Production license number:

Product Registration Certificate No.:

Technical Requirement No.:

Fully automatic pathology slide scanning analyzer

(Fully automatic pathological slide scanning analyzer)

Instructions

GK-APSSA8300\GK-APSSA8500\GK-APSSA8600

DeZhou GuoKe Medical Technology Co., Ltd

Number：(0534)7057266 Fax：(0534)7057266

E-mail：office@guoke-medical.com Web：http://www.guoke-medical.com

After sales service hotline number：0534-7057266。

Registrant/Manufacturer: Dezhou Guoketong Medical Technology Co., Ltd

Registered address/Production enterprise address: 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

Registered address: 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

Production address: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

After sales service company name: Dezhou Guoke Medical Technology Co., Ltd

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

Complaints Hotline：0534-7057266

This manual includes instructions for use and maintenance

Manual version number: V1.0

Equipment production date: see product label

Instruction manual preparation date: May 15, 2025

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

precautions

Before use

1.Before using this product, please read the user manual carefully and check if the standard configuration is complete. Before use, installation and debugging should be carried out by professional authorized technicians from the shipper. The machine can only be used after it is running normally, the software and hardware are coordinated correctly, and the debugging is qualified.

2. The operator or user must refer to the instruction manual at the locations marked on the equipment to identify potential hazards and take appropriate measures.

in use

1. Please use according to the factory regulations, otherwise the protection provided by the equipment may be damaged.

2.If any of the following abnormal situations occur during use, please stop using immediately! Turn off the power, unplug the power plug, and consult our after-sales service center. Do not attempt to disassemble the product for self repair without authorization!

1) When abnormal situations such as black smoke or odor are emitted.

2) When a sharp alarm sounds abnormally or the indicator light does not display.

3) When liquid or foreign matter infiltrates the interior of 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) Please do not disassemble the device casing without authorization.

3) When the product malfunctions, individuals or untrained personnel are prohibited from forcibly disassembling or repairing the product.

4) Do not place heavy objects above the instrument to avoid deformation caused by compression.

5) The equipment must be equipped with qualified glass slide consumables during use, and the consumables after use must not be discarded at will and must be treated as medical waste.

6) This device is a high-precision instrument. During transportation, please do not invert it, be waterproof and moisture-proof, handle it gently, and 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 lifespan should be handled in accordance with relevant local laws and regulations.

8) This device has a certain automatic recognition function, and the test results need to be determined by doctors based on their professional judgment.

9) Regularly maintain the hardware of the instrument.

10) After completing the daily testing, discard the discarded glass slides to avoid contamination.

11) The main part of the equipment is the motion mechanism. During normal operation, please do not block your hands or other parts of your body to prevent any impact on your own safety and the equipment.

12) When handling potential infectious substances (such as samples, waste boxes), please use protective gloves.

Catalogue

Version change record

Version number	release date	reason for modification
V1.0	2025.05.15	first issue

Chapter 1 Overview

1.1. Equipment Introduction

Product name：Fully automatic pathological slide scanning analyzer

Product model：GK-APSSA8300、GK-APSSA8500、GK-APSSA8600

Production date: see nameplate

Usage period: 5 years

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

The software in this product is a control type software component.

Model	Structural composition		net weight	Rated input power
	Host part	Software components		
GK-APSSA8300	Single channel sampling system,microscopic optical system, image scanning system, and software composition	Name:Pathological Slice Scanning Analysis System Model：GK-APSSA8300 Releases：V1.0	30KG	320W
GK-APSSA8500	Three channel sampling system,microscopic optical system, image scanning system, and software composition	Name:Pathological Slice Scanning Analysis System Model：GK-APSSA8500 Releases：V1.0	31KG	320W
GK-APSSA8600	Five channel sampling system,microscopic optical system, image scanning system, and software composition	Name:Pathological Slice Scanning Analysis System Model：GK-APSSA8600 Releases：V1.0	33KG	320W

Equipment working environment requirements:

- Input power supply：AC100-240V 50/60 Hz

- Rated power: 320W
- Temperature range: -40 ℃~55 ℃
- Relative humidity: ≤ 80%
- Atmospheric pressure range: 70 kPa to 106 kPa
- Altitude below 3000 meters
- Stay away from high-intensity electromagnetic interference sources
- Indoor use
- Avoid direct exposure to strong light

network security

(1) Network conditions: Can connect to LIS LAN.

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

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

(4) User access mechanism: username, password.

(5) Requirements for software environment and software updates: The software environment and software updates are maintained and updated by our professional engineers or designated engineers trained and recognized by our company who connect to the computer every quarter.

Microscope: 40 x objective lens

 Attention: This analyzer does not come with external devices such as printers. Users need to configure their own devices that comply with GB4943 or equivalent security standards.

The fully automatic pathological section scanning analyzer is a new type of intelligent digital section scanning instrument, which, together with a specially designed optical imaging system and precision motion mechanism, can obtain high-precision and high-quality panoramic digital section images, ensuring more natural and accurate color reproduction and image clarity. With one click operation, it is simple and

convenient. In conjunction with the pathology department management system, digital slides are integrated with clinical observations, gross examinations, and other information of cases, making them easy to read.

1.2Equipment features

1) Digitally scan standard slices

2) Realize automatic conversion of multiple slices and continuous scanning

3) Scanning the 15mm × 15mm area using fast scanning mode at 20x magnification takes an average of less than 60s

4) Repetitive positioning accuracy ± 0.01mm

5) Automatic lighting control

6) Automatic stitching of scanned images for clear imaging

7) Arbitrary browsing function for digital slice images

8) Automatic recognition of slice codes

9) The product comes with built-in encryption lock control

10)**Parameters：**

parameter	指标
scanning speed	Scanning speed: Under 40X magnification, the scanning and focusing completion time is ≤ 70s
Scanning method	area scanning
Objective lens parameters	40X
Adapt to the thickness of glass slides	0.9mm~1.2mm
Scanning method	XY high-speed scanning

Focusing method	Accurate focusing
Auto focus range	±300um
Camera parameters	5 million pixels, pixel size 3.45 microns x 3.45 microns
Light source adjustment	Software brightness adjustment
Regional settings	Software settings scanning range
SCAN	Equipped with manual and automatic scanning modes
picture format	Support exporting images separately
Equipment self-test mode	Support device self check
Information input	Manual input/barcode scanner recognition

1.3Product appearance

（1）Host volume：

Model	W（mm）	D（mm）	H（mm）
GK-APSSA8300	39	42	50
GK-APSSA8500	39	42	50
GK-APSSA8600	39	48	50

（2）Weight：

Model	net weight（Kgs）	gross weight（Kgs）
GK-APSSA8300	30	32
GK-APSSA8500	31	33
GK-APSSA8600	33	35

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

（4）Side view of the instrument (Figure 1.2, 1.3) Instrument modelGK-APSSA8300（8500/8600）

right 

left 

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

be careful:

Prevent electric shock and incorrect connections.

Avoid repeated startup and shutdown in a short period of time. This will overload the fuse and cause it to melt.

To prevent fires, use fuses of the specified model and rated current

（6）The appearance of the system is neat and tidy, with no scratches, bumps, edges,

or burrs on the outer surface.

(7) The various text markings on the external surface of the system are clear, accurate, and firm.

(8) The system fasteners are securely installed and the switch buttons are sensitive.

1.4 Product mix

This product consists of an XY scanning platform, a Z-axis focusing platform, an infinite imaging optical path, a camera, a control system, an embedded computer host, a display screen, and scanning software.

GK-APSSA8300 、 GK-APSSA8500 、 GK-APSSA8600 The differences in models are shown in the table below：

Project		GK-APSSA8300	GK-APSSA8500	GK-APSSA8600
系统主机	Number of glass slides loaded	1 piece	3 piece	5 piece
	Scan the moving axis	X、Y axle		
	focusing system	Z axle		
	controller	PCI Control card、USB data line		
	Software operation configuration	System software: Windows 10 and above (64 bit) Processor: i7 processor with 6 cores or above Memory: 16GB or above Graphics card: RTX 4060 and above Hard disk capacity: 512GB or above Essential software: Net framework Optional software: None Antivirus software: None Network environment: None		
	Display	BOE 13.3-inch capacitive touch screen		

成像系统	Acquisition	CMOS camera
	Light Cube	UV and Blue bands
	Lens barrel	Both ends support microscope objective interface and camera interface respectively
	Objective	40X 0.75
配套软件	Scanning Software	Pathological section scanning analysis system V1.0

1.5 Scope of application

The fully automatic pathological section scanning analyzer is mainly used for digitizing pathological and biological tissue sections.
Can be applied in pathology departments, research institutes, criminal investigation and forensic medicine, medical schools and other fields. Compared with traditional glass slices, digital slices are easier to browse and store, and have more expandable uses: establishing a pathology slice library and database, facilitating the search and storage of difficult cases and important data; It can also be used for pathological remote consultation, scientific research and analysis, morphological teaching, hospital information construction, etc.

1.6 Software environment

The software processing system of the fully automatic digital pathology slice scanning analyzer is a comprehensive control and application software for realizing the digitalization process of slices. It integrates functional modules such as mechanical control, lighting control, image acquisition, scanning stitching, image browsing, and network browsing, achieving high-speed, high-quality, and fully automated slicing digitalization process. The module structure is reasonable, the functions are complete and matched, it has open interfaces, and the operation is simple and convenient. This software is based on Windows 10 and above 64 bit systems.

1.7 Equipment working environment

● Indoor use, ambient temperature 5 ℃~35 ℃, relative humidity ≤ 80%; Atmospheric pressure ranging from 750 hPa to 1060 hPa, altitude below 3000 meters, pollution level: Level 2.

● Avoid installing instruments in places with high temperatures, humidity, dust, and direct sunlight.

● Avoid shaking and vibration.

●Ventilation requirements: Avoid using instruments in enclosed environments. Leave a minimum distance of 15cm between the instrument and walls or other surrounding equipment to ensure normal ventilation and heat dissipation.

● Avoid installing instruments near noisy equipment such as recorders, wireless communication devices, centrifuges, etc.

● 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.

1.8 Supplies information

Staining solution: Fungal fluorescent staining solution, a registered product of Dezhou Guoke Medical Technology Co., Ltd., used for staining suspected fungal samples, registration number: Lude Equipment Preparation 20210033; Fungal D-glucan detection fluorescent staining solution, a registered product of Dezhou Guoke Medical Technology Co., Ltd., used for staining suspected fungal samples, registration number: Lude Equipment Preparation 20210070.

Staining solution: Acid resistant mycobacterial fluorescent staining reagent, registered product of Dezhou Guoke Medical Technology Co., Ltd., used for staining acid resistant bacterial samples, registration number: Lude Medical Equipment No. 20220161.

Staining solution: Vaginal microbiota immunofluorescence staining reagent, registered product of Dezhou Guoke Medical Technology Co., Ltd., used for staining vaginal microbiota samples, registration number: Lude Medical Equipment No. 20220204.

Glass slide: Instrument specific glass slide from Dezhou Guoke Medical Technology Co., Ltd., made of ultra white glass material, without any shadow

impurities.

Cover glass: Instrument specific cover glass from Dezhou Guoke Medical Technology Co., Ltd., made of ultra white glass material, without any shadow impurities.

Chapter 2 Equipment installation requirements

2.1 Special requirements for use

This instrument is only suitable for fluorescence microscopy imaging and image observation and analysis of vaginal secretions, pus, dandruff, hair, sputum, bronchoalveolar lavage fluid and other specimens. It assists doctors in qualitative detection of fungi in vaginal secretions, dandruff, bronchoalveolar lavage fluid and semi quantitative detection of mycobacteria in sputum.

Special usage requirements also include disassembly, cleaning, and maintenance according to regulations.

2.2 General requirements

Before operating the instrument, carefully read this manual and keep it properly for future reference.

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

2.3 Precautions

• If the instrument emits an 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. If any of the above situations occur, please contact the company's after-sales service department and do not turn on the machine for self inspection.

• Do not let metal such as staples or paper clips fall into the instrument. Otherwise, it

may cause a short circuit. If the above situation occurs, 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 with wet hands, as 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 onto the power cord, and do not pull the power cord with force.

• Due to the instrument analyzing patient samples, all its components and surfaces have potential infectivity.

• Rubber gloves must be worn when operating, maintaining, and inspecting instruments. Only specified tools and parts can be used. After work, wash your hands with disinfectant.

• Do not touch waste or parts that have come into contact with waste with bare hands.

• If you accidentally come into contact with infectious substances or surfaces, immediately rinse your skin thoroughly with water and follow the disinfection procedures specified by your hospital or laboratory.

• Before carrying out repairs after equipment failure, maintenance personnel should clean and disinfect any biological contaminated components that may come into contact, or provide necessary protection.

• In order to ensure the safety of equipment operators, effective treatment and control of biological hazards on the equipment, and normal maintenance of the equipment, all operators, maintenance personnel should receive relevant training.

• In order to ensure the safety of equipment operators, they should avoid touching the moving mechanism during normal use to avoid the risk of biological infection and other hazards. If the equipment malfunctions, ordinary operators should immediately disconnect the power supply of the equipment and notify professional maintenance personnel or the manufacturer. Self disposal is strictly prohibited.

• Operators should undergo training before being allowed to perform hazardous operations.

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

•After the instrument is repaired or stopped, it needs to be marked with a special label and cleaned and disinfected.

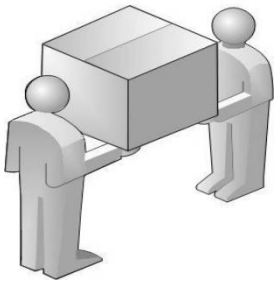
• Moving parts: board pushing claws. Attention operators, please do not place your hands near the operating parts area to avoid injury caused during the operation of the instrument.

ohazard

Due to the use of instruments for analyzing patient samples, the components and surfaces in contact with the samples have potential infectivity. To avoid infection, rubber gloves must be worn when loading samples, and hands should be washed with disinfectant after work..

warn

Do not place the device in places where it is difficult to operate disconnect devices (power switches, power connectors, plugs)!



2.4 Instrument transportation and storage conditions

2.4.1 Instrument transportation instructions

Due to the heavy weight (≥ 31kg) and large volume of the instrument host, special attention should be paid during transportation.

At least two or more people need to work together to lift the four corners of the instrument. Note that the point of force should be located on the base at the bottom of the instrument, and the instrument shell should not be used as the point of force to move the instrument, in order to avoid damage to the instrument shell.

When it is necessary to transport instruments over long distances, please first put the

instruments back into the packaging box and use bottom force to transport them.

After the equipment is delivered to the responsible party, it should be transported according to the markings on the packaging box, moisture-proof, rainproof, and handled with care, and should be avoided from being mixed with flammable and explosive materials during transportation.

warn

Never move the instrument without authorization, our company will not be responsible for any consequences caused by this!

2.4.2 keep in storage

The packaged analyzer should be stored in a clean room with a temperature range of 0 ℃ to+40 ℃, a relative humidity not exceeding 80%, an atmospheric pressure range of 750 hPa to 1060 hPa, no corrosive gases, and good ventilation.

2.5 Installation environment requirements

Before installation, check for any damage to the components of the instrument host.

The instrument must be installed indoors in a dry and dust-free environment.

The net weight of the instrument host is ≥ 31 kg. It should be installed on a platform or table that can withstand the load and be stable.

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

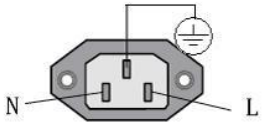
Do not install instruments near high-frequency devices such as recording equipment, communication equipment, etc.

The power cord is 1.5m. Ensure there is a suitable exit nearby.

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

It is prohibited to install the machine in areas with strong direct sunlight.

2.6 Instructions for the Host Power Input Socket

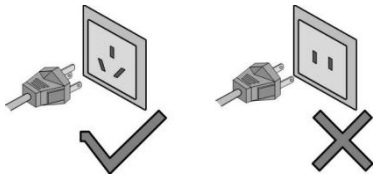
This instrument terminal is protected by 

grounding.

2.1power 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 selecting a power supply, users must choose a socket that has been reliably grounded to ensure the safety of the instrument and themselves：



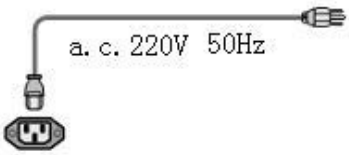


图 2.2 Power socket connection instructions

2.8 Ventilation requirements

Require good indoor ventilation and air circulation.

2.9 Maintenance requirements

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

Sports structure: Ensure that there is no abnormal noise during the movement process. If there is a problem, please shut down and restart. If it does not return to normal, please contact after-sales service.

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

Chapter 3 Equipment Installation

3.1 Equipment installation

This device has been debugged and installed by a professional authorized

technical engineer before leaving the factory, and has undergone strict inspection and testing. Attention should be paid during equipment installation:

1) The equipment should be installed in a place that is at room temperature, dry, and well ventilated, and attention should be paid to moisture, dust, ventilation, and fire prevention 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 placement, and try to avoid restricting or interfering with the operation of medical staff as much as possible.

3) The equipment will be delivered to the customer's location for on-site debugging by our professional authorized technical engineers or qualified trained agents, providing comprehensive and basic training on usage and operation to the customer.

3.2 Disposal of waste glass slides

3.2.1 Disposal of waste board boxes

Discard the disposable glass slides after testing into the instrument waste tray. The waste board box should be cleaned regularly, and discarded glass slides should be disposed of according to the hospital's regulations.

Biohazard

Due to the use of instruments for analyzing patient samples, waste board boxes have potential infectivity. To avoid infection, rubber gloves must be worn when cleaning the waste board box, and hands should be washed with disinfectant after work.

Chapter 4 Boot Up

4.1 Turn on the power

Turn on the device and follow the steps below:

1) First, plug in the power supply and turn on the power switch.
2) Then press the device start button for 2 seconds and release it.

4.2 Access to the Software

1. Click the "QiCytoSlice 1.0" 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 personnel.

Chapter 5 Specimen Testing

5.1 Specimen Preparation

5.1.1 Preparation of dander specimens (for example):

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:

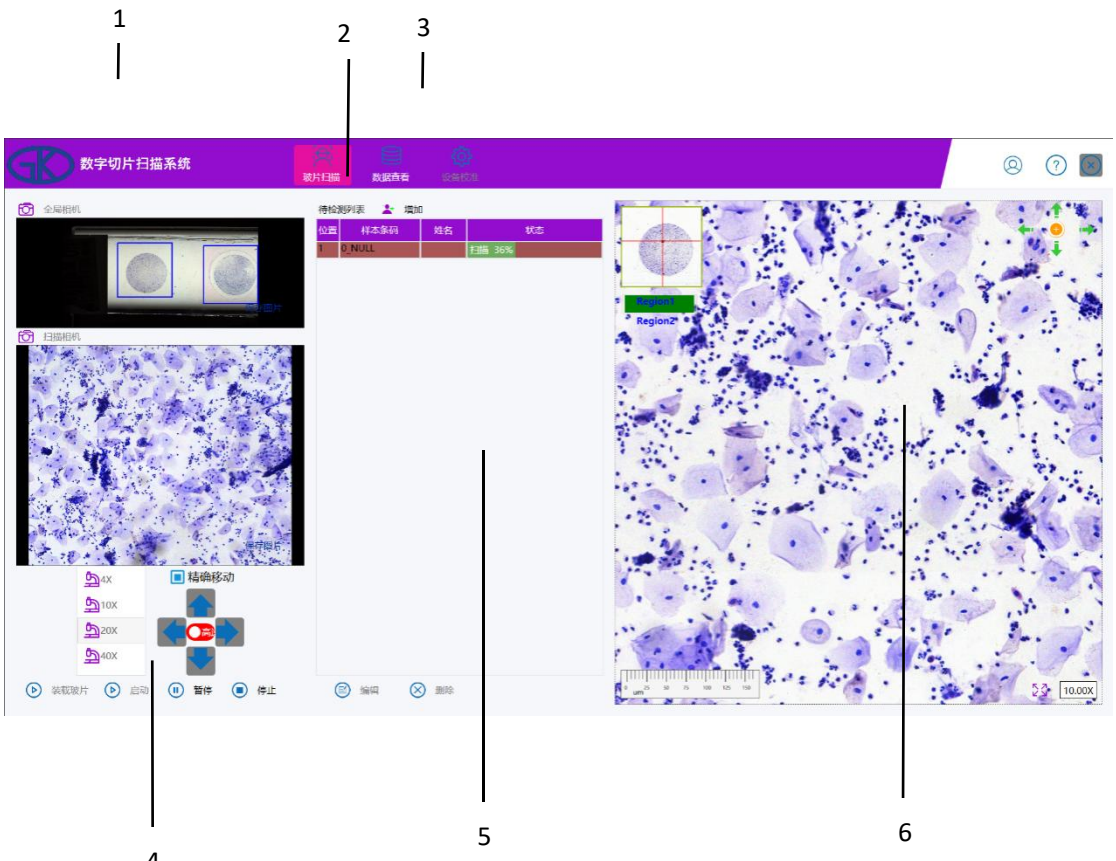
The laboratory physician will fluorescely stain the vaginal discharge sample into a piece and then put it into an instrument for testing.

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 Specimen testing operations

5.2.1 Interface introduction



Thereinto:

1 represents: the name and icon of the software

2 represents: the area to be tested

3 represents: system menu

4 represents: operation area

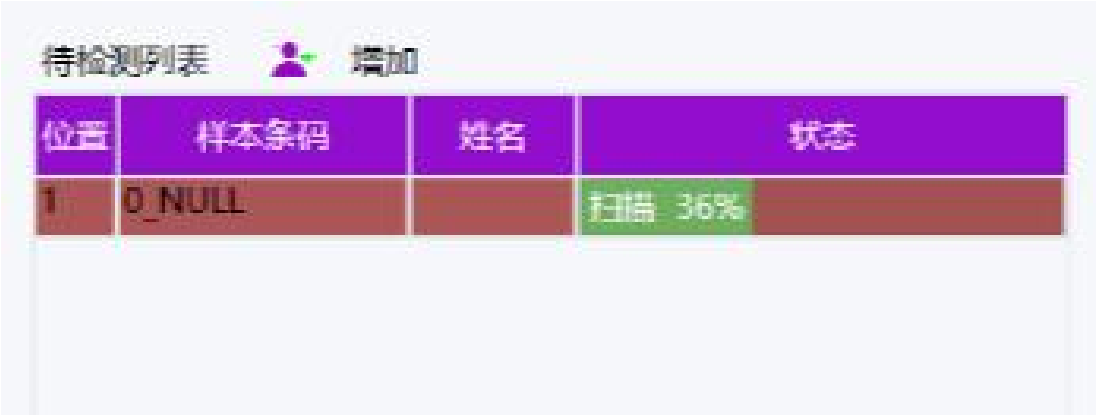
5 representatives: sample area to be reviewed

6 represents: sample data display area

5.2.2 Operation Procedure

5.2.2.1. Sample testing

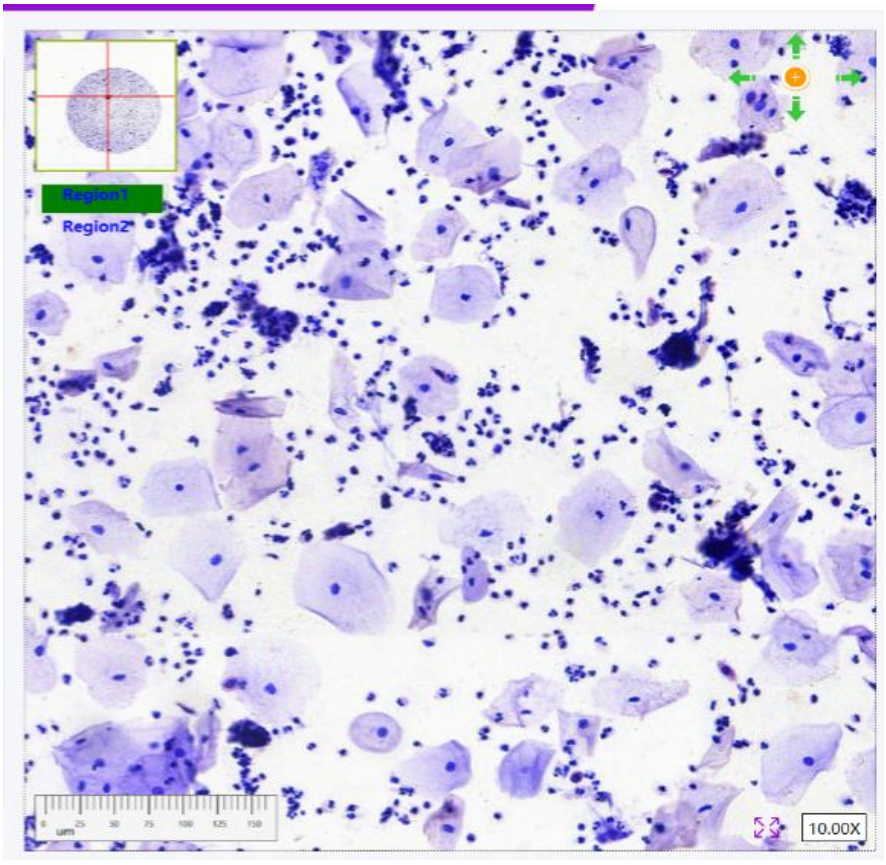
1）Click Slide Scan in the system menu area, and select the slide location in the Waiting List area to create a new test.



2）After the new test is completed, enter the corresponding information according to the candidate box (you can use the barcode scanner to scan the barcode in the input barcode candidate box).

3）Click the "Start" button and the instrument will start scanning normally.

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



5.2.2.2. Edit the report

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

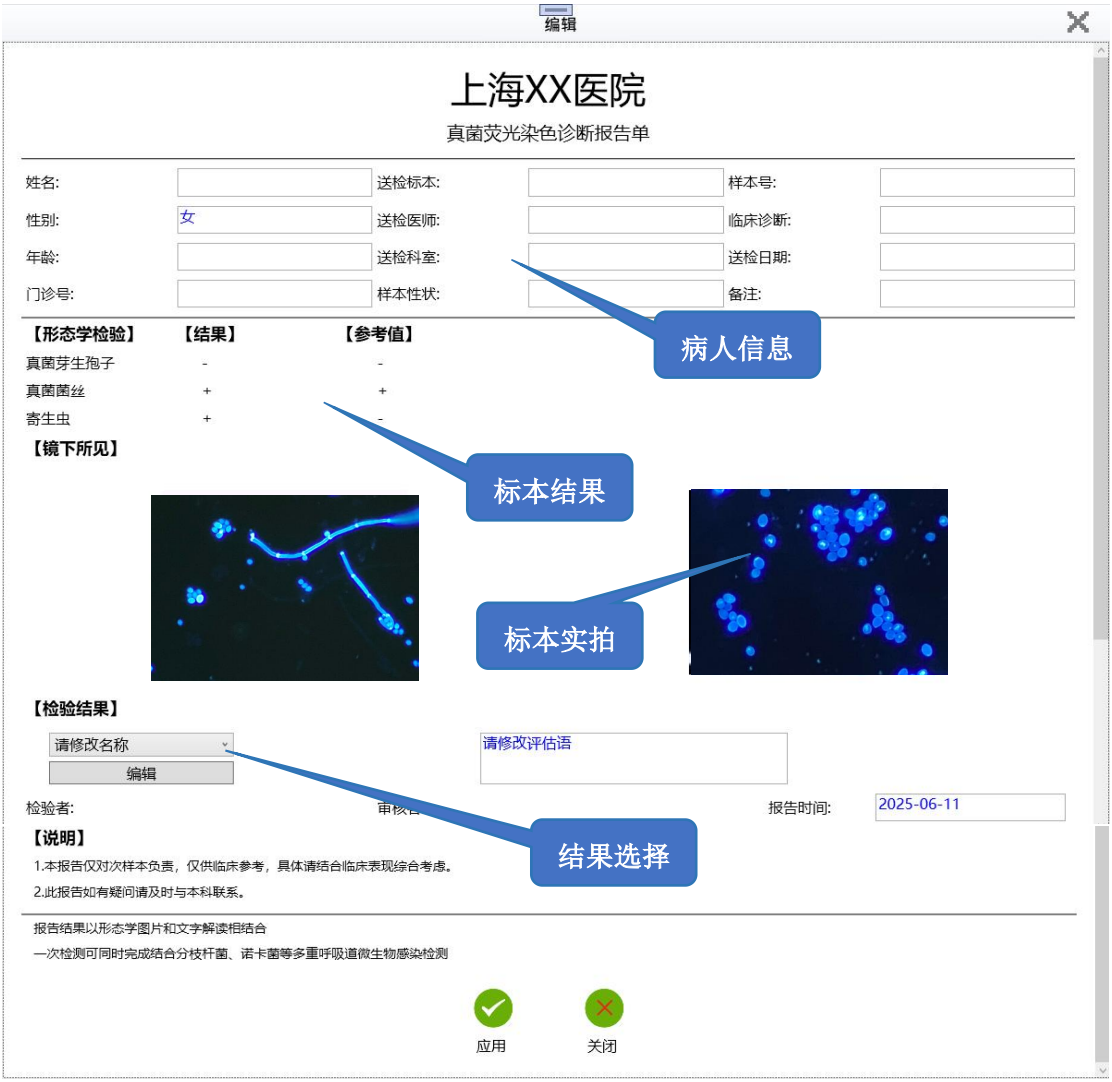
2）Under the "Pending Audit" area, you can manipulate the samples that have been tested;

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

> Note!
>
> Once a report is deleted, it cannot be repaired, so choose carefully

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

(1) "Fungal detection" 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.

(2) Editing of vaginal discharge test report

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.

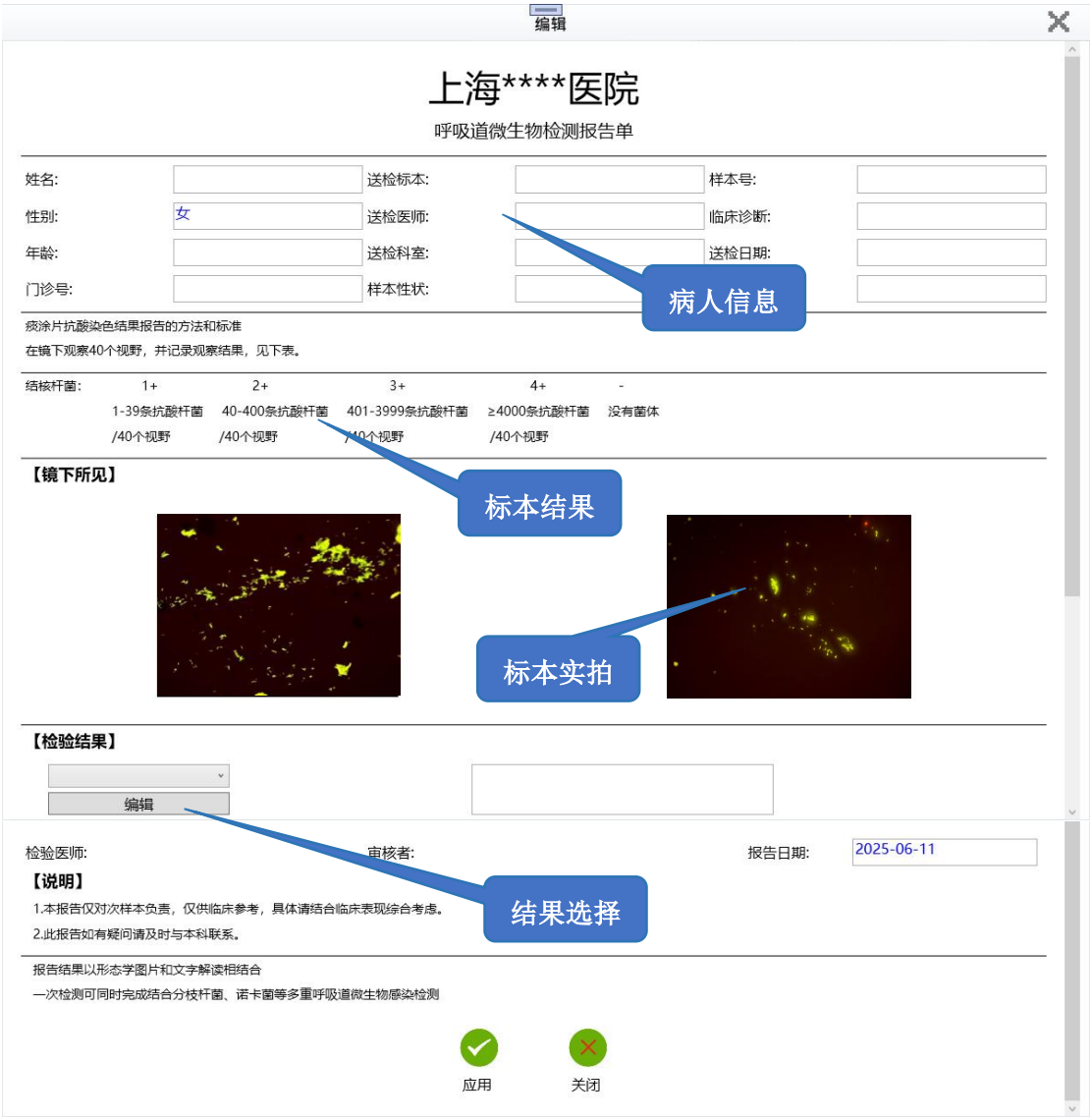
Specimen results: The [Result] column represents the result of automatic identification by the instrument, and the [Reference Value] column represents the result reference according to the expert consensus, and the specimen result is for reference only.

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.

(3) Editing of respiratory test reports



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 the report is finished editing, click "Apply" to save the 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

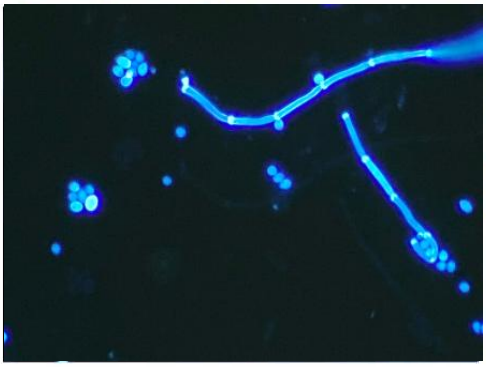
上海XX医院

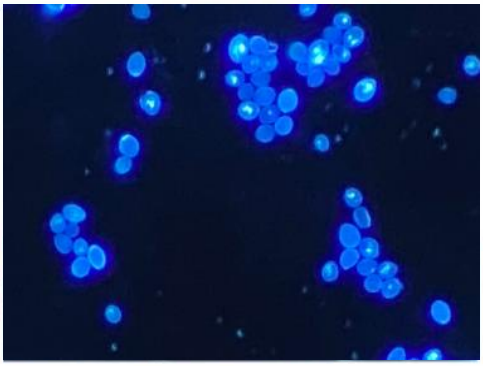
真菌荧光染色诊断报告单

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

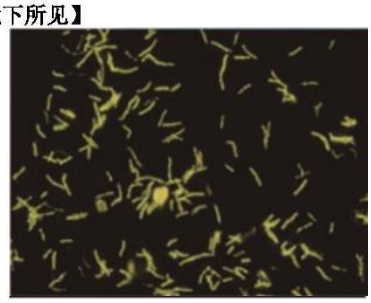
呼吸道微生物检测报告单

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

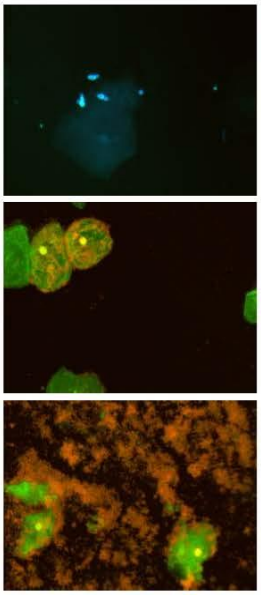
上海****医院

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!

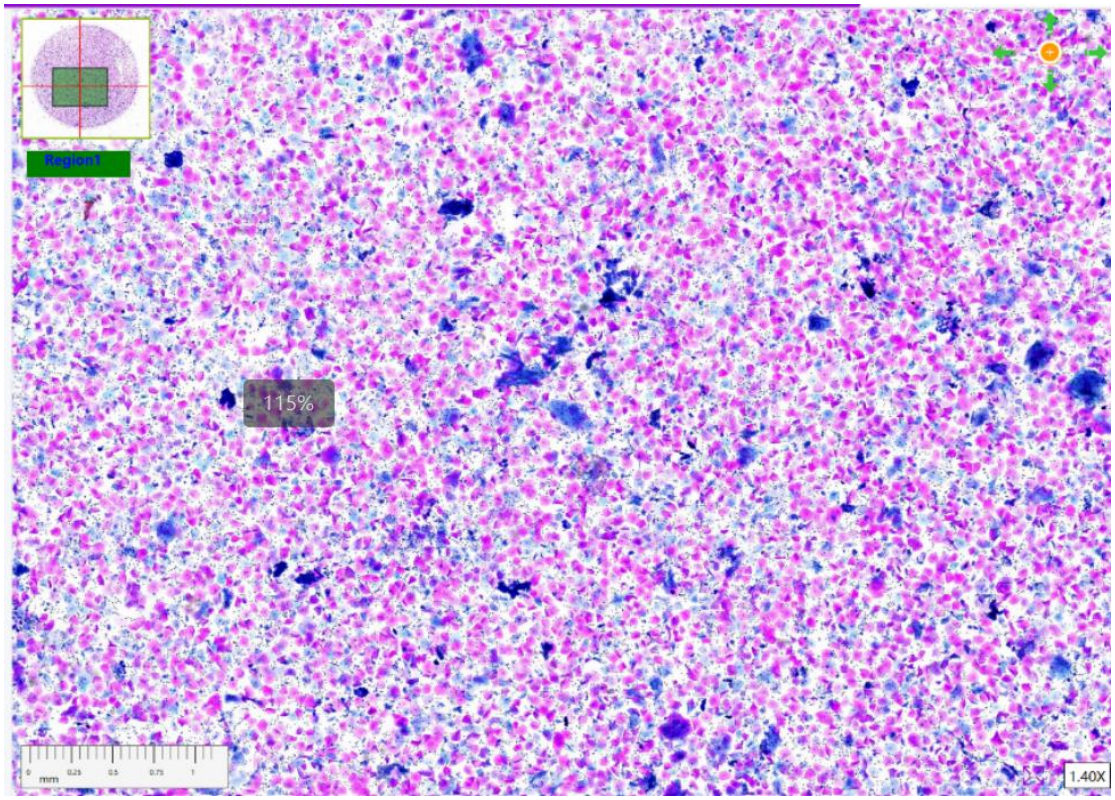
报告结果以形态学图片和文字解读相结合形式

5.2.2.4 View sample data

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

2）View sample data for different periods through different buttons

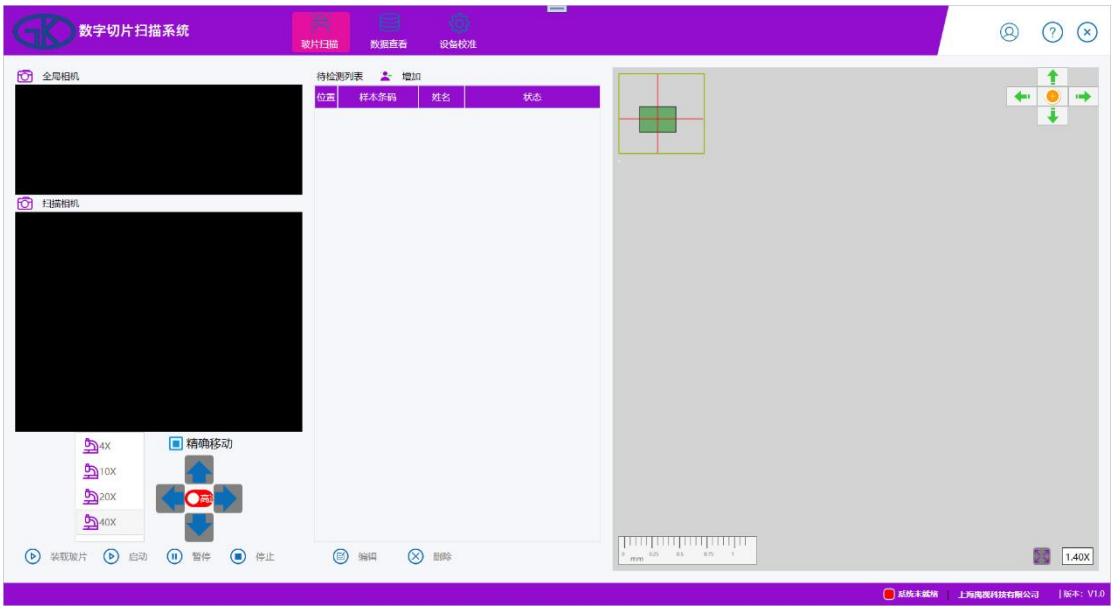
3）Select the corresponding sample, the corresponding picture and report will appear on the right, click on a single image, you can enlarge the picture.



5.2.2.7 Exit

When the device is turned off, perform the following steps:

1) Close the QiCytoSlice 1.0 software.



2) Power off the system.

Chapter VI Equipment Maintenance and Repair

7.1 Product Maintenance

7.1.1 Cleaning of the instrument host

Here's how:

Dust removal work is carried out on the outer surface of the instrument regularly. When dusting, gently wipe with a flexible material. Special attention should be paid to the cleaning of external metal devices, so as not to cause them to be corroded and rusted and affect the normal operation of the instrument. After the dust is removed, cover the instrument with a dust cover.

If samples or other hazardous substances leak on the surface of the equipment or enter the inside of the equipment, the instrument should be turned off and the power should be disconnected, the disinfectant should be sprayed on the contaminated area, the contaminated area should be cleaned, and the equipment should be allowed to dry before turning on the machine for resetting cleaning.

Disinfectants are recommended to use alcohol at a concentration of 75%. Do not use corrosive cleaning liquids or disinfectants, such as strong acids and alkalis. Do not use cleaning agents or disinfectants that may cause a hazard by chemical reaction with the parts or materials contained in the equipment.

If you have any doubts about the compatibility of disinfectants or cleaners with equipment parts or materials contained in the equipment, please consult the agent or Texas Guoke Medical Technology Co., Ltd.

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.

7.1.2 Waste slide disposal

After testing, dispose of the disposable slides and load them into waste plates. 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.

7.2 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.

7.3 Maintenance when not in use for a long period of 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.

7.4 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

Non-company after-sales maintenance personnel must first disconnect all power supplies when inspecting or repairing equipment to avoid electric shock.

7.4.1 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.

7.4.2 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.

7.5 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

- Electric control platform control board

• Power strip

7.6 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

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
	Radio frequency electromagnetic fields	GB/T 17626.3	3 V/m(80 MHz~1 GHz)	A
			3 V/m(1.4 GHz~2 GHz)	
			1 V/m(2.0 GHz~2.7 GHz)	
AC power (including protective grounding)	Voltage sag	GB/T 17626.11	0% half-cycle	B
			0% 1 cycle	B
			70% 25/30e 周期	C
	Short-term interruptions	GB/T 17626.11	0% 25/30e cycle	C
	Burst of			B

	pulses Surge Conducted disturbance induced by RF field	GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	1 kV(5/50 ns,5 kHz) 0.5 kVa/1 kVb 3 V(150 kHz~80 MHz)	B A
DC power supply d (including protective grounding)	Burst of pulses Surge Conducted disturbance induced by RF field	GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	1 kV(5/50 ns,5 kHz) 0.5 kVa/1 kVb 3 V(150 kHz~80 MHz)	B B A
I/O signaling/control (including cable for functional ground port)	Burst of pulses Surge Conducted disturbance induced by RF field	GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	0.5 kVd(5/50 ns,5 kHz) 1 kVb,c 3 Vd(150 kHz~80 MHz)	B B A
I/O signals/controls directly connected to the power supply	Burst of pulses Surge Conducted disturbance induced by RF field	GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	1 kV(5/50 ns,5 kHz) 0.5 kVa/1 kVb 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	The contact discharge is 4 kV and the air discharge is 8 kV	B
	Radiofrequency electromagnetic field radiation	GB/T 17626.3	10 V/m(80 MHz~1 GHz)	A
			3 V/m(1.4 GHz~2 GHz)	
	Rated power frequency magnetic field	GB/T 17626.8	1 V/m(2.0 GHz~2.7 GHz)	A
			30 A/mo	
AC power	Voltage sag	GB/T 17626.11	0% 1 cycle	B
			40% 10/12h cycle	C
			70% 25/30h cycle	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 kVa/2 kVb	B
	Conducted disturbance induced by RF field	GB/T 17626.6	3 Vf(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 kVa/2 kVb	B
	Conducted disturbance induced by RF field	GB/T 17626.6	3 Vf(150 kHz~80 MHz)	A

I/O signaling/control (including cable for functional ground port)	Burst of pulses Surge Conducted disturbance induced by RF field	GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	1 kV(5/50 ns,5 kHz)d 1 kVb,c 3 Vd,f（150 kHz～80 MHz）	B B A
I/O signal/control port directly connected to the power delivery network	Burst of pulses Surge Conducted disturbance induced by RF field	GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	2 kV(5/50 ns,5 kHz) 1 kVa/2 kVb 3 Vf(150 kHz~80 MHz)	B B 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) Radiofrequency electromagnetic field radiation	GB/T 17626.2 GB/T 17626.3	The contact discharge is 4 kV and the air discharge is 8 kV 1 V/m(80 MHz~1 GHz) 1 V/m(1.4 GHz~2 GHz) 1 V/m(2.0 GHz~2.7 GHz)	B A
AC power	Voltage sag Burst of pulses Surge Conducted disturbance induced by RF field	GB/T 17626.11 GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	0% half-cycle 1 kV(5/50 ns,5 kHz) 0.5 kVa/1 kVb 1 V(150 kHz~80 MHz)	B B B A
DC power supply c, d	Burst of pulses Surge Conducted disturbance induced by RF field	GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	1 kV(5/50 ns,5 kHz) Not requirement 1 V(150 kHz~80 MHz)	B A
I/O signaling/control (including cable for functional ground port)	Burst of pulses Surge Conducted disturbance induced by RF field	GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	0.5 kVc（5/50 ns，5 kHz） Not requirement 1 Vc(150 kHz~80 MHz)	B A

Measure I/Oc	Burst of pulses Surge Conducted disturbance induced by RF field	GB/T 17626.4 GB/T 17626.5 GB/T 17626.6	Vehicle Not requirement 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	Air discharge:2 kV、4 kV、8 kV, Contact discharge: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	not

		17626.5	
	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)	GB/T 17626.2	The contact discharge is 4 kV and the air discharge is 8 kV
	Radio frequency electromagnetic fields	GB/T 17626.3	3 V/m(80 MHz~1 GHz) 3 V/m(1.4 GHz~2 GHz) 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.

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

EU REP

Authorized European Representative:
RIOMAVIX SOCIEDAD LIMITADA

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

E-mail: leis@riomavix.com