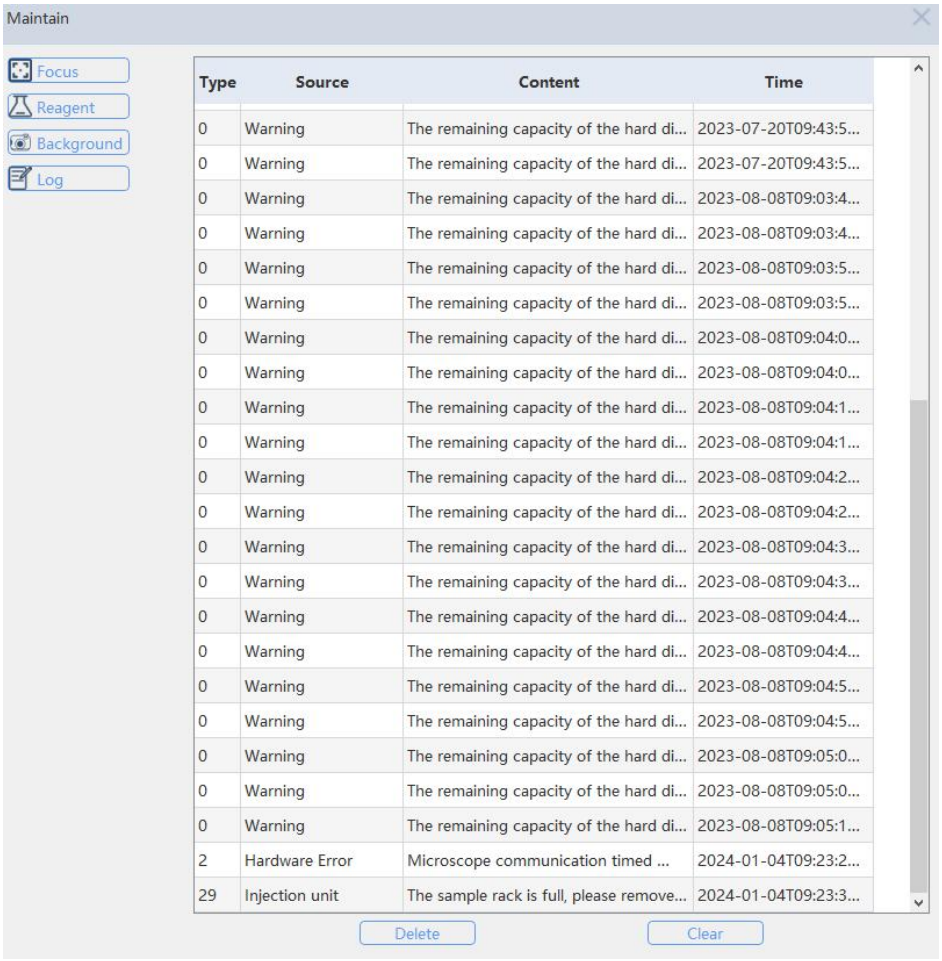


Fig. 5-4 Log

Errors and prompts appearing during running of the instrument are recorded to facilitate maintenance and timely troubleshooting of the instrument.

5.5 Shoot Parameters

Click <Manage> → <Options> → <Shooting Related> to enter the Shoot Parameter interface.

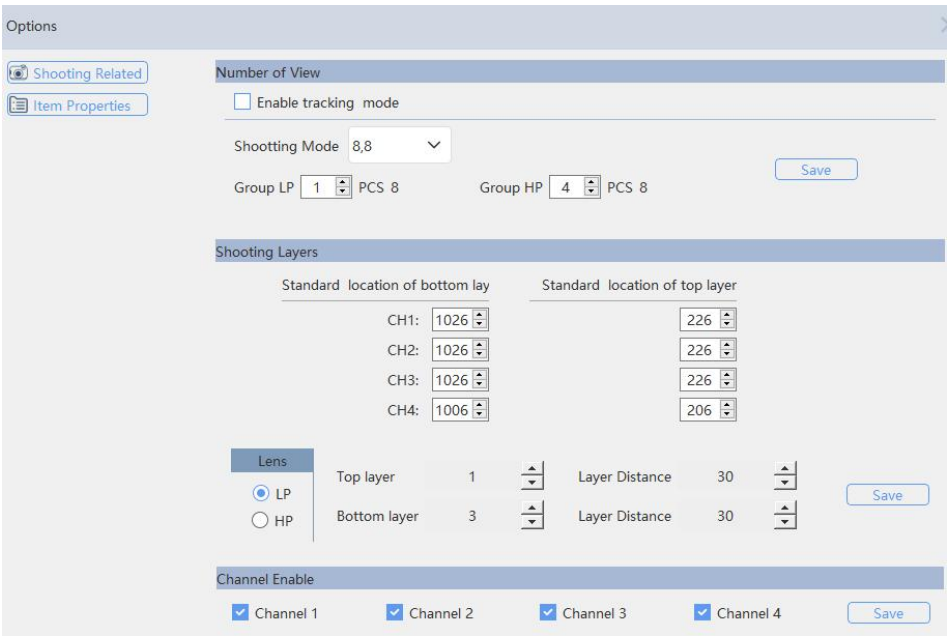


Fig. 5-5 Shoot Parameter Settings

5.5.1 Number of Views

- Set the number of images for objective A and objective B as needed and then click <Save>.
- You can choose to or not to enable the tracking mode.

5.5.2 Shooting Layers

Set the shooting layers and layer space for objective A and objective B as needed.

5.5.3 Enable Channels

Select the counting cell channel to be used by ticking.

5.6 Item Parameters

Click <Manage> → <Options> → <Item Properties> to enter the Item Parameter interface.

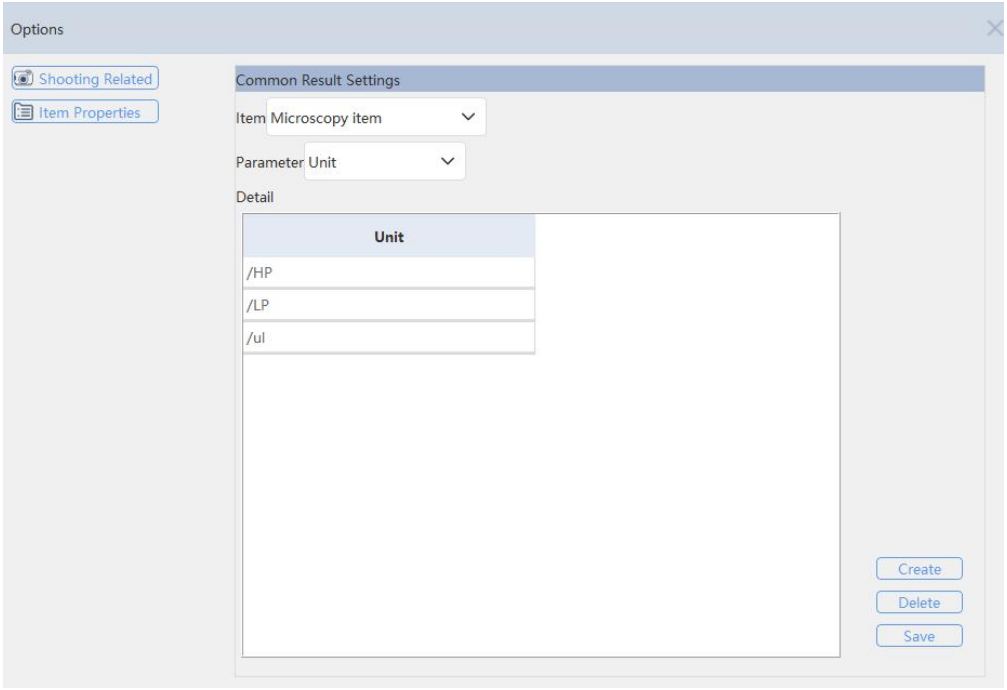


Fig. 5-6 Item Parameter Settings

- In "Common Results", you can choose to view the microscopy items, colloidal gold items, microscopy results, colloidal gold results, formed element of QC and colloidal gold of QC.
- You can "Add" or "Delete" item parameters.

5.7 Routine Maintenance of Instrument

According to the maintenance requirements, we divide the preventive maintenance schedule for the instrument to daily, weekly, quarterly and yearly routine maintenance, and targeted maintenance should be carried out according to actual needs.

⚠ NOTE

- If a standard maintenance plan is not implemented properly, failure of the instrument could be caused.

⚠ NOTE

- During maintenance, the operator must wear clean gloves.

5.7.1 Daily Maintenance

- Channel Washing

The instrument will automatically wash channels with diluent every time it is turned on,

and can perform channel washing several times if necessary.

- Maintenance

After the time of each normal shutdown, the instrument will perform channel maintenance with cleaning solution. If the instrument is not shut down or is shut down forcibly, it will not perform channel maintenance.

5.7.2 Weekly Maintenance

- Carry out manual focusing of the microscope once a week and maintenance of the microscope twice a week;
- Remove and clean any stain on the surface of the instrument on a weekly basis, especially possible residual stain at the sampling position and around the sampling probe, in order to prevent mildew and contamination;
- Remove the dust on the surface of counting cell every week.

⚠ NOTE

- It is forbidden to use corrosive acid, alkali or highly volatile organic solvents (e.g., acetone, diethyl ether, trichloromethane) to wipe the surface of the instrument; only use neutral detergents.

5.7.3 Monthly maintenance

Because the iodine staining solution has a staining and corrosive effect on the tube, it is necessary to replace the peristaltic pump tube when the sample volume of the iodine staining solution has a large deviation or monthly maintenance.

Procedure to find the iodine staining solution sample volume:

1. When creating a new iodine staining mode test sample, change the diluent volume to 0, put the empty specimen collection cup into the sample rack, and click to start the iodine staining mode test.

2. The specimen collection cup is not added diluent, so the liquid remaining in the cup is

iodine staining solution.

3. Weighing the specimen collection cup, subtract the weight of the empty specimen collection cup, which is the weight of iodine staining solution.

4. For ρ is the density of the iodine staining solution, it is close to the density of water 1g/ml. Calculate the volume of the iodine staining solution v=m/ρ

5. If the volume added deviation exceeds 20%, consider to replace the peristaltic pump tube.

During monthly maintenance, the peristaltic pump pipeline needs to be replaced. Peristaltic pump position show as below.

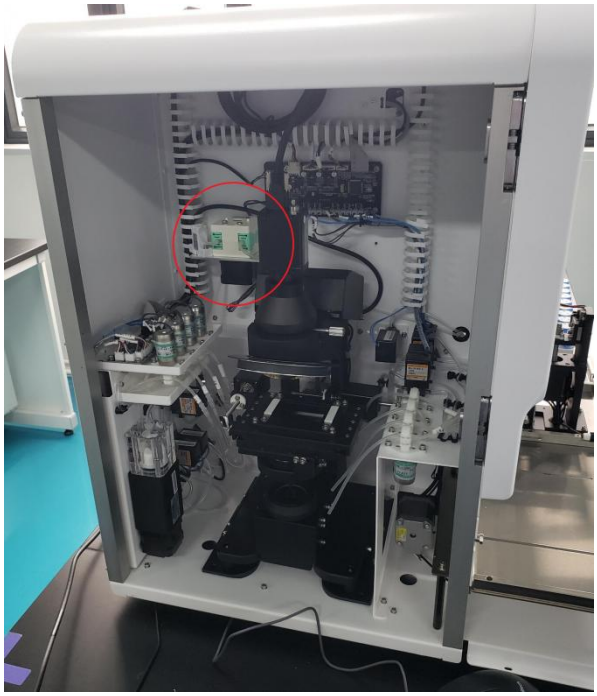


Fig. 5-7 Peristaltic pump position

Fig. 5-8 Peristaltic pump

The replacement procedures are as follows:

1. Exit the KU-F50 software normally, and the instrument will automatically empty the iodine staining solution tube
2. Press the emergency stop button, the circuit board will be disconnect
3. Unplug the peristaltic pump tube(Two end)

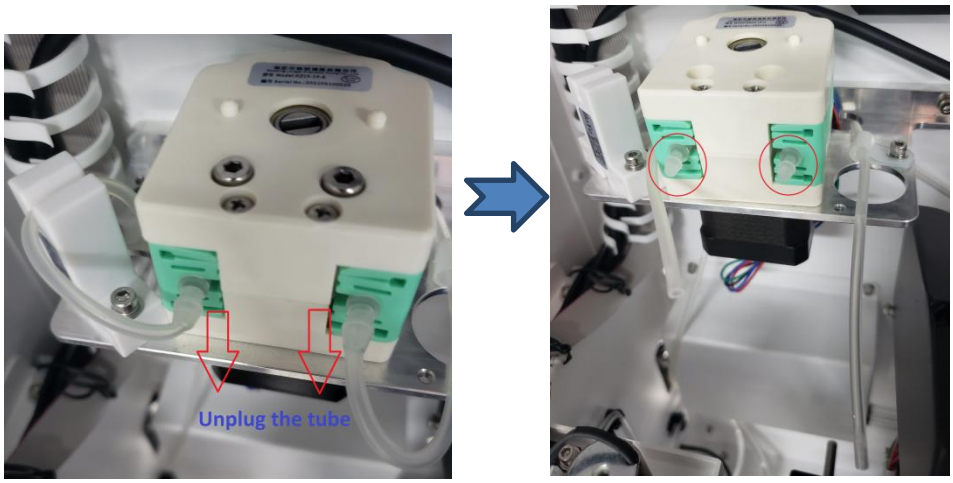


Fig. 5-9 The tubes connecting to peristaltic pump

4. Use the hexagon socket screwdriver to unscrew the fixing screw of the peristaltic pump

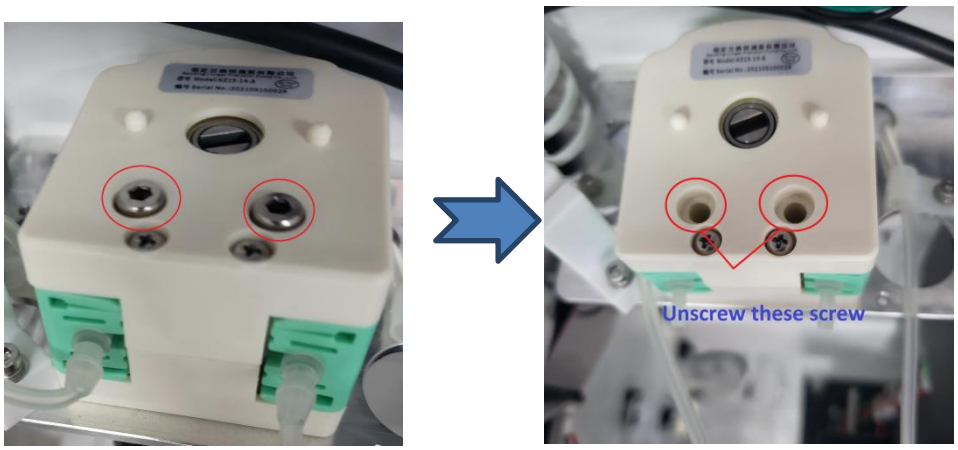


Fig. 5-10 Peristaltic pump screw

5. Take the peristaltic pump fixing piece apart

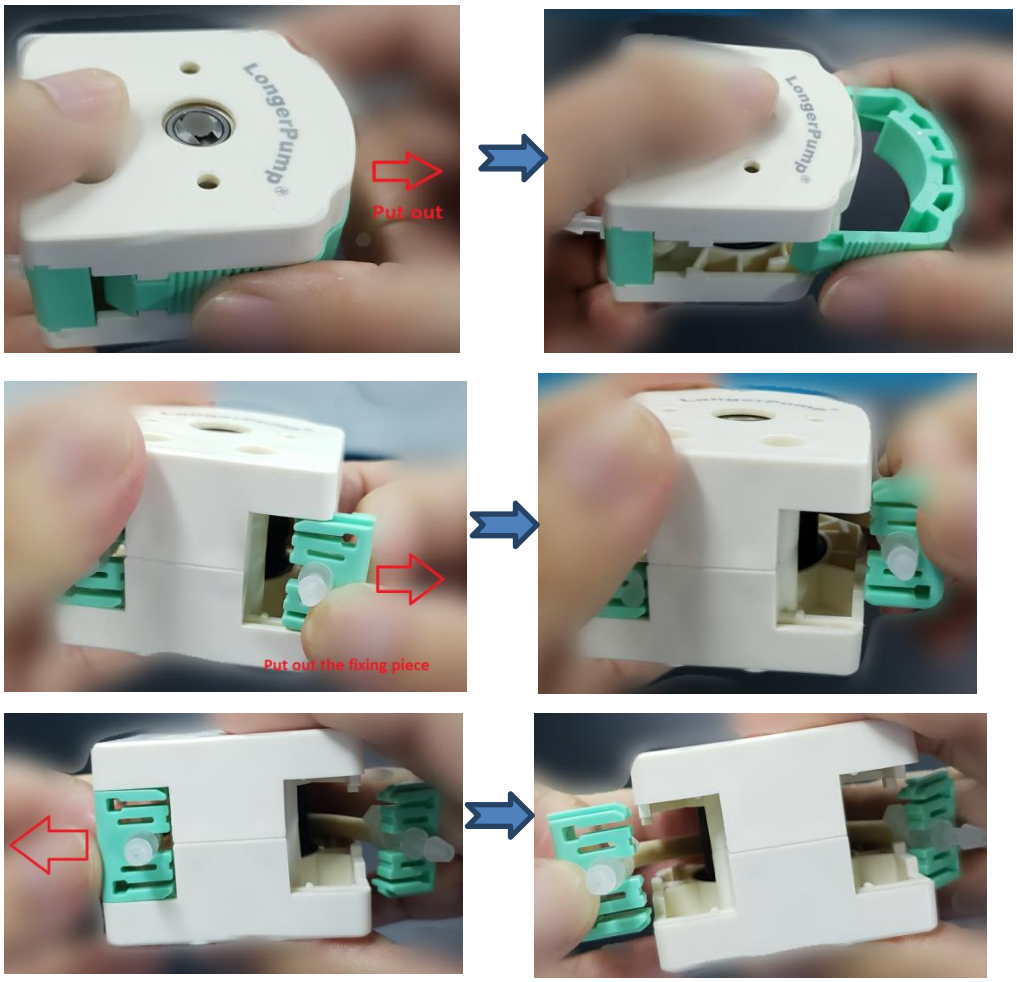


Fig. 5-11 Peristaltic pump fixing piece

6.Take out the peristaltic pump tube

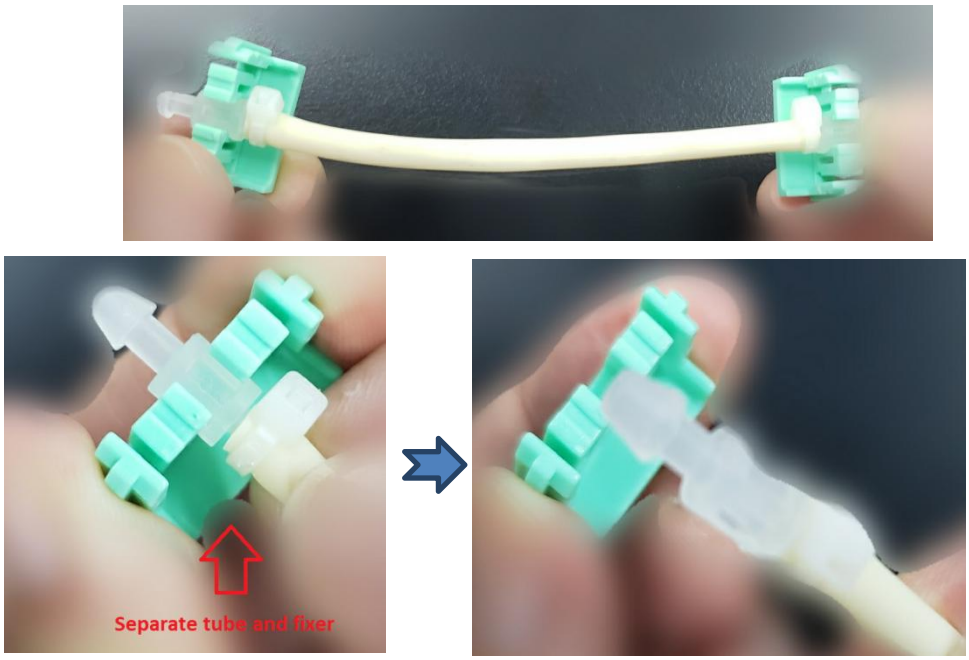


Fig. 5-12 Peristaltic pump tube

7. Replace the peristaltic pump tube

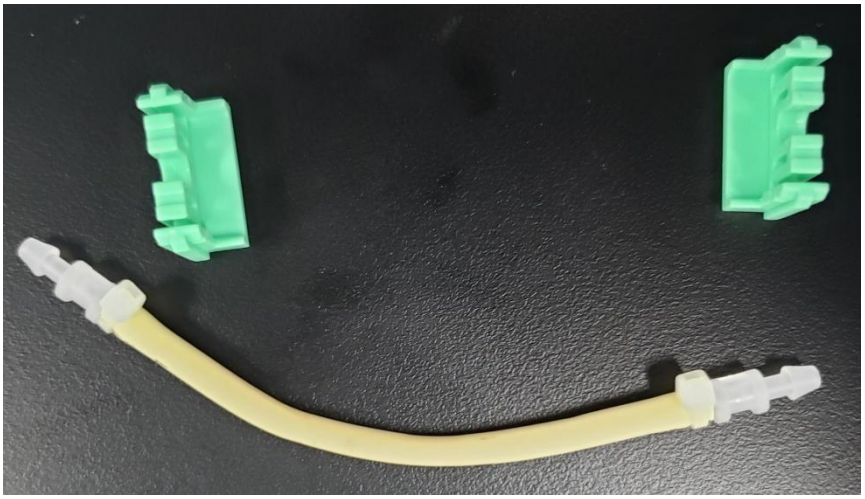


Fig. 5-13 Replace peristaltic pump tube

8. Install the peristaltic pump fixing piece
9. Install the peristaltic pump fixing screws with the hexagon socket screwdriver
10. Cut off the pipe joints at both ends by about 5mm, and connect the pipes at both ends of the peristaltic pump pipe.

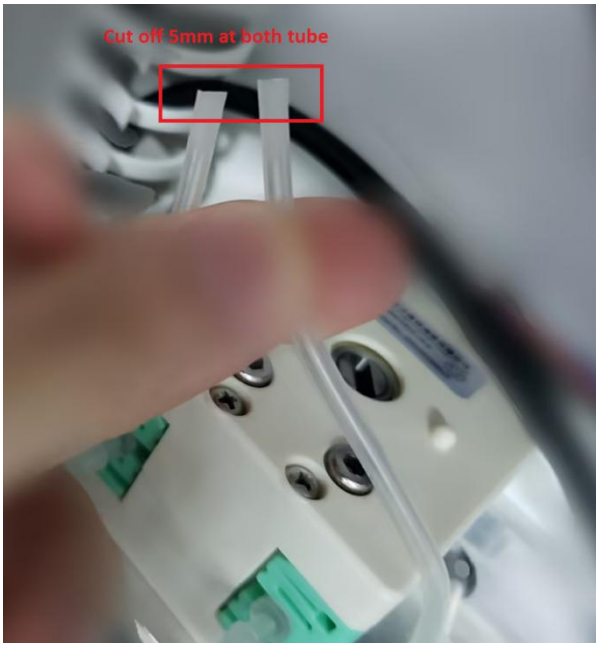


Fig. 5-14 Cut off tubes before plug in to peristaltic pump

5.7.4 Quarterly Maintenance

Remove the dust inside the instrument on a quarterly basis.

5.7.5 Yearly Maintenance

Good yearly maintenance is quite necessary to keep the best operating state and extend the service life of the instrument. Since yearly maintenance work is highly demanding, it should be carried out by engineers with KEYU's authorization. Please contact KEYU prior to yearly maintenance.

5.8 Maintenance of Instrument

5.8.1 Cleaning of Instrument

The surface of the instrument should be wiped with a soft cloth on a regular basis.

⚠ NOTE

- Do not use chemicals or organic solution for wiping. Dust in gaps can be removed with wet cotton swabs.
- Please turn off the power before cleaning, and do not wipe with a damp soft cloth to prevent water from entering the gaps of the

equipment, etc.

5.8.2 User Protection

The instrument is provided with safety design; when a fault occurs, the instrument will provide three-level protections to ensure safety. First, normal operating ranges are set in the software; second, the circuit design guarantees the operation will not exceed the valid values; last, the fuse will cut off the power supply. The instrument is designed in a way that its reliable operation can be guaranteed.

5.8.3 Instrument Protection

The instrument should not be turned on/off frequently; wait for at least 30s before turning it on again.

Do not turn off the power of the instrument directly. The instrument is equipped with a 2A fuse to protect it.

5.8.4 Fuse Replacement

When the fuse is damaged, you can replace it as follows: turn off the power of the instrument, disconnect the power cord from the power socket, use a slotted screwdriver to force the cover of the fuse box open, replace the fuse (fuse type: F2AL250V), and then close the cover of the fuse box.

⚠ NOTE

- Take care to avoid electric shock.

5.8.5 Pipe Maintenance

The pipes of the instrument are silicone hose. After one year of normal running, all connecting pipes inside the instrument should be inspected. If any problem such as aging, serious deformation or cracking is found, the pipe should be replaced promptly to avoid leakage of liquid caused thereby.

Check the condition of the silicone hose at the electromagnetic pinch valve. If any

adhesion of the silicone hose has been caused by long-term work, please change the pinch-off position of the electromagnetic pinch valve slightly. In case of serious adhesion, the silicone hose should be replaced promptly.

⚠ NOTE 

- In order to prevent pipe aging or blockage which may result in pipe burst and environmental pollution, please check and replace pipes regularly.

⚠ NOTE

- To replace a pipe, the operator must wear clean and dust-free gloves.

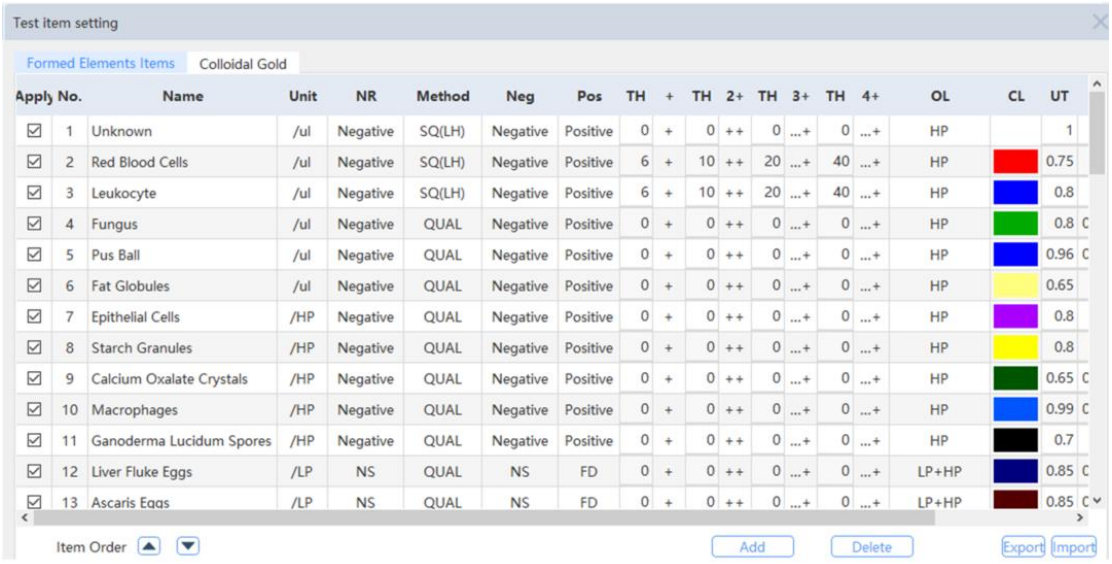
⚠ NOTE

- All reagents are used for in vitro tests; in case of contact with your eyes or skin, rinse with plenty of running water.

Chapter 6 Setting

6.1 Set Formed Element Items

Click <Manage> → <Items> to go to the Formed Element Items interface.



Apply	No.	Name	Unit	NR	Method	Neg	Pos	TH	+	TH	2+	TH	3+	TH	4+	OL	CL	UT
☑	1	Unknown	/ul	Negative	SQ(LH)	Negative	Positive	0	+	0	++	0	...+	0	...+	HP		1
☑	2	Red Blood Cells	/ul	Negative	SQ(LH)	Negative	Positive	6	+	10	++	20	...+	40	...+	HP		0.75
☑	3	Leukocyte	/ul	Negative	SQ(LH)	Negative	Positive	6	+	10	++	20	...+	40	...+	HP		0.8
☑	4	Fungus	/ul	Negative	QUAL	Negative	Positive	0	+	0	++	0	...+	0	...+	HP		0.8
☑	5	Pus Ball	/ul	Negative	QUAL	Negative	Positive	0	+	0	++	0	...+	0	...+	HP		0.96
☑	6	Fat Globules	/ul	Negative	QUAL	Negative	Positive	0	+	0	++	0	...+	0	...+	HP		0.65
☑	7	Epithelial Cells	/HP	Negative	QUAL	Negative	Positive	0	+	0	++	0	...+	0	...+	HP		0.8
☑	8	Starch Granules	/HP	Negative	QUAL	Negative	Positive	0	+	0	++	0	...+	0	...+	HP		0.8
☑	9	Calcium Oxalate Crystals	/HP	Negative	QUAL	Negative	Positive	0	+	0	++	0	...+	0	...+	HP		0.65
☑	10	Macrophages	/HP	Negative	QUAL	Negative	Positive	0	+	0	++	0	...+	0	...+	HP		0.99
☑	11	Ganoderma Lucidum Spores	/HP	Negative	QUAL	Negative	Positive	0	+	0	++	0	...+	0	...+	HP		0.7
☑	12	Liver Fluke Eggs	/LP	NS	QUAL	NS	FD	0	+	0	++	0	...+	0	...+	LP+HP		0.85
☑	13	Ascaris Eggs	/LP	NS	QUAL	NS	FD	0	+	0	++	0	...+	0	...+	LP+HP		0.85

Fig. 6-1 Formed Element Items Settings

- The instrument can set test items easily, including Add, Modify and Delete. To enable an item, tick <Apply>; this item will be tested during microscopy.
- Set gradient thresholds: for each item, you can set the gradient thresholds of level "+", "++", "+++" and "++++". If the maximum microscopy value of an item is lower than level "+", the result of this item will be reported in the form of xx-xx /HP or xx-xx /LP; if the maximum microscopy value is higher than any of the four levels, the result of this item will be reported in the form of "+", "++", "+++" or "++++".
- Negative: The expression when the item result can be set to Negative in the list.
- Positive: The expression when the item result can be set to Positive in the list.
- Color: The color of item can be set in the list; both the reminder and marks for the item will be shown in this color.

6.2 Set Colloidal Gold Items

Click <Manage> → <Items> to go to the Colloidal Gold Items interface.

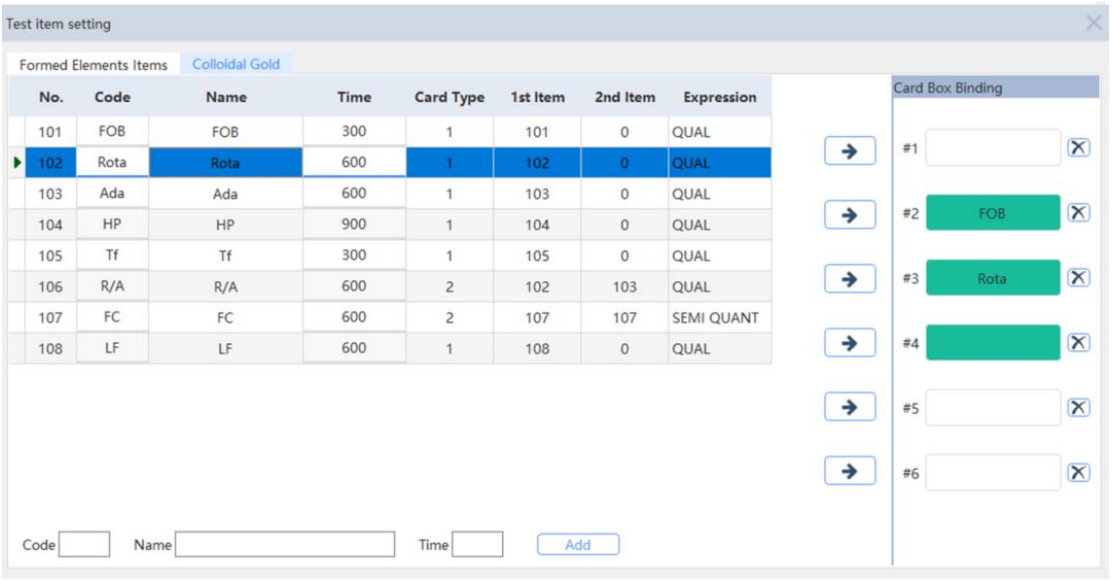


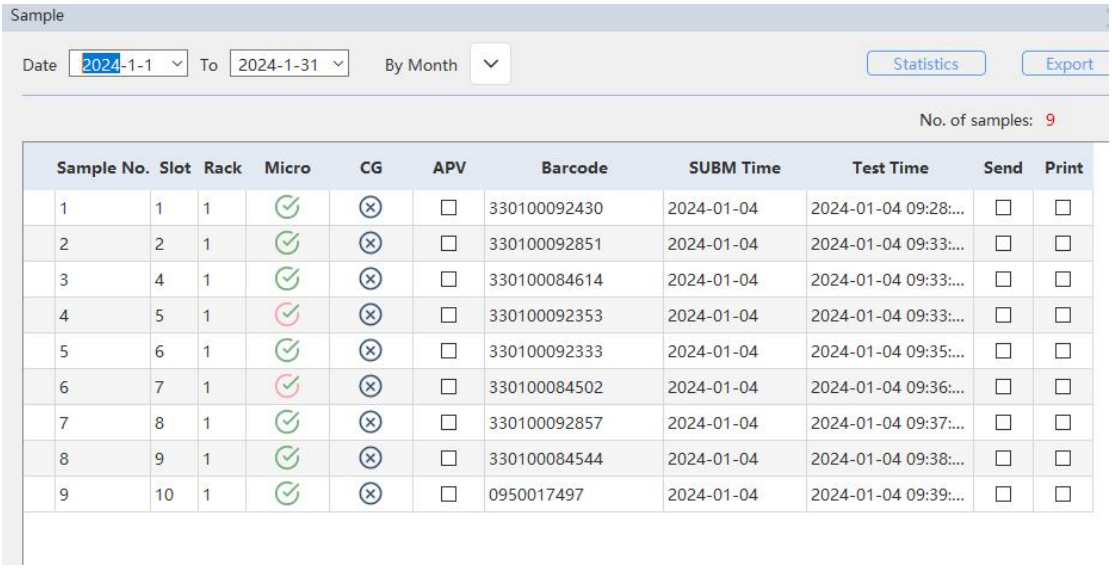
Fig. 6-2 Colloidal Gold Items Settings

⚠ NOTE

- Do not use the colloidal gold test reagent cards from any other manufacturer or of any other size, as they may cause failure of the instrument.
- You can add Fecal Occult Blood, Rotavirus, Adenovirus and Helicobacter Pylori as colloidal gold items.
- When selecting a colloidal gold item, user can click → under No. 1 to No. 6 card box to enable this colloidal gold item, and then place the relevant card in the corresponding card box position.
- Click ✕ to disable this item.

6.3 Sample Manage

Click <Manage> → <Samples> → to enter the Sample Manage interface.



Sample No.	Slot	Rack	Micro	CG	APV	Barcode	SUBM Time	Test Time	Send	Print
1	1	1	✓	⊗	☐	330100092430	2024-01-04	2024-01-04 09:28:...	☐	☐
2	2	1	✓	⊗	☐	330100092851	2024-01-04	2024-01-04 09:33:...	☐	☐
3	4	1	✓	⊗	☐	330100084614	2024-01-04	2024-01-04 09:33:...	☐	☐
4	5	1	✓	⊗	☐	330100092353	2024-01-04	2024-01-04 09:33:...	☐	☐
5	6	1	✓	⊗	☐	330100092333	2024-01-04	2024-01-04 09:35:...	☐	☐
6	7	1	✓	⊗	☐	330100084502	2024-01-04	2024-01-04 09:36:...	☐	☐
7	8	1	✓	⊗	☐	330100092857	2024-01-04	2024-01-04 09:37:...	☐	☐
8	9	1	✓	⊗	☐	330100084544	2024-01-04	2024-01-04 09:38:...	☐	☐
9	10	1	✓	⊗	☐	0950017497	2024-01-04	2024-01-04 09:39:...	☐	☐

Fig. 6-3 Samples

In this interface, you can view the statistics of test items completed on the selected date, or export files.

6.4 Camera

Click <Manage> → <Camera> → to enter the Camera interface.

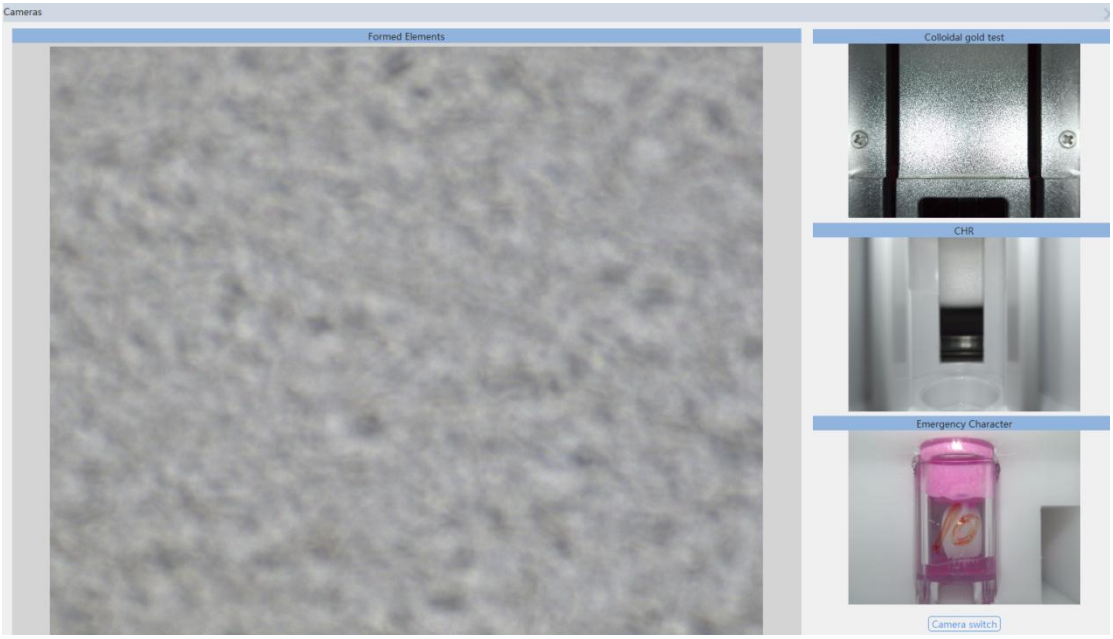


Fig. 6-4 Camera

In this interface, you can observe the colloidal gold image, character image and formed element image.

Chapter 7 System Manage

For management of operators, submission departments and submission physicians.

7.1 User Manage

Click <Manage> → <System> → to enter the User Manage interface.

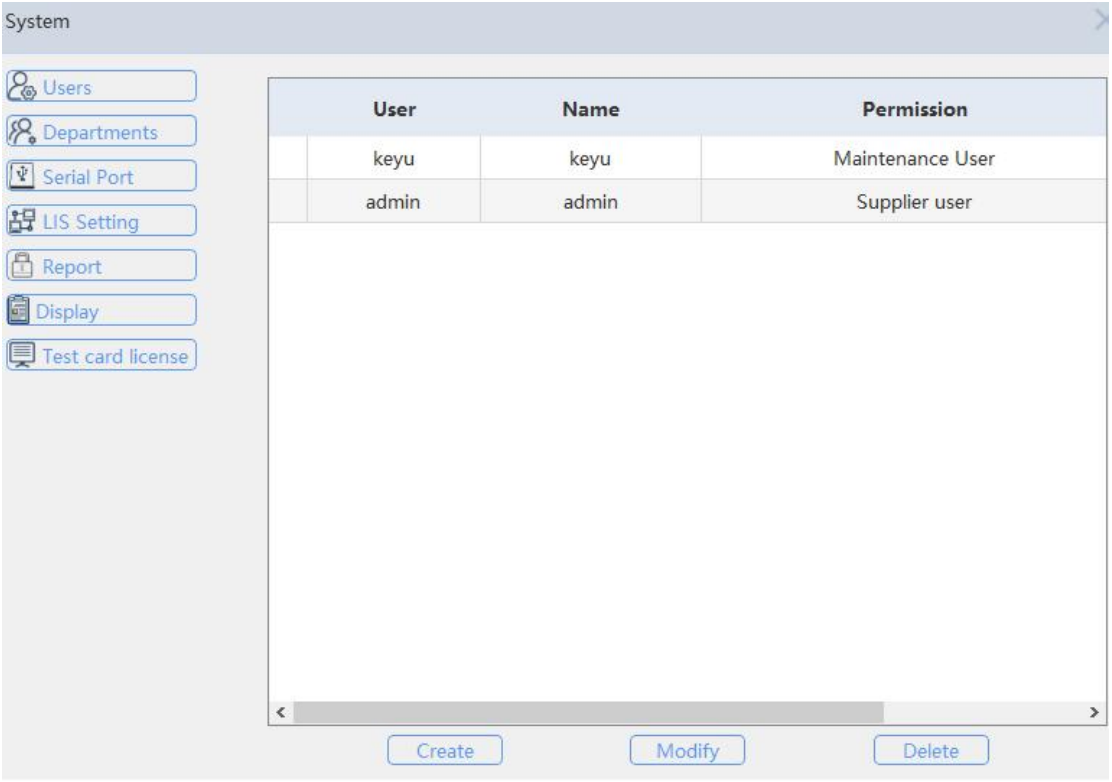


Fig. 7-1 User Manage

Username —— The name you need to use for login.

Name —— The operator's name.

Password —— Set your login password.

Permission——There are two user groups for system settings: "Advanced User" and "General User". Advanced User can use all functions, and General User cannot perform system settings and does not have the permission of adding/deleting users.

- Advanced User can add, modify and delete users.
- General User can modify his/her own password.

7.2 Dept. Manage

Click <Manage> → <System> → to enter the Department Manage interface.

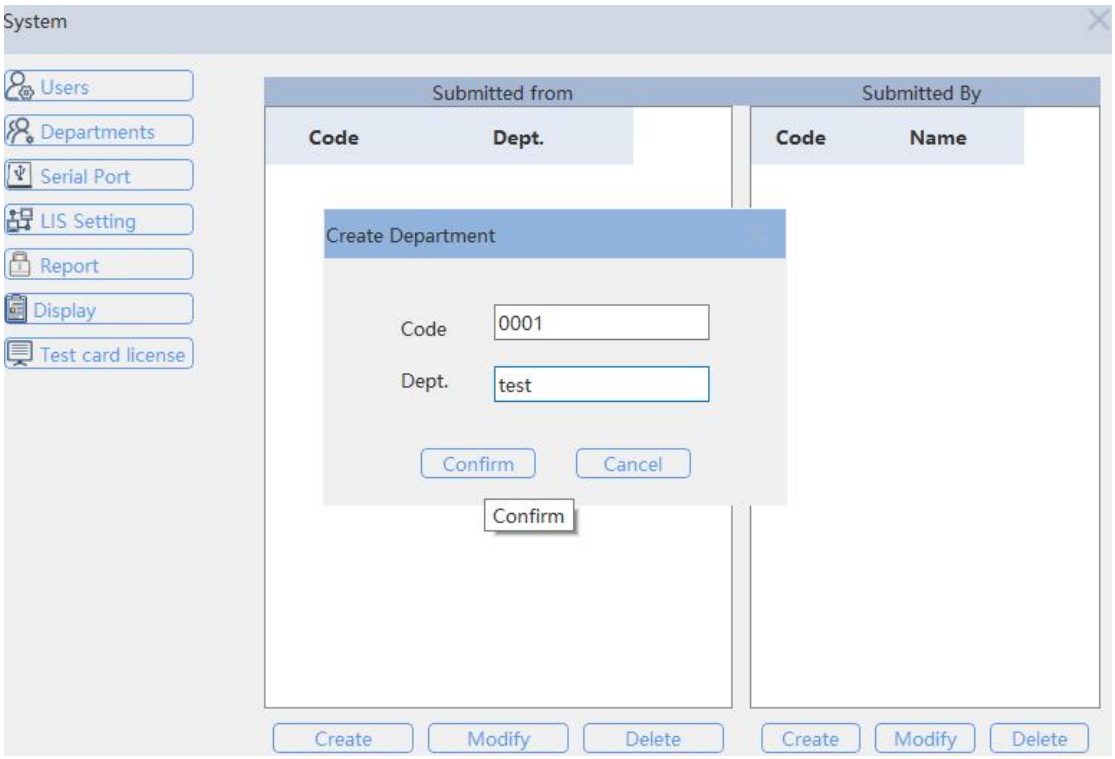


Fig. 7-2 Departments Manage

In the Department Manage interface, you can set the code and name of the submission department and submission physician. You can also add or delete common submission departments and submission physicians.

7.3 Port Manage

Click <Manage> → <System> → to enter the Port Manage interface.

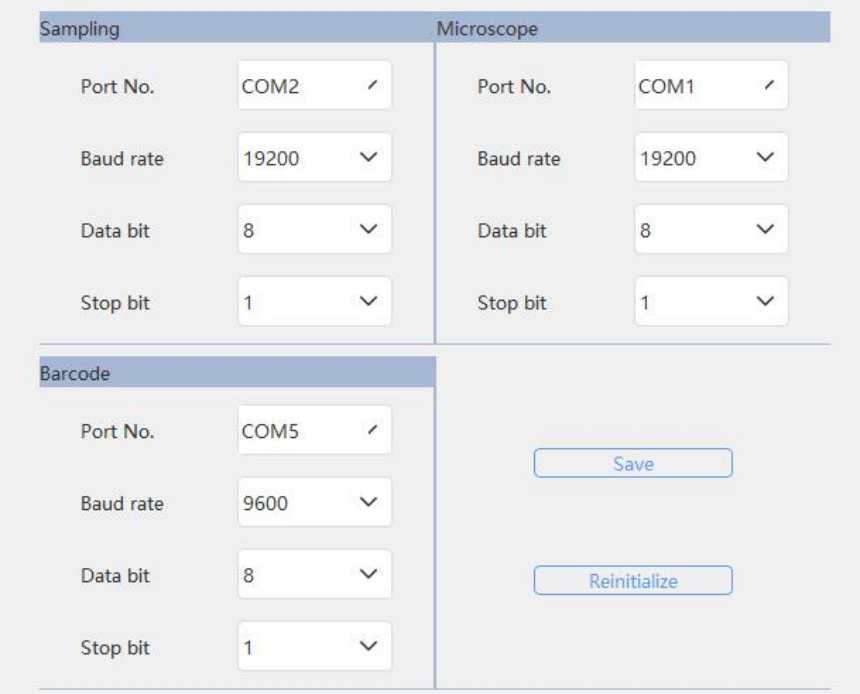


Fig. 7-3 Serial Port Manage

7.3.1 Port Settings

- Sampling port: set the communication port of sample pretreatment.
- Microscope Port: For setting the microscope communication port.
- Barcode port: set the communication port of barcode.

7.3.2 Port Parameters

1) User a crossover cable for connection, and set the parameters as follows.

Port No.	Com1	The default is Com1, and it is configurable.
Baud Rate	19200	The default is 19200, and it is configurable.
Databits	8	The default setting is not configurable.
Parity	none	The default setting is not configurable.
Stopbits	1	The default setting is not configurable.

2) Operation steps

a) Use the serial port cable to connect the instrument with the LIS server.

b) Launch the software control program of the instrument

c) Click <Save>.

d) Set the output port and baud rate under Port Output; please avoid conflicting with other ports.

Note: Due to the limitation of port output speed, images will not be sent under Port Output by default.

7.4 LIS Comm Manage

The port for connection between the instrument and LIS is developed based on HL7 Version 2.4. This port supports Single-way or Two-way communication. The LIS server can receive test data from the Feces Analyzer and also send sample request information to the Feces Analyzer. For detailed description of the port, see the *LIS Protocol Interface Manual*.

To facilitate connection with the LIS, the instrument can use serial communication protocol or TCP/IP communication protocol to connect the LIS server.

Click <Manage> → <System> → to enter the LIS Comm Manage interface.

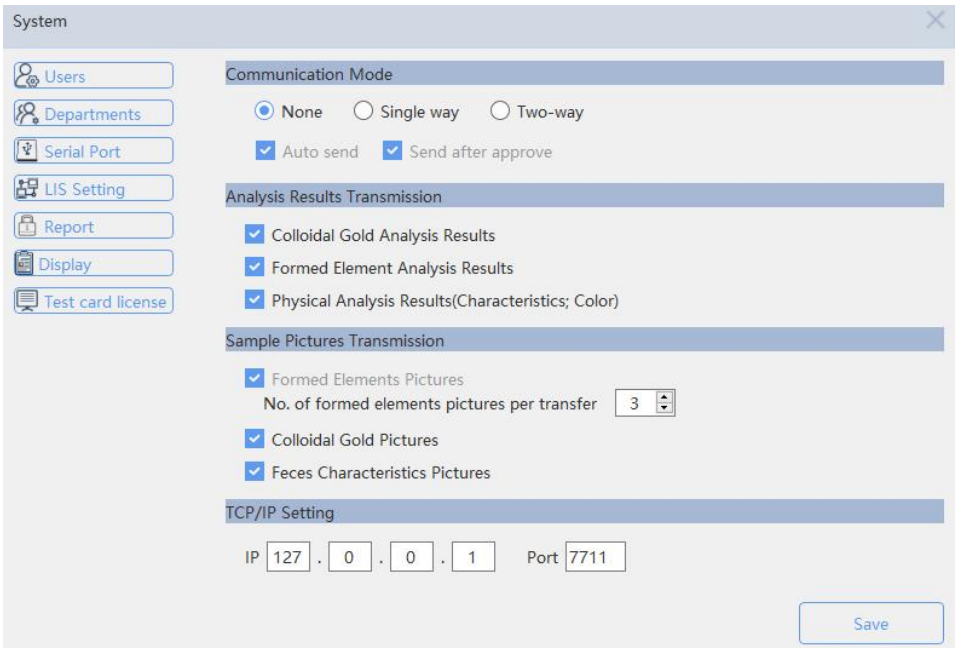


Fig. 7-4 LIS Setting

7.4.1 TCP/IP

1) Operation steps

a) Use the network cable to connect the RJ45 port of the instrument with the LIS server.

b) Launch the software control program of the instrument.

c) Click <Communication Mode> to select one-way or two-way communication.

d) You can tick <Auto Send>, <Send after Review> and <Send Images>.

e) Select <Network Port Output>.

f) Set the IP address and port of LIS server under Network Port; note that the server port should be consistent with the client port.

7.4.2 Result Sending

After ticking <Auto Send> in the Settings interface, click <Approve> below the Sample List or <Approve> in the Review interface to send results automatically. Also, user can click <Send> to send results manually.

⚠ NOTE

- For sample request information sent by the LIS server, only setting of colloidal gold test items is supported; formed element items can be set only on the instrument.
- During duplex communication, number of colloidal gold items are 1, 2, 3... from the top down according to the sequence in the Colloidal Gold Item List shown in Fig. 6-2.
- When the Feces Analyzer is set as One-way, the instrument will only send the test results and ignore any LIS messages received.

7.5 Setting of binding colloidal gold method license

It can be done by the following two ways.

7.5.1 Binding before inspection

Enter <Managerment>→<System>→<Test card license> interface, as shown in Fig. 7-5.

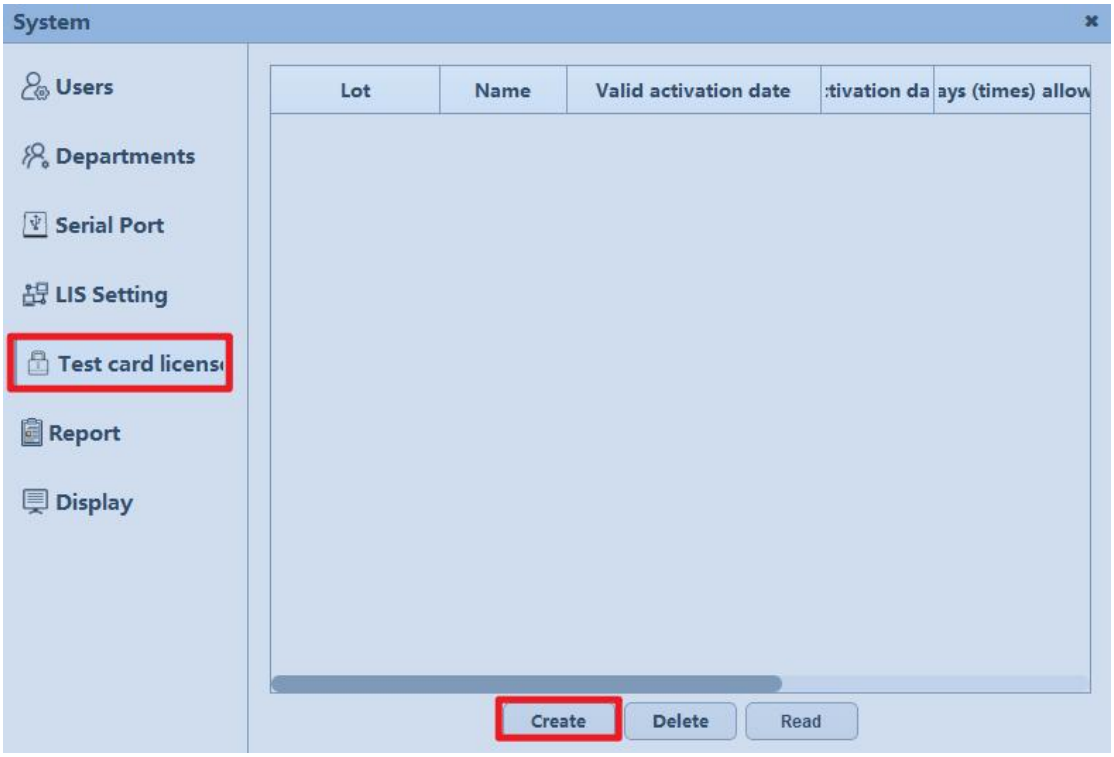


Fig. 7-5 Test card license information interface

Click the <Create> button in the Fig. 7-5 to pop up the colloid gold card license setting interface; input the QR code in the field of "license serial number" with the external scanning gun to read the information of QR code on the packag. The software will analyze the type of the colloidal gold card and durability period in the QR code automatically,as shown in Fig. 7-6.

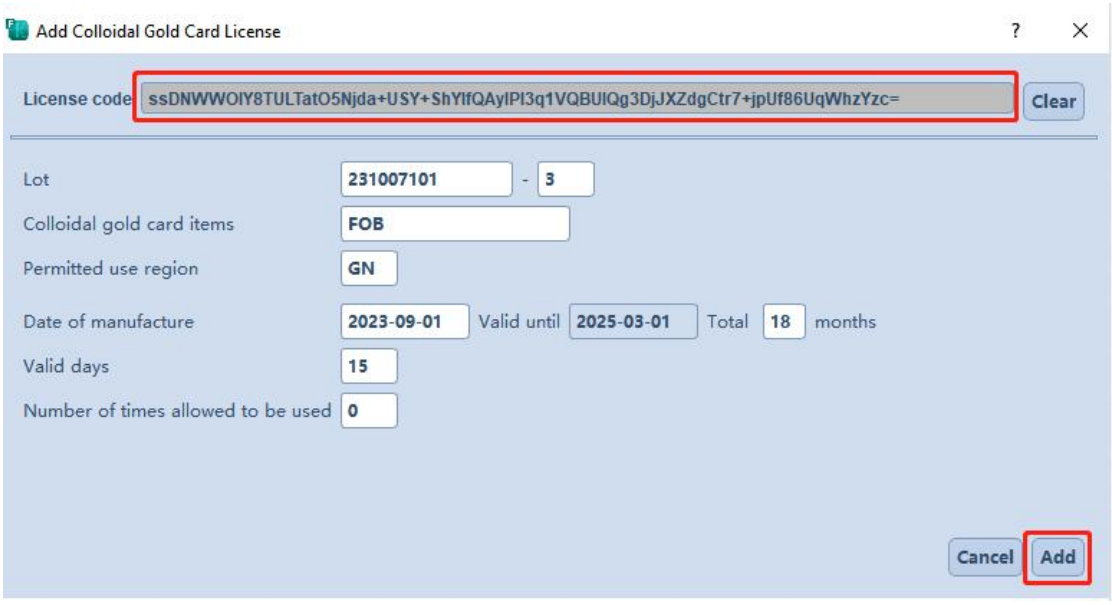


Fig. 7-6 Input colloidal gold card license interface

After input the license code, click the <add> button to finish the binding (Repeat the steps 1 to 3 to add the other kinds of colloidal gold card QR information.

7.5.2 Binding during inspection:

During the inspection, if there’ s no valid license for one kind of colloidal gold card, the instrument will pop up the indication of colloidal gold card that needs the license automatically (for example: Fecal occult Blood), as shown in Fig. 7-7.

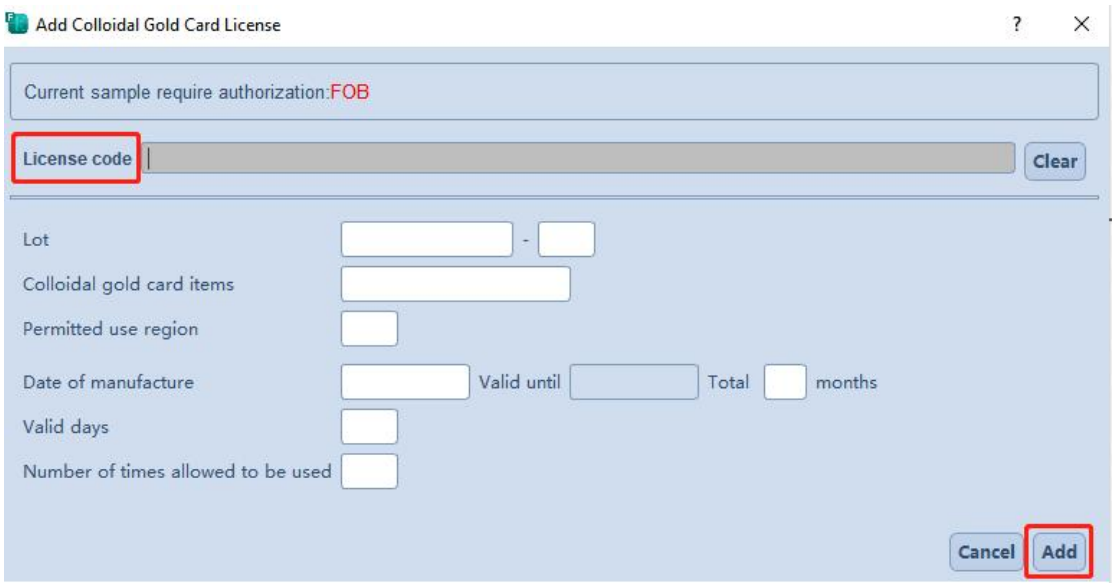


Fig. 7-7. Colloidal gold card pending for license interface

Input QR code in the field of "License code" with the external scanning gun to read the QR code information on the packag. Then click <add> to continue the inspection.

⚠ WARNING

- Only one valid QR code can be input for one kind of colloidal gold card at the same time.
- The license takes effect in the allowed-to-use days. After the number of days of allowed-to-use exceeds, the license that has not been used within the validity period should be re-input.

7.6 Report Format

Click <Manage> → <System Manage> → to enter the Report Format interface.

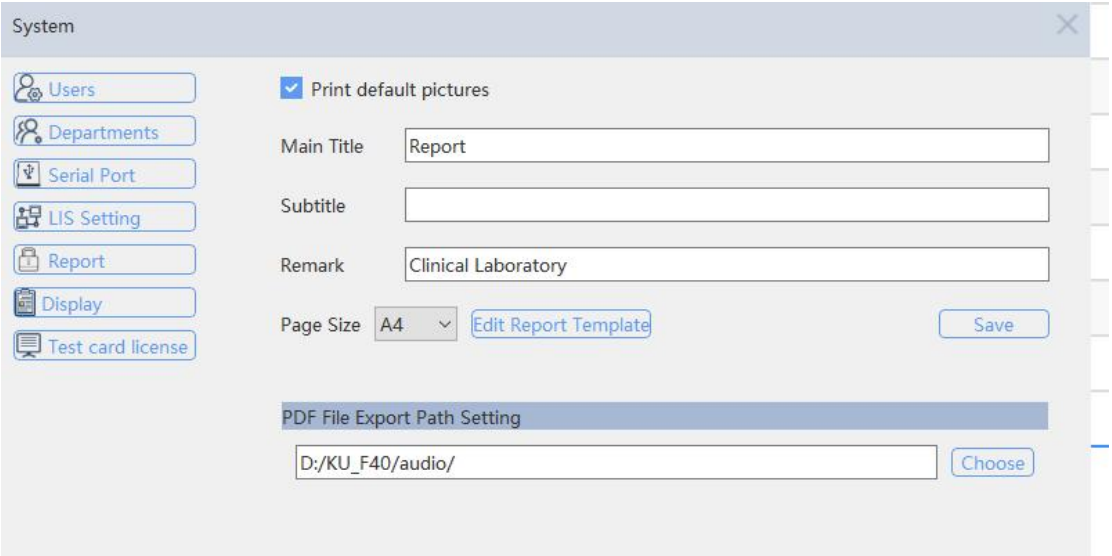


Fig. 7-8 Report Format

Set the report format of the instrument.

- Print default images —— During review and confirmation, default images will be selected automatically for printing.
- Main Title —— For setting the title of report, such as Feces Analysis Report.
- Subtitle—— For setting the subtitle of report.
- Remark —— For setting the Note column in the report.
- Page Size —— Select the format of report.
- PDF File Export Path Setting: set the path to save PDF file.

7.7 Display Settings

Click <Manage> → <System Manage> to go to the Display Settings interface.

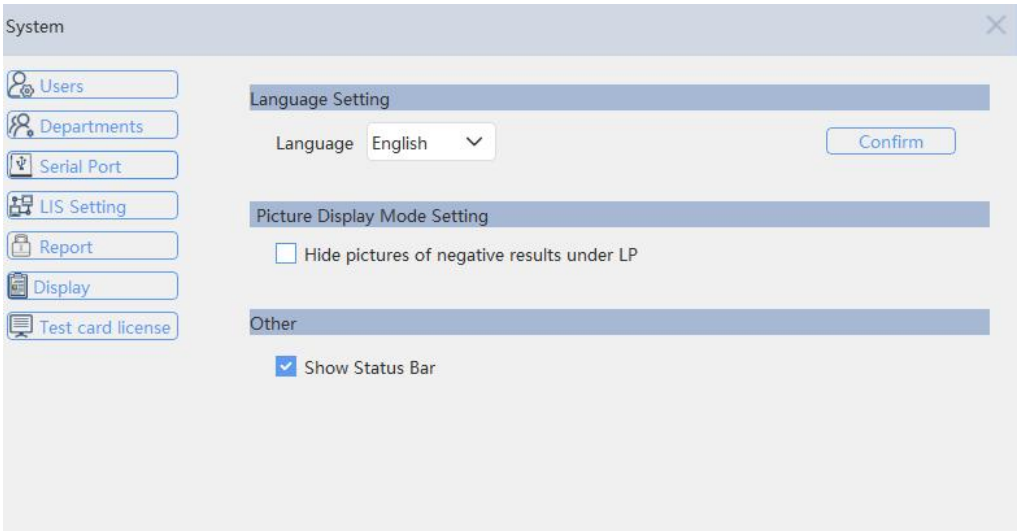


Fig. 7-9 Display Settings

- Set language: select Chinese or English and then click "OK".
- You can choose to or not to show the status bar.

Chapter 8 Troubleshooting

This chapter gives the list of common faults of the instrument and corresponding solutions. When the instrument malfunctions, the operator can perform troubleshooting according to the alarm message generated by the instrument.

If you cannot solve the problem or needs more technical support, please call our After-sales Service Department.

8.1 Troubleshooting Guide

The Troubleshooting Guide is specially designed for assisting user in finding and eliminating faults occurring during operation of the instrument. In order to accurately and quickly find and eliminate faults, please first carefully read this manual to know normal operation and preventive maintenance of the instrument.

Generally, troubleshooting should follow the three steps below:

Step 1: Confirm the fault

The operator should identify the cause of the fault before trying to eliminate it.

Step 2: Classify the fault

Basically, faults of the instrument can be classified into the following three types:

1. Faults related to hardware.

2. Faults related to software.

3. Test failures related to sample analysis.

In case of faults related to hardware and software, the instrument can be repaired only by qualified engineers of or authorized by KEYU. Test failures related to sample analysis can be eliminated by the operator under the guidance of KEYU's engineer.

Step 3: Eliminate the fault

Our service engineer will take proper measures to eliminate the fault. If the operator can eliminate the fault by himself/herself under the help of KEYU's engineer, there will be much less time delayed.

8.2 Seek Technical Support

If KEYU’s technical support is needed when the instrument malfunctions, please call our After-sales Service Department; see Copyright and Statement for the phone number and fax. When seeking technical support, please provide a detailed and clear description of the problem and relevant information as follows:

1. Model of the instrument.

2. SN on the instrument.

3. A detailed description of the fault symptom and operating environment (for example, what operation is performed under which window and in what status).

4. Data and report related to the fault.

8.3 Precautions for Operations before Repair and Disposal

When the instrument use is stopped due to repair or disposal, user should operate according to the following steps:

1. Take out all unused sample collection cups and gold-labeled cards.

2. Samples in unused sample collection cups should be manually tested according to the hospital's regulations.

3. Unused gold-labeled cards should be sealed for storage.

4. All used sample collection cups, waste gold-labeled cards and liquid waste should be disposed of according to the local laws and regulations on disposal of medical wastes.

5. cleaning solution, diluent and other reagents should be stored according to the storage requirements in relevant instructions.

The above handling steps can realize the minimization of biohazards to avoid biohazards during transport or handling.

If it is needed to return the instrument to the manufacturer, after operation according to the above steps, use the original package materials to pack the instrument and send it back to the manufacturer by logistics. See the Company's process flow for details.

8.4 Faults of PC Operating System and Hardware

No.	Symptom	Possible Cause	Solution
1	The PC cannot be started.	1) Power supply is not connected.	1) Test the power cord of the instrument.
2	The PC cannot enter the system.	1) Memory failure 2) Hard disk drive failure.	1) Replace the memory. 2) Detect whether any bad track exists. If yes, first repair the bad track; if it is unrepairable, please replace the hard disk drive, and copy data to the new hard disk drive.
3	PC crash	1) Hard disk drive failure. 2) USB port failure. 3) Virus infection.	1) See the solution for No. 2 fault in this table. 2) Disconnect the plug-and-play device from the USB port, and restart the PC. 3) Upgrade the antivirus software to kill virus; if the problem remains, please reinstall or restore the operating system.
4	The PC runs slowly.	1) Virus infection. 2) Camera disconnection.	1) Upgrade the antivirus software to kill virus; if the problem remains, please reinstall or restore the operating system. 2) Check the connection.

8.5 Faults of Applied Parts of the Instrument

No.	Symptom	Possible Cause	Solution
1	Image fuzziness	1) The focal length of the microscope is not properly adjusted.	1) Adjust the focal length.
2	Stop during test	1) Reagent is used up.	1) Change the reagent and reagent card.
3	Reagent alarm	1) There is no reagent in the pipe.	1) Change the reagent and perform filling.
4	Camera initialization failure.	1) Failure of camera data cable. 2) Failure of camera drive.	1) Replace the data cable. 2) Reinstall the camera driver.
5	Motor not reset upon startup.	1) Failure of motor reset sensor.	1) Replace the sensor.
6	After sampling, the sample	1) Failure of solenoid	1) Replace the solenoid

	in the counting cell cannot become still after a long period of time.	valve at both ends of the counting cell.	valve.

Chapter 9 Prevention, Restriction and Hazards

Improper use of any instrument will result in failure to achieve the expected result or even cause injury of the operator or other persons. Therefore, before operation and use of the instrument, it is necessary to standardize the rules for use and perfect the conditions for use to prevent the occurrence of hazards and achieve the optimum operation effect of the instrument.

9.1 Restriction on Use

1) KU Series Feces Analyzer is only used for analysis to provide reference for in vitro diagnosis.

2) Any person using, moving, installing or maintaining the instrument must carefully read this manual and strictly follow the requirements specified in the manual. Otherwise, occurrence of accidents could be caused, and our free warranty will be voided.

3) Repair of the instrument must be permitted by KEYU. For replacement of any part, the part specified by KEYU should be used; otherwise, occurrence of accidents could be caused, and our free warranty will be voided.

4) Failure to carry out periodic maintenance according to the maintenance procedure described in **Chapter 5 Maintenance** of this manual will affect the measurement and analysis results and shorten the service life of the instrument, and could result in occurrence of accidents. Also, our free warranty will be voided.

9.2 Restriction on Installation

1) Initial installation must be done by qualified engineers with KEYU's authorization.

2) The instrument must be placed on a horizontal and steady workbench without exposure to direct sunlight; it should be kept away from air vents that are too cold/hot, and also away from equipment like dryers, centrifuges, X-ray equipment, copiers and ultrasonic cleaning machines.

3) The reagent should be placed at the same height as the instrument, or kept on the same plane as the instrument.

4) To maintain a good ventilation, certain space must be reserved around the

analyzer. There should be a distance of at least 40cm between the instrument and surrounding objects to facilitate ventilation. The installation surface should be flat without vibration and have an area of at least 2000mm×800mm. There should be adequate space around the instrument to facilitate repair and maintenance.

5) Before initial operation of the instrument, please confirm the following: whether the pipeline of each reagent bottle is properly and reliably connected; whether the externally connected pipe is bent, affecting smooth liquid flow; whether liquid waste is discharged to a proper container.

6) When the instrument is in power-on state, it is forbidden to unplug/plug any electrical connector of the instrument. To prevent electricity interruption and protect user's personal safety, please confirm that the earthing conductor of the instrument housing is well grounded.

⚠ NOTE

- Any person not authorized or qualified to repair the instrument shall not loosen the screws in the housing or open the door lock at any time; otherwise, user himself/herself shall be responsible for any problem arising therefrom!

9.3 Personal Protection and Infection Control

1) During sample test and routine maintenance, user must observe the laboratory requirements or the operation requirements for clinical test, and wear medical gloves and safety goggles to avoid direct contact with samples.

2) All clinical samples could contain human feces and are potentially infectious. Therefore, when handling these samples, user must observe the established laboratory or clinical operation procedure and wear work clothes, medical gloves and safety goggles. Do not smoke, eat or drink in the work area; do not blow or suck the working pipe with your mouth.

3) Since feces samples and liquid waste produced by the instrument contain potential contaminants and may have biological and chemical hazards, user shall take extreme

care during handling. Please observe the applicable regulations of the local government during cleaning, treatment and discharge.

4) Do not pour the remaining unused reagent to a new reagent tank (bottle) to prevent contamination of the new reagent.

Reagents should be stored and kept according to the instructions for use. User of the instrument is obliged to establish and maintain effective storage and requisitioning measures to prevent use of reagents, calibrators and QCs beyond their shelf-life as well as deterioration, misuse or eating by mistake of these materials. Reagents should not be stored in an environment that is too cold/hot.

9.4 Names and Contents of Toxic or Hazardous Substances in the Product

Component	Hazardous Substances					
	Pb	Hg	Cd	Cr^{6+}	PBB	PBDE
PCBA	○	○	○	○	○	○
Plastic	○	○	○	○	○	○
Metal	○	○	○	○	○	○

○: Indicates that the content of this toxic or hazardous substance in all homogeneous materials of the corresponding part meets the limit specified in SJ/T 11363-2006.

×: Indicates that the content of this toxic or hazardous substance in a homogeneous material of the corresponding part is above the limit specified in SJ/T 11363-2006.

9.5 EMC

⚠ NOTE

- KU-F50 Feces Analyzer conforms to the requirements on emission and immunity to interference as specified in GB/T 18268.1/ IEC 61326-1 and GB/T 18268.26/ IEC 61326-2-6. See table below.
- User is responsible for guaranteeing an EMC environment for the instrument so that it can work normally.
- It is suggested to evaluate the electromagnetic environment prior to use of

the instrument.

⚠ NOTE

- KU-F50 Feces Analyzer is designed and tested as a Class A device specified in GB 4824/ CISPR 11: 2016. In a home environment, this instrument may cause radio interference; therefore, protective measures should be taken.
- It is forbidden to use this instrument near sources of intense radiation (e.g., unshielded RF source), which may disturb normal operation of the instrument.

Table 1:

Electromagnetic Emissions	
Emission test	**Compliance**
GB 4824/ CISPR 11: 2016 Conducted emissions	Group 1, Class A
GB 4824/ CISPR 11: 2016 Radiated emissions	
GB 17625.1/IEC 61000-3-2: 2001 Harmonic emissions	N/A
GB 17625.2/IEC 61000-3-3: 2005 Voltage fluctuations / flicker emissions	N/A

Table 2:

Electromagnetic Immunity			
Immunity test	**Basic standard**	**Test value**	**Performance criterion**
Electrostatic discharge (ESD)	GB/T 17626.2/IEC 61000-4-2	Contact: ±2kV, ±4kV Air: ±2kV, ±4kV, ±8kV	B
RF electromagnetic fields	GB/T 17626.3/ IEC 61000-4-3	3V/m,80MHz~2.0GHz, 80%AM	A
Burst	GB/T 17626.4/IEC 61000-4-4	Power cord: ±1kV (5/50ns,5kHz)	B
Surge	GB/T 17626.5-2019/IEC 61000-4-5	Line-to-ground: ±2kV Line-to-line: ±1kV	B
Conducted RF	GB/T 17626.6/IEC 61000-4-6	Power cord: 3V/m, 150kHz~80MHz, 80%AM	A
Power frequency magnetic field	GB/T 17626.8/IEC 61000-4-8	3A/m, 50Hz	A
Voltage dips and interruptions	GB/T 17626.11/IEC 61000-4-11	1 Cycle: 0%; 5 Cycles: 40%; 25 Cycles: 70%; 250 Cycles: 5%.	B C C C

Performance criteria:

A. The performance is normal within specified limits during test.

B. The function or performance is temporarily degraded or lost during test but can be recovered automatically.

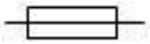
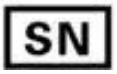
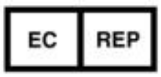
C. The function or performance is temporarily degraded or lost during test and needs operator intervention or system reset for recovery.

Appendix 1: List of Accessories

No.	Name & Specification	Total Quantity	Unit
1	Main unit of KU-F50 Feces Analyzer	1	Set
2	Monitor	1	Set
3	Wired keyboard and mouse	1	Set
4	User Manual	1	Copy
	Certificate of Conformity&Warranty Card	1	Sheet
	Morphological Image of Feces Analyzer	1	Copy
5	Fecal Sample Collection Steps Drawing of KU-F50	1	Bag
6	Operation Procedure for KU-F50 Feces Analyzer	2	Sheet
7	Maintenance Procedure for KU-F50 Feces Analyzer	2	Sheet
8	Pipe pack	1	Set
9	Accessory pack	1	Set
10	Sample rack	18	PCS
11	Sample collection cup	100	PCS
12	Gold-labeled card box kit (for 50 persons)	6	PCS
13	5L waste tank	1	PCS
14	Waste card collection box	1	PCS
15	Barcode scanner (give away)	1	Set
16	Quality control bottle sleeves	10	PCS
17	Power cord	2	PCS
18	Iodine pack	1	Set
19	Left tray (optional)	1	Set
20	Right tray (optional)	1	Set
21	Connection Bridge (optional)	1	Set

Note: Subject to the Packing List Provided with the instrument.

Appendix 2: Symbols

 **Caution, possibility of electric shock**	 **Caution**	 **Biological risks**	 **Consult instructions for use**	 **Manufacturer**
On (Power)	 **Off (Power)**	 **Earth (ground) TERMINAL**	 **Fuse**	 **Serial number**
 **In vitro diagnostic medical devices**	 **Serial port**	 **Sharp edges. Watch your fingers.**	 **Keep dry**	 **Temperature limit**
 **This way up**	 **Fragile**	 **Stacking limit by number**	 **Do not roll**	 **Network port**
~ **AC**	 **USB interface**	 **Keyboard Interface**	 **Authorized representative in the European Community**	 **CE marked according to Regulation(EU) 2017/746 In vitro diagnostic medical devices**