**Production license number：**

**Product registration number：**

**Technical requirement number：**

# Fully-Automatic fluorescence microscopic Images scanning and analysis system

（GK-IMG8000、GK-IMG8100、GK-IMG8200）

# Instructions

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**Registrant/Manufacturer: Dezhou Guoketong 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 No.2, 1st and 2nd span, 28-31 axis**
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**Name of after-sales service enterprise: Dezhou Guoke Medical Technology Co., LTD.**
**After-sales service email: office@guoke-medical.com Complaint phone: 0534-7057266**

**This manual includes instructions for use and maintenance**
**Instructions Manual version number: V1.0**
**Production date of the equipment: see product label Date of preparation of the manual: May 15,2025**

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

## points for attention

Before Use

1. Please read the instruction manual carefully before using this product and check if the standard accessories are complete. Before use, have the installation and commission done by the professional authorized technicians from the shipping party. The equipment can be used only after it operates normally, the software and hardware match without errors, and the commissioning is.

2. The operator or user must refer to the instruction manual to understand the potential dangers and the corresponding measures to be taken wherever there are marks on the equipment  。

Use it in

1. Use it in accordance with the factory regulations, otherwise the protection provided by the equipment may be destroyed.

2. If the following abnormal conditions occur use, please stop using it immediately! Turn off the power, unplug the power plug, and consult our after-sales service center. Do not attempt to disassemble the product self-repair!

1) When there is abnormal conditions such as emitting black smoke or emitting strange odors.

2) When there is a sharp alarm sound or the light does not display.

3) When liquid or foreign objects penetrate into the interior of the product, causing damage to the product.

Other precautions

1) All markings or hazard warnings on the device should be clear and complete.

2) Do not disassemble the device without permission.

3) When the product fails, it is forbidden for individuals or untrained personnel to forcibly disassemble or repair the product.

4) Do place heavy objects on top of the instrument to avoid causing compression deformation.

5) When using the device, it is necessary to use qualified glass slides as consumables. After use the consumables should not be discarded arbitrarily, and must be handled as medical waste.

6) This device is a high-precision instrument. During transportation, please do not in it, keep it waterproof and moisture-proof, handle it with care, and do not press or shake it.

7) Any waste generated during the use of the device, well as the scrapping treatment of the device at the end of its life, should be handled in accordance with the relevant local laws and regulations.

8) This device has certain identification functions, and the test results need to be determined by doctors based on their professional judgment.

9) Regular maintenance of the instrument hardware should be carried out.

10 After each day's test is completed, discard the used glass slides to avoid contamination.

11) The main part of the device is the moving mechanism, please do not block it with your hand or other parts of your body during normal operation to accidents that may affect your own safety and the equipment.

12) When handling potentially infectious materials (such as samples, discarded plate boxes, etc.), please wear protective.

# Table of Contents

# Version change record

| Version number | Release date | Reason for modification |
|---|---|---|
| V1.0 | 2025.05.15 | First issue |
| | | |
| | | |

# Chapter 1 Overview

1.1. Introduction to the equipment

Product name: Fully automatic fluorescence microscopic images scanning analyzer

Product model: G-IMG8000, GK-IMG8100, GK-IMG8200

Production date: See the nameplateService life: 5 years (based on 365 days/year, 8 hours of work time per day, working overtime will reduce the life of the equipment)

composition: The analyzer consists of an injection system, a microscopic optical system, an image scanning system, and software.

The software in this product composition is a control- software component.

| Model | Structural composition | | Net weight | Rated input power |
|---|---|---|---|---|
| | Host part | Software components | | |
| GK-IMG8000 | Fifty-channel sample system, automatic staining system, microscope optical system, image scanning system and software composition. | Name: Fluorescence Microscopy Image Analysis System<br>Model: GK-IMG8000<br>Release Version: V1.0 | 50KG | 320W |
| GK-IMG8100 | Eighty-channel sample system, automatic staining system, microscope optical system, image scanning system and software composition. | Name: Fluorescence Microscopy Image Analysis System<br>Model: GK-IMG8100<br>Release Version: V1.0 | 50KG | 320W |
| GK-IMG8200 | Eighty-channel sample system, automatic staining system, microscope optical system, image scanning system and software composition. | Name: Fluorescence Microscopy Image Analysis System<br>Model: GK-IMG8200<br>Release Version: V1.0 | 50KG | 320W |

**Device working environment requirements:**

· **Input power: AC100-240V 50/60 Hz**

· **Rated power: 20W**

· **Temperature range: -40℃~55℃** • Relative humidity：≤80%

- Atmospheric pressure range: 70 kPa to 106 kPa
- Elevation below 3000 meters
- way from high-intensity electromagnetic field interference sources
- For indoor use
- Avoid direct exposure to strong light

**Network security**

Network conditions: can connect to the LIS LAN.

(2) Security software: the software supports common security (such as 360 Security Guard, 360 Antivirus, QQ PC Manager, Kingsoft Antivirus).

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

(4) User access mechanism: username, password.

(5) Software environment and software update requirements the software environment and software updates are maintained and updated by our company's professional engineers or designated engineers trained and recognized by our company every quarter.。

Microscope: 40× objective lens

Note: This analyzer does not come with peripherals such as printers. Users need to configure devices that meet the safety level of GB4943 or its.

The analyzer uses a detection method combining automatic staining technology, fluorescence microscopy, and image scanning technology. After the sample is stained with fluorescent staining through automatic staining technology, the cells in the sample will emit specific fluorescence under the excitation of the fluorescence light source. The optical microscope system and image scanning system are used to images to obtain clear fluorescence microscopic images after enlargement, which is convenient for doctors to detect and accurately identify fungi or mycobacteria in the sample. At the same time under the control of the microcontroller, the motor is controlled to perform various actions to complete the function of automatic operation.

1.2 Characteristics of the equipment

(1) High degree of automation: The analyzer has automatic functions such as automatic coating, automaticaining, automatic selection of slides, automatic pushing of slides, and automatic scanning.

(2) Clear field of view: The automatic microscope device automatically returns to its original position, automatically, scans automatically, adjusts brightness automatically, and locates automatically, providing clear microscopic images. This reduces visual fatigue and can effectively reduce the possibility of misdiagnosis to visual fatigue.

(3) No cross-contamination: Disposable glass slides are used, which are clean and free of cross-contamination.

() Efficient image processing and counting: The application of modern image processing technology allows for the simple and quick counting of observed data required for diagnosis using computer technology, avoiding human errors and the accuracy of analysis and diagnosis.

(5) Large image storage capacity: Using a large-capacity disk storage device, a large number of images can be stored and can be for review, comparison, analysis, and printing at any time, reducing the expenditure of manpower, material resources, and financial resources for the preservation, custody, and reproduction of specimens

（6）主要参数：

| parameter | indicator; |
|---|---|
| **Scanning speed** | Scanning speed: The time to complete scanning and focusing at 40X magnification is ≤70s. |
| **Scanning method** | Face array scanning |
| **Objective parameters** | 40X |
| **Fit slide thickness** | 0.9mm~1.2mm |
| **Scanning method** | XY high-speed scanning |
| **Focusing method** | Precise focusing |
| **Autofocus range** | ±300um |
| **Excitation light source** | Include UV band and Blue band |

| | |
|---|---|
| **Camera parameters** | 5 million pixels, pixel size 3.45 microns x 3.45 microns |
| **Emit fluorescence** | Excitation at 365nm UV wavelength with a bandwidth of 40nm, emission at 420nm long pass;<br>Blue excitation at470nm with a bandwidth of 30nm, emission at 520nm long pass； |
| **Light source adjustment** | Software brightness adjustment |
| **Region Settings** | Software settings scanning range |
| **Scan mode** | Manual and automatic scanning methods |
| **Image format** | Support separate export of images |
| **Equipment self-test mode** | Support device self-test |
| **Information entry** | Manual input/Scan gun recognition |

## 1.3Product appearance

（1）Host volume：

| Model | wide（mm） | Deep（mm） | High（mm） |
|---|---|---|---|
| GK-IMG8000 | 570 | 513 | 552 |
| GK-IMG8100 | 570 | 513 | 552 |
| GK-IMG8200 | 570 | 513 | 552 |

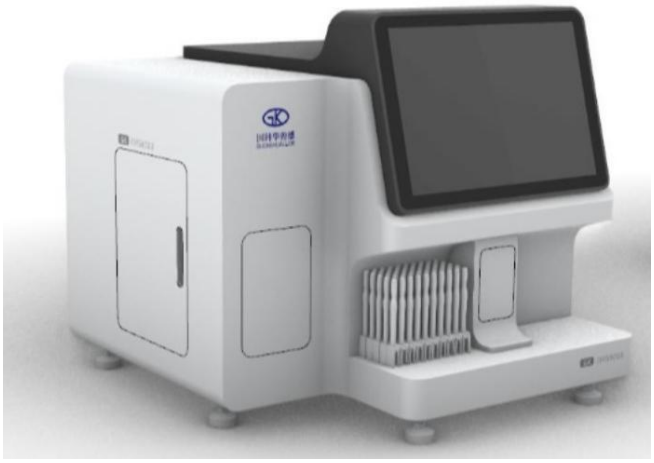
（2）Host weight：

| Model | Net weight（Kgs） | Gross weight（Kgs） |
|---|---|---|
| GK-IMG8000 | 50 | 57 |
| GK-IMG8100 | 50 | 57 |

| | | |
|---|---|---|
| GK-IMG8200 | 50 | 57 |

（3）Front view of the instrument（1.1）

（4）Side view of the instrument（1.2、1.3） Model of instrumentGK-IMG8000（8100/8200）



**Notice:** Prevent electric shock and incorrect connection. Avoid repeated power on and off in a short time. This will cause the fuse to overload and cause a fuse。

(5) To prevent fire, use a fuse of the specified model and current rating.

(6) The system appearance is neat, the outer surface is, and there is no scratch, depression, sharp edge, or burr.

(7) The various words and signs 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

## 1.4Product structure

The product consists of XY scanning platform, Z-axis focusing platform, infinity imaging optical path, fluorescence light cube, camera, control system, embedded computer host, and scanning software.The product consists of XY scanning platform, Z-axis focusing platform, infinity imaging optical path, fluorescence light cube, camera, control system, embedded computer host, and scanning software.。

GK-IMG8000、GK-IMG8100、GK-IMG8200 Model differences are shown in the table below：

| ProjectProject | | GK-IMG8000 | GK-IMG8100 | GK-IMG8200 |
|---|---|---|---|---|
| System host | Sample loading quantity | 60 | 80 | 80 |
| | Scanning mobile axis | X、YShaft | | |
| | Focusing system | ZShaft | | |
| | Control part | PCIControl card、USBData line | | |

| | | |
|---|---|---|
| | Computer configuration | CPU i7-13620H<br>GPU RTX 4060<br>16GMemory /32GMemory<br>512GSolid State Drive; SSD/1TSolid State Drive; SSD |
| | Monitor | BOE13.3inch capacitive touch screen |
| Imaging system | Image capturel | CMOSCamera |
| | Light cube | UV and Blue bands |
| | Objective lens | With microscope objective and camera interfaces at each end |
| | Objective lens | 40X 0.75 |
| Supporting software | Scanning software | Automatic fluorescence microscopic image scanning analysis system V1.0 |

Scope of Application

1.5 The fully automatic fluorescence microscope image scanning analysis instrument is suitable for the automatic staining and scanning imaging of samples such as secretions, pus, scales, hair, sputum, bronchial lavage fluid, or various body fluid samples. It can be applied to departments such as path, laboratory medicine, gynecology, respiratory medicine, infectious diseases, dermatology, etc.

1.6 Software Environment

The software of the fully automatic fluorescence microscope image scanning instrument is a comprehensive control and application software for the automatic scanning imaging of fluorescence-stained slides. It integrates mechanical control, lighting control, image acquisition, and image browsing function to achieve high-speed and high-quality slide fluorescence scanning. The module structure is reasonable, the functions are complete and matched, and it has an open interface, which is simple convenient to operate. This software is based on Windows 10 and above 64-bit system software.

1.7 Working environment of the device

● Indoor use, ambient temperature 5℃～35℃, relative humidity ≤80 atmospheric pressure 750 hPa-1060 hPa, altitude below 3000 meters, pollution level: Grade 2.

● Install the away from high temperature, humidity, dust and direct sunlight.

● Avoid shocks and vibrations.

● Ventilation requirements: avoid using the instrument in a closed environment, leave a of at least 15cm between the instrument and the wall or other surrounding equipment to ensure normal ventilation and heat dissipation.

● Avoid installing the instrument next to devices that emit, such as tape recorders, radio communication equipment, centrifuges, etc.

● Avoid installing the instrument next to computer monitors affected by electronic noise.

● The instrument be installed in places where chemicals are stored and gases are generated.

1.8 Consumable Information

Staining solution: Fungal Fluorescent Staining Solution, a product registered by Dezhou Guokang Technology Co., Ltd., is used for the staining of fungal suspected samples, Registration Number: Lu De Jian Bei 2021003; Fungal D-glucan Detection Fluorescent Staining Solution, a product registered by Dezhou Guokang Medical Technology Co., Ltd., is used for theaining of fungal suspected samples, Registration Number: Lu De Jian Bei 20210070.

Staining solution: Anti-acid Branch Bacillus Fluorescent Staining Reagent, a product registered by Dezhou Guokang Medical Technology Co., Ltd., is used for the staining of antiacid bacillus samples, Registration Number: Lu De Jian Bei 20220161.

Staining solution: Vaginal Microota Immunofluorescence Staining Reagent, a product registered by Dezhou Guokang Medical Technology Co., Ltd., is used for the staining of vaginal microbiota samples, Registration Number: Lu De Jian Bei 20220204.

Slide: Instrument-specific slide made of ultra-white glass no shadows or impurities by Dezhou Guokang Medical Technology Co., Ltd.

Cover glass: Instrument-specific cover glass made of ultra-white glass with no shadows impurities by Dezhou Guokang Medical Technology Co., Ltd.

Disposable sampler: Special sampler produced by Dezhou Guokang Medical Technology Co., Ltd., can

achieve automatic sample loading and staining by instrument.

# Chapter 2 Equipment Installation Requirements

## 2.1 Special Requirements for Use

This instrument is only suitable for the automatic staining of vaginal secretions pus, skin scales, hair, sputum, bronchoalveolar lavage fluid specimens, and for fluorescence microscopy and image observation, analysis, to assist doctors the in vitro qualitative detection of fungi in vaginal secretions, skin scales, bronchoalveolar lavage fluid, and the in vitro semi-quantitative detection of myobacterium in sputum. Special use requirements also include disassembly, cleaning, and maintenance according to regulations.

## 2.2 General Requirements

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

The instrument must be installed according to the requirements of this instruction manual.

## 2.3 Precautions

· the instrument emits an unusual odor or smoke, immediately stop using it, turn off the power switch, and unplug the power cord. Continued use of the instrument may cause a, electric shock, or personal injury. In the event of the above situation, please contact the Tianhai After-sales Service Department and do not attempt to open the instrument inspection on your own.

·Do not allow staples or paper clips or other metal objects to fall into the instrument. Otherwise, it will cause a short circuit. If the situation occurs, please immediately turn off the main switch, unplug the power cord, and

contact the Tianhai After-sales Service Department

•Do not touch the circuits of the instrument, especially with wet hands, otherwise there will be a risk of electric shock. • The power plug can only be inserted into a ~220V socket, and pay attention to the protective grounding.

• Avoid damaging the power cord, do press any device on the power cord, and do not pull the power cord with force.

• Generally speaking, since the instrument analyzes the patient's samples, all parts and surfaces have potential infectiousness.

• Rubber gloves must be worn when operating, maintaining, and inspecting the instrument. Only designated tools and parts can be used. hands with disinfectant after work.

• Do not touch waste and parts that have contacted waste with bare hands.

•If you accidentally come into contact with infectious substances or, thoroughly wash your skin with water immediately, and then operate according to the disinfection procedures specified by the hospital or laboratory where you are located.

• Before the maintenance personnel out repairs after equipment failure, clean and disinfect the biological contaminated parts that may be contacted, or take necessary protective measures.

• In order to ensure the safety of the equipment, the biological hazard sources on the equipment are effectively treated and controlled, and the equipment is properly maintained, all operators, maintenance, and maintenance personnel should undergo relevant training.

In order to ensure the safety of the equipment operators, avoid touching the moving mechanism during normal use to avoid potential dangers such as biological infection. If the equipment fails, the ordinary operator immediately disconnect the power supply of the equipment and notify the professional maintenance personnel or the manufacturer, and it is strictly forbidden to deal with it by oneself.

• The operator should be before allowing dangerous operations.

• This instrument will not release potentially toxic and harmful gases during use and placement.

• After the instrument is repaired or out of service, it needs be marked with special signs, and at the

same time, the instrument should be cleaned and disinfected.

• Moving parts: slide plate pusher. Please be aware operators should not place their hands near the area of the moving parts to avoid injury caused by the operation of the instrument.

 Biohazard

Since the instrument is used to analyze patient samples, all parts and surfaces that come into contact with the sample are potentially infectious. To avoid, rubber gloves must be worn when loading the sample and hands must be washed with disinfectant at the end of the procedure.

 **Warning**

Do not place the unit where it is difficult to operate the disconnection device (power switch, power connector, plug).！

2.4 Instrument Transportation and Storage Conditions

2.4.1 Instrument Transportation Instructions

Since the main part of the instrument is heavy (7 kg) and large in size, special attention is required during handling.

The transportation should be completed by at least two people, lifting the four corners of the instrument separately Note that the force point should be located at the base of the instrument at the bottom, and it is strictly prohibited to use the instrument's casing as a force point to the instrument, to avoid damage to the instrument's casing.

When it is necessary to transport the instrument over a long distance, please first pack the instrument back into the box and transport it in the same way with the bottom bearing the weight.

After the equipment is delivered to the responsible party, it should be transported according to the labels on the box, keeping it moisture-proof, rain-proof, and placed gently. It should be avoided to mix it with flammable and

explosive materials during transportation

**Warning**

Do not move the instrument by yourself, otherwise our company will not be responsible for any consequences arising therefrom;

2.4.2 Storage

The packaged analyzer should be stored at 0℃～ 40℃, with relative humidity not exceeding 0%, atmospheric pressure: 750 hPa～1060hPa, no corrosive gases, in a well-ventilated clean room.

25 Installation environment requirements

Check whether there is any damage to the components of the instrument host before installation.

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

The net weight of the instrument host is 50 kg. It should be installed on a platform or table that can bear the load, and it must be stable

There must be enough space for maintenance or service work. Due to heat radiation, the right side, back, and top of the instrument should be at least 15 away from the wall. Do not install the instrument near equipment that generates high frequencies, such as recording equipment, communication equipment, etc.

The power cord is .5m. Ensure that there is a suitable exit nearby.

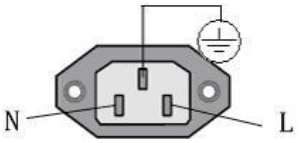
Do not place the equipment in a position where it is difficult to operate the

disconnection device (switching supply).

It is forbidden to install the machine in a place where it is directly shot by strong light.

## 2.6 Explanation of the mains power input socket

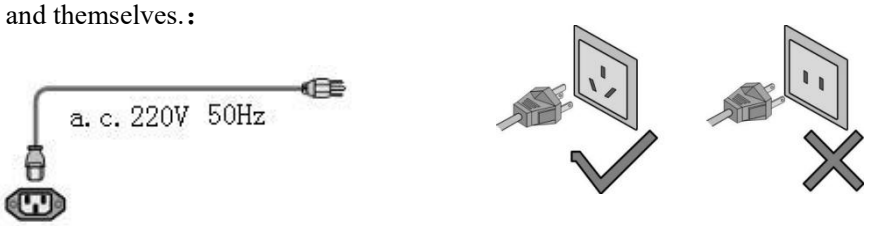
The terminal of this instrument is protected by grounding。




2.1 Power interface

## 2.7 Connection to the power supply

Plug the power cord into the power connection hole at the back of the instrument, and connect the other end to the AC power outlet. When selecting a power source, must choose a grounded outlet to ensure the safety of the instrument and themselves.：




Power socket connection instructions

## 2.8 Ventilation Requirements

It is required that the indoor ventilation is good and the air can be convection.

## 2.9 Maintenance Requirements

**Indoor air**: Indoor air should be kept circulating and free of dust.

**Exercise structure**: ensure that there is no abnormal sound during the exercise, if there is a problem, please shut down and restart, if it does not return to the normal state, please contact the after-sales service.

**Test host**: Keep the surface of the instrument clean, please use the instrument dust cover after shutting down.

# Chapter 3 Equipment Installation

3.1 Equipment Installation

Before leaving the factory, this equipment has been commissioned and installed by professional authorized technical and has passed strict inspection and testing. When installing the equipment, please pay attention to the following points:

1) The equipment should be installed in a place with normal temperature,ness, and good ventilation, and pay attention to moisture-proofing, dust-proofing, ventilation, and fire prevention to ensure product quality and safety.

2) When the equipment for placement before use, the operator should pay attention to the reasonable placement position of the equipment, and avoid the equipment limiting or interfering with the operation of medical staff as much possible.

3) When the equipment arrives at the customer's site, it will be commissioned on-site by professional authorized technical engineers of our factory or by agents who have qualified training, and provide comprehensive and basic operation training for the customer.

3.2 Treatment of Waste Liquid and Waste Paper

3.2.1 Treatment of Waste LiquidIt is strictly forbidden to discharge the waste liquid produced by the instrument into ordinary sewers or discard it arbitrarily. It should be handled as follows:

1. Connect to the waste bottle through a pipeline, and the waste liquid recovered by the waste liquid bottle should be handled according to the hospital's regulations. Among them, the entrance height of the waste liquid should be lower than the waste liquid discharge port of the instrument to prevent waste liquid from flowing back.

2. Connect to the hospital's dedicated waste liquid recovery pipeline, and placement position of the instrument should be higher than the entrance height of the hospital's dedicated waste liquid recovery pipeline.

**3.3 Disposal of waste boards**

**3.3.1 Disposal of waste board boxes**

Discard the disposable slides after the test to the instrument waste plate box. Waste plate boxes should be cleaned regularly, and discarded slides should be disposed of in accordance with hospital

regulations.

**biohazard**

Since the instrument is used to analyze patient samples, waste cartridges are potentially infectious. To avoid infection, wear rubber gloves when cleaning waste boxes and wash your hands with disinfectant at the end of work.

# Chapter 4 Boot Up

## 4.1 Turn on the power

After confirming that all parts of the machine are connected properly, check the cleaning solution and disposable slide to ensure that it is enough for one day, turn on the power behind the main unit, and start the computer.

## 4.2 Access to the Software

**1. Click on the "" icon on the desktop to enter the software**

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

# Chapter 5 Specimen Testing Operation Process

## 5.1 Specimen Preparation

5.1.1 Preparation of dander specimens:

5.1.1.1 Dander specimen collection and sample size:

The dandruff specimen should be scraped by a professional dermatologist according to the size of the lesion, and the lesion tissue debris should be scraped to avoid large tissues. The sample size should be smaller than the coverslip size.

5.1.1.2 Preparation of danders slides:

Place the specimen on a glass slide, add a drop of fluorescent stain, cover the coverslip, then gently press the coverslip, expel the air bubbles and thin the specimen, use a blotting paper to absorb the surrounding overflow, and then put it into the instrument for testing.

5.1.1.3 Preservation of dander specimens:

Due to the fluorescence quenching phenomenon, the specimen should be detected in time and should not be retained.

5.1.2 Preparation of sputum specimens:

The sputum sample will be stained into a piece by the hospital examiner and then put into the instrument for testing.

5.1.3 Preparation of vaginal discharge specimens:

1) Use a cotton swab to take the secretion of the hole in the back of the vagina and insert it into the sample tube, add about (500~1000) microliter of sample dilution to the test tube, squeeze the wall of the test tube by hand after full washing, so that the liquid adsorbed by the cotton swab fully flows back into the test tube, discard the cotton, and put the test tube into the tube rack.

2) If the specimen is not processed within one hour after collecting the specimen, keep the tube in an environment of 2 °C~8 °C.

3) Very thick or very thick specimens may result in poor slide injection, which need to be re-diluted before these specimens can be detected on a fully automated fluorescence microscope

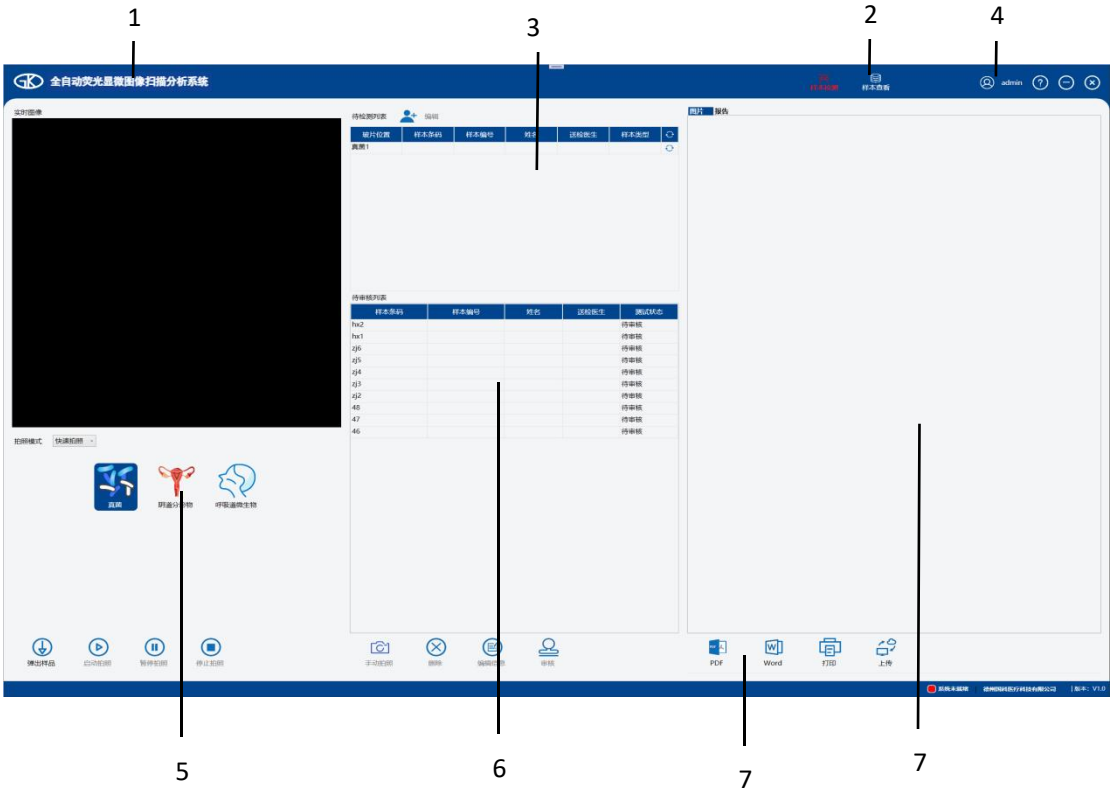
image scanning analyzer.

5.1.4 Alveolar lavage fluid specimen preparation:

The alveolar lavage fluid specimen will be fluorescently stained into a piece by the laboratory physician of the hospital, and then put into the instrument for testing.

## 5.2 Use of Equipment

### 5.2.1 Interface introduction



Thereinto:

1 represents: the name and icon of the software

2 represents: menu bar

3 represents: the area of the list to be tested

4 represents: system menu

5 represents: select the detection area for the user's sample type

6 representatives: sample area to be reviewed

7 representatives: test report text and printing area

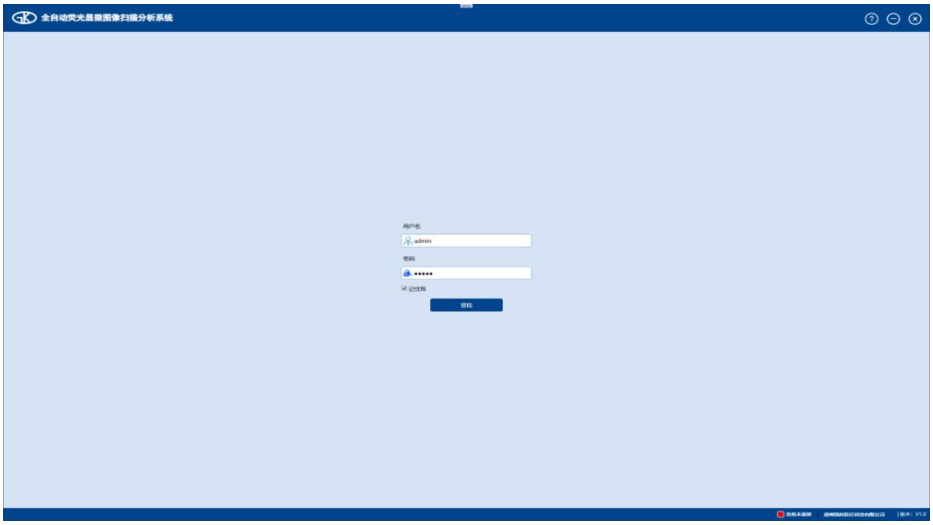
8 represents: sample data display area

5.2.2 Operation Procedure

5.2.2.1 Login

1）Open the software on your computer 

2）Click "Login" (username and password are already set in advance).



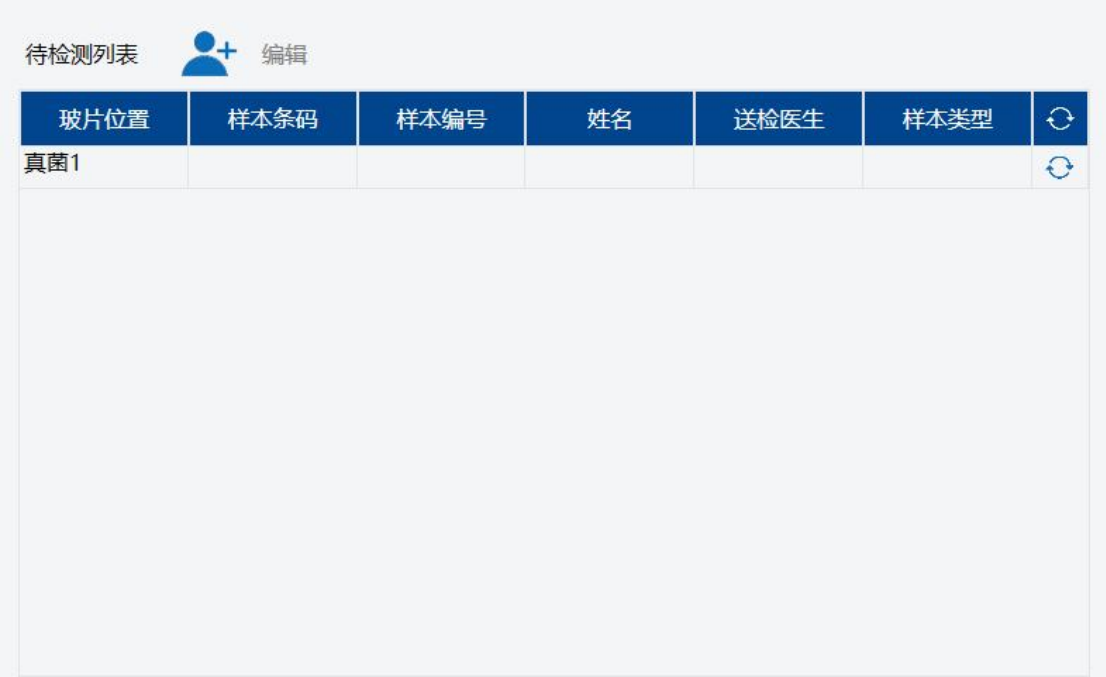
5.2.2.2 Sample testing

If the sample is a vaginal discharge sample, the sample collection tube is placed on the injection tube rack; If it is a respiratory secretion and fungal sample, the following steps are carried out after staining by a doctor.

1）Click on the "Sample Testing" button in the menu bar


2) There are two parts in the sample detection type selection area, where in the photo mode, you can choose "Quick photo" and "Fine photo; in the sample type, you can choose "Fungi", "Vaginal secretion" and "Respiratory microorganism".

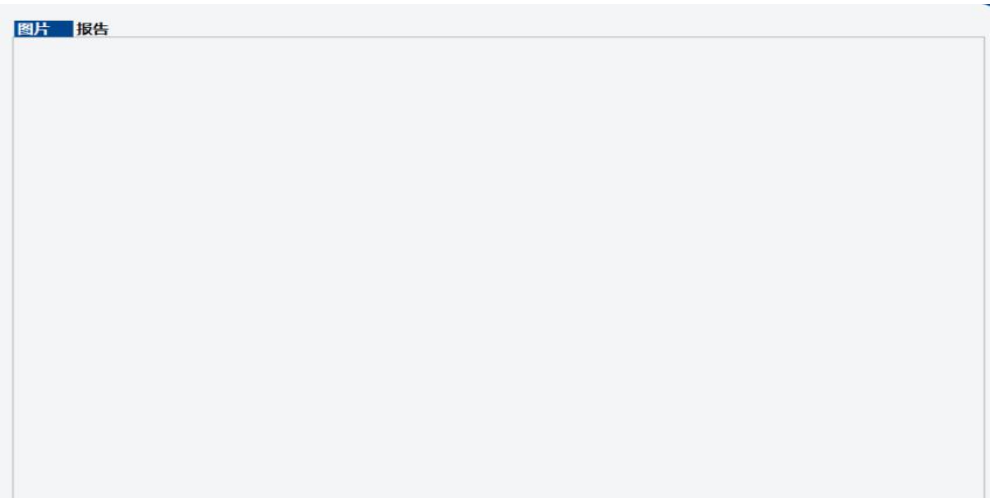

3）Once you have selected the type of sample to be tested, select the paddle location in the To be tested area to create a new test, which is not required for vaginal discharge samples.




4）After creating the test, enter the corresponding information according to the candidate box (you can use the barcode scanner to scan the barcode in the input barcode candidate).


5）Click the "Start Scan" button and the instrument will start scanning normally。


6）After the photo is taken, the image data is displayed in the image bar on the far right.




5.2.2.3 Edit the report sheet (here you need to show and explain the three report sheets in detail).

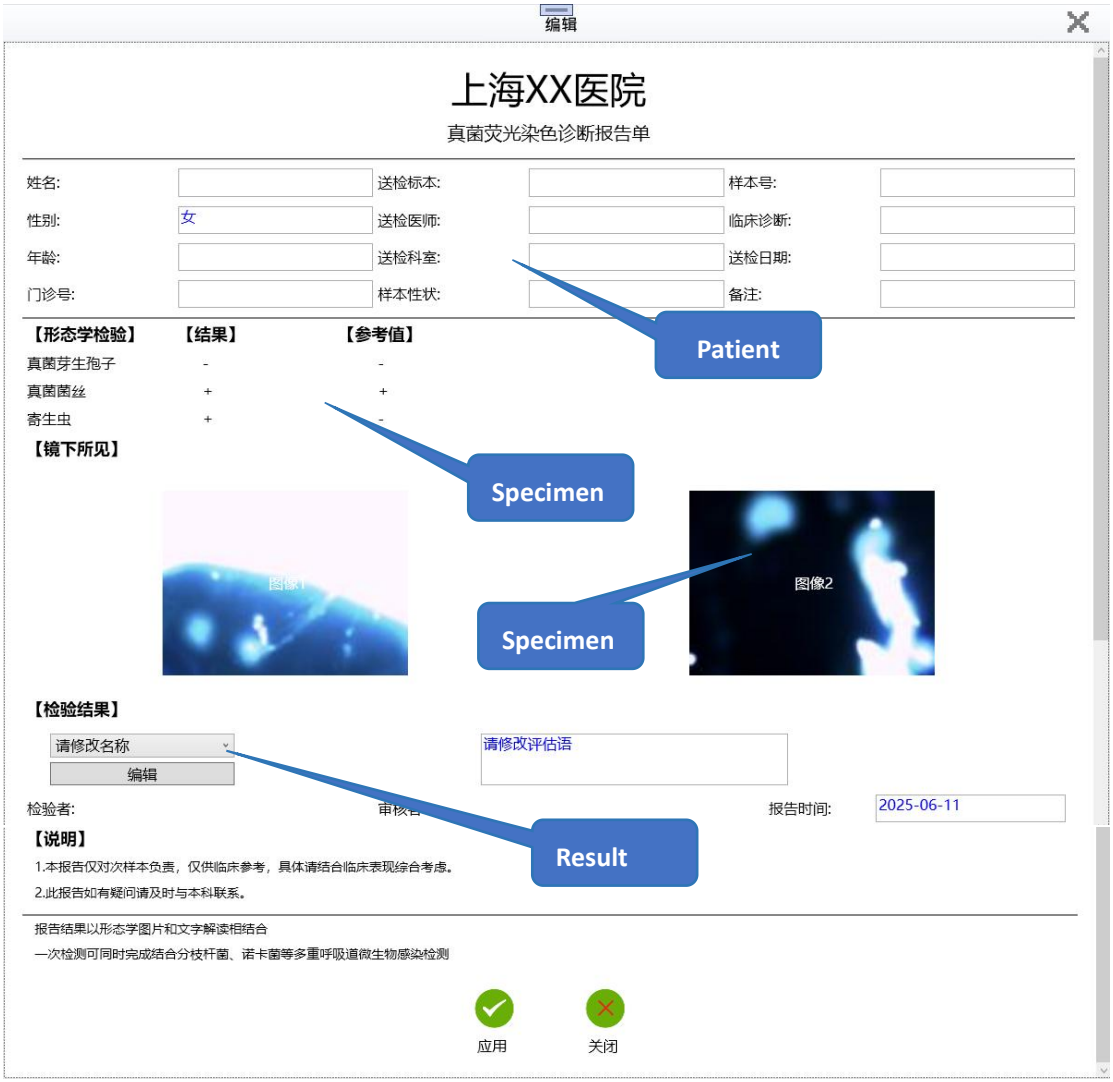
1）In the To be reviewed list, select the sample barcode for the report you want to edit, and then click Report


2）Under the "Pending Audit" area, you can manipulate the samples that have been tested


a) "Delete": Deletes the selected test sample;

b) "Edit Information": edit the content of the report;

Fungal test report editing




Explanation to the editors of the report:

Patient information: Normally, the patient information is synchronized with the patient information entered before the test, and if the input is incorrect, it can also be modified in the report editing area.

Specimen results: The [Result] column represents the result of automatic identification by the

instrument, and the [Reference Value] column represents the result reference according to the expert consensus, and the specimen result is for reference only.

Specimen shooting: The instrument will automatically select two images from the 40 photos taken during specimen testing to embed in the report, and the operator can also change the pictures in the report by himself.

Result selection: The operator can select the preset diagnostic terms in the drop-down menu, or edit the diagnostic terms in the "Edit" column; In the evaluation on the right, you can edit and modify the text description.

Vaginal discharge test report editing


Explanation to the editors of the report:

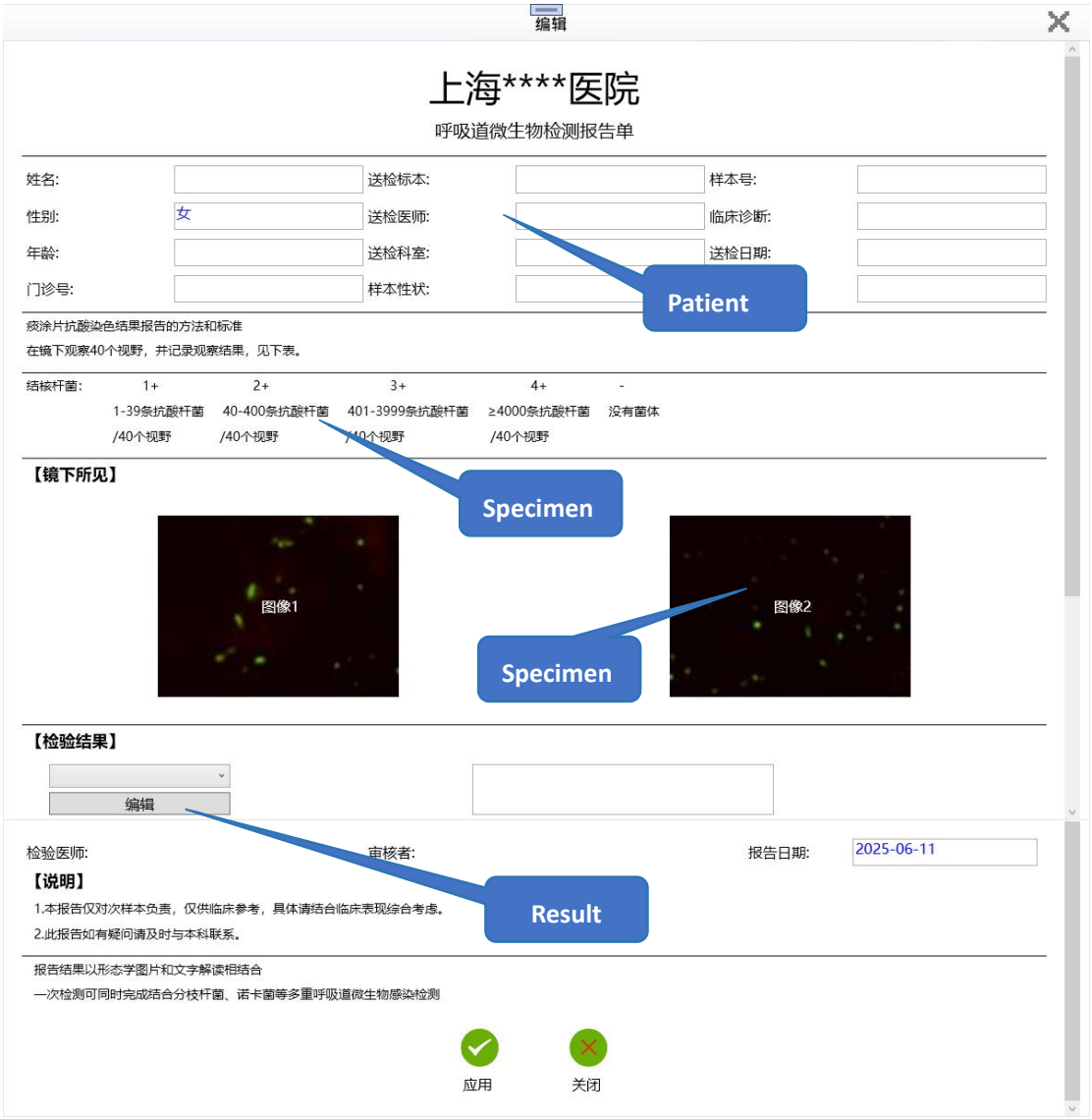
Patient information: Normally, the patient information is synchronized with the patient information entered before the test, and if the input is incorrect, it can also be modified in the report editing area.

Specimen results: The [Result] column represents the result of automatic identification by the instrument, and the [Reference Value] column represents the result reference according to the expert consensus, and the specimen result is for reference only.

Specimen shooting: The instrument will automatically select two images from the 40 photos taken during specimen testing to embed in the report, and the operator can also change the pictures in the report by himself.

Result selection: The operator can select the preset diagnostic terms in the drop-down menu, or edit the diagnostic terms in the "Edit" column; In the evaluation on the right, you can edit and modify the text description.

Respiratory test report editing




Explanation to the editors of the report:

Patient information: Normally, the patient information is synchronized with the patient information entered before the test, and if the input is incorrect, it can also be modified in the report editing area.

Specimen results: The [Result] column represents the result of automatic identification by the instrument, and the [Reference Value] column represents the result reference according to the expert consensus, and the specimen result is for reference only.

Specimen shooting: The instrument will automatically select two images from the 40 photos taken during specimen testing to embed in the report, and the operator can also change the pictures in the report by himself.

Result selection: The operator can select the preset diagnostic terms in the drop-down menu, or edit the diagnostic terms in the "Edit" column; In the evaluation on the right, you can edit and modify the text description.

When you're done editing, click "Apply" to save your edits.

c) Review: Review the current sample information (After the review is passed or failed, the sample test results will be deleted from the "To be reviewed" list and entered the sample viewing page.)


3）In the "Sample Test Report Text and Print Area": You can generate sample test reports, print paper documents, and upload them to the LIS system.


4）The contents of the report

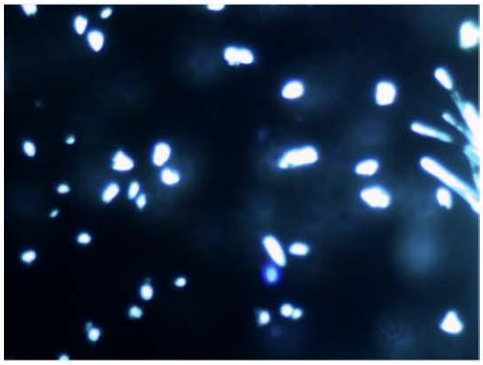
# 上海XX医院

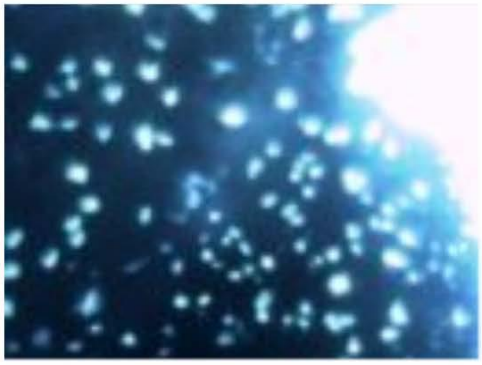
## 真菌荧光染色诊断报告单

| | | | | | |
|---|---|---|---|---|---|
| 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

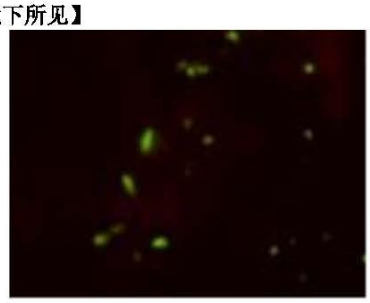
## 呼吸道微生物检测报告单

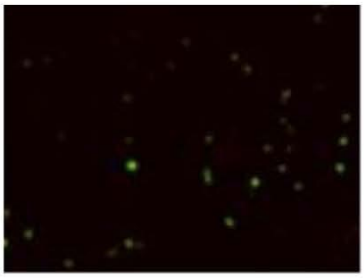
| | | | | | |
|---|---|---|---|---|---|
| 姓名: | | 送检标本: | | 样本号: | |
| 性别: | 女 | 送检医师: | | 临床诊断: | |
| 年龄: | | 送检科室: | | 送检日期: | 2025-06-11 11:11 |
| 门诊号: | | 样本性状: | | 备注: | |

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】





【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

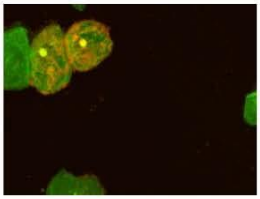
# 上海****医院

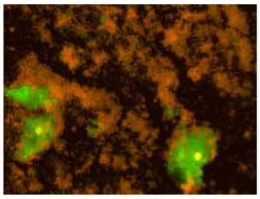
## 阴道分泌物荧光检验报告单

| | | | |
|---|---|---|---|
| 姓名: | 送检标本: | 样本号: | |
| 性别: | 送检医师: | 临床诊断: | |
| 年龄: | 送检科室: | 送检日期: | 2025-06-18 11:11 |
| 门诊号: | 分泌物性状: | 备注: | |

| 【形态学检验】 | 【结果】 | 【参考值】 |
|---|---|---|
| 上皮细胞 | - | +/++ |
| 白细胞 | - | +/++ |
| 乳酸杆菌 | - | ++/+++ |
| 短杆菌 | + | - |
| 杆菌聚集 | + | - |
| 细胞裸核 | - | - |
| 线索细胞 | + | - |
| 念珠菌 | - | - |
| 芽生孢子 | + | - |
| 孢子 | + | - |
| 菌丝 | - | - |
| 滴虫 | + | - |

【镜下所见】





【微生态形态学指标】

| | | |
|---|---|---|
| 清洁度 | Ⅱ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 | 加德纳菌 | 乳酸杆菌 |

【Av评分】

| | | |
|---|---|---|
| Av分值 | 2 | 0~2 |

【检验结果】

镜下可见孢子或菌丝或念珠菌，双球菌或链球菌及白细胞，为需氧菌性阴道炎与外阴阴道假丝酵母菌病混合感染。

【说明】

1. 标本采集前应排除月经期、24h盆浴、性交、局部用药、阴道洗及污染等情况。
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: ☐ | 微生物培养 ☑ | 支原体培养或RNA检测: ☐ |
| 实时PCR: ☐ | 沙眼衣原体RNA检测: ☐ | 淋球菌培养或RNA检测: ☐ |

检验医师: 审核者: 报告日期:2025-06-18

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形式

5.2.2.4 View sample data

1）Click the "Sample View" button in the menu bar


2）View sample data for different periods through different buttons


3）Select the corresponding sample, the corresponding picture and report will appear on the right, click on a single image, you can enlarge the picture.

5.2.2.5 Print Reports


5.2.2.6 Retest

For samples that fail, retesting requires repeating all steps of sample testing, re-sampling, and re-testing.

5.2.2.7. Exit

Click on the "System Menu"  and select "Yes" to close (remove the slide holder before exiting). 

# Chapter VI Equipment Maintenance and Repair

## 6.1 Product Maintenance

### 6.1.1 Cleaning of the instrument host

As an important part of the instrument, the pipeline of the instrument should be cleaned with a special cleaning solution (isopropanol or computer special cleaning solution) when using the instrument every day, and the specific operations are as follows:

When the instrument is turned on for the first time every day to enter the detection interface, it is recommended to clean it once and wait for the cleaning to be completed before the detection operation.

Carry out daily maintenance and cleaning when the machine is shut down, and cut off the power supply after the action is completed.

Dust removal is carried out on the tray of the injection mechanism and the outer surface of the instrument on a regular basis. When dusting, gently wipe with a flexible material, and never use a corrosive cleaning liquid. Special attention should be paid to the cleaning of the injection tray so that it does not affect the normal operation of the instrument due to corrosion and rust surfaces. After the dust is removed, cover the instrument with a dust cover

Use a medical cotton swab to wipe the surface of the needle weekly.。

**biohazard**

Since the instrument is used to analyze patient samples, it is potentially infectious. To avoid infection, wear rubber gloves when cleaning equipment and wash your hands with disinfectant at the end of work.

### 6.1.2 Waste liquid treatment

The waste liquid generated by the instrument is strictly forbidden to be discharged into the ordinary sewer or discarded at will, and shall be carried out in the following manner:

1. Connect to the waste bottle with a pipeline, and the waste liquid recovered from the waste bottle should be disposed of in accordance with the regulations of the hospital. Among them, the inlet

height of the waste liquid bottle should be lower than the waste liquid discharge outlet of the instrument to prevent liquid backflow.

2. Connect to the hospital's special waste liquid recovery pipeline with a pipeline, and the instrument should be placed at a higher height than the inlet of the hospital's special waste liquid recovery pipeline.

 **warn**

It is strictly forbidden to discharge the waste liquid into the ordinary sewer or discard it at will, and the outlet of the waste liquid of the instrument should have an appropriate height to prevent the backflow of the waste liquid.

### 6.1.3 Waste board box disposal

After the test, the disposable slide is automatically loaded into the waste board box. Waste boxes should be cleaned regularly and disposed of in accordance with the regulations of the hospital

 **biohazard**

Since the instrument is used to analyze patient samples, waste cartridges are potentially infectious. To avoid infection, wear rubber gloves when cleaning waste boxes and wash your hands with disinfectant at the end of work.

### 6.1.4 Hose inspection

After the whole machine is used for 1 year, the internal hose is inspected, and the aging or leakage phenomenon is immediately contacted by the manufacturer to replace the new pipe and then checked once a year.

 biohazard

Since the instrument is used to analyze patient samples, the tubing is potentially infectious. To avoid infection, wear rubber gloves when cleaning the tubing and wash your hands with disinfectant at the end of the work.

## 6.2 Product Contraindications

1. The power supply must have a protective grounding terminal, and the instrument must be reliably grounded through the power socket.

2. The user can not open the chassis without authorization, so as to avoid danger due to high voltage, and the unpacking maintenance work is completed by professional engineers.

## 6.3 Maintenance when not in use for a long time

Perform monthly preventative maintenance and inspections of the equipment, and run the equipment for 10 minutes at a time.

Empty the slide holder and sterilize the instrument before use.

## 6.4 Instrument Maintenance

Due to the failure of the instrument caused by uncertain factors, the user can make a preliminary judgment on the fault phenomenon according to the content of this section. If it is a minor fault, the user can troubleshoot it as follows; If the following situations occur, please contact our after-sales service department in time. When the user reports for repair, please provide detailed fault information to facilitate timely and accurate maintenance.

a) Operate according to the operation instructions of the instruction manual, and the instrument cannot operate normally.

b) The characteristics of the instrument have changed significantly, and the test results have been significantly deviated.

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

**note**

When replacing the fuse, it is necessary to disconnect all power sources before to avoid electric shock.

### 6.4.1 The instrument cannot be started

Press the I/O switch of the instrument, the instrument does not operate, you can check it as follows:

1. Check whether the power cord of the instrument is reliably connected and whether there is a ~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 out, the user can replace it by himself. However, the power switch of the host must be turned off, the power cord must be unplugged, and the operation must be carried out under the condition of ensuring that there is no risk of electric shock, or in accordance with the relevant regulations of the user unit.

Fuse (fuse) specification: F3A L250V:

**note**

When replacing the fuse, it is necessary to disconnect all power sources before to avoid electric shock.

## 6.5 Description of other replaceable parts

Some parts may be damaged after long-term use, and these parts must be provided by our company because they are related to the stability and safety of the instrument. When it needs to be replaced, please contact the company's after-sales service department directly to purchase, and the professional will replace it. The specific components are as follows:

Electronic control platform control board

- Power strip

Spotting needles

Syringe pumps

Liquid pumps

Test tube racks

## 6.6 Handling of instruments

After the instrument is installed and operated normally, it should generally not be moved, so as to avoid vibration and damage to the high-precision components and wearing 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 in a packing box and then carry it by two or more people.

**warn**

Do not move the instrument without authorization, our company will not be responsible for all the consequences caused by this!

# Chapter VII Meaning of Warnings and Other Signs

Table 1: Symbols, logos and their meanings

| Symbolic identification | meaning |
|---|---|
|  | Note! Check out the attached documents! |
|  | A biological risk identifier that indicates the presence of a potential biological risk associated with a medical device |
|  | Be careful with your hands |
|  | In vitro diagnostic medical device identification, indicating that the medical device is an in vitro diagnostic medical device |
|  | The "I" and "0" on the power switch indicate the "on" and "off" of the total power supply respectively |
|  | Communication |

| | |
|---|---|
|  | USB port identification |
|  | up |
|  | Afraid of rain |
|  | Afraid of the sun |
|  | Fragile items, handle them carefully |
|  | Stacking is prohibited |
|  | Tumbling is prohibited |
|  | Medical Waste Mark |
|  | Be careful that there is electricity |
|  | CE marking |

# Chapter VIII Electromagnetic Compatibility

1. This device uses radio frequency energy for specific functions. It has low RF emissions and a low chance of interference with nearby electronics.

2. Portable and mobile radio frequency communication equipment may have an impact on this equipment, and other equipment used in the vicinity of this equipment at the same time shall meet the relevant requirements for electromagnetic compatibility.

3. Suitable for use in all facilities that are not domestic and not directly connected to the public low-voltage power supply network of domestic residences.

4. The power socket should have reliable protective grounding measures and use the supplied power cords, components and accessories.

5. The floor should be wooden, concrete, or tile, and if the floor is covered with synthetic material, the relative humidity should be at least 30%.

6. The power supply should be of the quality typical of a commercial or hospital environment.

7. If the user needs to keep the equipment running continuously during the power outage, then the user is recommended to use an uninterruptible power supply.

8. The power frequency magnetic field in the intended installation site should be measured to ensure that it is low enough. This equipment should be kept 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 its internal functions.

11. Category A: Equipment used in non-residential environments and facilities that are not directly connected to the residential low-voltage power grid.

12. RF interference may occur when operating in certain environments.

**Warning: The use of accessories and cables other than those specified by the manufacturer of this equipment may result in an increase in emissions or a decrease in the immunity of the device, except for accessories and cables sold by the manufacturer of this equipment as spare parts for internal components.**

**Warning: This device should not be used in close proximity to or stacked with other devices, and if it must be used in close proximity or stacking, it should be observed to verify proper operation in the configuration it is using.**

**Note: It is forbidden to use this device next to strong radiation sources (e.g., unshielded RF sources), as this may interfere with the normal operation of the device.**

**Note: This equipment is designed and tested as 1 group A device in GB 4824. In a domestic environment, this device may cause radio interference and protective measures are required.**

**Note: It is recommended to evaluate the electromagnetic environment before using the device, and it is the user's responsibility to ensure that the electromagnetic compatibility environment of the device is enabled to work properly.**

This device provides electromagnetic compatibility information. This equipment meets the emission and immunity requirements specified in GB/T 18268; It is designed and tested according to Class A equipment in GB 4824. In the environment of use, this equipment may cause radio interference and precautions are required.

It is forbidden to use this device next to strong radiation sources (such as unshielded RF sources), as this may interfere with the normal operation of the equipment.

Annex:

Table 1 Basic requirements for immunity test

| port | Pilot project | Basic Standards | Test values | Performance criteria |
|---|---|---|---|---|
| enclosure | Electrostatic Discharge (ESD) | GB/T 17626.2 | contact discharge 4 kV; Air discharge 4 kV | B A |
| | Radio frequency electromagnetic fields | GB/T 17626.3 | 3 V/m(80 MHz~1 GHz)<br>3 V/m(1.4 GHz~2 GHz)<br>1 V/m(2.0 GHz~2.7 GHz) | |
| AC power (including protective grounding) | Voltage sag | GB/T 17626.11 | 0% half-cycle<br>0% 1 cycle<br>70% 25/30e 周期 | B<br>B<br>C |
| | Short-term interruptions | GB/T 17626.11 | 0% 25/30e cycle | C |
| | Burst of pulses | GB/T 17626.4<br>GB/T 17626.5 | 1 kV(5/50 ns,5 kHz)<br>0.5 kV[a]/1 kV[b] | B<br>B |

| | | | | |
|---|---|---|---|---|
| | Surge<br>Conducted disturbance induced by RF field | GB/T 17626.6 | 3 V(150 kHz~80 MHz) | A |
| DC power supply d (including protective grounding) | Burst of pulses<br>Surge<br>Conducted disturbance induced by RF field | GB/T 17626.4<br>GB/T 17626.5<br>GB/T 17626.6 | 1 kV(5/50 ns,5 kHz)<br>0.5 kV[a]/1 kV[b]<br>3 V(150 kHz~80 MHz) | B<br>B<br>A |
| I/O signaling/control (including cable for functional ground port) | Burst of pulses<br>Surge<br>Conducted disturbance induced by RF field | GB/T 17626.4<br>GB/T 17626.5<br>GB/T 17626.6 | 0.5 kV[d](5/50 ns,5 kHz)<br>1 kV[b,c]<br>3 V[d](150 kHz~80 MHz) | B<br>B<br>A |
| I/O signals/controls directly connected to the power supply | Burst of pulses<br>Surge<br>Conducted disturbance induced by RF field | GB/T 17626.4<br>GB/T 17626.5<br>GB/T 17626.6 | 1 kV(5/50 ns,5 kHz)<br>0.5 kV[a]/1 kV[b]<br>3 V(150 kHz~80 MHz) | |

[a] Wire-to-line.

[b] Line to ground.

[c] Applies only to long-distance lines (see 3.6).

[d] Only applicable if the length of the line exceeds 3m.

[e] "25/30 cycles" means that 25 cycles are for tests rated at 50 Hz and 30 cycles are for tests rated at 60 Hz.

Table 2 Immunity test requirements for equipment used in industrial sites

| port | Pilot project | Basic Standards | Test values | Performance criteria |
|---|---|---|---|---|
| enclosure | Electrostatic Discharge (ESD) | GB/T 17626.2<br>GB/T 17626.3 | The contact discharge is 4 kV<br>and the air discharge is 8 kV | B<br>A |
| | Radiofrequency electromagnetic field radiation | GB/T 17626.8 | 10 V/m(80 MHz~1 GHz)<br>3 V/m(1.4 GHz~2 GHz)<br>1 V/m(2.0 GHz~2.7 GHz) | A |
| | Rated power frequency magnetic field | | 30 A/mo | |
| AC power | Voltage sag | GB/T 17626.11 | 0% 1 cycle<br>40% 10/12h cycle<br>70% 25/30h cycle | B<br>C<br>C |
| | Short-term interruptions | GB/T 17626.11 | 0% 250/300h cycle | C |
| | Burst of pulses | GB/T 17626.4 | 2 kV(5/50 ns,5 kHz) | B |
| | Surge | GB/T 17626.5 | 1 kV[a]/2 kV[b] | B |
| | Conducted disturbance induced by RF field | GB/T 17626.6 | 3 V[f](150 kHz~80 MHz) | A |
| DC power supply g | Burst of pulses | GB/T 17626.4 | 2 kV(5/50 ns,5 kHz) | B |
| | Surge | GB/T 17626.5 | 1 kV[a]/2 kV[b] | B |
| | Conducted disturbance induced by RF field | GB/T 17626.6 | 3 V[f](150 kHz~80 MHz) | A |
| I/O signaling/control (including cable for functional ground port) | Burst of pulses | GB/T 17626.4 | 1 kV(5/50 ns,5 kHz)[d] | B |
| | Surge | GB/T 17626.5 | 1 kV[b,c] | B |
| | Conducted disturbance induced by RF field | GB/T 17626.6 | 3 V[d,f]（150 kHz～80 MHz） | A |
| I/O | Burst of pulses | GB/T 17626.4 | 2 kV(5/50 ns,5 kHz) | B |

| | | | | |
|---|---|---|---|---|
| signal/control port directly connected to the power delivery network | Surge<br>Conducted disturbance induced by RF field | GB/T 17626.5<br>GB/T 17626.6 | 1 kV[a]/2 kV[b]<br>3 V[f](150 kHz~80 MHz) | B<br>A |

[a] Wire-to-line.

[b] Line to ground.

[c] Applies only to long-distance lines (see 3.6).

[d] Only applicable if the length of the line exceeds 3m.

[e] For devices that are sensitive to magnetic fields only. When the magnetic field strength is greater than 1 A/m, the display interference of the cathode ray tube is allowed.

[f] The conducted RF test is rated lower than the radiated RF test because it simulates the resonance state at each frequency, making it a harsher test.

[g] The DC connection between the parts of the equipment/system, if not connected to the DC distribution network, should be treated as an I/O signal/control port.

[h] "25/30 cycles" means that 25 cycles are for tests rated at 50 Hz and 30 cycles are for tests rated at 60 Hz.

Table 3: Immunity test requirements for equipment used in a controlled electromagnetic environment

| port | Pilot project | Basic Standards | Test values | Performance criteria |
|---|---|---|---|---|
| enclosure | Electrostatic Discharge (ESD)<br>Radiofrequency electromagnetic field radiation | GB/T 17626.2<br>GB/T 17626.3 | The contact discharge is 4 kV and the air discharge is 8 kV<br>1 V/m(80 MHz~1 GHz)<br>1 V/m(1.4 GHz~2 GHz)<br>1 V/m(2.0 GHz~2.7 GHz) | B<br>A |
| AC power | Voltage sag<br>Burst of pulses<br>Surge<br>Conducted disturbance induced by RF field | GB/T 17626.11<br>GB/T 17626.4<br>GB/T 17626.5<br>GB/T 17626.6 | 0% half-cycle<br>1 kV(5/50 ns,5 kHz)<br>0.5 kV[a]/1 kV[b]<br>1 V(150 kHz~80 MHz) | B<br>B<br>B<br>A |
| DC power supply [c, d] | Burst of pulses<br>Surge<br>Conducted disturbance induced by RF field | GB/T 17626.4<br>GB/T 17626.5<br>GB/T 17626.6 | 1 kV(5/50 ns,5 kHz)<br>Not requirement<br>1 V(150 kHz~80 MHz) | B<br><br>A |
| I/O signaling/control (including cable for functional ground port) | Burst of pulses<br>Surge<br>Conducted disturbance induced by RF field | GB/T 17626.4<br>GB/T 17626.5<br>GB/T 17626.6 | 0.5 kV[c]（5/50 ns，5 kHz）<br>Not requirement<br>1 V[c](150 kHz~80 MHz) | B<br><br>A |
| Measure I/O[c] | Burst of pulses<br>Surge<br>Conducted disturbance induced by RF field | GB/T 17626.4<br>GB/T 17626.5<br>GB/T 17626.6 | Vehicle<br>Not requirement<br>Vehicle | |
| [a] Wire-to-line. | | | | |

[b] Line to ground.

[c] Only applicable if the length of the line exceeds 3m.

[d] The DC connection between the parts of the equipment/system, if not connected to the DC distribution network, should be treated as an I/O signal/control port.

[e] The set nuisance value should be stated in the manufacturer's product specifications.

Table 4: Minimum immunity requirements for in vitro diagnostic (IVD) medical devices

| port | Pilot project | EMC Basic Standards | Test values |
|---|---|---|---|
| enclosure | Electrostatic Discharge (ESD) | GB/T 17626.2 | 空气放电:2 kV、4 kV、8 kV,<br>接触放电:2 kV、4 kV |
| | Radiating electromagnetic fields | GB/T 17626.3 | 3 V/m,80 MHz~2.0 GHz,80% AM |
| | Rated power frequency magnetic field a | GB/T 17626.8 | 3 A/m，50/60 Hz |
| AC power | Voltage sag d | GB/T 17626.11 | 1 cycle 0%; 40% for 5/6 cycles; 25/30 Cycle 70% |
| | Voltage interrupt d | GB/T 17626.11 | 5%, duration: 250/300 cycles |
| | Burst of pulses | GB/T 17626.4 | 1 kV(5/50 ns,5 kHz) |
| | Surge | GB/T 17626.5 | Line-to-ground: 2 kV / Line-to-wire: 1 kV |
| | Radio frequency conduction | GB/T 17626.6 | 3 V, 150 kHz~80 MHz, 80%AM |
| DC power supply | Burst of pulses | GB/T 17626.4 | 1 kV(5/50 ns,5 kHz) |
| | Surge | GB/T 17626.5 | Line-to-ground: 2 kV / Line-to-wire: 1 kV |
| | Radio frequency conduction | GB/T 17626.6 | 3 V, 150 kHz~80 MHz, 80%AM |
| I/O signals | Burst of pulses | GB/T 17626.4 | 0.5 kV(5/50 ns,5 kHz) |
| | Surge | GB/T 17626.5 | not |
| | Radio frequency conduction | GB/T 17626.6 | 3 V, 150 kHz~80 MHz, 80%AM |
| I/O signals connected to the mains power supply | Burst of pulses | GB/T 17626.4 | 1 kV(5/50 ns,5 kHz) |
| | Surge | GB/T 17626.5 | not |
| | Radio frequency conduction | GB/T 17626.6 | 3 V, 150 kHz~80 MHz, 80%AM |
| [a] Testing is only available for potentially magnetically sensitive devices. CRT shows that the interference value is allowed to be greater than 1 A/m. | | | |

[b] Only applicable if the cable is longer than 3m.

[c] Does not apply to input ports that are intended to be connected to a battery or rechargeable battery (to be removed or disconnected from the device when recharged). Equipment with a DC power supply port (using an AC-DC power adapter) should be tested at the AC input port of the AC-DC power adapter specified by the manufacturer. Unless specified, a typical AC-DC power adapter should be used. This test is for DC power input ports that are expected to permanently connect to long-distance lines.

[d] "5/6 cycles" means "5 cycles for the 50 Hz test" and "6 cycles for the 60 Hz test".

Table 5 Immunity test requirements for portable test and measurement equipment

| port | Pilot project | Basic Standards | Test values |
|---|---|---|---|
| enclosure | Electrostatic Discharge (ESD)<br>Radio frequency electromagnetic fields | GB/T 17626.2<br>GB/T 17626.3 | The contact discharge is 4 kV and the air discharge is 8 kV<br>3 V/m(80 MHz~1 GHz)<br>3 V/m(1.4 GHz~2 GHz)<br>1 V/m(2.0 GHz~2.7 GHz) |

The power chargers used in products within the scope of this part of GB/T 18268 do not have further immunity requirements.

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