



# 工业 内毒素检测

## Bacterial Endotoxin Detection

# COMPANY PROFILE



Dynamiker Biotechnology (Tianjin) Co.,Ltd is a comprehensive biomedical national high-tech enterprise, built by Dr. Zeqi Zhou from Harvard Medical School. Established in March 2014, Dynamiker is dedicated to R&D, production, clinical application and technical service of Invasive Fungal Disease (IFD) diagnosis. With the mission of building international renowned brands for early and rapid IVD products for IFD, Dynamiker has become the global leader in IFD diagnosis. With its headquarters in Sino-Singapore Tianjin Eco-City, Dynamiker has established an international R&D and Production base, which is accredited by ISO13485.

Till now, Dynamiker has 20 products approved by NMPA, and 52 products got CE marks. Our rich technology rises us in a high position in the global competition. In 2021, Dynamiker launched 3 products with our technology accumulation. it covers:

**Gen1: Gel Clot Tachypleus Amebocyte Lysate assay (Vacuum tube)**

**Gen2:**

**Gen3: Automatic bacterial endotoxin/fungal glucan detector**

Dynamiker always put users' satisfaction the first priority. We will document users' circumstances and remain scheduled maintenance. Meanwhile, an emergency team will always stand by for any support.

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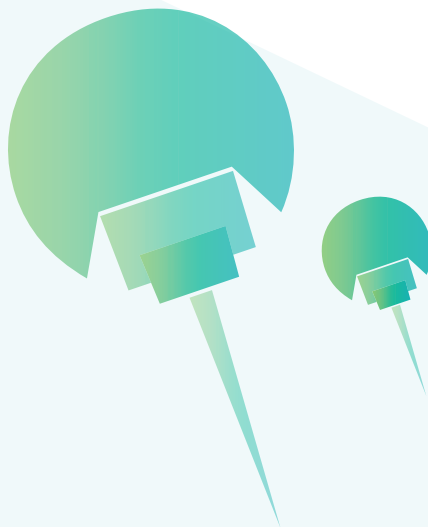
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## Gel Clot Tachypleus Amebocyte Lysate assay (Vacuum tube)

### ■ INTRODUCTION

Gel Clot TAL reagent can indicate the bacterial endotoxin content according to the firmness of the gel formed by the agglutination reaction.

This assay is normally used for qualitative or semi-quantitative determination of bacterial endotoxin content in human and animal injection drugs, biological products, and medical equipment.

This product is a freeze-dried product of the blood amoebocyte lysate from the horseshoe crab.

It contains Proclottingenzyme and Coagulogen that can be activated by bacterial endotoxins. In suitable conditions (temperature, pH, and no interfering substances), bacterial endotoxin can activate the procoagulase in the TAL reagent, causing the Limulus reagent to agglutinate and form a gel.

- Single-test packaged in Vacuum tube, Can be opened at any time as you need.
- Conforms to the Chinese Pharmacopoeia guidelines and United States Pharmacopeia, process standardly.

\* Standard products, quality control products, and endotoxin-free water are available for order.

### ■ SPECIFICATIONS

Package	50 Pcs/kit
Time to report	60±2 min
Used for	Injection drugs, Biological products and Medical devices
Sensitivity	0.125EU/mL, 0.25EU/mL, 0.5EU/mL
Storage and expiry	At 2-8°C the product can be stored for 24 months before opening.
Traits	White or almost white freeze-dried powder, easily soluble in water.
Catalog No.	NJF00125 / NJF00250 / NJF00500



## Control Standard Endotoxin (CSE)

### ■ INTRODUCTION

Bacterial endotoxin standard are extracted from *Escherichia coli* (E.coliO111:B4), freeze-dried with lactose and polyethylene glycol as excipients, and their titer is calibrated based on the national standard bacterial endotoxin. It normally will be used to

- Perform Limulus Reagent Sensitivity Recheck Test
- Perform Interference test,
- Serve as various positive controls.

This product is not only used in the gel method Limulus reagent series experiments but also in the colorimetric method Limulus reagent series experiments.

Serve as various positive controls.

### ■ SPECIFICATIONS

Package	10 Pcs/kit
Potency	10-100EU/Pcs. Bacterial endotoxin content is expressed in endotoxin units (EU) 1EU is equivalent to 1 international unit of endotoxin content (IU).
Used for	Test for Confirmation of Labeled Lysate Sensitivity, Test for Interfering Factors, positive controls.
Storage and Expiry	At 2-8°C the product can be stored for 24 months before opening.
Traits	White or almost white freeze-dried powder, easily soluble in water.
Catalog No.	XSF0004



## Endotoxin Challenge Vial (ECV)

### INTRODUCTION

Endotoxin Challenge Vial (ECV) is formed by freeze-drying lipopolysaccharide (LPS) extracted from *Escherichia coli* (E.coliO111:B4). Its titer is calibrated based on the national standard of bacterial endotoxin.

Put ECV along with the things that need to be sterilized into the sterilization instrument. Run the sterilization process. Use Limulus reagent to determine the endotoxin content of ECV, compare the content between before and after the sterilization process. The sterilization process is valid if the content reduces to 1/1000 or less of the mark content.

### SPECIFICATIONS

Package	10 Pcs/kit
Potency	10-100EU/Pcs. Bacterial endotoxin content is expressed in endotoxin units (EU) 1EU is equivalent to 1 international unit of endotoxin content (IU).
Used for	To confirm the effect of high-temperature removal of bacterial endotoxins. In the field of pharmaceuticals, biological products, medical devices, etc.
Storage and Expiry	At 2-8°C the product can be stored for 24 months before opening.
Traits	White or almost white freeze-dried powder, easily soluble in water.
Catalog No.	XSF0005



## 01 Bacterial endotoxin test water

### INTRODUCTION

This product is made of purified water. It is sterile and endotoxin-free, with No interference with bacterial endotoxin test; It is suitable for different brands of limulus reagent products. This product is high-quality water for the endotoxin inspection method in Pharmacopoeia.

### INTENDED USE

1. Negative control.
2. Dissolve and dilute CSE& ECV.
3. Dissolve and dilute Samples

### SPECIFICATIONS

8mL/bottle 10 bottles/box;  
250mL/bottle; 500mL/bottle



500mL/bottle  
Catalog No.: XSF0003



8mL/bottle 10 bottles/box  
Catalog No.: XSF0001



## 02 Endotoxin-free vials

These are endotoxin-free vials, used for the preparation and dilution of CSE& ECV.

### INTRODUCTION

High airtightness and its transparency; Good pressure resistance; Uniform tube wall thickness; environmentally friendly; No toxic substances; sterile and endotoxin-free.

### SPECIFICATION

10mL vials, 50 pcs/box



Catalog No.: ZYG00002

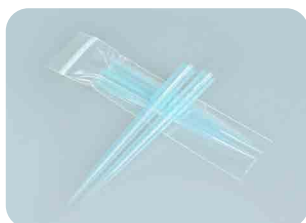


## 03 Pyrogen free tip

Used with a pipette for transferring small or trace amounts of liquid in the laboratory.



1000mL 96pcs/box



1000mL 2pcs/pouch



200mL 96pcs/box



200mL 42pcs/pouch



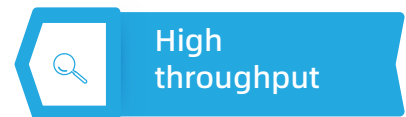
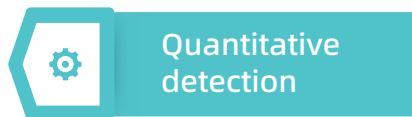
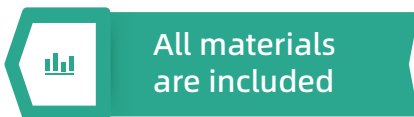


## 细菌内毒素检测 (动态显色法)

### INTRODUCTION

This assay is normally used for quantitative determination of bacterial endotoxin content in human and animal injection drugs, biological products, and medical equipment.

Bacterial endotoxin can specifically activate factor C in Limulus reagent, activated factor C activates factor B, activated factor B then activates procoagulase, coagulase hydrolyzes the chromogenic substrate in the reaction, and produces free pNA (P-Nitroaniline) to cause absorbance changes, and the endotoxin concentration is quantified based on the dynamic detection solution absorbance change rate.



### SPECIFICATIONS

Methodology	Dynamic Chromogenic method
Report time	1.5 hours
Use for	Injection drugs, Biological products and Medical devices
Storage and expiry	At 2-8°C the product can be stored for 24 months before opening.
Equipment & Consumables	Microplate reader, vortex shaker, pipette, Endotoxin-free tip are available. Welcome inquire us at <a href="mailto:marketing@dynamiker.com">marketing@dynamiker.com</a>



# TECAN.

## Sunrise™



● **ADVANCED.**

● **RELIABLE.**

● **VALIDATED.**

- Ideal for colorimetric ELISAs, kinetic assays and agglutination readings
- Advanced 12-channel optics for fast results
- Powered by Magellan data analysis software
- Advanced curve fitting and QC functions, plus data export to your LIS

## Dual wavelength detection

405nm and 492nm wavelengths are used to eliminate background interference.

96-well plate can be measured within six seconds.

## Data management

The closed software system guarantees the security of data and can set permissions for different types of accounts to manage data more effectively.

96 tests 4x24 sensitivity 0.01-1EU/ML,

Catalog No.:XSF0596TZ

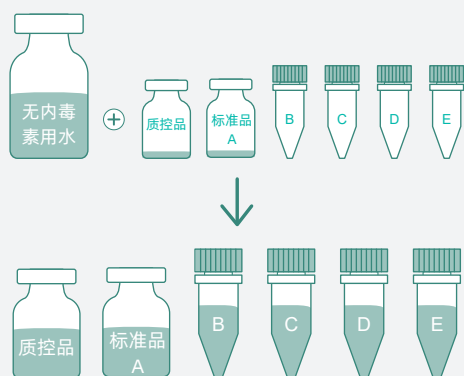
96 tests 4x24 sensitivity 0.005-5EU/ML,

Catalog No.:XSF0596TK

Items	components	Quantity	Specification
R1 Limulus reagent	Chromogenic substrates with factor C, factor B, and procoagulase;	4 Pcs	2.6mL
R4 Control Standard Endotoxin (CSE)	Lyophilized powder with gram-negative bacteria LPS;	3 Pcs	1.5mL
R5 Quality control	Lyophilized powder with gram-negative bacteria LPS;	3 Pcs	1.5mL
R6 CSE & Control dissolving solution	Bacterial endotoxin test water;	3 Pcs	8mL
R7 Limulus reagent solution	Tris-HCl buffer;	4 Pcs	3mL
R8 Microplate	----	1 Pcs	96 wells

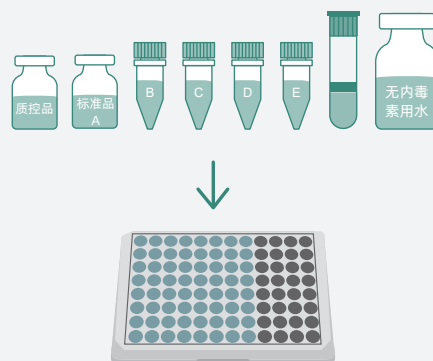
# Operation Flow Chart of Limulus reagent by Dynamic Chromogenic method

## 01 Reconstituted CSE and Control



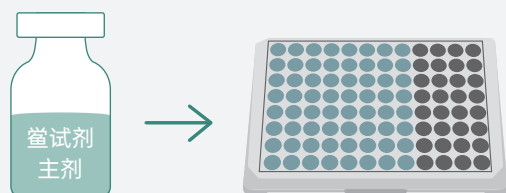
Reconstitute CSE and Quality Controls with endotoxin-free water

## 02 Add CSE, Control, blank, and samples



Add CSE (A, B, C, D, E), Quality control, blank, and samples into microplate respectively.

## 03 Add Limulus Reagent



Add the Limulus Reagent to each microwell containing liquid

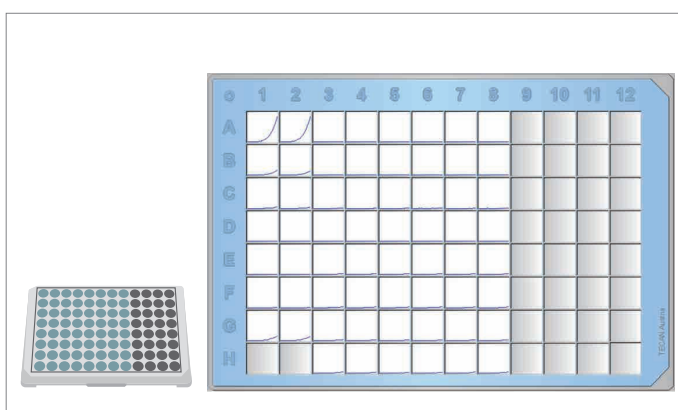
## 04 Read data & report results



Put the microplate into the microplate reader for reading, and wait for the result.

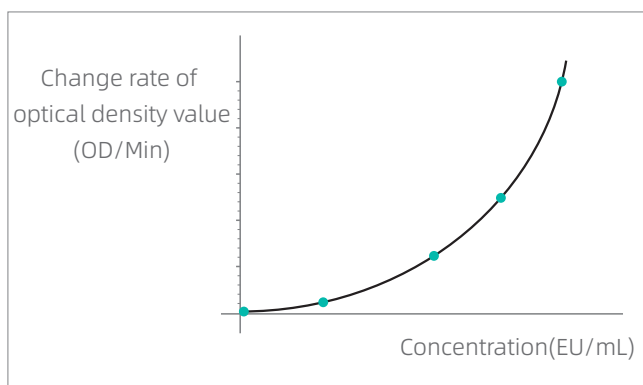
## Dynamic curve display

- The calculation software layout, are corresponds to the position of the microplate by each well makes it intuitive and clear.
- The result of each well is calculated by the average rate value. It can eliminate the influence of sample color, make the result more accurate and
- The concentration value can be indicated export/ed by the curve.



## Standard curve display

- The standard curve is plotted by CSE concentration as X-axis, average velocity as Y-axis, and fitted by 4PL.
- There are 5 concentrations of CSE (1EU/ml, 0.5EU/ml, 0.25 EU/ml, 0.05 EU/ml, 0.01EU/ml), each sample 2 duplicate.
- $R^2$  is greater than 0.99, and the recovery rate meets the requirements of the Chinese Pharmacopoeia 2020.



## Quantitative Report results

1

AVG concentration value.

2

Auto erify  $R^2$  and quality control

3

Automatic reports

4







Data are available for audit trail



## DNK-A200 Fully automatic enzyme-linked immunoassay analyzer



## Features

-  Automatic test of bacterial endotoxin
-  Multiple joint inspections of fungi and bacteria
-  Error alarm
-  Automatic report
-  Statistical sample amount
-  LIS available

## Performance

### Adding sample precisely, No pollution

- Disposable TIP is used to prevent cross-contamination
- Liquid level detection, clot detection, to avoid error adding
- Accuracy, deviation:  $100\mu\text{L}\leq\pm 1\%$ ,  $50\mu\text{L}\leq\pm 1\%$ ,  $10\mu\text{L}\leq\pm 3\%$
- Precision, CV:  $100\mu\text{L}\leq 1\%$ ,  $50\mu\text{L}\leq 2\%$ ,  $10\mu\text{L}\leq 5\%$

### Integration of Shaking, Incubating ,and Dilution

- 2 independent Temp control and shaking incubator, with light-proof
- The incubation module is also a dilution module.
- Temp overload protection to prevent sensor failure
- Temp control range: room temperature -60°C
- Temp accuracy: set temperature  $\pm 0.5^\circ\text{C}$

### Data transmission, barrier-free

- Fully compatible with LIS system one-way/two-way connection
- Report printing, data query, data analysis are all available
- Quality control chart can be carried out to ensure the results

### Double storage insurance

- Tip record, not cleared when power off, selection remembered.
- Dilution board records, clarify the remaining amount.
- Closed operation, ultraviolet sterilization, High biological safety

### Custom washing plate, Super clean!

- 16-channel independent washing channel
- Liquid level detection, timely alarm
- Plate washing mode and soaking time are adjustable, Ensure that the washing residue  $\leq 2\mu\text{L}/\text{well}$

### "Almighty" reading, strong compatibility

- TECAN reader, multiple filter configurations (405nm, 450nm, 492nm, 620/630nm)
- Single wavelength/dual-wavelength detection, endpoint/Dynamic reading
- Temp control, record temp changes during reading
- Dynamic curve reading, details can be reviewed

### Emergency treatment available

- Emergency switch, one-key pause
- Step shielding, incubation adjustment, immediate response
- Resume transmission after power failure, no redo needed, no delay
- Temp and humidity records, tracker available

### Device parameters

- DNK-A200
- Size: 660mm\* 775mm\* 750mm
- Weight: 60kg

## Operating procedures



Scan code of Sample



Test Automatically



Report results

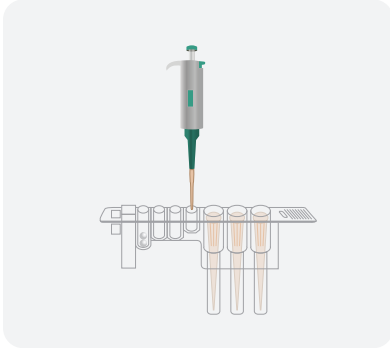
# Automatic bacterial endotoxin /fungal glucan detector Funguy D240

Escort for quality and safety!  
Plug and play! World premiere!

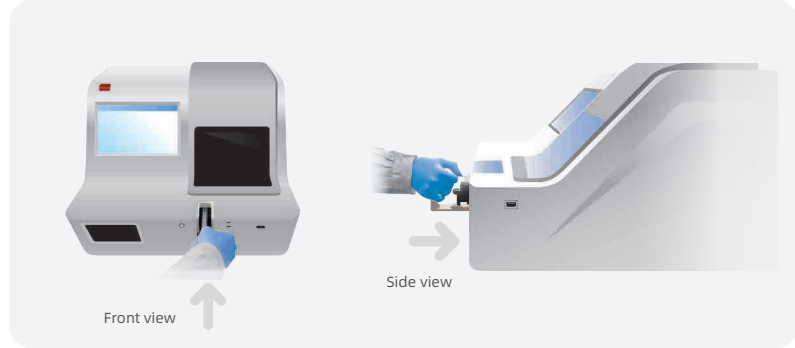


## ■ OPERATING PROCEDURES

Step 1: Add 120 $\mu$ L sample to the reagent strip.



Step 2: Insert the reagent strip into the instrument and wait for the report.



## ■ PRODUCT ADVANTAGES

Simple

Single package,  
Only adding sample operation needed.

Fast

Quick response

Convenient

Scan code to enter information,  
Send report automatically

Accurate

Closed system, Stable!  
Avoid operation error

## ■ PERFORMANCE PARAMETER

全自动细菌内毒素 / 真菌葡聚糖检测仪???

Size: 572mm×580mm×395mm

Wave length : 405 $\pm$ 2nm、490 $\pm$ 2nm

Analysis method: photometric method

Throughput: 24 channel

细菌内毒素检测试剂盒

Sample type: Injection drugs, Biological products,  
and Medical devices

Specification: 12 tests/kit

Detection range: 0.01-1EU/mL

Accuracy: relative deviation  $\leq$  15%





Technology is life!

Quality is life!



**Dynamiker Biotechnology (Tianjin) Co., Ltd.**

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