



EXS2600 Mass Spectrometry System

Based on matrix-assisted laser desorption/ionization time-of-flight mass spectrometry technology, EXS2600 is used in diagnostic identification for microbes, include several kinds of bacteria, fungi, molds and etc. Compared with traditional microbe diagnosis method, EXS2600 mass spectrometry system could offer our end-user high-throughput screening, convenient operation and more sensitive and accurate identification result via advanced sample pretreatment kit technology, user-friendly software and comprehensive strains database.



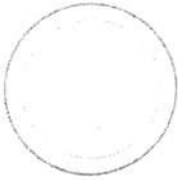
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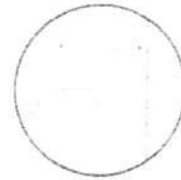
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Highlight Feature



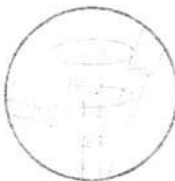
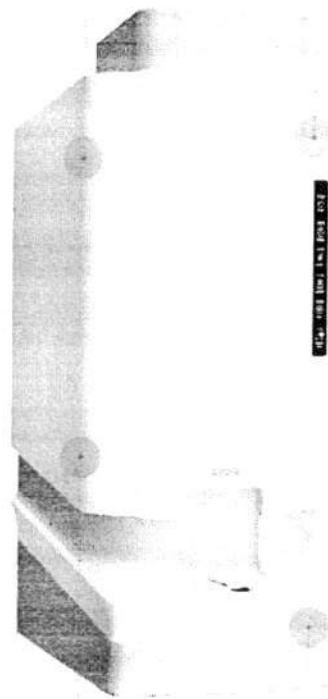
Accurate result

- Intuitively and synchronously display identification result and morphological reference
- Clinical database including over 4,051 species, covering 15000 strains to account for diversity greater accuracy.
- 300 kinds of specialty bacteria covering filamentous, fungal, yeasts, nona bacteria, legionella and etc.
- Customize database to meet need of different microbial labs.



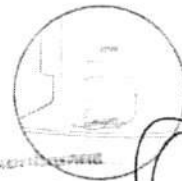
Reliable hardware performance

- Vacuum pump without oil is free of maintenance and less cost.
- Distinctive integrated circuit design to improve signal-to-noise ratio and reduce error rate.
- Advanced hyper-efficient ion propulsion patent technology to improve ion transmission capacity and increase the sensitivity and resolution of mass spectrometry systems.
- Flight tube temperature compensation technology to ensure the stability of the instrument.



Cost-effective Tool

- Acquisition and identification function realized in one application software.
- Target plate is reusable that help to save cost and could add sample at 96 spot at most at the same time.
- Strains identification applied in EXS2800 makes turn around-time just about two days to 10min, which save more time for doctor to give medicine and even rescue critical patients.



Convenient operation

- One step to target-in for detection with reusable and traceable plate.
- Rapidly test 96 samples in one plate only within 12 min.
- Freely set control target location for monitoring process.
- Several sample pretreatment reagent selection for several microbes

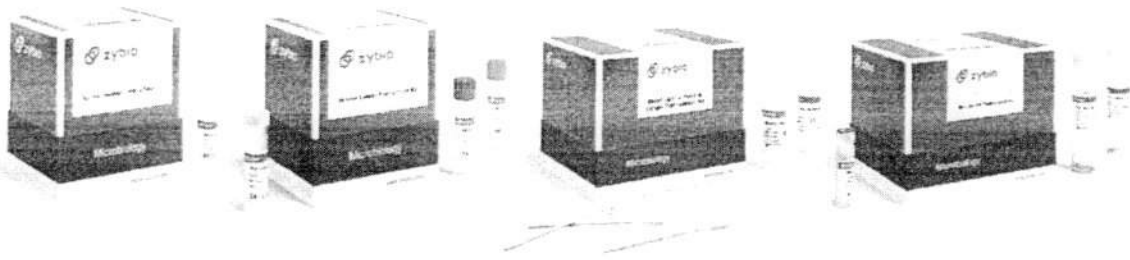
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Highlight Feature



Advanced and distinctive microbe pretreatment reagent technology:

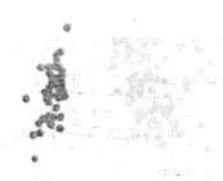
- Less pretreatment procedure and more effectively break down dense mold ball walls, which takes less than 2 min for mold identification
- Directly identify the microbe from blood culture positive bottle without subculture again.
- Ready-to-use matrix solution, good stability and room temperature storage.

Name	Storage Temperature	Shelf Life	Open-vial Stability
Microbe Sample Pretreatment Kit	15-25 °C	12 months	7 days
Mold Sample Pretreatment Kit	15-25 °C	12 months	7 days
Blood Culture Positive Sample Pretreatment Kit	2-8 °C	12 months	90 days
Sample Treatment Matrix Solution	15-25 °C	12 months	7 days
Sample Pretreatment Solution	4-25 °C	12 months	90 days
Microbiology Calibrator	-20±5 °C	12 months	-20±5 °C 90 days 2-8 °C 7 days

More Function for RUO : Cluster Analysis Software

- Combined with principal component analysis, EXS2600 could apply in clinical research such as antibiotic-resistant bacteria research, serotypes, strain traceability analysis and difficult-to-identified bacteria.

• Setosa • Versicolor



Principal Component Analysis



Principal Coordinates Analysis

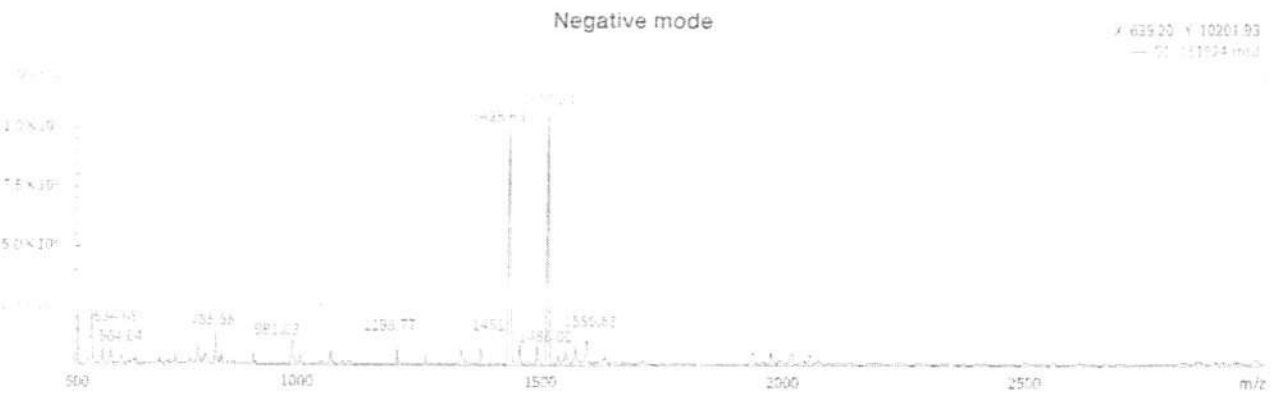
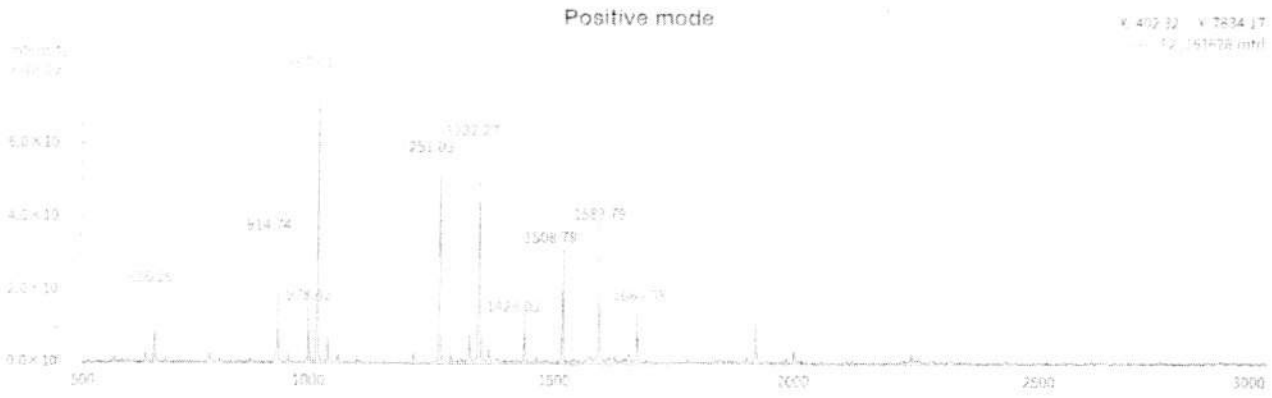


t-distributed Stochastic Neighbor Embedding

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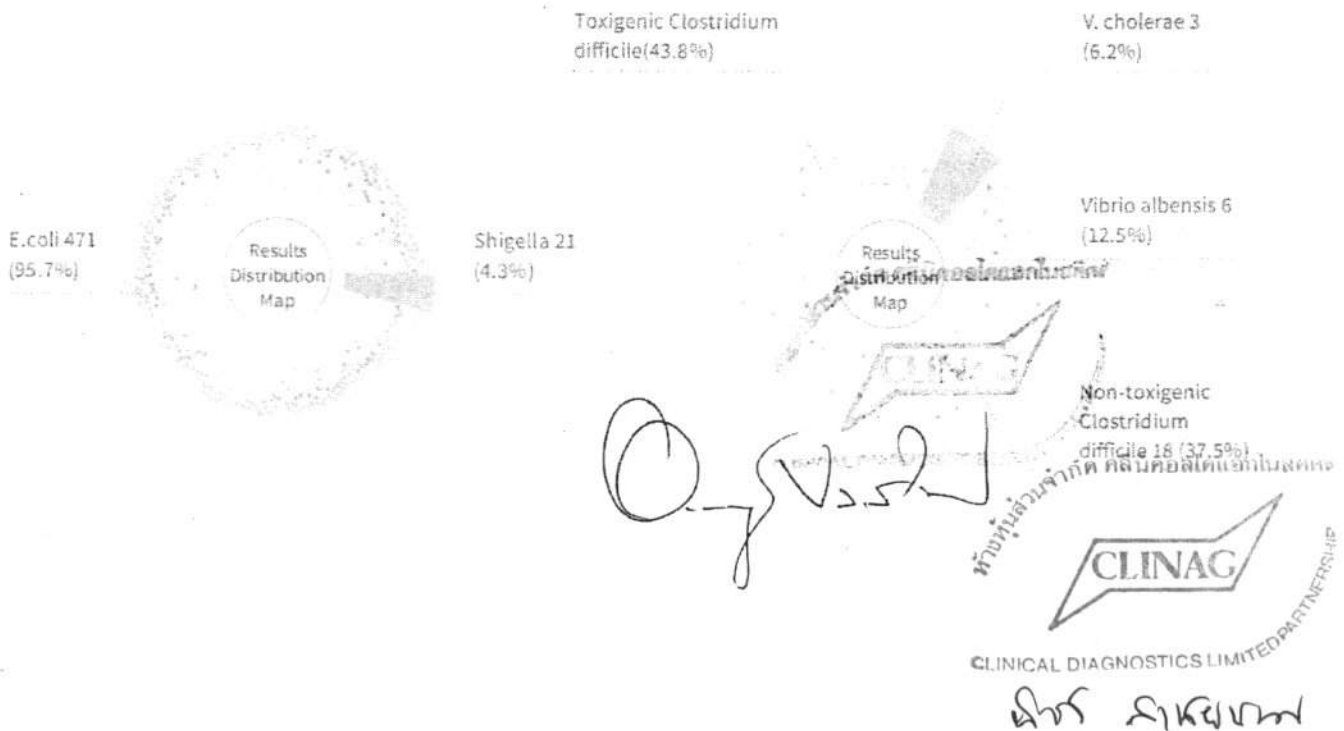
Positive & Negative Ion Detector

- Positive & negative ion mode could be applied in the phosphate protein detection among antibiotic-resistant bacteria and drug sensitivity analysis.



Artificial Intelligence Typing Software

- Combined with artificial intelligence algorithms, microbial intelligent type software show excellent performance for routine microbe and also could help to identify some difficult-to-identify bacteria, such as E.coli and Shigella.



Technical Specification

Work Principal MALDI-TOF
 M/Z Range 1-4000 (optional)
 Mass Accuracy Relative Indication Error: 500 ppm

Sensitivity
 S/N ratio ≥ 100 (0.04 $\mu\text{g/mL}$ (Goat human fibrin peptide B)
 S/N ratio ≥ 100 (4 $\mu\text{g/mL}$ horse myoglobin)

Mass Resolution R2500
 Repeatability ≤ 600 ppm
 Mass Stability ≤ 500 ppm

Laser Nd:YAG Laser
 60 Hz Repetition rate
 400 million laser shot

Pump Oil-free turbomolecular pump (340 l/s) Vacuum up to 10^{-5} mbar

Pre-treatment Reagents Microbe Sample Pretreatment Kit, Mold Sample Pretreatment Kit
 Blood Culture Positive Sample Pretreatment Kit, Sample Treatment Matrix Solution

Strains database $\geq 4,051$ species, 15000 strains in local database

Temperature: (10-30) °C
 Operation Environment Relative Humidity: (20-85)%
 Atmospheric Pressure: (70-105)Kpa

Target-in/out Time ≤ 1 min

Throughput Test 96 samples in one plate within 12 min

Operation System Windows 7(64 bit) and above, support LIS

Power Supply 100-240 V, 50/60 Hz, 300 W

Weight 115.1 kg

Dimension (mm) 490(M) * 300(D) * 112(H) mm

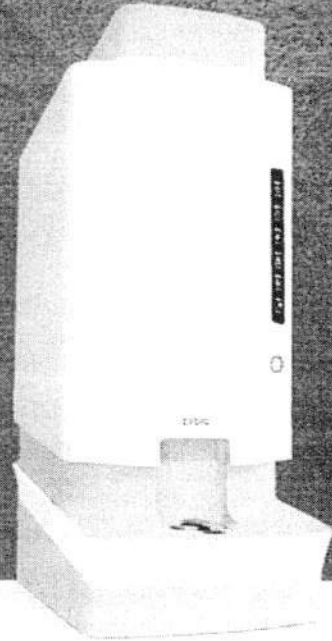
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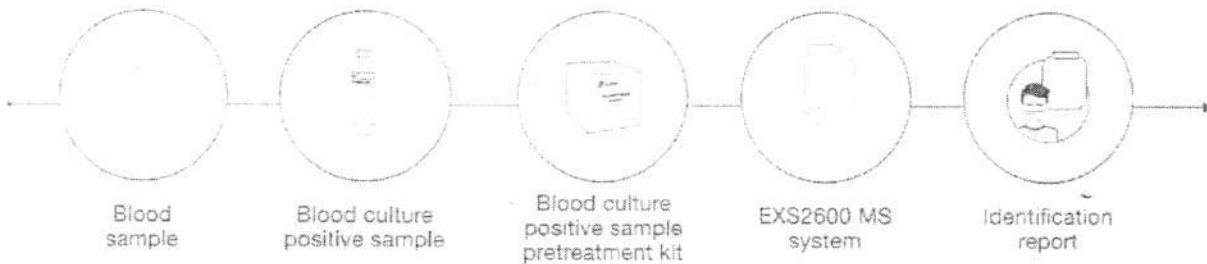
EXS2600 Mass Spectrometry System

A Convenient and Rapid Identification Tool for Microbial Application

- Cost-effective
- A benchtop system
- Easy to use software
- Applicable to a wide range of microorganisms
- Accuracy comparable to Nucleic Acid Sequencing
- Measurements in positive and negative ion mode
- Much faster than traditional methods, 96 samples identification within 12min

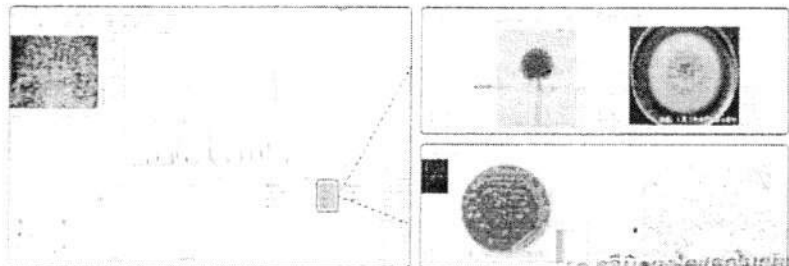


Rapid Blood Culture Identification Module



Morphological reference picture application

Support identification results of mass spectrometry, as well as the morphological diagrams of microorganisms (plate colony map and staining map) to assist the identification results



Contact: Charles Chen
 Email: Charles@zybio.com
 Mobile/WhatsApp: 0086 158185 09431



Zybio Inc. Zybio Zybio Inc. Zybio Inc.

Sample Treatment Matrix Solution

IFU

Date of Issue	August 2022
Current Version	02
Language	English
Document ID	Z01-004-IFU-001
Applicable Instruments	Mass Spectrometry System (Model: EKS2000, EKS2500, EKS3000, EKS3600)

Intended Use

This kit is used for *in vitro* diagnostic use in the pretreatment of microbial samples subcultured from human specimens (sputum, urine, stool, blood, etc.) or enriched from primary clinical specimens (positive hemoculture or positive urine sample) to assist in the analysis and identification of mass spectrometry system.

Test Principle

The matrix solution is mixed with the microbial sample (with or without pretreatment) to form cocrystallization after drying. When an ultraviolet laser is pulsed on the crystalline deposit, excitation of the matrix causes sublimation from the solid phase to the gas phase. The ions fly into the flight tube and travel toward an ion detector at a speed that depends on their mass-to-charge ratio. By measuring each ion's time-of-flight using the ion detector, the mass-to-charge ratio can be calculated and a mass spectrum generated. The generated mass spectrum is compared to the database of mass spectra and the microbe is identified based on the closest match.

Materials Provided

REF	Specification	Packing Size
02096301.01.14	Model I	25 T/Kit
02096301.01.15	Model II	500 T/Kit
02096301.01.17	Model II	48 T/Kit
02096301.01.18	Model II	480 T/Kit

Main Components

Table 1 Main Components of Model I

Components	Model I		Main Constituents
	25 T/Kit	500 T/Kit	
Matrix solution	25 µL x 1 vial	500 µL x 5 vials	o-Cyano-L-hydroxyindanic acid

Model I does not contain the disposable silicon target plate, and needs to be used with the reusable target plate that accompany the EKS series Mass Spectrometry System produced by Zybco.

Table 2 Main Components of Model II

Component	Model II		Main Constituents
	48 T/Kit	480 T/Kit	
Matrix solution	48 µL x 1 vial	96 µL x 5 vials	o-Cyano-L-hydroxyindanic acid
Disposable silicon target plate	48 tests x 1 plate	48 tests x 10 plates	Silicon water

Model II contains the **disposable silicon target plate**. Materials required but not provided:

ultrapure water, ethanol, 70% formic acid, acetonitrile.

Storage and Stability

Stored at 15-25°C for 12 months. Once matrix solution is opened, cap the vial and store at 15-25°C for no more than 7 days.

Sample Requirements

Sample preparation should be carried out according to the Operation Manual of the EKS series Mass Spectrometry System.

Warnings and Precautions

- For professional use only.
 - Instructions for use must be carefully followed.
 - Do not use the kit beyond the expiration date.
 - Before use, check and confirm that the reagents in the kit are well sealed. Do not use if leaked.
 - Covered tightly in time after using to prevent the volatilization of Matrix solution.
 - A small amount of precipitation appears in the matrix solution during storage and transportation is normal, and the product performance will not be affected if it is dissolved again by shaking.
 - The surface of the disposable target plate should be free of stains, burrs, damage, cracks or distortion.
 - All samples, reagents and used waste should be considered as potential infectious substances and should be disposed in accordance with local requirement.
 - The instrument should be calibrated before using.
 - Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- [Matrix solution] contains acetonitrile. Please operate under ventilated conditions. If overdose inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.

Application Procedures

The operation process of the experiment is as follows:

Direct colony transfer method:

- Transfer isolate (single colony, medium size) from the culture medium to the sample target plate without transferring any medium.
- Cover the isolate with 1 µL matrix solution and allow it to dry. Put the target plate into the Mass Spectrometry System for analysis.

On-target extraction method:

- Transfer isolate (single colony, medium size) from the culture medium to the sample target plate without transferring any medium.
- Cover the isolate with 1 µL 70% formic acid and allow it to dry.
- Cover the isolate with 1 µL matrix solution and allow it to dry. Put the target plate into Mass Spectrometry System for analysis.

Tube extraction method:

- Transfer the appropriate amount of bacteria isolates (without transferring any medium) into a 1.5 ml centrifuge tube containing 300 µL ultrapure water, fully mixed.
- Add 900 µL ethanol and mix well.
- Centrifuge at 12,000 rpm for 2-3 min, remove and

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Sample Treatment Matrix Solution

IFU

discard the supernatant. Centrifuge at the same speed for another 2 min, and remove the residual supernatant. Let the pellet dry at room temperature for 5 min.

4. Add 20 µL 70% formic acid to the pellet and mix well with pipette (for gram-positive bacteria and some fungi, let the solution stand at room temperature for 5 min).

5. Add 20 µL acetonitrile, mix well, and centrifuge at 12,000 rpm for 2 min.

6. Add 1 µL supernatant to the target plate and allow it to dry. Cover with 1 µL matrix solution and allow it to dry.

7. Put the target plate into Mass Spectrometry System for analysis.

Note: For most gram-negative bacteria and gram-positive cocci, direct colony transfer method is applicable; for mucinous bacteria and yeast, on-target extraction method is applicable; for mold, actinomycetes, mycobacteria, Nocardia and other gram-positive bacteria, vial extraction method is applicable.

Test Results Explanation

- This kit cannot be used alone. It should be used with Mass Spectrometry System.
- Refer to the Operation Manual of Mass Spectrometry System for information on interpreting results.

Product Performance Indicator

1. Accuracy

Standard strains and negative samples were tested and the total correct rate was calculated as 100%.

Test samples	Test results		
	Batch 1	Batch 2	Batch 3
<i>Enterococcus faecium</i> ATCC 700221	3/3	3/3	3/3
<i>Escherichia coli</i> ATCC 25922	3/3	3/3	3/3
<i>Candida albicans</i> ATCC 10231	3/3	3/3	3/3
Negative samples	3/3	3/3	3/3
Total correct rate	100%		

Note:

*Negative samples: Add 1 µL matrix solution to the sample target plate and allow it to dry.

2. Repeatability

Standard strains were tested by two operators using two instruments of three batches reagents for three consecutive days, and each sample was tested once in the morning and once in the afternoon. The total correct rate was calculated to be 100%.

Test strains	Test results		
	Batch 1	Batch 2	Batch 3
<i>Enterococcus faecium</i> ATCC 700221	24/24	24/24	24/24
<i>Escherichia coli</i> ATCC 25922	24/24	24/24	24/24
<i>Candida albicans</i> ATCC 10231	24/24	24/24	24/24
Total correct rate	100%		

Note: "3/3" or "24/24" means "Correct results / Total results"

Limitations of Procedures

- Only microbes that have been involved in the Mass Spectrometry System spectrum database can be identified.
- For closely-related strains that cannot be distinguished by the Mass Spectrometry System, this kit cannot improve the result reliability.
- If there are two or more species of microorganisms in the

sample, the kit cannot be used to accurate identification.

4. Too much sample collection may reduce the effect of wall-breaking, thereby affecting the results. Too few sample collection (lower than the sensitivity of the instrument) will also affect the identification results.

5. Try to avoid the introduction of culture medium when picking up colonies, because medium will affect the identification results.

References

- Expert consensus on the application of clinical microbial mass spectrometry in China [J]. Chinese Journal of Nosocomial Infection, 2016, 26(11): 2641-264.
- Direct identification of urinary tract pathogens from urine samples by matrix-assisted laser desorption/ionization-time of flight mass spectrometry. J Clin Microbiol. 2010 Jun;48(6):2110-5.

Explanations on Symbols

Symbol	Title and Description	Symbol	Title and Description
IVD	In vitro diagnostic medical device		Date of manufacture
LOT	Batch code		Use-by date
CE	CE marking of conformity		Authorized Representative in the European Community
	Consult instructions for use		Temperature unit
REF	Catalogue number		Manufactures
	Contains sufficient for use tests		Do not reuse
	Warning		Caution

Manufacturer Information

Zybio Inc.
 Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jiantiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
 Web: www.zybio.com
 E-mail: info@zybio.com
 Tel: +86(0)23 6895 9999
 Fax: +86(0)23 6895 9779

EC Representative

Lotus NL B.V.
 Koningin Julianaplein 10, 1a Verd, 2595AA, The Hague, Netherlands.

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1 Product overview

1.1 Introduction

The Mass Spectrometry System is a device which is intended to identify bacterium and fungus by matrix-assisted laser desorption/ ionization time-of-flight (MALDI-TOF) mass spectrometry technology which can greatly improve the efficiency of clinical laboratories, and provide better laboratory evidence for disease diagnosis and timely treatment.

1.2 Basic principle

The basic schematic diagram of linear time-of-flight mass spectrometer Mass Spectrometry System is as follows:

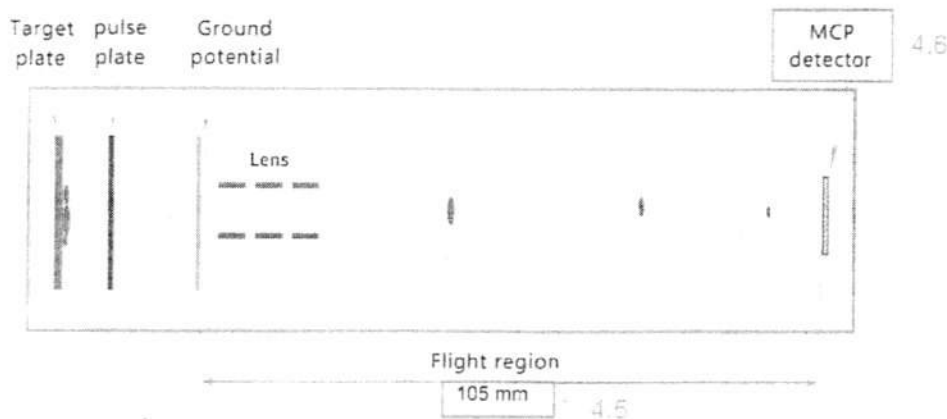


Figure 1 The basic schematic diagram of Mass Spectrometry System

The sample mixed with matrix on the sample target are converted from molecules to ions triggered by laser power. At the same time, a high voltage is applied to the sample target to form a high-voltage electric field between sample target and ion source to make the sample matrix ions fly to the right side of the figure. The ions fly at a constant speed in the flight tube until to the detector after they are out from the ion source. The time to the detector differs due to different m/z (mass-to-charge ratio) of these ions. The electronic signals generated on the detector can be converted into digital signals after be processed by a digital converter, and thus to generate the corresponding mass spectrum through processing and analyzing of the computer. Search the spectra of the samples with the microbial protein fingerprint database to identify or classify samples.

1.3 Instrument components

The instrument includes main unit, software (database included) and accessories. The main unit consists of ion detector, vacuum system, mass analyzer, ion source, laser, XY mobile platform, target spot camera

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400062 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Tel: +86 (0) 23 6865 5509 Fax: +86 (0) 23 6869 9779 Email: info@zybio.com Website: www.zybio.com

1.6.8 Electromagnetic compatibility

Comply with the requirements specified in:

EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements for in vitro diagnostic (IVD) medical equipment

1.6.9 Environmental test

Comply with the requirements of the climate environmental test group I, mechanical environmental test group I and the table specified in Chinese standard GB/T 14710-2009. Comply with the requirements specified in GB/T 14710-2009 Chapter 4, Chapter 5 for the transport test and power supply voltage adaptability test.

1.7 Software requirements

1.7.1 Software introduction

Software Name: Mass Spectrometry System software

Model: EX-Accuspec

Software Version: V1

Software operating environment:

Table 1 Software operating environment

Name	Minimum configuration requirements
Computer	CPU: Intel i3 or above; Memory: above 2 GB; Hard disk: above 60 GB. Note: Computer shall comply with requirements of latest IEC 60950-1 or IEC 61010-1 or IEC 62368-1.
Display	21 inches and above, and the resolution is recommended to be not less than 1920×1080.
Operating System	Windows 7 (64-bit) and above.

1.7.2 Network requirements

The network type is LAN.

Network connection or bandwidth is not required necessarily.

