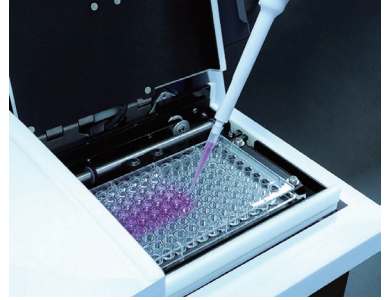


## Recombinant Proteins Endotoxin Assay rFC and rCR reagents & Lyophilized Amebocyte Lysate Products & Services



Website : [www.bioendo.com](http://www.bioendo.com)  
Email : [sales@bioendo.com](mailto:sales@bioendo.com)  
Tel : +86-592-6885886  
Xiamen Bioendo Technology Co.,Ltd.

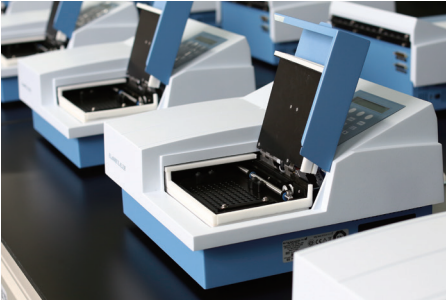
## Company Profile



Xiamen Bioendo Technology Co., Ltd. founded in 1978, is the expert in the field of endotoxin detection and endotoxin-free products. We provide Limulus Amebocyte Lysate for pharmaceutical industries to ensure that their products are free of bacterial endotoxin contamination. We are the first LAL reagent manufacturer to register the products at CFDA. We participated in preparing national standard endotoxin testing reagent and Reference Standard Endotoxin for the Authority Institute of China. We provide overall endotoxin detection solutions, includes gel clot assays, kinetic chromogenic assays, kinetic turbidimetric assays, end-point chromogenic assays, recombinant factor C (rFC) fluorometric assays, recombinant Cascade Reagents (rCR) chromogenic assays, monocyte activation test (MAT) pyrogen test, endotoxin removal solution, and top quality of endotoxin free consumables. We also provide (1,3)- $\beta$ -D-glucan assay kits for the clinical diagnosis of invasive fungi disease and endotoxin assay kits for human plasma to diagnosis of sepsis. Our products always the best solutions for the field of endotoxin testing.

Bioendo's Amebocyte Lysate reagent vial and endotoxins assay kits feature strong resistance to interference. We firmly believe quality is the life of an enterprise, therefore we strictly implement GMP regulations and ISO9001 standard management, and have gained certificate of ISO13485 quality system. Our clinical diagnostic assay kit (1-3)- $\beta$ -D-Glucan Detection Kit (Kinetic Chromogenic Method) has Obtained EU CE qualification certification.

## Company Profile



Our mission is to provide for global users with high-quality sustainable endotoxin testing products and suitable solutions in the analysis of endotoxins, endotoxin removal and endotoxin free accessories. Bioendo looks forward to cooperating with all partners and distributors!

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# Product Introduction

## 1. Gel Clot Endotoxin Assay

The Gel Clot technique is used for detecting or semi-quantifying endotoxins based on clotting of the lysate reagent in the presence of endotoxin. The minimum concentration of endotoxin required to cause the lysate to clot under standard conditions is the labeled sensitivity of the lysate reagent. Incubate the reaction mixture for a constant period according to the directions indicated on COA (usually at  $37\pm 1^\circ$  for  $60\pm 2$  min.) Then identify the sample that is positive or negative based on whether an intact gel is formed or not.



Multi test result



G02 series result



G01 series result

### 1.1 Gel Clot Lyophilized Amebocyte Lysate Single Test in Vial

Gel Clot Lyophilized Amebocyte Lysate Single Test in Vial contains 0.2 ml Amebocyte Lysate which is sealed in a standard reaction tube under vacuum condition. For our Single Test in Vial, you could add a sample to the reaction tube directly. This means you don't need to dilute Amebocyte Lysate at first, and you will decide how many vials use each time to avoid waste. No tube for dilution of CSE is needed. Operation of endotoxin detection by employing our Gel Clot Lyophilized Amebocyte Lysate Single Test in Vial conforms to USP and EP .



## Product Introduction

### Gel Clot Lyophilized Amebocyte Lysate Single Test in Vial

Catalog No.	Sensitivity EU/ml	Tests/Vial	Vials/Pack
G020030	0.03	Single Test per Vial	50
G020060	0.06		
G020125	0.125		
G020250	0.25		
G020500	0.5		



### Bioendo™ Gel Clot Endotoxin Test Kit

Catalog No.	Sensitivity EU/ml	Tests/Kit	Kit Contents
GS50020030	0.03	50	50 Gel Clot Lyophilized Amebocyte Lysate; 2 CSE; 2 TRW 50
GS50020060	0.06		
GS50020125	0.125		
GS50020250	0.25		
GS50020500	0.5		

## Product Introduction

### 1.2 Gel Clot Lyophilized Amebocyte Lysate Single Test in Ampoule

Gel Clot Lyophilized Amebocyte Lysate Single Test in Ampoule is the economic type of gel clot single test. The Amebocyte Lysate produced by Bioendo features strong resistance to interference and strong improvement for heat stability, allowing shipping at room temperature. Sensitivity of our Single Test in Ampoule covers 0.015EU/ml, 0.03 EU/ml, 0.06 EU/ml, 0.125 EU/ml, 0.25 EU/ml, 0.5 EU/ml.



Catalog No.	Sensitivity EU/ml	Test/Ampoule	Ampoules/Pack
G010015	0.015	Single Test per Ampoule	50
G010030	0.03		
G010060	0.06		
G010125	0.125		
G010250	0.25		
G010500	0.5		





## Product Introduction

### Bioendo™ Gel Clot Endotoxin Test Kit

Catalog No.	Sensitivity EU/ml	Description	Kit Contents
GS44010015	0.015	Bioendo™ Gel Clot Endotoxin Test Kit, (Single Test in Ampoule, 44Tests/Kit)	44 Gel Clot Lyophilized Amebocyte Lysate; 1 CSE 10A; 5 TRW02.
GS44010030	0.03		
GS44010060	0.06		
GS44010125	0.125		
GS44010250	0.25		
GS44010500	0.5		

### 1.3 Gel Clot Lyophilized Amebocyte Lysate Multi-test Vial

Gel Clot Lyophilized Amebocyte Lysate Multi-test Vial includes 1.7 ml/vial, and 5.2 ml/vial; and sensitivity covers 0.03 EU/ml, 0.06 EU/ml, 0.125 EU/ml, 0.25 EU/ml, 0.5 EU/ml. The Multi-test Vial is available for you when you are doing large-scale Gel Clot assays.



Catalog No.	Sensitivity EU/ml	ml/vial	Tests/Vial	Vials/Pack
G170030	0.03	1.7	16	10
G170060	0.06			
G170125	0.125			
G170250	0.25			
G170500	0.5			
G520030	0.03	5.2	50	
G520060	0.06			
G520125	0.125			
G520250	0.25			
G520500	0.5			

## Product Introduction

### 1.4 Bioendo™ GC Endotoxin Test Kit (Gel Clot Assay)

GC Endotoxin Test Kit (Gel Clot Assay) contains 128 Tests/Kit, 400 Tests/Kit, and 4500 Tests/Kit. And sensitivity of Amebocyte Lysate included by the kit could cover 0.03 EU/ml, 0.06 EU/ml, 0.125 EU/ml, 0.25 EU/ml, 0.5 EU/ml. For Bioendo GC Endotoxin Test Kit, lyophilized Amebocyte Lysate, CSE and Water for BET are included, which will avoid the mismatching between Amebocyte Lysate and CSE. Bioendo GC Endotoxin Test Kit is specially suitable for you when you need to do lots of endotoxin detection. Customized Gel Clot endotoxin assay kit is available upon your demand.



Catalog No.	Sensitivity EU/ml	Description	Kit Contents
GC90520030	0.03	Bioendo™ GC Endotoxin Test Kit (Gel Clot Assay) 4500 Tests/Kit	90 Gel Clot Lyophilized Amebocyte Lysate, 5.2ml (50 Tests/Vial); 20 CSE10V;
GC90520060	0.06		
GC90520125	0.125		
GC90520250	0.25		
GC90520500	0.5		
GC08520030	0.03	Bioendo™ GC Endotoxin Test Kit (Gel Clot Assay) 400 Tests/Kit	8 Gel Clot Lyophilized Amebocyte Lysate, 5.2ml (50 Tests/Vial); 4 CSE10V; 2 Water for BET, 50ml/vial
GC08520060	0.06		
GC08520125	0.125		
GC08520250	0.25		
GC08520500	0.5		
GC08170030	0.03	Bioendo™ GC Endotoxin Test Kit (Gel Clot Assay) 128 Tests/Kit	8 Gel Clot Lyophilized Amebocyte Lysate, 1.7ml (16 Tests/Vial); 4 CSE10V; 2 Water for BET, 50ml/vial;
GC08170060	0.06		
GC08170125	0.125		
GC08170250	0.25		
GC08170500	0.5		

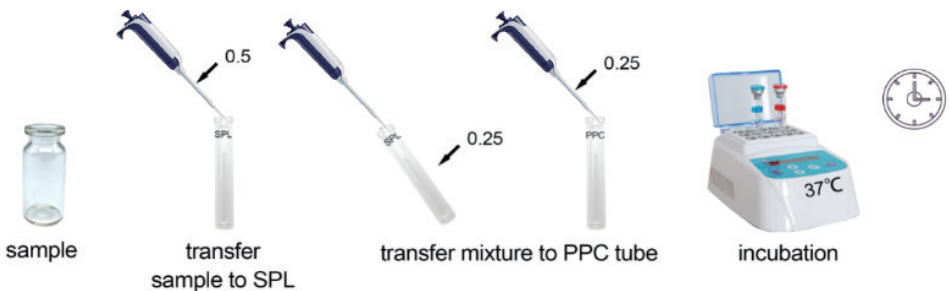
## Product Introduction

### 2. Endotoxin Test Kit for Water and Dialysate

LPS can be transferred through a membrane with large pore size by back-filtration from the dialysis fluid to the blood, inflammatory problems may be caused accordingly. No matter if it is a pharmaceutical factory providing dialysis solution or hospital treating patients with dialysate, they all should do endotoxin detection for related dialysis solutions. We offer two kits for easily detecting endotoxin in dialysate and water for dialysis purposes.

#### 2.1 Bioendo™ Rapid Gel Clot Endotoxin Assay Kit

Rapid Gel Clot Endotoxin Assay Kit is designed to rapidly quantify endotoxin in water or dialysate. Our Rapid Gel Clot Endotoxin Assay Kit contains sample tube (SPL), positive product control (PPC) tube, endotoxin-free sample bottle, and pyrogen-free pipettors. You don't need to dilute Control Standard Endotoxin. All accessories you need are included by the kit. The shortest time to get a result is about 25minutes. The assay doesn't require any sophisticated instrument. It is a convenient and rapid way to quantify endotoxin.



## Product Introduction



Catalog No.	Description	Kit Contents	Sensitivity EU/ml	Reaction Time Minutes
RG05003	Bioendo™ Rapid Gel Clot Endotoxin Assay Kit, One Sample Kit	1 SPL Tube;	0.03	≤ 60
RG05006		1 PPC Tube;	0.06	≤ 60
RG050125		1 Endotoxin-free Sample Bottle;	0.125	≤ 45
RG05025		One pack	0.25	≤ 30
RG05050		Pyrogen-free Tip;	0.5	≤ 30



Catalog No.	Description	Kit Contents	Sensitivity EU/ml	Reaction Time Minutes
RG1005003	Bioendo™ Rapid Gel Clot Endotoxin Assay Kit, 10 Samples Kit	10 SPL Tubes;	0.03	≤ 60
RG1005006		10 PPC Tubes;	0.06	≤ 60
RG10050125		10 Endotoxin-free Sample Bottles;	0.125	≤ 45
RG1005025		10 Packs of	0.25	≤ 30
RG1005050		Pyrogen-free Tips;	0.5	≤ 30

### 3. End-point Chromogenic Endotoxin Assay

#### 3.1 Bioendo™ EC Endotoxin Test Kit



Bioendo™ EC Endotoxin Test Kit provides a fast measurement for endotoxin quantification. The endotoxin in the sample activates a cascade of enzymes in Lyophilized Amebocyte Lysate, the activated enzyme splits the synthetic substrate, releasing a yellow-colored product with maximum absorbance at 405 nm. The yellow product can further react with diazo reagents forming a purple product with maximum absorbance at 545 nm. The absorbances of both yellow product and purple product are proportional to endotoxin levels, therefore, endotoxin is quantified. A regular spectrophotometer or plate reader is required for the assay.

Recommended standard curve range is 0.1-1.0EU/ml for about 16 minutes assay time. You may increase the incubation time to 40 minutes to 60 minutes to reach the sensitivity of 0.01-0.1EU/ml. Please see the package insert for the instruction.

## Product Introduction

Catalog No.	Description	Kit Contents	Sensitivity EU/ml
EC64405	Bioendo™ EC Endotoxin Test Kit (End-point Chromogenic Assay), 64 Tests/Kit	2 Lyophilized Amebocyte Lysate, 1.7ml/vial; 3 Water for BET, 50ml/vial; 2 CSE; 4 Chromogenic Substrate, 1.7ml/vial;	0.1 - 1 EU/ml
EC64405S			0.01 - 0.1 EU/ml; 0.1 - 1 EU/ml
EC32545	Bioendo™ EC Endotoxin Test Kit (End-point Chromogenic Assay, Diazo Coupling), 32 Tests/Kit	2 Lyophilized Amebocyte Lysate, 1.7ml/vial; 3 Water for BET, 50ml/vial; 2 CSE; 2 Chromogenic Substrate, 1.7ml/vial; 2 Diazo Reagent 1, 10ml/vial; 2 Diazo Reagent 2, 10ml/vial; 2 Diazo Reagent 3, 10ml/vial;	0.1 - 1 EU/ml
EC32545S			0.01 - 0.1 EU/ml; 0.1 - 1 EU/ml
EC80545	Bioendo™ EC Endotoxin Test Kit (End-point Chromogenic Assay, Diazo Coupling), 80 Tests/Kit	5 Lyophilized Amebocyte Lysate, 1.7ml/vial; 4 Water for BET, 50ml/vial; 5 CSE; 5 Chromogenic Substrate, 1.7ml/vial; 5 Diazo Reagent 1, 10ml/vial; 5 Diazo Reagent 2, 10ml/vial; 5 Diazo Reagent 3, 10ml/vial;	0.1 - 1 EU/ml
EC80545S			0.01 - 0.1 EU/ml; 0.1 - 1 EU/ml

### 4. Kinetic Turbidimetric Endotoxin Assay

Kinetic Turbidimetric Endotoxin Assay is a simple measurement for endotoxin quantification. Based on the principle that in the presence of Lyophilized Amebocyte Lysate becomes turbid, the increase rate of turbidity is proportional to the endotoxin concentration of the sample, the endotoxin is quantified. The highest sensitivity of kinetic turbidimetric assay is 0.005EU/ml. The detection range is up to four orders of magnitude in a single standard curve. Using kinetic microplate reader ELx808IU-SN and software, kinetic turbidimetric assay automatically quantifies endotoxins in a single step for 96 tests at a time. The test efficiency could be improved dramatically with the help of multi-channel pipettor or automatic sample processing device. Kinetic turbidimetric assay is applicable to the pharmaceutical industry endotoxin monitoring in the manufacturing process, including raw materials, water for injection, intermediate products and end products endotoxin tests.

## Product Introduction

### Bioendo™ KT Endotoxin Test Kit (Kinetic Turbidimetric Assay)



Catalog No.	Description	Kit Contents	Sensitivity EU/ml
KT0817	Bioendo™ KT Endotoxin Test Kit (Kinetic Turbidimetric Assay), 128 Tests/Kit	8 Lyophilized Amebocyte Lysate, 1.7ml (16 Tests/vial);	0.01 - 10 EU/ml
KT0817S		8 Reconstitution Buffer, 3.0ml/vial; 4 CSE; 2 Water for BET, 50ml/vial;	0.005-5 EU/ml 0.01-10 EU/ml
KT0852	Bioendo™ KT Endotoxin Test Kit (Kinetic Turbidimetric Assay), 400 Tests/Kit	8 Lyophilized Amebocyte Lysate, 5.2ml (50 Tests/Vial);	0.01 - 10 EU/ml
KT0852S		8 Reconstitution Buffer, 6.0ml/vial; 4 CSE; 2 Water for BET, 50ml/vial;	0.005-5 EU/ml 0.01-10 EU/ml

## 5. Kinetic Chromogenic Endotoxin Assay

In kinetic chromogenic assay method, Lyophilized Amebocyte Lysate is co-lyophilized with chromogenic substrate. Same as the kinetic turbidimetric assay, the assay is performed in an incubating microplate reader ELx808IU-SN. The increase of OD at 405 nm is recorded and interpreted by the instrument and software, the endotoxin concentration is also calculated. Kinetic chromogenic assay combines the advantages of kinetic turbidimetric and end-point chromogenic method. Without depending on the activity of clotting protein to form the gel clot, the assay is strong resistance to interference. Especially suitable for the biological samples, such as a vaccine, antibody, protein, nucleic acid, etc. Sensitivity of our Kinetic Chromogenic Amebocyte Lysate could reach 0.001 EU/ml.

## Product Introduction

### 5.1 Bioendo™ KC Endotoxin Test Kit (Kinetic Chromogenic Assay)



Catalog No.	Description	Kit Contents	Sensitivity EU/ml
KC5028	Bioendo™ KC Endotoxin Test Kit (Kinetic Chromogenic Assay), 1300 Tests/Kit	50 Chromogenic Amebocyte Lysate, 2.8ml (26 Tests/vial);	0.005-5 EU/ml
KC5028S		50 Reconstitution Buffer, 3.0ml/vial; 10 CSE;	0.001-10EU/ml
KC0828	Bioendo™ KC Endotoxin Test Kit (Kinetic Chromogenic Assay), 208 Tests/Kit	8 Chromogenic Amebocyte Lysate, 2.8ml (26 Tests/vial);	0.005 - 5 EU/ml
KC0828S		8 Reconstitution Buffer, 3.0ml/vial; 4 CSE; 2 Water for BET, 50ml/vial;	0.001-10 EU/ml
KC0817	Bioendo™ KC Endotoxin Test Kit (Kinetic Chromogenic Assay), 128 Tests/Kit	8 Chromogenic Amebocyte Lysate, 1.7ml (16 Tests/vial);	0.005-5 EU/ml
KC0817S		8 Reconstitution Buffer, 2.0ml/vial; 4 CSE; 2 Water for BET, 50ml/vial;	0.001-10 EU/ml



## Product Introduction

### 5.2 Bioendo™ MicroKC Endotoxin Test Kit (Micro Kinetic Chromogenic Assay)

Bioendo™ MicroKC Endotoxin Test Kit uses Kinetic chromogenic microtechnology, which is equipped with a specially customized micro-detection 96-well plate/strip. The microKC assay is realized on the ELx808IU-SN instrument and other conventional endotoxin detection equipment, which is in line with the provisions of the bacterial endotoxin detection method.

Each test only needs 25µL of test sample and 25µL of Chromogenic Amebocyte Lysate. The detection principle is the same as that of the traditional Kinetic chromogenic endotoxin detection. It has strong anti-interference ability and It is suitable for quantitative endotoxin detection of injectable drugs, vaccines, antibodies and biological agents, etc.

#### ***Recommended users:***

pharmaceutical manufacturers, biological product manufacturers, scientific research institutes, biological companies, etc.

#### ***Performance characteristics***

- The sample consumption is small, and each test only needs 25µL of the test sample.
- It is a photometric chromogenic substrate method included in the Pharmacopoeia, which can meet the requirements of GMP for data integrity and traceability.
- High sensitivity, up to 0.005EU/ml.
- Strong anti-interference ability, no need to coagulate protein to form gel, accurate quantification of bacterial endotoxin according to chromogenic reaction.
- Easy-of-use, the reaction is carried out in a high-throughput 96-well plate, and the system automatically detects and analyzes it in one step.
- Excellent Cost Performance, lower price and better performance.

#### ***Purchase recommendation***

Catalog No.	Description	Kit Contents	Sensitivity EU/ml
MKC0505VS	Bioendo™ KC Endotoxin Test Kit (Micro Kinetic Chromogenic Assay), 90 Tests/Kit	5 Chromogenic Amebocyte Lysate, 0.5ml (18 Tests/Vial); 5 Reconstitution Buffer, 0.8ml/vial;	0.005-10 EU/ml
MPMC96	8 wells per strip	96 wells per microplate, 12pcs detachable strips.	

## Product Introduction

### 5.3 Bioendo™ rCR Endotoxin Test Kit (Recombinant Cascade Reagents Chromogenic Assay)

**Bioendo™ Bioendo rCR Endotoxin Test Kit** (Recombinant Cascade Reagents Chromogenic Assay) uses gene recombinant technology to express Factor C pathway serine zymogen proteases of horseshoe crab amebocyte in eukaryotic cells. The cascade reagents include Factor C which can be activated by bacterial endotoxins, Factor B and proclotting enzyme. Endotoxins bind to and convert Factor C to its active form, which subsequently activates Factor B, which in turn activates the proclotting enzyme. The activated proclotting enzyme then cleaves chromogenic substrate, releasing a yellow-colored pNA. The released pNA can be measured photometrically at 405 nm. Based on which, the endotoxin concentration of test sample can be quantified. rCR endotoxin test kit does not use animal source materials, protects the horseshoe crabs.



#### Features:

- 1. Convenient detection: the same detection instrument as the Chromogenic LAL reagent is used, and there is no need to replace the detection instrument.
- 2. High sensitivity: the sensitivity can be as high as 0.001EU/ml.
- 3. Stability: good repeatability between production batches
- 4. Specificity: does not react with fungal (1,3)- $\beta$ -D-glucan, avoiding false positives caused by factor G bypass.

#### Order information

Catalog No.	Description & Kit Contents	Sensitivity Range
RCR0428S	4 Recombinant Cascade Reagents -- 2.8ml/vial 4 Reconstitution Buffer -- 3.0ml/vial 2 Control Standard Endotoxin -- CSE10V	0.001-10EU/ml
RCR0428	2 Water for BET -- 50ml/vial	0.005-5EU/ml

## Product Introduction

### 6. Bioendo™ rFC Endotoxin Test Kit (Recombinant Factor C Fluorometric Assay)

Bioendo™ rFC Endotoxin Test Kit (Recombinant Factor C Fluorometric Assay) uses gene recombination technique to express the serine protease catalytic cascade protein Factor C which reacts with endotoxin in *Tachypleus Amebocyte* in eukaryotic cells. After binding with endotoxin, recombinant Factor C is transformed from inactive proteasogen to bioactive protease, which recognizes and catalyzes the downstream Fluorometric substrate to produce Fluorometric signals. The intensity of fluorescence signal is positively correlated with the concentration of endotoxin, so endotoxin can be detected quantitatively. The recombinant Factor C endotoxin test does not use natural horseshoe crab amebocyte, which protects horseshoe crab resources. It is a new generation of endotoxin test technology.



#### **Instrument required:**

Professional incubating fluorescence microplate reader is required with excitation wavelength 380nm /emission wavelength 440nm filters (please consult our sales department for details).

#### **Features:**

- Rapid Reaction: 30-60 minutes to complete the detection.
- Endotoxin Specificity: only reacts with endotoxin, avoiding beta-glucan interference
- High sensitivity: the minimum detection can reach 0.005EU/ml
- Lot-to-lot Repeatability: recombinant expression, good repeatability between lots
- Reagents are in lyophilized form, easy to store and transport
- Easy-of-use, the system automatically detects and analyzes in one step.

#### Purchase recommendation

Catalog No.	Description & Kit Contents	Sensitivity Range
RFC96TS	2 Recombinant Factor C -- 2.5ml/vial; 2 Reconstitution Buffer -- 3.0ml/vial; 2 Control Standard Endotoxin -- CSE10V; 1 Water for BET -- TRW50;	0.005-5EU/ml
RFC96T	15 Endotoxin-free black 8-well microplate strip. 1 Strips bracket; 96Tests/Kit.	0.01-10EU/ml

## Product Introduction

### 7. Clinical Diagnostic Reagents

#### 7.1 Fungi (1,3)- $\beta$ -D-glucan Assay Kit



Based upon Factor G mediated TAL pathway, Fungi (1,3)- $\beta$ -D-glucan assay detects (1 $\rightarrow$ 3)- $\beta$ -D-glucan in human plasma or serum in one hour. The highly sensitive, rapid assay assists clinicians in identifying Invasive Fungal Disease (IFD) early in the disease process. The kit is CE certified for clinic diagnostic purposes.

Immunosuppressed patients are at high risk for developing invasive fungal disease, which is often difficult to diagnose.

Affected patient populations include:

- Cancer patients undergoing chemotherapy
- Stem Cell and Organ Transplant patients
- Burn patients
- HIV patients
- ICU patients...

Catalog No.	Description	Kit Contents
KCG50	Fungi (1,3)- $\beta$ -D-glucan Assay Kit (Kinetic Chromogenic Method), 50 Tests/Kit	5 Chromogenic Amebocyte Lysate 1.1ml/vial; 2 (1,3)- $\beta$ -D-Glucan Standard, 5-10ng/vial; 2 Reconstitution Buffer, 10ml/vial; 1 Tris Buffer, 6ml/vial; 1 Sample Treatment Solution A, 3ml/vial; 1 Sample Treatment Solution B, 3ml/vial; Glucan-free and Endotoxin-free accessories
KCG80	Fungi (1,3)- $\beta$ -D-glucan Assay Kit (Kinetic Chromogenic Method), 80 Tests/Kit	5 Chromogenic Amebocyte Lysate 1.7ml/vial; 2 (1,3)- $\beta$ -D-Glucan Standard, 5-10ng/vial; 2 Reconstitution Buffer, 10ml/vial; 1 Tris Buffer, 6ml/vial; 1 Sample Treatment Solution A, 3ml/vial; 1 Sample Treatment Solution B, 3ml/vial; Glucan-free and Endotoxin-free accessories
KCG100	Fungi (1,3)- $\beta$ -D-glucan Assay Kit (Kinetic Chromogenic Method), 100 Tests/Kit	5 Chromogenic Amebocyte Lysate 2.2ml/vial; 2 (1,3)- $\beta$ -D-Glucan Standard, 5-10ng/vial; 2 Reconstitution Buffer, 10ml/vial; 1 Tris Buffer, 6ml/vial; 1 Sample Treatment Solution A, 3ml/vial; 1 Sample Treatment Solution B, 3ml/vial; Glucan-free and Endotoxin-free accessories

# Product Introduction

## 7.2 Endotoxin Assay Kit for Human Plasma



### PRODUCT

#### PERFORMANCE INDEX

Sensitivity: 0.01EU/ml

Standard curve range: 0.1~10EU/ml

Accuracy (relative deviation):  $\pm 30\%$

In-batch precision:  $CV \leq 20\%$

Batch precision:  $CV \leq 25\%$

Kinetic Turbidimetric LAL Kit For Endotoxin Detection is used to quantitatively detect bacterial endotoxin (lipopolysaccharide) in human samples. Based on the factor C bypass reaction sensitive to bacterial endotoxin in Lyophilized Amebocyte Lysate reagent, Kinetic Turbidimetric LAL Kit For Endotoxin Detection can quickly and accurately quantify extremely small amount of bacterial endotoxin, providing diagnostic basis for Gram-negative bacterial infection related diseases. It can also be used for quantitative pyrogen detection of dialysate, dialysate water, and other dialysate related supplies in the field of biological therapy.

Catalog No.	Description	Kit Contents
KTE20	Endotoxin Assay Kit for Human Plasma (Kinetic Turbidimetric Method), 20 Tests/Kit	20 Lyophilized Amebocyte Lysate 0.1ml/vial, Single Test Vial; 20 Sample Treatment Solutions 0.9ml/vial;

## Product Introduction

### 8. Bacterial Endotoxin Detection Accessories

#### 8.1 Endotoxin-free Buffers



Catalog No.	Description	Note	Package
BH10	50mM Tris Buffer, pH7.0, 10ml/vial	Used to dilute highly acidic or basic samples.	10 Vials/Pack
BH50	50mM Tris Buffer, pH7.0, 50ml/vial		
BY10	10mM Magnesium Buffer, 10ml/vial	Used to overcome chelation effect.	
BT10	$\beta$ -glucans Blocker, 10ml/vial	Used to block $\beta$ -glucan interference in Amebocyte Lysate endotoxin reactions.	

## Product Introduction

### 8.2 Control Standard Endotoxin (CSE)



Control Standard Endotoxin (CSE) is an economic alternative to Reference Standard Endotoxin (RSE) in constructing standard curves, validating products and preparing controls in endotoxin tests. The potency of CSE is referenced against USP Reference Standard Endotoxin, and labeled in the Certificate of Analysis.

Catalog Number	Potency (EU/vial)	Package
CSE10A	1-99	In Ampoule, 10 Ampoules/Pack
CSE10V	1-199	In Vial, 10 Vials/Pack

## Product Introduction

### 8.3 Water for Bacterial Endotoxins Test



Water for Bacterial Endotoxins Test is specially processed water intended for endotoxin detection. Its endotoxin concentration is less than 0.005EU/ml. We also provide water for BET with endotoxin level less than 0.001EU/ml for the assay sensitivity 0.001 - 10EU/ml kinetic chromogenic assay. Water for Bacterial Endotoxins Test (i.e. Water for BET) could be used as the negative control in endotoxin assay to dilute the Control Standard Endotoxin, to extract the endotoxin in the test samples and to dilute samples. Various packages, such as 2ml, 5ml, 10ml, 50ml, 100ml, 500ml/vial, are provided for users' convenience.



Catalog Number	Volume (ml/Vial)	Package
TRW02	2ml in Ampoule	In Ampoule, 10 Ampoules/Pack
TRW05	5ml in Ampoule	
TRW10A	10ml in Ampoule	
TRW50	50ml in Vial	In GlassVial, 10 Vials/Pack
TRW100	100ml in Vial	



## Product Introduction

### 8.4 Endotoxin Challenge Vial (Endotoxin Indicator)



The Endotoxin Challenge Vial (Endotoxin Indicator) is used in the validation of dry heat depyrogenation cycles. Endotoxin Challenge Vials are placed in the cold spots of five samples in the dry heat ovens ( or dry heat tunnels ). After cycle completion, a minimum of 5 samples should be taken in the monitored positions of ovens ( tunnels ), the reduction of endotoxins levels can be determined by comparing the endotoxin levels in the baked vs non-baked Endotoxin Indicators. The Endotoxin Challenge vials are designed to indicate NMT 0.1EU of reduction in endotoxin per sample when tested using gel clot, kinetic turbidimetric or chromogenic endotoxin assays. Endotoxin Challenge Vial, ECV10000V contains 1000-200000EU Endotoxin content which is considered acceptable subpackage . ECV1250V is sealed in vials with heat resistant stoppers and labels, and can be placed in dry heat oven without removal of stoppers and caps. ECV1250A is sealed in ampoules.

Catalog Number	Endotoxin Level(EU/Vial)	Package
ECV1250A	1000-10000	In Ampoule, 10 Ampoules/Pack
ECV1250V		In Vial, 10 Vials/Pack
ECV1250VR	2000-10000	In ISO 2R Vial, 10 Vials/Pack
ECV10000V	50000-200000	In Vial, 10 Vials/Pack

## Product Introduction

### 8.5 Endotoxin-free Glass Test Tubes



Endotoxin-free glass test tubes contain less than 0.005 EU/tube endotoxin. Catalog numbers T107505, T107530 and T105005 are recommended for use as reaction tubes in gel clot and end-point chromogenic assays. Catalog number T1310005 is recommended for dilution of endotoxin standards and test samples. T105005C is a specially designed short endotoxin reaction tube that allows the pipette tips to reach the tube bottom.

Catalog No.	Size mm (outside diameter)	With Aluminum Cap	Package tubes/pack
T105005C	$\phi 10 \times 50$	Yes	5
T107505C	$\phi 10 \times 75$	Yes	5
T107505		No	5
T107540		No	40
T127505C	$\phi 12 \times 75$	Yes	5
T127505		No	5
T127525		No	25
T1310005C	$\phi 13 \times 100$	Yes	5
T1310005		No	5
T1310018		No	18

## Product Introduction

### 8.6 Pyrogen-free plastic accessories Pyrogen-free microplates & Reagent Reservoir



Catalog No.	Description
MP96	Pyrogen-free 96-well Microplate with Lid
MPMC96	Special for the mKC kits, 96-well microplate
MPF96	Endotoxin-free black 8-well microplate strip. Special for Recombinant Factor C Fluorometric Assay kits.
RR5	Pyrogen-free Reagent Reservoir, 5pcs/pack



### Pyrogen-free tips

Catalog No.	Description	Package
PT2505	Pyrogen-free 250ul Pipette Tips	5 Tips/Pack
PT10004	Pyrogen-free 1000ul Pipette Tips	4 Tips/Pack
PT25096	Pyrogen-free 250ul Pipette Tips	96 Tips/box
PT100096	Pyrogen-free 1000ul Pipette Tips	96 Tips/box

## Product Introduction



### Pyrogen-free centrifuge tubes

Catalog No.	Description	Package
CT2515	Polypropylene, Pyrogen-free centrifuge tube, 15ml	25 pcs/pack
CT2550	Polypropylene, Pyrogen-free centrifuge tube, 50ml	25 pcs/pack
CT2515PS	Polystyrene, Pyrogen-free centrifuge tube, 15ml	25 pcs/pack

### 8.7 Endotoxin-free Sample Bottles



Endotoxin-free sample bottles contain less than 0.005EU/ml endotoxin. It would be used to store test sample or to transport product samples.

Catalog No.	Description	Package
PA10	Endotoxin-free sample bottle, 10ml	10 pcs/Pack
PA50	Endotoxin-free sample bottle, 50ml	10 pcs/Pack

## Product Introduction

### 9. Lab Equipment and Software

#### 9.1 Kinetic Incubating Microplate Reader ELx808IU-SN



Kinetic Incubating Microplate Reader ELx808IU-SN is a multifunctional kinetic reader designed for bacterial endotoxin assay, fungi (1,3)- $\beta$ -D-glucan assay and ELISA assays. The reader is a highly accurate, easy to use instrument for kinetic turbidimetric assay, kinetic chromogenic assay and end-point chromogenic assay.

#### Instrumental Parameters:

- wavelength range of 340-900nm, suitable for ultraviolet and visible light detection.
- 6 filter wheel, standard configuration with 5 filters (340, 405, 490, 540 and 630nm).
- temperature control range: room temperature+5 °C to 50 °C
- standard curve linear correlation coefficient:  $|r| \geq 0.99$
- assay repeatability:  $CV \leq 5\%$
- 96 tests per plate

#### Application Range:

- Bacterial endotoxin (pyrogen) assay of drugs, vaccines, Water for Injection medical devices, infusion, transfusion related devices dialysate, dialysis water endotoxin testing cell suspension, cell culture media, cell culture related products recombinant protein, nucleic acid and other molecular biological products
- Endotoxin level monitoring during production: pharmaceutical raw materials, intermediate products, end product endotoxin daily monitoring.
- Clinical diagnostic of sepsis and invasive fungi disease: plasma, serum, urine, cerebrospinal fluid endotoxin and (1,3)- $\beta$ -D-glucan detection.

## Product Introduction

Catalog No.	Description
KPR808IULAL	Kinetic incubating microplate reader ELx808IU-SN for Endotoxin and $\beta$ -glucan detection

### 9.2 Endotoxin and (1,3)- $\beta$ -D-glucan Assay Software

EndoMaster™ endotoxin and (1,3) - $\beta$ -D-glucan professional analysis software is a powerful kinetic data analysis software, which gives the user data acquisition and processing of the maximum flexibility.

#### Features:

- Apply to Endotoxin assay, (1,3) - $\beta$ -D-glucan assay and ELISA data analysis
- With standard version and clinical diagnostic version for the different user groups.
- Data could be output transitions and connected to the LIS system.
- Customizable endotoxin test reports.
- Data analyzed by onset time, average rate, maximum rate and other methods.
- Data linear fitting or polynomial fitting.
- Real-time backup of the original data read.
- Integration of variety of kinetic microplate readers.

Catalog Number	Description
Gen5	Gen5 Software for BioTek ELx808IU-SN
SGen5S	Gen5 Secure Software for BioTek ELx808IULALXH
EM01	Endotoxin and (1,3)- $\beta$ -D-glucan Assay Software EndoMaster

## Product Introduction

### **Gen5 (Basic Version) :** (Standard configuration)

The data analysis software is a microplate data acquisition and analysis software developed by an American company. Simple maneuverability, flexibility, and powerful functions to meet the needs of bacterial endotoxin and fungal glucan detection. Data can be analyzed by starting world method, average speed method, maximum speed method and other methods. Linear fitting and polynomial simulation can be used Together.

### **Gen5 Secure:** (Optional charge)

Comply with FDA certification

Unique software verification system

User rights management can create new groups, and each group can be assigned designated rights. Each user has an independent password, and the password has a set of management system.

Timely lock the software window function to prevent the misoperation of other personnel and affect the experimental results when the operator is away.

The experiment is completed (or experiment error, or user login software failure, etc.), which is convenient for the administrator to monitor the experiment and is extremely safe.

Audit tracking function, customized audit tracking records, key audit tracking records for software. Track all system, program, data increase and decrease records, and have the function of reviewing records everywhere, which is convenient for GMP inspection.

## Product Introduction

### 10.Dry Heat Incubator Series

#### 10.1 Dry Heat Incubator



#### Mini Dry Heat Incubator

Catalog No.	TAL-MT
Product Name	TAL-MT Mini Dry Heat Incubator
Temperature Range	Ambient+5 °C -110 °C
Time Required	≤15 min. (from 20 °C rise to 100 °C);
Temperature Stability @100 °C	≤±0.5 °C
Temperature Uniformity@40 °C	≤±0.3 °C
Temperature Displayed Precision	0.1 °C
Temperature Control Time	0-999 min.
Highest Temperature	110 °C
Power	60W
Weight	≤1kg

#### Dry Heat Incubator

Catalog No.	TAL-M2
Product Name	TAL-M2 Dry heat incubator (60 wells)
Temperature Range	ambient+5 °C ~ 150 °C
Time Required	≤ 30min (from 20 °C rise to 150 °C)
Temperature Stability @100~150 °C	≤±1 °C
Temperature Stability @40~100 °C	≤±0.5 °C
Temperature Uniformity 40 °C	0.3 °C
Displayed Precision	0.1 °C
Temperature Control time	99h59min
Highest Temperature	150 °C
Power	400W
Dimension	260x220x95mm



## Product Introduction

### 10.2 Channel Mechanical Pipettes



#### Single-Channel Mechanical Pipettes

Catalog No.	Description
PSB0010	0.5 - 10ul
PSB0100	10 - 100ul
PSB0220	20 - 200ul
PSB1100	100 - 1000ul

#### Eight-Channel Mechanical Pipettes

Catalog No.	Description
P80020	2 - 20ul
P80050	5 - 50ul
P80100	10 - 100ul

### 10.3 Vortex Mixer



Catalog No.	Description
VXH	Vortex Mixer

## Product Introduction

### 10.4 Bioendo™ Nymph X Water Purification System

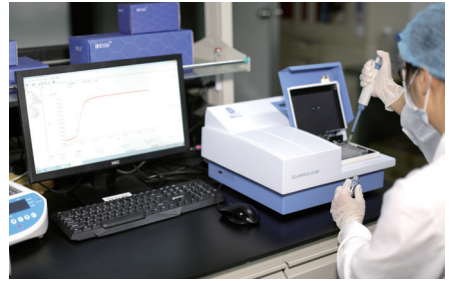
Nymph X Water Purification System could transfer tap water into pure water and ultrapure water. Equipped with a pressure stabilizer and low flow-rate operating mode, the system can adapt to various source conditions without any extra pre-treatment necessary. The system also supports multiple water dispensing modes, and the precision of quantitative and quality-controlled dispense of water could reach  $\pm 1\%$ . Meanwhile, comprehensive monitoring could be done by the system to produce pure water and ultrapure water with stable and eligible quality.

Endotoxin concentration of water produced through Nymph X Water Purification System is lower than 0.001EU/ml. Such water could be used to culture cells, reconstitute culture medium and endotoxin-free buffer solution, dilute sample, refine protein and plasmid, wash and digest medical apparatus and instruments, etc.. And bag-tank storage is employed by the system, that you just need to change the inner water bags, and don't need to clean the water storage tank. Integrated pretreatment-water tank unit will save space. Easy operation requires none extra training or instruction. Furthermore, the system could alarm and implement safeguard procedures at the same time. And replacement of all consumable items could be done by yourselves.



Catalog No.	Description	Reference Photo
NYMPHX	Nymph X Water Purification System	

### 11. Endotoxin Testing Services and Other Services



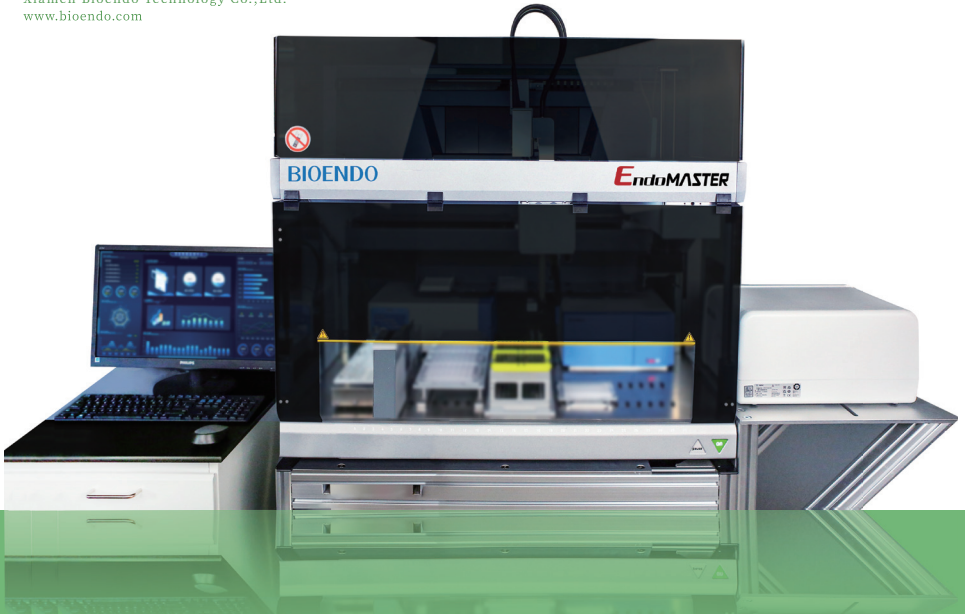
We are expertise in endotoxin detection. We provide endotoxin testing services to customers from the pharmaceutical industry, medical device companies, research and environmental laboratories. Pharmaceutical-grade testing includes all of the validation steps required during a product validation program, the test complied with the requirement of Bacterial Endotoxins Test (BET) in Pharmacopoeia.

As a primary manufacturer of Lyophilized amebocyte lysate, we offer a wide range of endotoxin testing solutions to fit your requirements. From the simplicity of gel clot testing to the productivity of fully robotic systems, we cover the TAL evolutionary scale. We also provide 3Q services and the annul calibration of for the endotoxin detection instruments.

Catalog No.	Product Description
TEST001	Gel Clot Endotoxin Test
TEST002	Quantitative Endotoxin Assay
SER001	Test Validation
SER002	Exclusion of $\beta$ -D-glucan Activity
SER003	Oven Validation Tests
SER004	Sample Container Study
SER3Q	3Q Service for BioTek Kinetic Incubating Microplate Reader
SER005	BioTek Kinetic Incubating Microplate Reader Calibration and Maintenance Services
SER006	Low Endotoxin Recovery (LER) consulting services

# BIOENDO

Xiamen Bioendo Technology Co.,Ltd.  
www.bioendo.com



## ENDOMASTER INTELLIGENT AUTOMATIC ENDOTOXIN DETECTION SYSTEM



[www.bioendo.com](http://www.bioendo.com)

**Xiamen Bioendo Technology Co.,Ltd.**

Tel : +86-592-6885886

Website : [www.bioendo.com](http://www.bioendo.com)

Email : [sales@houshiji.com](mailto:sales@houshiji.com) [tech@houshiji.com](mailto:tech@houshiji.com)

Adress : 131 Xinjia Road, Haicang

Xinyang Industry Zone, Xiamen, P.R. China