Fully Automatic Culture Sterility Detector

Microflex is a detailed and efficient, rapid and sterile detection system
A fully automatic culture sterility testing instrument specially designed to comply with the regulations of the Chinese, American and European pharmacopoeias



salvisLAB

Company Introduction

SALVISLAB is a subsidiary of the RENGGLI Group, which was founded in 1927. As a leading European manufacturer and a market leader in Switzerland, the group is dedicated to the research and development, design, and production of laboratory research instruments and general laboratory instruments. Its products include sterile culture testing instruments, incubators, Raman testing instruments, and other devices. In 2023, RENGGLI Group was fully acquired by China's Tofflon Group and became a wholly-owned subsidiary of Tofflon. Tofflon Group introduced SALVISLAB's advanced technology to China, carried out localization of the technology, and aimed to provide Chinese customers with higher-quality technical products and services.

Dongfulong Technology Group Co., LTD. (Stock code: 300171) was established in 1993 and listed on the Growth Enterprise Market in 2011. Its headquarters is located in Shanghai. It is a comprehensive solution service provider that offers process services and consumables, core equipment and engineering to global pharmaceutical companies. Dongfulong adheres to the core value of "Heaven rewards the diligent", upholds the mission of "Professional technology serving biomedicine", and keeps moving forward with the development strategy of "systematization, internationalization and digitalization". At present, more than 3,000 pharmaceutical factories in over 50 countries around the world are using over 16,000 sets of equipment from Dongfulong, which holds a leading market share in the domestic pharmaceutical equipment sector.



Microflex fully automatic culture aseptic detection system



Product Overview



Based on the world's leading temperature control technology, SalvisLab has launched a brand-new generation of Microflex fully automatic culture aseptic detection system. This system is based on the preferred microbial rapid detection technology recommended by the Chinese, American and European pharmacopoeias: the Respiration Based Method. The core mechanism is to monitor and analyze the changes in carbon dioxide (CO_2) concentration in the culture flask in real time through high-precision color sensors, thereby indirectly reflecting the metabolic activity and growth status of microorganisms. The aim is to achieve early warning of microbial contamination and provide reliable quality inspection tools for high-risk production processes such as cell therapy and finished product inspection.



The Microflex system has completely transformed the limitations of traditional aseptic detection methods, such as long cycles and cumbersome operations, providing efficient, accurate and reliable microbiological detection solutions for the biomedicine, scientific research and food industries.

Continuous detection technology

The independent color sensor synchronously samples once per minute, with a detection sensitivity of 1 CFU

Dual-temperature simultaneous cultivation

It meets the requirements of the pharmacopoeia and is equipped with dual-temperature zone culture of 30-35℃ and 20-25℃ within a single instrument

Large-capacity culture detection

The single instrument has a sample capacity of 72 and can be modularly expanded to 576 sample capacities

Dual dynamic cultivation simultaneously

The internal modules of the instrument can be independently set to both dynamic and static culture modes

Compliance specification

Comply with GMP standards and meet the audit requirements of Part 2.1

Instrument dimensions

69*46*52cm

Core advantage

Ultra-early warning and continuous monitoring

The fully automatic continuous monitoring mode scans samples at high frequency, with a detection sensitivity of ≤1 CFU, achieving ultra-early warning of microorganisms. Compared with traditional methods (which take 14-30 days), microorganisms can be detected within 3 hours at the fastest, significantly shortening the detection cycle. Real-time data collection and trend analysis are available to identify contamination risks in advance.

Dual-temperature simultaneous cultivation

The instrument meets the relevant culture conditions required by the Chinese Pharmacopoeia. It adopts a single-device built-in dual-temperature zone independent culture design, which can simultaneously meet the culture needs of two temperature ranges: 30-35 ℃ and 20-25 ℃. The two temperature zones are each equipped with an independent temperature control system, which can be set, adjusted and operated separately according to the requirements of different culture projects without interfering with each other, effectively improving the utilization efficiency of equipment and the utilization rate of experimental space.

Flexible expansion and high-throughput detection

A single device can simultaneously test 72 samples, meeting the needs of medium and large-scale testing. With a modular stacking and intelligent interconnection design, it can be expanded up to 576 testing channels, adapting to the production needs of different scales. It supports the simultaneous testing of multiple sample types, including cell therapy products, biological products, culture media, raw materials, etc.

Precise temperature control and stable environment

Adopting honeycomb solid temperature control technology, a single instrument can simultaneously cultivate and detect at two different culture temperatures, unaffected by operations such as opening the instrument door. The temperature fluctuation is controlled within ±0.1℃, ensuring a stable culture environment, maintaining the best culture conditions, and guaranteeing the normal growth and metabolism of microorganisms

Intelligent analysis and compliance assurance

Equipped with AI intelligent algorithms, it can automatically identify the growth curve of microorganisms, reducing human judgment errors.
It complies with the requirements of FDA 21 CFR Part 11. The data is automatically recorded and cannot be tampered with. It supports audit trails and automatically generates compliance test reports, which can be directly used for GMP applications and quality traceability.

Easy operation and maintenance

The one-click operation process enables users to get started without professional training, lowering the operational threshold. It uses disposable culture bottles, eliminating the need for cleaning and disinfection, reducing the risk of cross-contamination and maintenance costs. It also features remote monitoring and diagnosis functions, supporting rapid troubleshooting and maintenance of equipment failures.

Independent honeycomb culture system

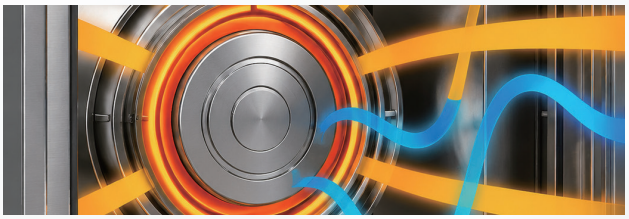
The instrument adopts honeycomb solid-state heating and TEC semiconductor solid-state cooling technology, optimizing the traditional air temperature radiation conduction method to the direct contact temperature conduction method of solids.

Advantages of Microflex honeycomb solid-state heating and cooling

- The module adopts metal materials as the heating and cooling conduction method, featuring good temperature uniformity and a small temperature error of less than 0.1℃.
- It is not afraid of the impact of opening the door. Within 30 minutes of opening the door, the temperature change is less than 0.2℃, and it has no adverse effect on temperature-sensitive microorganisms, achieving faster positive detection.
- The temperature transfer efficiency is high, with the solid temperature transfer efficiency being over 7,000 times that of gas. The temperature rise curve of the culture bottle is fast, enabling faster positive detection.
- The modules do not rely on gas radiation temperature. Within the same instrument box, high and low temperature culture conditions can be set in zones or synchronously, fully meeting the pharmacopoeia detection standards, effectively avoiding missed detections, and achieving the integrity and reliability of product sterility testing.



Microflex honeycomb solid-state heating and cooling technology



Temperature control of traditional aseptic testing instrument

Application scenarios

- **Cell therapy field (Core Applications)**
  - Cell therapy product release testing shortens the release cycle and accelerates product launch
  - Sterile testing of raw materials and consumables ensures the safety of the production process
  - Environmental monitoring ensures that the clean area meets GMP requirements
- **Biopharmaceutical field**
  - Aseptic monitoring of bioreactors enables real-time quality control of the fermentation process
  - Detection of the production process of sterile drugs to enhance production efficiency and product quality
  - Sterile testing of culture media and buffers reduces the risk of contamination
  - Sterility confirmation after filter integrity verification
- **Scientific research field**
  - Screening of antibacterial drugs and rapid assessment of the antibacterial effect of drugs
  - Strain activity assessment accelerates the progress of microbiological research
  - Microbial interaction research provides real-time data support
  - Aseptic monitoring during the vaccine development process
- **Food industry**
  - Raw materials and finished products are released quickly, shortening the inspection cycle and improving the turnover rate
  - Monitor and trace the production process to promptly identify contamination points
  - Product development and formula optimization, as well as assessment of microbial stability
  - Food safety emergency testing, rapid response to quality incidents

Customer value

Risk control

- Detect pollution risks in advance to avoid major losses.

Cost optimization

- The inspection cycle has been shortened by over 70%, significantly enhancing equipment utilization and saving hundreds of hours of production capacity annually
- Reduce manual operations and the demand for training space, and lower operating costs
- The design of disposable consumables reduces the cost of cleaning and disinfection and the risk of cross-contamination

Efficiency improvement

- Automated operation and intelligent analysis reduce human errors and enhance the reliability of test results
- The modular expansion design meets the production demands of different scales and reduces equipment investment costs

Compliance guarantee

- It complies with international and domestic regulations such as the FDA, EU GMP, and the Chinese Pharmacopoeia
- Data is automatically recorded and audited, meeting the requirements of 21 CFR Part 11
- Provide a complete validation document package to support customers' GMP certification and application

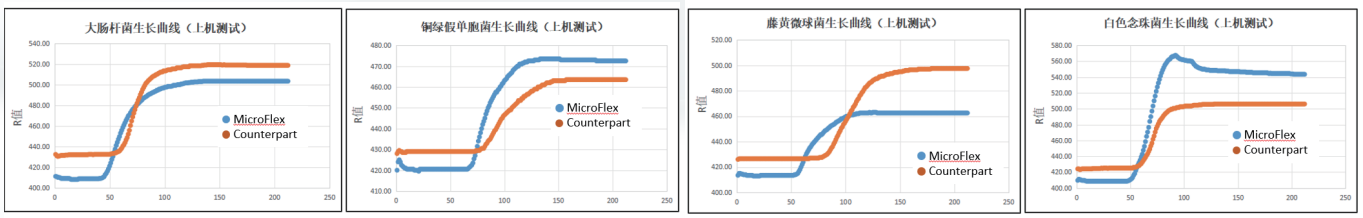
Comparison between Microflex Fully automatic culture Sterility Testing Instrument and traditional sterility testing methods

Project	Microflex	Traditional cultivation method	Advantage description
Detection cycle	0.5 to 5 days	14 to 30 days	67%+ shortened, accelerated product release
Manual demand	Low (fully automatic)	High (Full manual labor)	Reduce 1 to 2 full-time operators to lower labor costs
Data recording	Automatic audit Trail	Manual recording is prone to errors	Comply with global regulatory requirements and reduce compliance risks
Pollution warning	Real-time early warning	Lag by 4 to 14 days	Identify problems in advance to avoid scrapping the entire batch
Space occupation	Small (modular)	Large (requires an incubator + operation area)	Save over 30% of laboratory space
Single inspection cost (including labor)	120	150	Save 20%

Customer case



In an application case for CAR-T cell samples, the Microflex system was compared and tested with imported brand instruments. The test was conducted using the recommended method of USP1072, adding various types of microorganisms with a concentration of less than 100CUF to the samples. The results show that the Microflex system has reached the international advanced level in terms of detection sensitivity, detection time and result accuracy, and has obvious advantages in terms of cost performance and localized services.

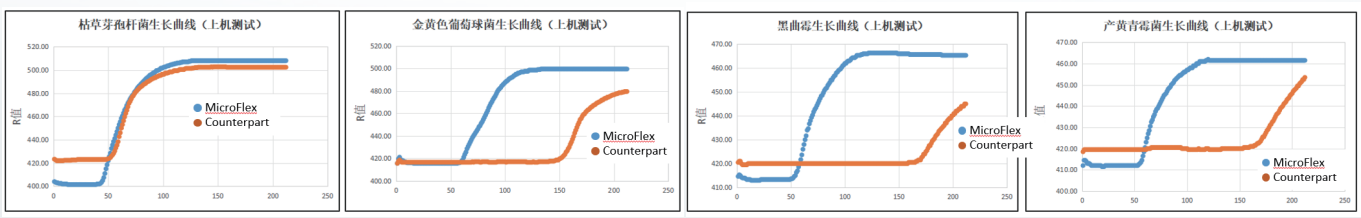


E. coil
16.5 CFU/ml

pae
43.5 CFU/ml

C. Glabrata
3 CFU/ml

C. albicans
63.5 CFU/ml



KP
1.5 CFU/ml

S.aureus
3.5 CFU/ml

AN
0.5 CFU/ml

AFL
3 CFU/ml

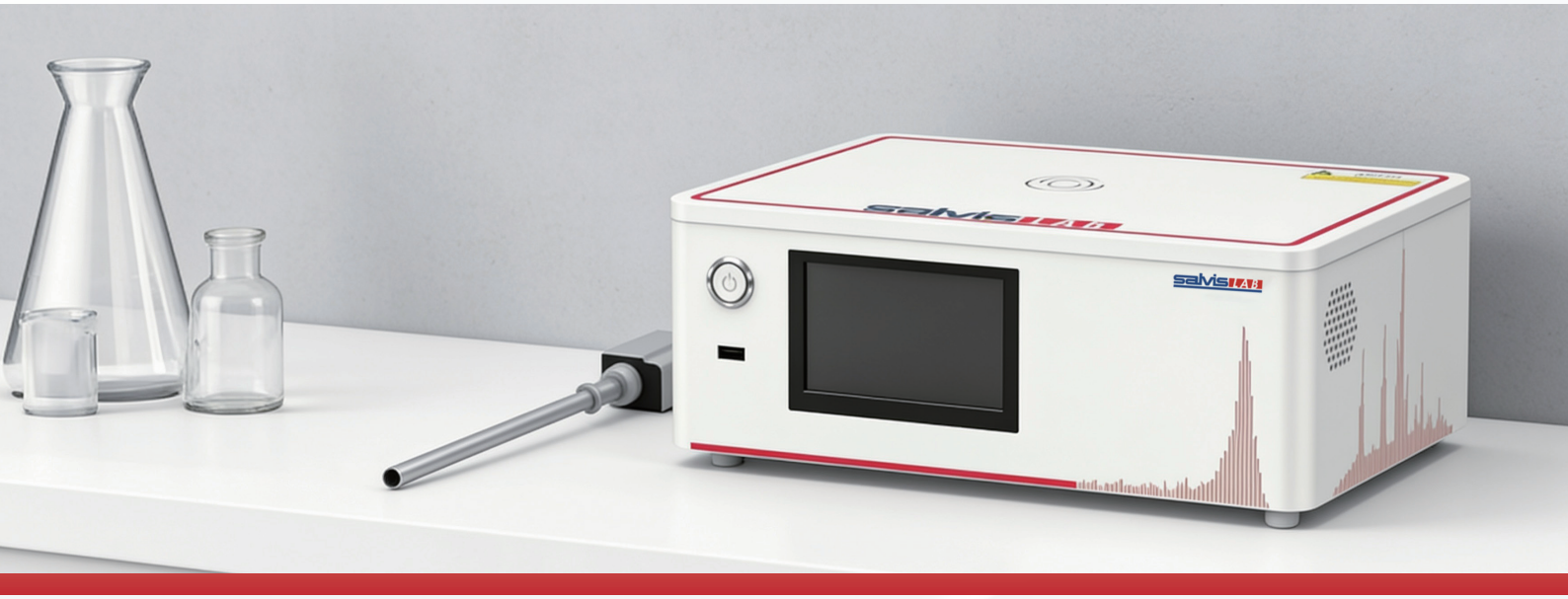
A comparison of the Microflex fully automatic culture sterility detector with a certain product from France

Online real-time Raman detection system

An innovator of Process Analysis (PAT) technology, providing real-time insights and precise regulation
Specifically designed for online monitoring of biological change processes in life sciences to enhance yield and quality



Orion Online Real-time Raman Detector

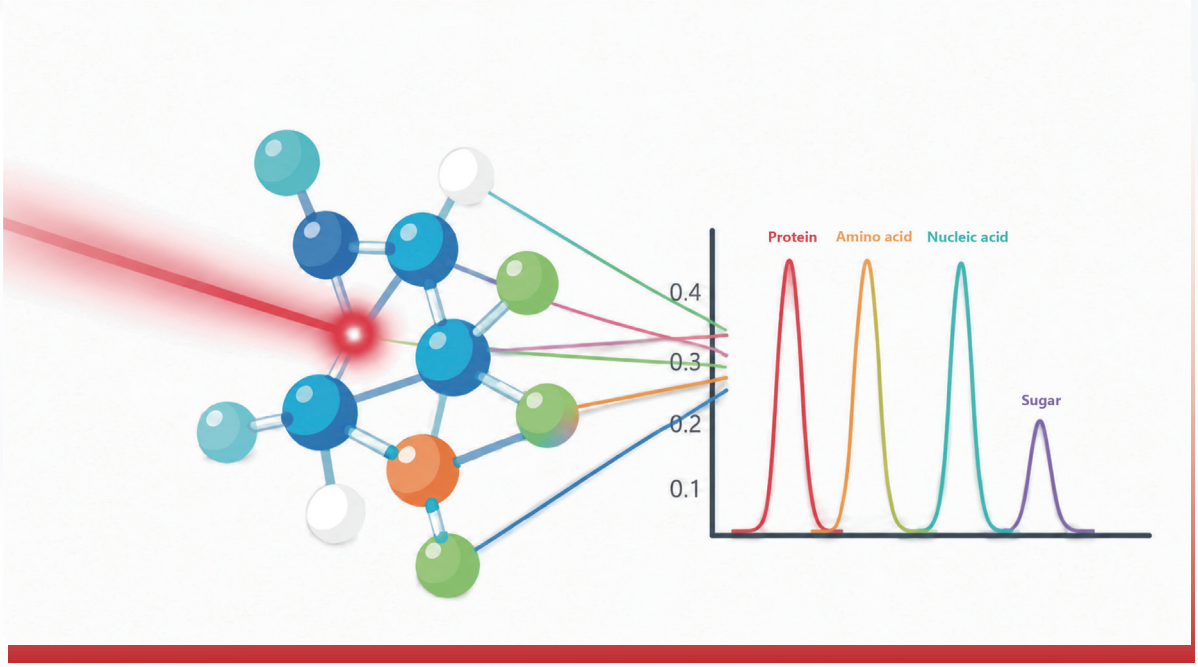


Product Overview

Raman spectra is a scattering spectral analysis technique based on the Raman scattering effect. When a laser is shone on a sample, photons undergo inelastic scattering with the molecules of the sample, causing a change in the frequency of the emitted light. By analyzing the scattering spectrum with a different frequency from the incident light, information such as molecular vibration and rotation can be obtained. So as to conduct research on the structure of molecules.

The Orion online real-time Raman detector adopts an immersed spherical sapphire probe, which can withstand high temperature and high pressure. Through the data acquisition of high-performance lasers and high-precision spectrometers, combined with the OrionSYS online analysis software, it can achieve online real-time detection of sample data, monitoring and adjustment of sample status, and meet the requirements of process analysis (PAT) capabilities.





The Orion online real-time Raman detector fully meets the key requirements of Process Analysis Technology (PAT).

Non-destructive testing

Raman light is the inelastic scattering of photons with sample molecules, and detection can be achieved without processing the sample.

Qualitative and quantitative analysis

Any molecule has a unique Raman "fingerprint" spectrum. By superimposing the spectral intensity expression, not only can the sample components be identified, but also the content data of substances can be detected.

Multi-parameter detection

Raman spectrometers have high spatial resolution and can detect over a hundred substances at a time.

In-situ analysis

Precise targeted analysis, real-time monitoring of the change process, and achieving precise regulation.

Core advantage

Non-destructive online testing

Based on Raman spectroscopy technology, in-situ and online detection of samples can be achieved without damage or complex pretreatment.

- The domestic exclusive and one of only two in the world sapphire probe technology
- Sapphire ball material, resistant to high pressure and high temperature
- The maximum pressure resistance reaches 3000 psi, approximately 40 MPa
- All-optical design, meeting the requirements of explosion-proof applications
- Supports intrusive installation and is suitable for large industrial tanks
- The probe can be sterilized and reused repeatedly, reducing long-term operation and maintenance costs

OrionSYS integrated software

OrionSYS integrates spectral acquisition, model establishment, real-time analysis and data presentation on a single software platform, simplifying the operation process and lowering the threshold for system usage.

- The engineering project management model complies with GMP and other audit requirements.
- For large model databases, scene-adaptive model analysis can be selected, or private libraries can be added for use in the analysis.
- Multi-channel and multi-model operation: In the case of multi-channel detection, each channel application scenario model can be independently selected, and multiple application scenario samples can be synchronously and in real time detected.
- One-click modeling. The software will automatically classify the data and complete the modeling analysis without the need for professionals.

High-precision detection

For key process parameters such as glucose and lactic acid, Orion can achieve high-precision real-time detection, helping users promptly grasp changes in the production process.

- High detection accuracy for glucose, lactate and other parameters
- Typical detection error can be less than 0.1 g/L
- Support data accumulation and model optimization
- Integrating deep learning capabilities, the model can be continuously iterated
- The richer the data, the stronger the model adaptability and predictive capabilities.

Precise temperature control

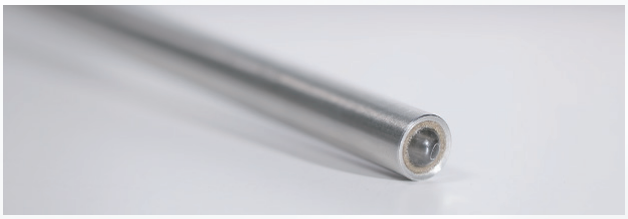
Compared with traditional offline biochemical analysis methods, Orion does not rely on expensive detection reagents and can significantly reduce the long-term costs brought about by high-frequency detection.

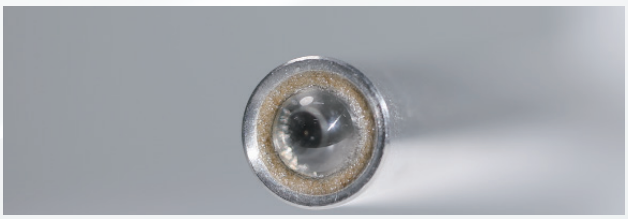
- There is no need to purchase single test reagents repeatedly
- Reduce manual sampling, testing and record-keeping work
- Reduce the frequency of offline testing and the burden on laboratories
- Reduce sample loss and testing waiting time
- Support high-frequency, continuous and real-time monitoring
- Help enterprises upgrade from "offline spot checks" to "online process control"

Product application

Wide application fields: Materials science, chemistry and pharmacy (chemical drug synthesis, raw material drug analysis), life sciences, medicine (pathological imaging), environmental monitoring (water quality), industrial food safety (detection of







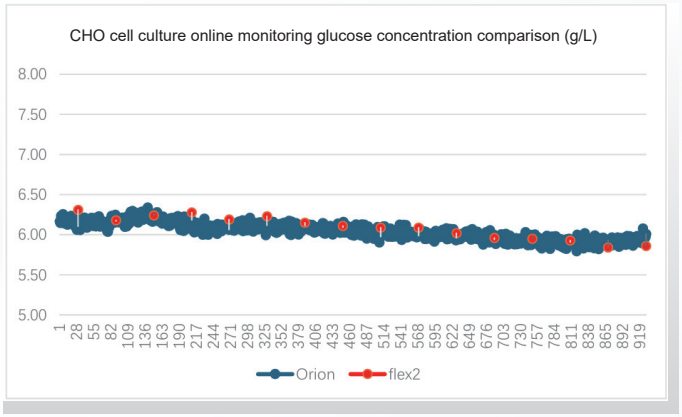
- Upstream cell culture (core) : Real-time monitoring of key process parameters such as glucose, lactic acid, glutamine, and cell density in CHO cell culture, as well as key quality attributes such as protein titer and glycosylation;
- Microbial fermentation: Online monitoring of substrate consumption, bacterial density and accumulation of target products (such as astaxanthin, antibodies, enzymes, etc.);
- Chemical synthesis and enzyme catalysis: Monitor the concentration changes of reactants and products in polypeptide synthesis and enzyme catalysis reactions, and determine the reaction endpoint.
- Downstream purification process: Real-time monitoring of antibody monomer and aggregate concentrations during chromatography, and real-time monitoring of excipients (such as sucrose and histidine) in antibody formulation prescriptions;
- Drug crystal form research: Real-time monitoring of crystal form changes during crystallization and drying processes to ensure crystal form consistency.

Project parameters

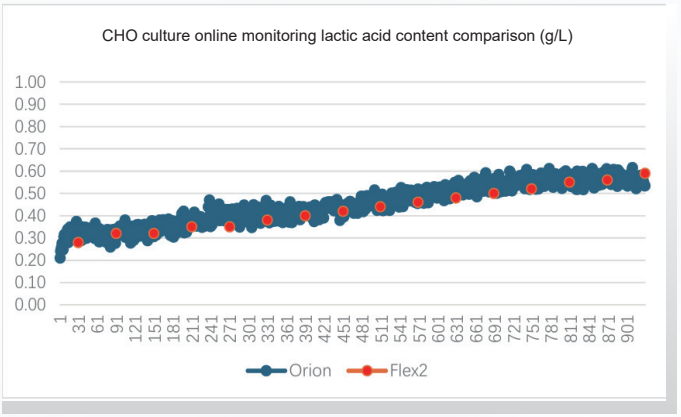
Item	Description
Laser	785nm 50mw-500mw
Beam resolution	5cm^{-1}
Beam range	50 cm^{-1}-3250 cm^{-1}
CCD	Two-stage cooling type -25℃, transmission grating
Comply with normative	Comply with GMP standards and meet the audit requirements of Part 2.1
Immersion probe	The immersion probe adopts sapphire ball structure and can withstand high temperature and high pressure.
Instrument dimensions	32*22*13*cm

Application scenarios

Cell Category - CHO Cell Culture (Partial Data)

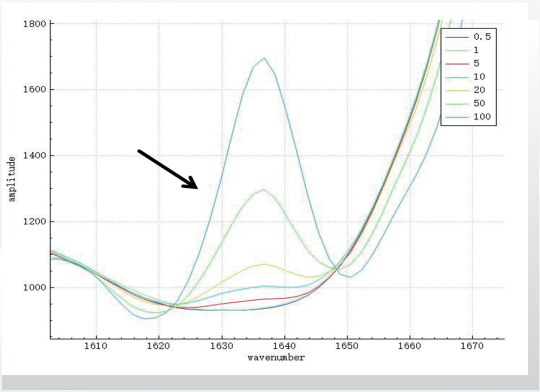


Glucose detection

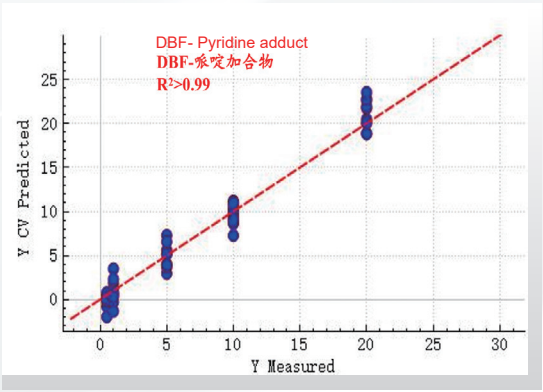


Lactic acid detection

Monitoring of piperidine in polypeptide synthesis



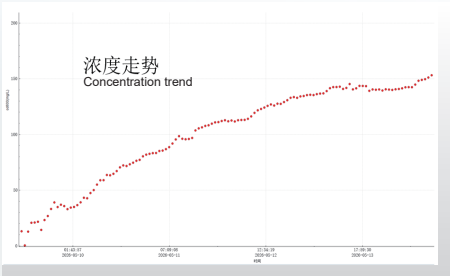
Dbf-piperidine adduct



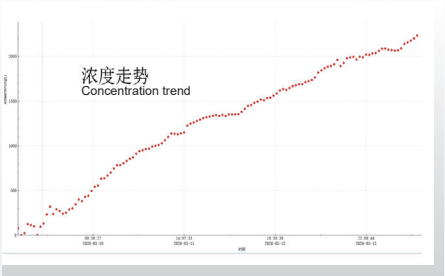
Model evaluation

Effectively monitor 50ppm of micropiperidine residue, meeting national standards.

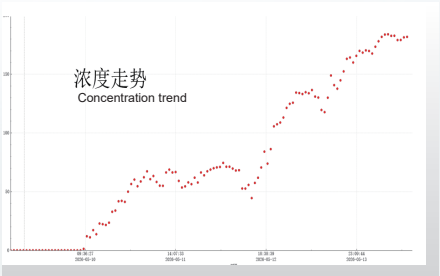
Yeast fermentation



Yeast concentration trend



Product astaxanthin concentration trend



Product echinone concentration trend

Monitor the fermentation process and product concentration to provide data support for real-time adjustment.



Service support

- SalvisLAB offers comprehensive service support to ensure that customers have the best user experience.
- Installation and commissioning: Professional engineers will provide on-site installation and commissioning to ensure the normal operation of the equipment.
- Operation training: Provide on-site operation training and online training courses to ensure that operators are proficient in using the equipment.
- Verification service: We provide a complete set of equipment verification document packages and verification services to support customers' GMP certification.
- After-sales service: A 24-hour response after-sales service system, multiple service outlets across the country, and prompt resolution of customer issues.
- Consumables supply: Stable supply of disposable culture flasks and other consumables to ensure the continuity of customers' production.

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