

Production license number:

Medical device registration certificate number:

Product technical requirement number:

Automatic fluorescence microscopic image scanning analyzer

instructions

GK-IMG1000 / GK-IMG3000 / GK-IMG5000

DeZhou GuoKe Medical Technology Co., Ltd.

Company phone: (0534) 7057266 Fax: (0534) 7057266
(0534) 7057266 Fax: (0534) 7057266

Company phone:

E-mail : office@guoke-medical.com

Web : <http://www.guoke-medical.com>

E-mail: office@guoke-medical.com

Web: <http://www.guoke-medical.com>

After-sales service hotline: 0534-7057266.

Registered person/manufacturer: Dezhou Guoke Medical Technology Co., LTD.

Registered address/production enterprise address: No.6596, Dongfanghong East Road, Yuanqiao Town, Dezhou Economic and Technological Development Zone, Shandong Province (Zhongyuan Science and Technology Innovation Park)

Workshop 2, 1st and 2nd span 28-31 axis

Registered address: No.6596, Dongfanghong East Road, Yuanqiao Town, Dezhou Economic and Technological Development Zone, Shandong Province (Zhongyuan Science and Technology Innovation Park) Workshop 2, 1st and 2nd span 28-31 axis

Production address: No.6596, Dongfanghong East Road, Yuanqiao Town, Dezhou Economic and Technological Development Zone, Shandong Province (Zhongyuan Science and Technology Innovation Park) Workshop 2, 1st and 2nd span 28-31 axis

Name of after-sales service enterprise: Dezhou Guoke Medical Technology Co., LTD

After-sales service email: office@guoke-medical.com

Call 0534-7057266 for complaints

This manual includes instructions for use and maintenance

Version number of specification: V1.0


Equipment production date: see product label

Preparation date of the specification: May 15,2025

**Please read this manual in detail before first use. If you have any questions,
please contact our after-sales service department!**

matters need attention

Use before

1. Before using this product, please read the instruction manual carefully and check whether the standard equipment is complete. Before use, the professional authorized technical personnel of the shipper shall install and debug the machine. Only after the machine runs normally, the software and hardware cooperate correctly and the debugging is qualified can it be used.
2. Where the equipment  is marked, the operator or user should consult the manual to understand the potential hazards and take measures.

In use

1. Please use it according to the factory specified method, otherwise the protection provided by the equipment may be damaged.
2. If the following abnormal conditions occur during use, please stop using immediately! Turn off the power, unplug the power plug, and consult our after-sales service center. Do not try to disassemble the product for self-repair!
 - 1) Abnormal conditions such as black smoke or odor.
 - 2) When the sharp alarm abnormal sound is issued or the indicator light does not display.
 - 3) When the liquid or foreign matter penetrates into the product and causes damage to the product.

Other precautions

- 1) All markings or hazard warnings on the equipment should be clear and complete.
- 2) Do not dismantle the equipment shell without permission.
- 3) When the product fails, individuals or untrained personnel are prohibited from forcibly disassembling or repairing the product.
- 4) Do not place heavy objects above the instrument to avoid compression deformation.
- 5) The equipment should be equipped with qualified glassware consumables when in use. The consumables after use shall not be discarded at will, but must be treated as medical waste.

- 6) This equipment is a high-precision instrument. Do not invert it during transportation, waterproof and moisture-proof, handle it gently, do not press or shake it.
- 7) Any waste generated during the use of the equipment and the disposal of the equipment at the end of its life shall be handled in accordance with relevant local laws and regulations.
- 8) This equipment has a certain automatic identification function, and the test results need to be determined by doctors according to their own professional judgment.
- 9) Regular maintenance of instrument hardware.
- 10) After the daily test, the waste slides should be poured out to avoid contamination.
- 11) The main part of the equipment is the motion mechanism. When working normally, please do not block your hands or other parts of the body to prevent affecting your own safety and equipment.
- 12) Use protective gloves when handling potentially infectious substances (e.g., samples, waste board boxes).

Catalogue

Chapter I. Overview	1
1.1. Equipment introduction	1
1.2 Equipment features	2
1.3 Product appearance	4
1.4 Product structure	6
1.5 Scope of application	7
1.6 Software environment	7
1.7 Equipment working environment	8
1.8 Consumables information	9
Chapter II Equipment installation requirements	10
2.1 Special requirements for use	10
2.2 General requirements	10
2.3 Precautions	10
2.4 Transportation and storage conditions of instruments	12
2.5 Installation environment requirements	13
2.6 Description of the host power input port	14
2.7 Connection to power supply	14
2.8 Ventilation requirements	14
2.9 Maintenance requirements	14
Chapter three Equipment installation	16
3.1 Equipment installation	16
3.2 Waste slides are treated	16
Chapter 4 On and Off	17
4.1 Turn on the power	17
4.2 Enter the software	17



4.3 Exit software	18
4.4 Shutdown	18
Chapter V Specimen testing	19
5.1 Sample preparation	19
5.2 Specimen detection operation	20
Chapter VI Equipment maintenance and repair	35
6.1 Product maintenance	35
6.2 Product prohibition	36
6.3 Maintenance when not in use for a long time	36
6.4 Instrument maintenance	36
6.5 Description of other replaceable parts	38
6.6 Handling of instruments	38
Chapter VII Warning and other signs	39
Chapter VIII Electromagnetic Compatibility	41

Chapter I. Overview

1.1. Equipment introduction

Product name: Automatic fluorescence microscopic image scanning analyzer
(Automatic fluorescence microscopic image scanning analyzer)

Product model: GK-IMG1000, GK-IMG3000, GK-IMG5000

Production date: see nameplate

Usage period: 5 years

The software in the composition of this product is a control type software component.

model	structural composition		net weight	Rated input power
	Main body	Software components		
GK-IMG1000	The product consists of a computer, power adapter, microscopic optical system, image scanning system, display screen and software. The software release version is 1.	Name: Fluorescence microscopic image analyzer Model: GK-IMG1000 Release version: V1.0	30KG	320W
GK-IMG3000	The product consists of a computer, power adapter, microscopic optical system, image scanning system, display screen and software. The software release version is 1.	Name: Fluorescence microscopic image analyzer Model: GK-IMG3000 Release version: V1.0	31KG	320W
GK-IMG5000	The product consists of a computer, power adapter,	Name: Fluorescence microscopic image analyzer	33KG	320W

	<p>microscopic optical system, image scanning system, display screen and software. The software release version is 1.</p>	<p>Model: GK-IMG5000 Release version: V1.0</p>		
--	---	--	--	--



Note: This analyzer does not have printer and other peripherals. Users need to configure equipment that meets GB4943 or equivalent safety level.

The analyzer employs a detection method that combines fluorescence microscopy and image scanning. After the sample is stained with a fluorescent dye, it is excited by a light source, causing the cells to emit specific fluorescence. The optical microscope system and image scanning system capture these images, producing clear, magnified fluorescence microscopic images. This facilitates doctors in detecting and accurately identifying fungi, trichomonads, clue cells, or mycobacteria in the sample. Additionally, under the control of a microcontroller, the motor performs various actions, enabling automated operation.

1.2 Equipment features

- (1) High degree of automation: the analyzer has automatic processing functions such as automatic selection, automatic push and automatic scanning.
- (2) Clear vision: automatic microscope device can automatically return, focus, scan, adjust brightness and locate, which can provide clear images under the microscope, reduce human visual labor, and effectively reduce the possibility of misdiagnosis caused by visual fatigue.
- (3) No cross-contamination: disposable glass slides are used, which are clean and free from cross-contamination.

(4) Efficient image processing and counting: The application of modern image processing technology in the analysis of cell images can easily and quickly count the required data of observed items according to diagnostic needs by using computer technology, which avoids human error and improves the accuracy of analysis and diagnosis.

(5) Large image storage capacity: using large-capacity disk memory, a large number of images can be stored, and can be called up for reference, comparison, analysis and printing at any time, reducing the human, material and financial costs of saving, keeping and copying specimens.

(6) Main parameters:

parameter	metric
scanning speed	In the fast photography mode, the time for single-channel scanning 40 fluorescence images is less than or equal to 70 seconds; In the fine photography mode, the time for a single channel to scan 40 fluorescence images is less than or equal to 3 minutes.
scanning mode	Face array scanning
Objective lens parameters	40X
Adapt slide thickness	0.9mm~1.2mm
scanning mode	XY high-velocity scanning
Focus mode	Precise focus
Auto focus range	$\pm 300\mu\text{m}$
excitation light	It includes UV band and B band

source	
Camera parameters	5 megapixels, 3.45 micron x3.45 micron pixel size
Fluorescence is emitted	Uv band 365nm excitation, bandwidth 40nm, emission 420nm long pass; The B band is excited at 470nm with a bandwidth of 30nm and a long pass at 520nm;
Light source adjustment	Software brightness adjustment
page range	The software sets the scanning range
scan pattern	It has manual and automatic scanning modes
picture format	Supports exporting images separately
Device self-test mode	Supports device self-test
Information entry	Manual input/scanner gun recognition

1.3 Product appearance

(1) Host volume:

model	wide (mm)	deep (mm)	tall (mm)
GK-IMG1000	39	42	50
GK-IMG3000	39	42	50
GK-IMG5000	39	48	50

(2) Machine weight:

model	net weight (Kgs)	rough weight (Kgs)
GK-IMG1000	30	32
GK-IMG3000	31	33
GK-IMG5000	33	35

(3) Front view of the instrument (Figure 1.1)



(4) Side view of the instrument (Fig. 1.2, 1.3) Instrument model GK-IMG1000 (3000/5000)



(5) Back view of the instrument (Figure 1.4)





pay attention to

Prevent electric shock and wrong connections.

Avoid repeated on and off in a short time. This will cause the fuse to overload and cause it to blow.

To prevent fire, use fuses of the specified model and rated current power.

(6) The appearance of the system is correct, the outer surface is clean, no scratches, concavities, edges, burrs.

(7) All kinds of text marks on the outer surface of the system are clear, accurate and firm.

(8) The system fasteners are firmly installed and the switch keys are sensitive.

1.4 Product structure

The product consists of a computer, power adapter, microscopic optical system, image scanning system, display screen and software. The software release version is 1.

The differences between GK-IMG1000, GK-IMG3000 and GK-IMG5000 are shown in the following table:

project		GK-IMG1000	GK-IMG3000	GK-IMG5000
Number of slides loaded		1 sheet	Three pieces	Five pieces
	control section	PCI control card, USB cable		
computer	Java runtime environment Java	hardware environment : CPU: i7 processor with 6 cores or above; Graphics card: RTX 4060 and above; Memory: 16GB or above; Hard disk: 512G SSD or above; External software environment: Operating system: Windows11 24H2 and compatible versions;		

		<p>General-purpose applications:</p> <p>(1). Net framework, 4.8.9032.0 and compatible versions;</p> <p>(2) Database: Sqlite, 1.0.113.0 and compatible versions;</p> <p>network environment :</p> <p>1) Network architecture: C/S architecture;</p> <p>2) Network type: LAN;</p> <p>3) Network bandwidth: 100Mbps and above;</p>
	display screen	BOE 13.3-inch capacitive touch screen
Microscopic optical system	image acquisition	CMOS camera
	Cube of light	UV and Blue bands
	lens cone	Both ends support microscope objective interface and camera interface
	objective	40X 0.75
Image scanning system	image acquisition	CMOS camera
	Scan the moving axis	X、 Y axle
	Focus system	Z axle
Supporting software	software	Automatic fluorescence microscopic image scanning analysis system V1.0

1.5 Scope of application

It is suitable for fluorescence microscopic scanning imaging of vaginal secretions, scales, sputum and other samples, as well as observation, screening, marking and analysis of microscopic images.

1.6 Software environment

The automatic fluorescence microscopic image scanning analyzer software is a

comprehensive control and application tool designed to automate the scanning and imaging of fluorescently stained slides. It integrates various functional modules, including mechanical control, lighting control, image acquisition, and image browsing, to achieve high-speed, high-quality fluorescence scanning of slides. The software features a well-structured module design, complete functionality, open interfaces, and user-friendly operation. This software is compatible with Windows11 (and its compatible versions) 64-bit systems.

1.7 Equipment working environment

- For indoor use
 - The altitude does not exceed 2000 meters
 - Environmental temperature: 5°C~35°C
 - Relative humidity: less than 80%
 - Pollution level: 2
 - Power supply: AC220V,50Hz
 - Rated power: 320W
- Stay away from sources of high intensity electromagnetic field interference
- Avoid installing the instrument in high temperature, humidity, dust and direct sunlight.
- Avoid shocks and vibrations.
- Ventilation requirements: avoid using the instrument in a closed environment, and leave at least 15cm distance between the instrument and the wall or other equipment around to ensure normal ventilation and heat dissipation.
- Avoid installing instruments such as tape recorders, radio communication equipment, centrifuges, etc. near noisy equipment.
- Avoid installing instruments near computer monitors that are affected by electronic noise.
- Instruments cannot be installed in places where chemicals are stored and gases

are generated.

network security

(1) Network conditions: can be connected to LIS LAN.

(2) Security software: The software supports general security software (such as 360 Security Guard, 360 Antivirus, qq computer manager, Kingsoft Antivirus).

(3) Data and device (system) interface: RS-232 serial port.

(4) User access mechanism: user name and password.

(5) Requirements for software environment and software update: The software environment and software update shall be carried out by the professional engineers of the company or the designated engineers who have been trained and approved by the company.

1.8 Consumables information

Fungal Fluorescent Staining Solution: This solution, registered with the product filing number Lu De Medical Equipment 20210033, is used for staining suspected fungal samples. Fungal D-glucan Detection Fluorescent Staining Solution: This solution, also registered with the product filing number Lu De Medical Equipment 20210070, is used for staining suspected fungal samples.

Staining solution: anti-acid mycobacterium fluorescent staining reagent, registered product of Dezhou Guoke Medical Technology Co., LTD., used for staining anti-acid bacilli samples, registration number: Lu Dejianbei 20220161.

Staining solution: Vaginal microbial immunofluorescence staining reagent, a registered product of Dezhou Guoke Medical Technology Co., LTD., used for staining vaginal microbial samples. Registration number: Lu De Jie Bei 20220204.

Slide: Slide for instrument of Dezhou Guoke Medical Technology Co., LTD. Made of ultra-white glass, without any shadow impurities.

Cover slip: Cover slip for instruments of Dezhou Guoke Medical Technology Co., LTD., made of ultra-white glass, without any shadow impurities.

Chapter II Equipment installation requirements

2.1 Special requirements for use

This instrument is only suitable for the fluorescence microscopic scanning imaging of vaginal secretions, dander, sputum and other samples, as well as the observation, screening, marking and analysis of microscopic images.

Special use requirements also include disassembly, cleaning and maintenance as required.

2.2 General requirements

Read this manual carefully before operating the instrument and keep it properly for future reference.

The instrument must be installed in accordance with the requirements of this manual.

2.3 Precautions

- If the instrument emits odor or smoke, stop using it immediately, turn off the power switch and unplug the power cord. Continuing to use the instrument may cause fire, electric shock or personal injury. In case of the above situation, please contact the company's after-sales service department and do not turn on the machine for inspection.
- Do not let staples or paper clips and other metals fall into the instrument. Otherwise, it will cause a short circuit. If this happens, please immediately turn off the main switch, unplug the power cord, and contact the company's after-sales service department.
- Do not touch the circuit of the instrument, especially not with wet hands, otherwise there is a risk of electric shock.

- Only plug the power plug into a 220V socket and pay attention to protective grounding.
- Avoid damaging the power cord, do not press any equipment on the power cord, do not pull the power cord hard.
- Because the instrument analyzes patient samples, all of its parts and surfaces are potentially infectious.
- Wear rubber gloves when operating, maintaining and checking the instrument. Use only designated tools and parts. Wash your hands with disinfectant after work.
- Do not touch waste and parts that have been in contact with waste by hand.
- If you accidentally come into contact with an infectious substance or surface, wash your skin thoroughly with water immediately and then follow the disinfection procedures prescribed by your hospital or laboratory.
- Before repairing the equipment after a failure, maintenance personnel shall clean and disinfect the parts that may be contaminated by biological pollution, or take necessary protection.
- In order to ensure the safety of equipment operators, biological hazard sources on the equipment should be effectively treated and controlled, and the equipment should be maintained normally. All operation, maintenance and maintenance personnel should be trained.
- In order to ensure the safety of equipment operators, the movement mechanism should be avoided during normal use to avoid biological infection and other dangers. If the equipment fails, ordinary operators should immediately disconnect the power supply of the equipment and notify professional maintenance personnel or factory, and it is strictly prohibited to dispose of it by themselves.
- Operators should be trained to perform hazardous operations.
- This instrument will not release potential toxic and harmful gases during use and placement.
- After the instrument is repaired or out of service, it needs to be marked with

special marks and cleaned and disinfected.

- Moving parts: push claw. Please pay attention to the operator, do not put your hands near the moving parts area, to avoid injury caused by the operation of the instrument.



biohazard

Because the instrument is used to analyze patient samples, parts and surfaces that come into contact with samples are potentially infectious. To avoid infection,



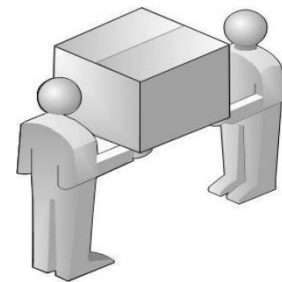
warn

Do not place the device in a location where it is difficult to operate the disconnect device (power switch, power connector, plug)!

2.4 Transportation and storage conditions of instruments

2.4.1 Instrument transportation instructions

Because the instrument host part is heavy ($\geq 31\text{kg}$) and large in size, special attention should be paid to handling.

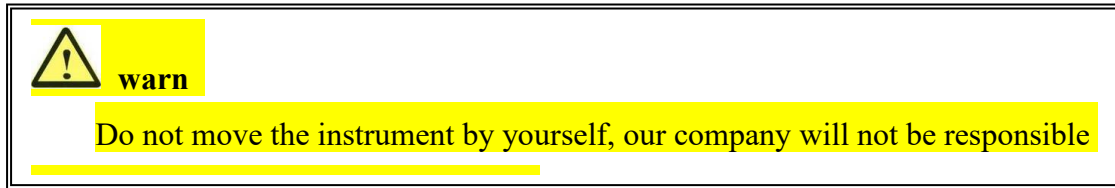


At least two people are required to carry the instrument together, lifting the four corners of the instrument respectively. Note: The force point should be located at the base of the instrument bottom, and do not use the shell of the instrument as the force point to move the instrument, so as to avoid damage to the shell of the instrument.

When you need to move the instrument over a long distance, please put the instrument back into the packing box and carry it with the same bottom force.

After the equipment is delivered to the responsible person, it should be transported according to the marking on the packing box, moisture-proof, rainproof and light. It should avoid mixing with inflammable and explosive articles during

transportation.



2.4.2 Storage

The packaged analyzer should be stored in a clean room with no corrosive gas and good ventilation at an altitude of less than 2000m, with a relative humidity not greater than 80% and a temperature of 0°C~+40°C.

2.5 Installation environment requirements

Before installation, check whether any parts of the instrument host are damaged.

The instrument must be installed in a dry, dust-free room.

The net weight of the instrument host shall be at least 31 kg. It shall be installed on a load-bearing platform or table and shall be stable.

There must be enough space for maintenance or service work. Due to heat radiation, the right side, rear and top of the instrument should be at least 15cm away from the wall.

Do not install instruments near high frequency equipment such as recording equipment, communication equipment, etc.

The power cable is 1.5m long. Make sure there are suitable outlets nearby.

Do not place the device in a position where it is difficult to operate the disconnect device (switch power supply).

Do not install the machine in a place where the machine is directly exposed to strong light.

2.6 Description of the host power input port

The terminals of this instrument are protected by grounding.

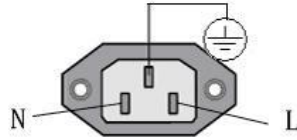


Figure 1 Power interface

2.7 Connection to power supply

Insert the power cord into the power connection hole on the back of the instrument, and connect the other end to the AC outlet. When choosing the power supply, users must choose a socket that has been reliably grounded to ensure the safety of the instrument and themselves:

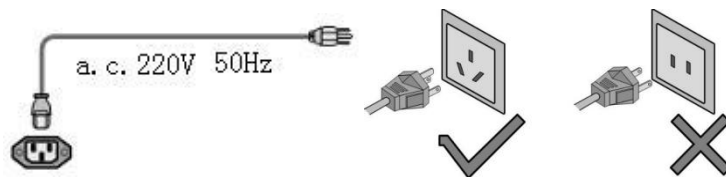


Figure 2 Power socket connection instructions

2.8 Ventilation requirements

Indoor ventilation should be good and air can flow.

2.9 Maintenance requirements

Indoor air: indoor air should be kept circulating and dust-free.

Motion structure: ensure that there is no abnormal sound during the motion process. If there is any problem, please turn off and restart. If it does not return to normal state, please contact after-sales service.

Test host: Keep the instrument surface clean, and use the dust cover after



shutdown.

Chapter three Equipment installation

3.1 Equipment installation

The equipment has been tested and installed by professional authorized technical engineers before leaving the factory, and passed strict inspection and testing.

Attention should be paid to the installation of the equipment,

1) The equipment should be installed in a normal temperature, dry and well ventilated place, and pay attention to moisture-proof, dust-proof, ventilation and fireproof, so as to ensure product quality and safety.

2) When positioning and placing the equipment before use, the operator should pay attention to the reasonable position of the equipment, and try to avoid the limitation or interference caused by the equipment to the operation of medical staff.

3) Upon arrival at the customer's place, the equipment will be debugged on site by professional authorized technical engineers of the manufacturer or qualified agents, and comprehensive and basic operation training will be provided to the customer.

3.2 Waste slides are treated

3.2.1, waste plate box treatment

After the test, the disposable slide should be discarded into the waste plate box of the instrument. The waste plate box should be cleaned regularly, and the discarded slide should be treated according to the regulations of the hospital.



biohazard

Because the instrument is used to analyze patient samples, the waste plate box is potentially infectious. To avoid infection, rubber gloves must be worn when cleaning the waste plate box and hands should be washed with disinfectant after work.

Chapter 4 On and Off

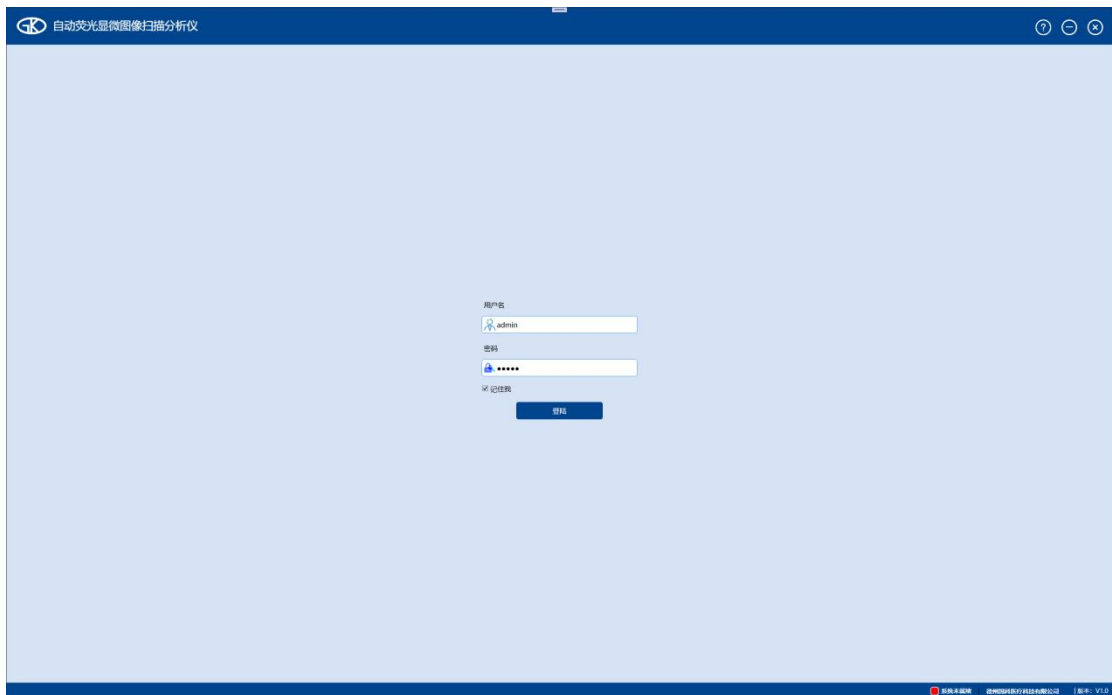
4.1 Turn on the power

After confirming that all parts of the machine are connected properly, turn on the power supply behind the host and start the computer.


4.2 Enter the software




1. Click the "" icon on the desktop to enter the software, as shown in the following figure:




After entering the user name and password, click the login button to complete the user login. For user number management, please contact the after-sales maintenance personnel.

2. After entering the software, click "System  menu" to minimize the software.

3. Click on the "System menu  " to switch users.

4. Click on "System menu  " to get help.

4.3 Exit software


Click on "System menu  ", then select "Yes" to close the software (remove the slide holder before exiting).



4.4 Shutdown

Click the icon in the  lower left corner of the  screen, click in



the  pop-up interface, and finally click. After the screen is completely dark, turn off the power supply of the whole machine.



pay attention to

Do not directly close the power I/O key of the whole machine, otherwise it will cause the software to crash and cannot be used normally.

Chapter V Specimen testing

5.1 Sample preparation

5.1.1 Preparation of dander specimens (illustrated):

5.1.1.1 Collection of dander specimens and sample size:

Dermatograph specimens should be scraped by a professional dermatologist according to the size of the lesion site. The debris of the lesion tissue should be scraped to avoid large pieces of tissue. The sample size should be smaller than the cover glass size.

5.1.1.2 Preparation of dander slide:

The specimen is placed on the slide, a drop of fluorescent staining solution is added, and the cover glass is covered. Then the cover glass is pressed lightly to expel bubbles and press the specimen thin. The surrounding overflow is sucked up with paper, and then the specimen is put into the instrument for testing.

5.1.1.3 Dander specimen preservation:

Due to the phenomenon of fluorescence quenching, specimens should be tested in time and should not be retained.

5.1.2 Sputum specimen preparation:

The sputum specimen is stained and placed in an instrument for testing by a hospital laboratory physician.

5.1.3 Preparation of vaginal secretion specimens:

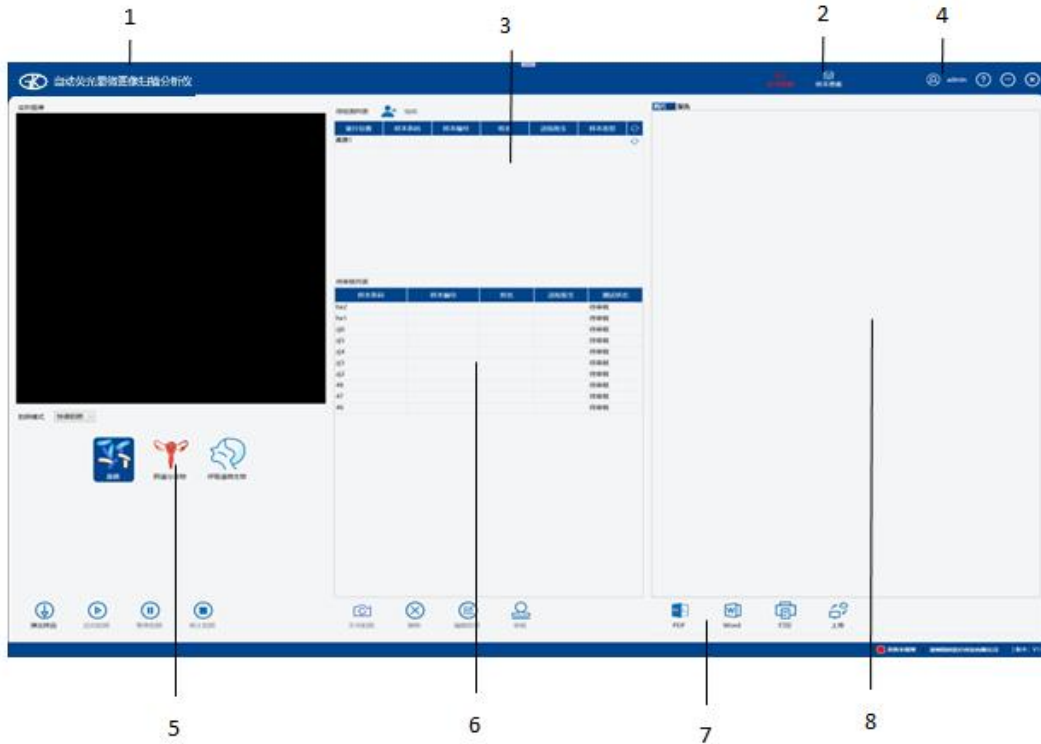
The vaginal secretion specimen was stained with fluorescence and then put into the instrument for testing by the hospital's laboratory physician.

5.1.4 Preparation of alveolar lavage fluid specimens:

The alveolar lavage fluid specimen was stained with fluorescence and then put into the instrument for testing by the hospital's laboratory physician.

5.2 Specimen detection operation

5.2.1 Interface Introduction



among :

1: Software name and icon

2 representatives: menu bar

3: The area where the list to be tested is to be detected

4: System menu

5 representatives: sample test type selection area

6: The pending review list area

7 representatives: sample test report text and printing area

Eight representatives: sample data show the district

5.2.2 Operation process

5.2.2.1 Sample testing

- 1) Click the Sample Test button in the menu bar to display the sample test interface.



- 2) There are two parts in the "Sample detection type selection area", in which "quick photo" and "fine photo" can be selected in the photo mode; in the sample type, "fungus", "vaginal discharge" and "respiratory tract microorganism" can be selected.



- 3) After selecting the sample testing type, select the slide position in the pending test list area. Click [Edit] to switch to the patient information editing interface, where you can input the corresponding information into the candidate box (you can use a barcode scanner to scan the barcode). After entering the information, click [Apply], and the patient information will be displayed in the pending test list. At this point, place the slide holder.



The image shows a '待检测列表' (Pending Test List) interface. At the top left is the title '待检测列表' and a '+ 编辑' (Edit) button. Below is a table with 7 columns and 1 row. The columns are: 玻片位置 (Slide Position), 样本条码 (Sample Barcode), 样本编号 (Sample Number), 姓名 (Name), 送检医生 (Referring Doctor), 样本类型 (Sample Type), and a refresh icon. The first row is highlighted in red and contains the number '1' in the first column.

玻片位置	样本条码	样本编号	姓名	送检医生	样本类型	刷新
1						刷新

信息录入
✕

真菌1

输入条码
查询信息

姓名

性别

年龄

住院号

床位号

登记号

送检科室

送检医生

样本类型

样本编号

送检时间

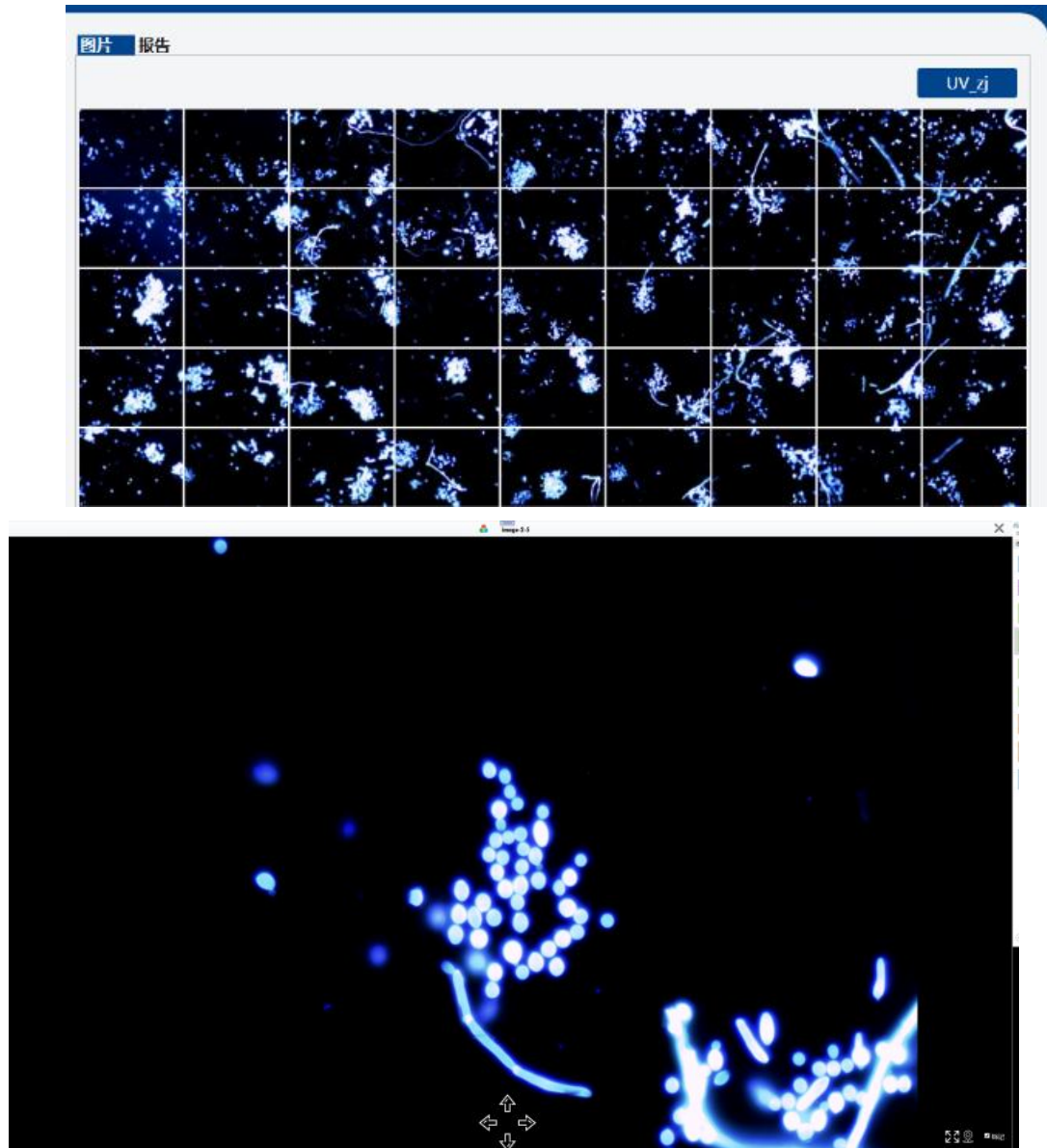
应用
关闭




- 4) Click the [Start Taking Photos] button to start the scanning process. During the scan, the sample image will be displayed in real-time in the real-time image area. Click [Pause Taking Photos] to pause the process, and click again to resume. Click [Stop Taking Photos] to stop the process. After the automatic or manual photo-taking ends, click [Pop Out Sample] to remove the slide holder.



5.2.2.2 Image viewing

- 1) After the photo is taken, the patient information is displayed in the pending review list, and the captured image data is shown in the image column of the 'Sample Data Display Area' on the far right. Clicking UV or B allows you to view images from different bands (only samples with 'Vaginal Microbiota' and 'Respiratory Microbiota' can view the B-band images). Double-clicking an image will zoom in for a closer look, and you can check to show markers.



The button in the middle and  lower part of the enlarged picture can  quickly switch photos, and the button  in the lower right corner can further enlarge the picture. The button in the lower right corner can quickly locate the slide to the position of the picture, which is convenient for manual photography.

- 2) After the automatic photo-taking is completed, users can click [Manual Photo] to enter the manual photo-taking interface. Here, they can manually focus and move the selected sample, observe a specific location directly, and take photos. Users can also choose to delete the images taken manually. After closing the manual

photo-taking interface, the images taken manually will be displayed in the image column of the Sample Data Display Area.

5.2.2.3 Edit the report sheet

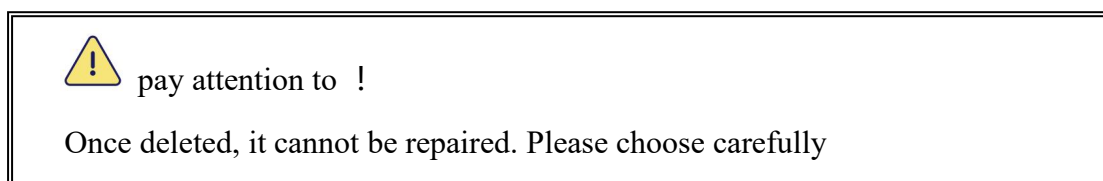
1) Select the sample bar code corresponding to the report to be edited in the pending review list area, and then click the report.



2) The samples that have been detected are available below the "Pending review list" area

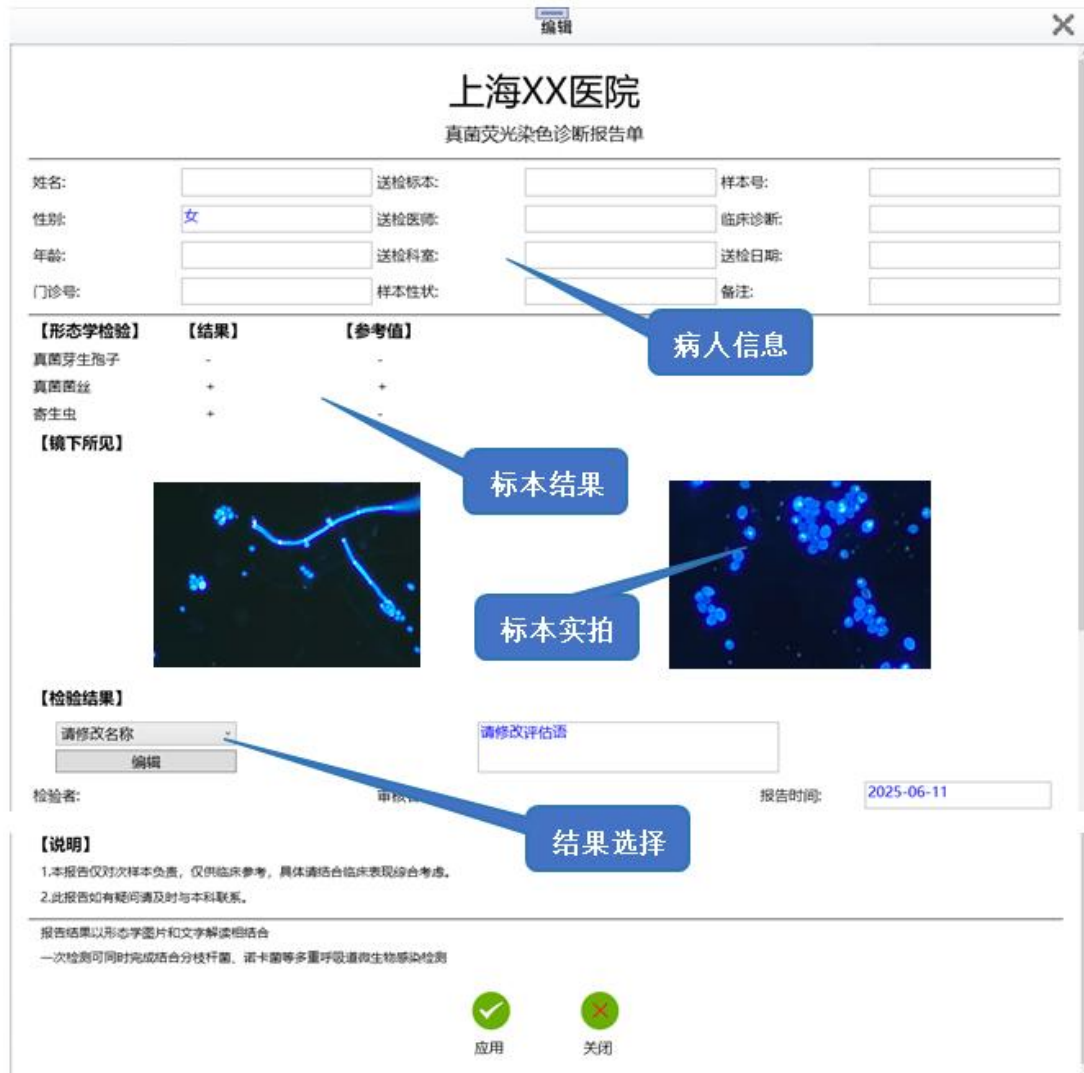


a) Delete: Click to delete the selected sample data;



b) Edit information: Edit the content of the report. After the report is edited, click [Apply] to save the edited content;

(1) "Fungal detection" report editing



Explanation of the report editor:

Patient information: In general, patient information is synchronized with the patient information entered before the test. If there is an error in the input, it can also be modified at the report editing place.

Specimen results: The [Results] column indicates the results identified by the instrument, and the [Reference value] column indicates the reference

results based on expert consensus. The specimen results are for reference only.

Specimen photography: The instrument will select two images from the images taken during specimen detection and display them in the report. Users can also select and replace the images in the report.

Result selection: Users can select the preset diagnostic phrases in the drop-down menu, or edit the diagnostic phrases in the [Edit] column; the evaluation phrases on the right side can be edited and modified by themselves.

(2) Editing of vaginal secretion test report

上海****医院
阴道分泌物荧光检验报告单

姓名: [] 送检标本: [] 样本号: []
 性别: 女 送检医师: [] 临床诊断: []
 年龄: [] 送检科室: [] 送检日期: 2025-06-11 11:22
 门诊号: []

【形态学检验】	【结果】	【参考值】	【镜下所见】
上皮细胞		+/-	
白细胞		+/-	
乳酸杆菌		+/+++	
短杆菌		-	
杆菌聚集		-	
细胞核		-	
线索细胞		-	
念珠菌		-	
芽生孢子		-	
孢子		-	
菌丝		-	
滴虫		-	
【微生态体系指标】			
清洁度		I度/II度	
球菌		-	
双球菌		-	
链球菌		-	
菌群多样性		+/+++	
菌群密集度		+/+++	
优势菌		乳酸杆菌	
【Av评分】			
Av分值		0-2	
【检验结果】			
细胞堆积		2132	
【说明】			
1.标本采集前应排除月经期、24h盆腔、性交、局部用药、阴道冲洗等情况。			
2.Av评分: 0-2分提示正常, 3-4分提示轻度Av, 5-6分提示中度Av, ≥7分提示重度Av。			
【建议进一步检查】			
NGS: <input checked="" type="checkbox"/>	支原体培养或RNA检测: <input type="checkbox"/>	<input type="checkbox"/>	
实时PCR: <input checked="" type="checkbox"/>	沙眼衣原体RNA检测: <input type="checkbox"/>	淋球菌培养或RNA检测: <input checked="" type="checkbox"/>	
检验者: []	审核者: []	报告时间: 2025-06-11	

本报告仅对此样本负责, 仅供临床参考!
报告结果以形态学图片和文字解读相结合

应用 关闭

Explanation of the report editor:

Patient information: In general, patient information is synchronized with the patient information entered before the test. If there is an error in the input, it can also be modified at the report editing place.

Specimen results: The [Results] column shows the results identified by the instrument, and the [Reference value] column indicates the reference results based on expert consensus. The specimen results are for reference only.

Specimen photography: The instrument will automatically select three images from the images taken during specimen detection and embed them in the report. Users can also choose to replace the images in the report.

Result selection: Users can select the preset diagnostic phrases in the drop-down menu, or edit the diagnostic phrases in the "Edit" column; the evaluation phrases on the right side can be edited and modified by themselves.

(3) Respiratory test report editing

上海**医院**
呼吸道微生物检测报告单

姓名: 送检标本: 样本号:
 性别: 送检医师: 临床诊断:
 年龄: 送检科室: 送检日期:
 门诊号: 样本性状:

痰涂片抗酸染色结果报告的方法和标准
在镜下观察40个视野,并记录观察结果,见下表。

结核杆菌:	1+	2+	3+	4+	-
	1-39条抗酸杆菌 /40个视野	40-400条抗酸杆菌 /40个视野	401-3999条抗酸杆菌 /40个视野	≥4000条抗酸杆菌 /40个视野	没有菌体

【镜下所见】

标本结果

标本实拍

【检验结果】

检验医师: 审核者: 报告日期:

【说明】

- 1.本报告仅对本次样本负责,仅供临床参考,具体请结合临床表现综合考虑。
- 2.此报告如有疑问请及时与本科联系。

报告结果以形态学图片和文字解读相结合
一次检测可同时完成结合分枝杆菌、诺卡菌等多重呼吸道微生物感染检测

应用 关闭

Explanation of the report editor:

Patient information: In general, patient information is synchronized with the patient information entered before the test. If there is an error in the input, it can also be modified in the report editing section.

Specimen results: The [Results] column indicates the results identified by the instrument, and the [Reference value] column indicates the reference results based on expert consensus. The specimen results are for reference only.

Specimen photography: The instrument will select two images from the images taken during specimen detection and embed them in the report. Users can also choose to replace the images in the report.

Result selection: Users can select the preset diagnostic phrases in the drop-down menu, or edit the diagnostic phrases in the "Edit" column; the evaluation phrases on the right side can be edited and modified by themselves.

c) "Review": Review the current sample data (After selecting [Pass] or [Fail], the sample test result will be deleted from the "pending review list" and enter the sample view interface.)



3) In the "Sample Test Report Text and Printing Area", click [PDF] or [Word] to export the report in PDF or Word format. Click [Print] to print the report sheet. Click [Upload] to upload the sample data.



4) Report form template content

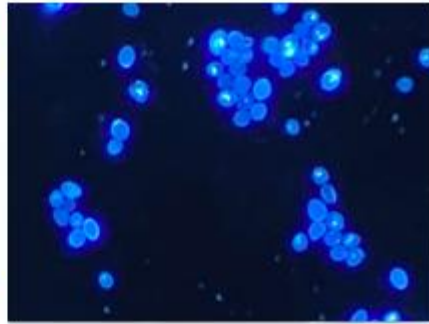
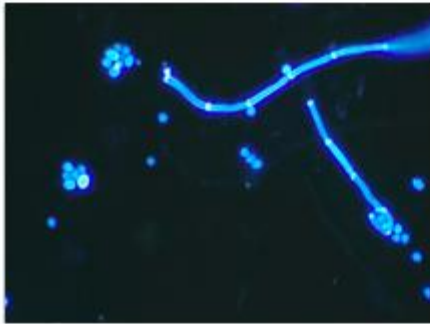
上海XX医院

真菌荧光染色诊断报告单

姓名:		送检标本:		样本号:	
性别:	女	送检医师:		临床诊断:	
年龄:		送检科室:		送检日期:	2025-06-11 11:11
门诊号:		样本性状:		备注:	

【形态学检验】	【结果】	【参考值】
真菌芽生孢子	-	-
真菌菌丝	+	+
寄生虫	+	-

【镜下所见】



【检验结果】

镜下可见孢子或菌丝，可见寄生虫，疑似寄生虫真菌混合感染。

检验者: 审核者: 报告时间:2025-06-11

【说明】
1. 本报告仅对此样本负责，仅供临床参考，具体请结合临床表现综合考虑。
2. 此报告如有疑问请及时与本科联系。

报告结果以形态学图片和文字解读相结合形式

上海****医院

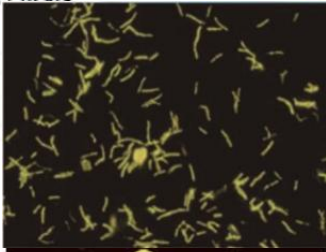
呼吸道微生物检测报告单

姓名:	送检标本:	样本号:
性别: 女	送检医师:	临床诊断:
年龄:	送检科室:	送检日期: 2025-06-11 11:11
门诊号:	样本性状:	备注:

痰涂片抗酸染色结果报告的方法和标准
再镜下观察40个视野，并记录观察结果，见下表。

结核杆菌:	1+	2+	3+	4+	-
	1-39条抗酸杆菌	40-400条抗酸杆菌	401-3999条抗酸杆菌	≥4000条抗酸杆菌	没有菌体
	/40个视野	/40个视野	/40个视野	/40个视野	

【镜下所见】



【检验结果】

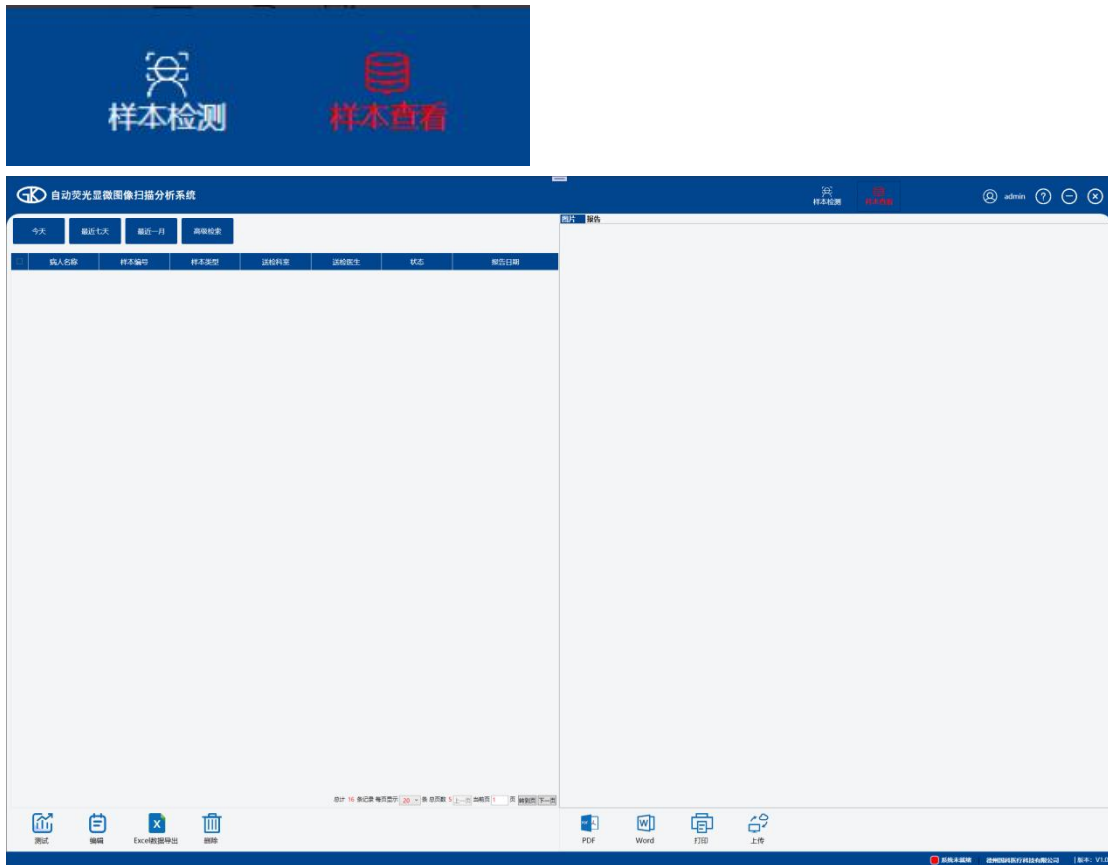
1+

检验医师: _____ 审核者: _____ 报告日期: 2025-06-11

【说明】

1. 本报告仅对此样本负责，仅供临床参考，具体请结合临床表现综合考虑。
2. 此报告如有疑问请及时与本科联系。

报告结果以形态学图片和文字解读相结合
一次检测可同时完成结合分支杆菌、诺卡菌等多重呼吸道微生物感染检测



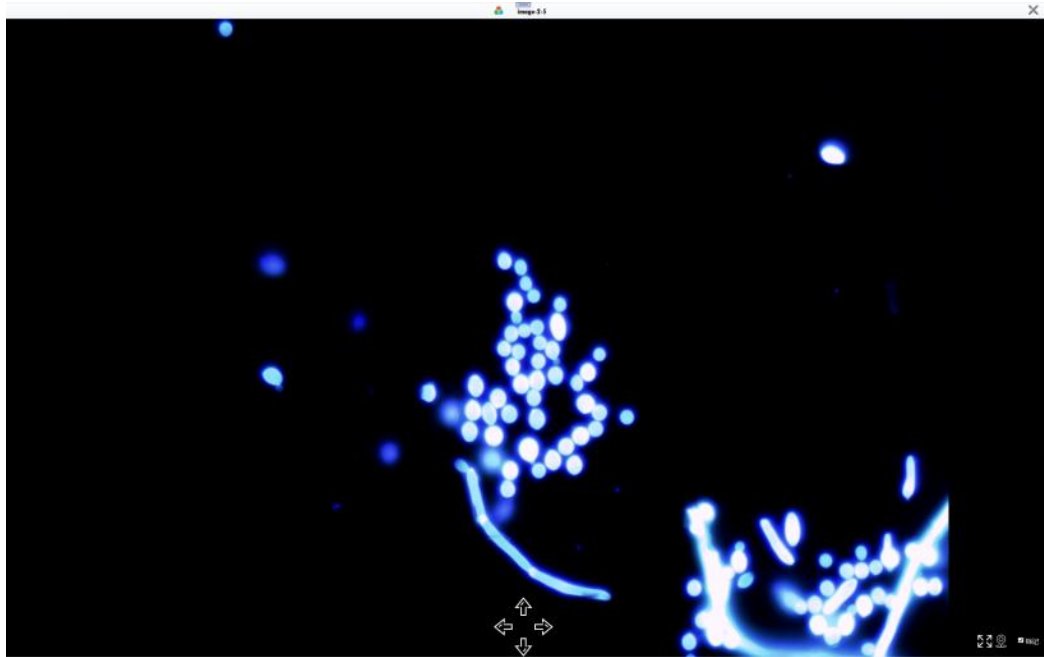
2) By clicking [Today], [Last Seven Days], or [Last Month], you can view the sample data that has been reviewed at different times, which is displayed in the data list. Alternatively, you can click [Advanced Search] and enter the patient name, application number, department of submission, submitting doctor, start date, and end date to search for sample data.





3) After selecting a sample, click [Test] below the data list to automatically fill in the patient information into the pending test list. You can retest the selected sample. Click

[Edit] to edit the report of the selected sample. Click [Excel Data Export] to export the selected patient information as an Excel file. Click [Delete] to delete the selected sample data.

4) Select a sample in the data list, and the corresponding picture and report will appear on the right side. Click a single picture to zoom in the picture.



The button in the  middle below allows you to quickly  switch photos, and the button in the lower right corner allows you to zoom in further.

5) After selecting the sample, click [PDF] or [Word] to export the report in PDF or Word format. Click [Print] to print the report. Click [Upload] to upload the selected sample data.



5.2.2.5 Re-test

For samples that fail, retesting requires repeating all the steps of sample testing, resampling and retesting.

Chapter VI Equipment maintenance and repair

6.1 Product maintenance

6.1.1 Cleaning of the instrument host

The specific operation is as follows:

Clean the outer surface of the instrument regularly. When cleaning, gently wipe with flexible materials. Pay special attention to the cleaning of external metal components to prevent corrosion and rust, which may affect the normal operation of the instrument. After cleaning, cover the instrument with a dust cover.

If the sample or other dangerous substances leak on the surface of the equipment or enter the interior of the equipment, the instrument should be turned off and the power cut off. The disinfectant should be sprayed on the contaminated area and the contaminated area should be cleaned. Wait for the equipment to dry and then start up and reset the cleaning.

It is recommended to use a disinfectant with a concentration of 75% alcohol. Do not use corrosive cleaning liquids or disinfectants such as strong acids or strong alkalis. Do not use cleaning agents or disinfectants that can cause dangerous chemical reactions with equipment parts or materials contained in the equipment.

If you have any questions about the compatibility of disinfectant or detergent with equipment parts or materials contained in the equipment, please consult your agent or DeZhou GuoKe Medical Technology Co., Ltd.



biohazard

As the instrument is used to analyze patient samples, it is potentially infectious. To avoid infection, rubber gloves must be worn when cleaning the equipment and hands should be washed with disinfectant after work.

6.1.2, waste slide treatment

After the test, the disposable glass slide will be discarded and put into the waste plate box. The waste plate box should be cleaned regularly and disposed of according to the hospital regulations.



biohazard

Because the instrument is used to analyze patient samples, the waste plate box is potentially infectious. To avoid infection, rubber gloves must be worn when cleaning the waste plate box and hands should be washed with disinfectant after work.

6.2 Product prohibition

1. The power supply must have a protective grounding terminal, and the instrument must be reliably grounded through the power socket.
2. Users should not open the case without authorization to avoid danger caused by high pressure. The opening and maintenance work should be completed by professional engineers.

6.3 Maintenance when not in use for a long time

Conduct preventive maintenance and inspection of the equipment every month, and power on the equipment for 10 minutes each time.

Before use, empty the slide holder and disinfect the instrument.

6.4 Instrument maintenance

Due to the malfunction of the instrument caused by uncertain factors, users can make an initial assessment of the fault based on this section. If it is a minor issue, follow the methods outlined below to resolve it; if any of the following situations occur, please contact our company's after-sales service department immediately.

When reporting the issue, please provide detailed fault information to facilitate timely and accurate repairs.

A) The instrument cannot operate normally according to the operation instructions in the instruction manual.

b) The characteristics of the instrument change significantly, and the test results deviate significantly.

c) The instrument is dropped or the appearance is seriously damaged



pay attention to

Non-company after-sales maintenance personnel must disconnect all power before checking or repairing the equipment to avoid electric shock.

6.4.1 The instrument cannot be started

Press the I/O switch of the instrument, and the instrument does not move. You can check the following steps:

1. Check whether the power cord of the instrument is reliably connected and whether there is 220V power supply.
2. Check whether the fuse (fuse) of the instrument is damaged.

6.4.2 Replace the host fuse

When the fuse (fuse) of the instrument is blown, the user can replace it by himself. However, the power switch of the host must be turned off and the power cord must be removed. It should be done under the condition that there is no danger of electric shock, or in accordance with the relevant regulations of the user unit.

Circuit breaker (fuse) specification: F3A L250V:



pay attention to

When replacing the fuse, you must disconnect all power first to avoid electric shock.

6.5 Description of other replaceable parts

Some parts may be damaged after long-term use. Since these parts are related to the stability and safety of the instrument, they must be provided by our company. If you need to replace them, please contact our after-sales service department directly and purchase them, and replace them by professionals. The specific parts are as follows:

Electronic control platform control board
power panel

6.6 Handling of instruments

After the instrument is installed and running normally, it should not be moved to avoid vibration and damage of high-precision components and vulnerable parts inside the instrument, which will affect the normal operation of the instrument. If you want to move the instrument, you must put the instrument into a packing box and carry it by more than two people.


















warn

Do not move the instrument by yourself, our company will not be responsible for all the consequences caused by this!

Chapter VII Warning and other signs

Table 1 Symbols, marks and their meanings

Signs	meaning
	Attention! Refer to the attached documents!
	Biological risk identification indicates the potential biological risk associated with medical devices
	Watch out for fingers
	The label of in vitro diagnostic medical device indicates that the medical device is an in vitro diagnostic medical device
	The "I" and "O" on the power switch indicate the "on" and "off" of the total power supply, respectively
	exchange
	USB interface identification
	upward
	Afraid of the rain
	Afraid of the sun
	Handle fragile items with care
	Piling is prohibited

	Rolling is prohibited
	Medical waste signs
	Be careful with electricity

Chapter 8 Electromagnetic Compatibility

1. This device uses radio frequency energy for specific functions. Its radio frequency emission is very low and the possibility of interference to nearby electronic equipment is minimal.
2. The possible effects of portable and mobile radio frequency communication equipment on this equipment, other equipment used simultaneously near this equipment shall comply with the relevant requirements for electromagnetic compatibility.
3. Suitable for use in all facilities not connected directly to the public low-voltage power supply network of household and residential use.
4. The power socket shall have reliable protective grounding measures and use the accompanying power cord, components and accessories.
5. The floor shall be wood, concrete or tile, and if the floor is covered with synthetic materials, the relative humidity shall be at least 30%.
6. The network power supply should have the quality typical of commercial or hospital use.
7. If the user needs to keep the device running continuously during a power outage, it is recommended that the user use an uninterruptible power supply.
8. The power frequency magnetic field in the expected installation site should be measured to ensure that it is sufficiently low. The equipment should be far away from the power frequency magnetic field source, and magnetic shielding materials should be installed under special circumstances to ensure the normal operation of the equipment.
9. This IVD device complies with the emission and immunity requirements specified in GB/T 18268.

10. Group 1: RF energy is used only for internal functions.

Category 1A: Equipment used in non-residential environments and facilities not directly connected to the residential low-voltage power supply network.

12. Equipment operation in a specific environment may cause radio frequency interference.



Warning: In addition to the accessories and cables sold by the manufacturer of this equipment as spare parts for internal components, the use of accessories and cables other than those specified may result in increased emissions or reduced immunity of the equipment.



Warning: This equipment should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed and verified that it can operate normally under the configuration in which it is used.



Note: Do not use this equipment near a strong radiation source (such as an unshielded RF source), otherwise it may interfere with the normal operation of the equipment.



Note: This equipment is designed and tested according to GB 4824 group 1 Class A equipment. In a home environment, this equipment may cause radio interference and protective measures should be taken.



Note: It is recommended to evaluate the electromagnetic environment before using the equipment, and the user is responsible for ensuring that the electromagnetic compatibility environment of the equipment enables normal operation.

This equipment provides electromagnetic compatibility information. This equipment complies with the emission and immunity requirements specified in part of

GB/T 18268; it is designed and tested according to group 1 Class A equipment in GB 4824. In the use environment, this equipment may cause radio interference, and protective measures should be taken.

Do not use this equipment near a strong radiation source (such as an unshielded RF source), otherwise it may interfere with the normal operation of the equipment.

appendix :

port	test item	basic standard	trial value	performan ce criterion
hull	Electrostatic discharge (ESD)	GB/T 17626.2	Air discharge: $\pm 2/4/8$ kV; Contact discharge: $\pm 2/4$ kV; Indirect discharge: $\pm 2/4$ kV;	A
	Radiate electromagnetic field	GB/T 17626.3	Frequency: 80MHz~2.0GHz; Level: 3V/m; Modulation: 80%AM@1kHz;	A
	Rated power frequency magnetic field	GB/T 17626.8	Level 3A/m, 50Hz	A
Alternating current power supply	voltage dip	GB/T 17626.11	0%,1 cycle	A
			40%,5 cycles	A
			70%,25 cycles	A
	Voltage interruption	GB/T 17626.11	5%, 5s	C
	pulse group	GB/T 17626.4	± 1 kV; (5/50ns, 5kHz)	A

(including protective grounding)	surge	GB/T 17626.5	Line to line: ± 1 kV; Line to ground: ± 2 kV;	A
	Radio frequency conduction	GB/T 17626.6	Frequency: 150kHz~80MHz; Level: 3V; Modulation: 80%AM@1kHz;	A
<p>Performance discrimination:</p> <p>During the test, the performance was normal within the standard limit.</p> <p>During testing, the function or performance is temporarily reduced or lost, but can be restored by itself.</p> <p>During testing, the function or performance is temporarily reduced or lost, but the operator needs to intervene or the system needs to be reset.</p>				



Manufacturer:

Dezhou Guoke Medical Technology Co., Ltd.

Add: 28-31 axis.1 and 2 span.No.2 workshop, (Zhongyuan Science and Technology Innovation Park) No.6596 Dongfanghong East Road, Yuanqiao Town, Economic and Technological Development Zone, Dezhou City, Shandong Province, China

E-mail: office@guoke-medical.com



Authorized European Representative:

RIOMAVIX SOCIEDAD LIMITADA

Add.: Calle de Almansa 55,1D, Madrid 28039 Spain

E-mail: leis@riomavix.com

The contents of this manual may be changed without consent.

No part of this manual may be reproduced, reproduced or translated without the written permission of DeZhou GuoKe Medical Technology Co., Ltd.