FUJIFILM
Value from Innovation

Wako

Endotoxin Measurement System

Toxinometer® ET-7000

- Supports "the Bacterial Endotoxin Test" in the United States / European / Japanese Pharmacopoeias
- Compliant with FDA 21 CFR, Part 11
- Conforms to the international certification standards for C-UL(CSA) and CE

Since 1985

State-of-the-art analysis system configured to ensure data integrity*

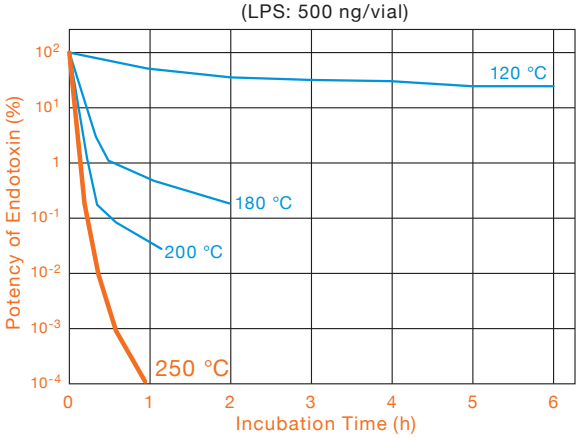
* Data integrity refers to the completeness, accuracy, and consistency of data.

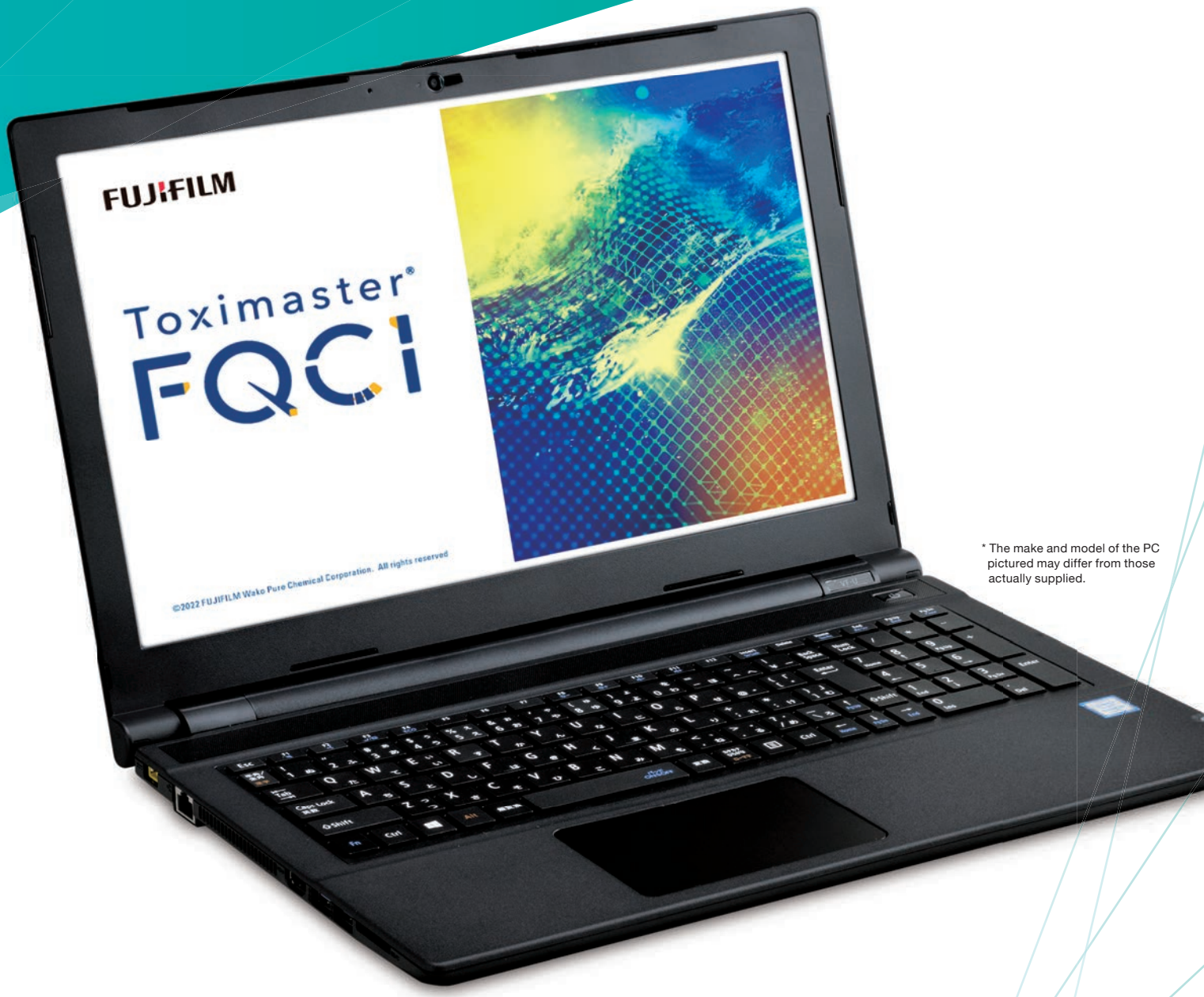
Endotoxin

What is Endotoxin?

Endotoxin is a lipopolysaccharide (LPS) that comprises the cell wall of Gram-negative bacteria. Endotoxin induces various biological reactions, such as fever, when even a small amount (ng) enters the bloodstream. Endotoxins exist in environments where gram-negative bacteria reside and remain even after the bacteria die. They cannot be deactivated completely by autoclaving because of their resistance to heat.
According to the Pharmacopoeia, **dry heat sterilization for at least 30 minutes at a temperature equal to 250 ° C or higher** is required for complete deactivation of endotoxins.

Heat stabilization of endotoxin
(LPS: 500 ng/vial)





* The make and model of the PC pictured may differ from those actually supplied.

High Reliability

High quality specialized glass tubes make it possible to maintain...

- Complete Sterilization
- Endotoxin Free Environment
- No Cross Contamination

High Sensitivity

When combined with our Chromogenic reagent can offer...

- A maximum sensitivity of 0.0002 EU/mL.
- More than 3 digits dynamic range of 0.0002 - 0.5 EU/mL.

(when using Limulus Color KY single test.)

Flexibility

ALL 3 methods available in just one system.

- Gel-clot technique
- Turbidimetric technique
- Chromogenic technique

Expandability to Support Future Growth

- Controlled remotely from a Windows® PC
- Up to 8 measurement modules can be additionally installed

Allows for continuous sample measurement Measures Max. 128 samples simultaneously

Wako's Toxinometer®, Highly Advanced Technology for Bacterial Endotoxin Testing

Gel-clot technique

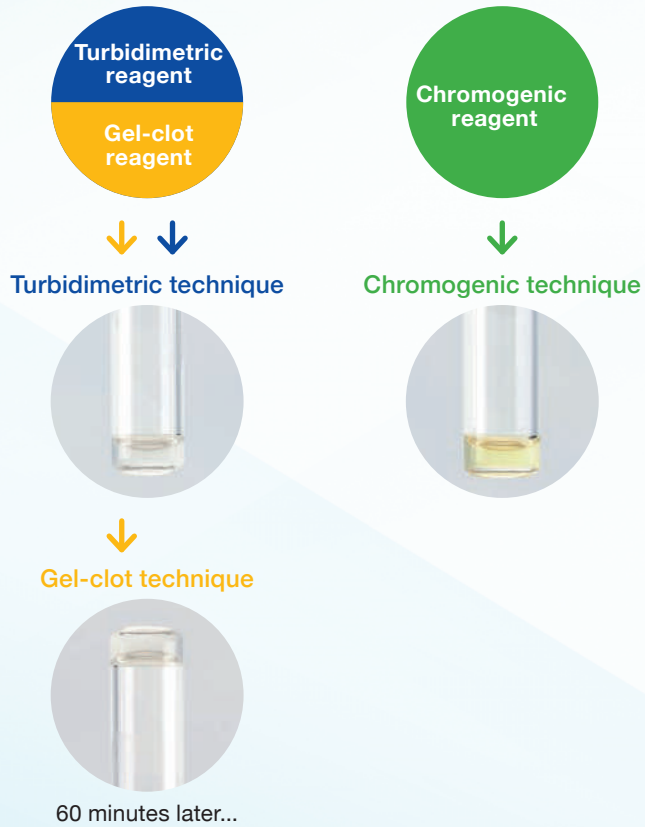
Chromogenic technique

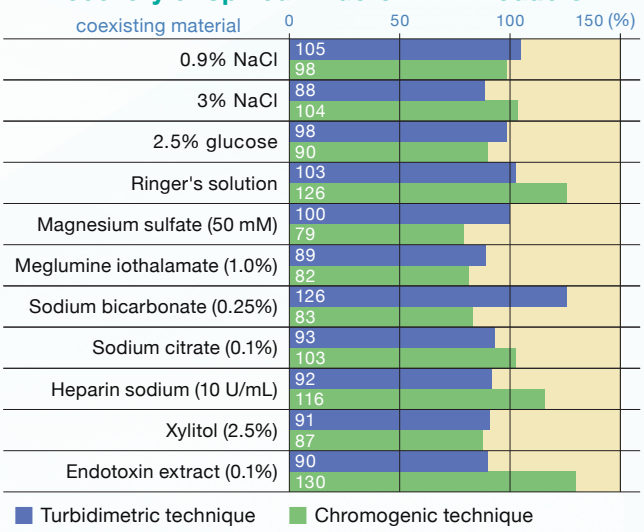
Turbidimetric technique

Offering reliable systems that satisfy global needs

- Meets Global Standards (C-UL(CSA)・CE).
- Pre-installed BET compliant software

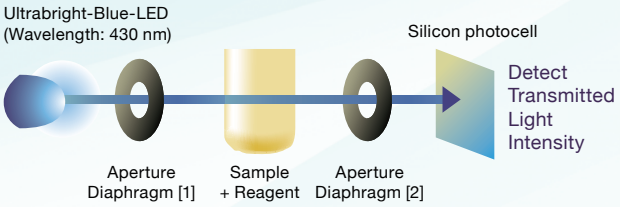
All 3 techniques for BET are available on one system





Principal of Measurement

Light from an LED goes through the reaction tube filled with reaction mixture via aperture diaphragm 1.
The light passes through the reaction mixture and then, while coming through aperture diaphragm 2, is detected by the silicon photocell.

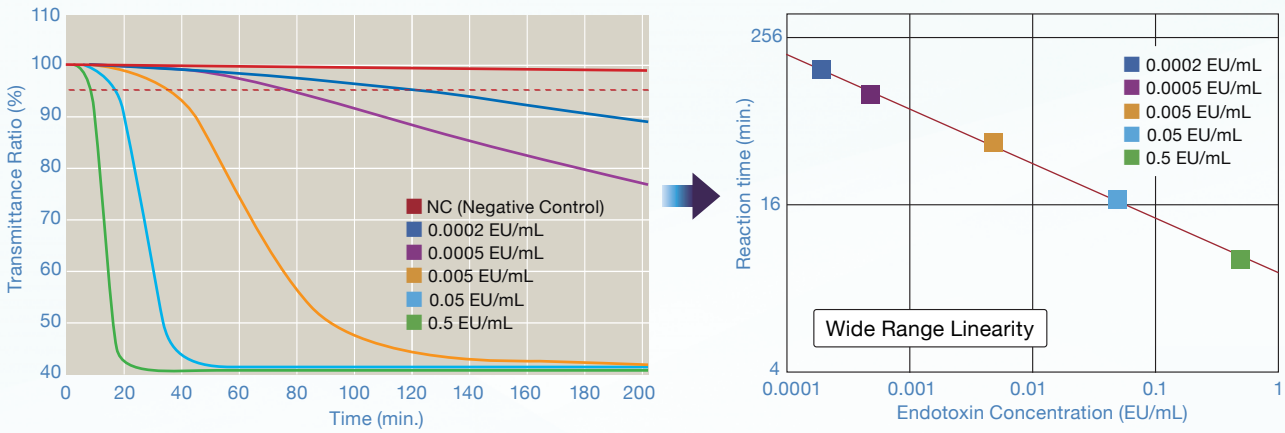


Determination of Kinetic Measurement

The Toxinometer® reports your Reaction Time as either Gelation Time (Tg for Turbidimetric technique) or Activation Time (Ta for Chromogenic technique) based on the methodology used.
The higher the concentration of endotoxin present, the shorter the reaction time.
The Toxinometer® measures the Transmittance Ratio of each well independently and simultaneously.
The Reaction Time is determined when the Transmittance Ratio falls below the Threshold value.

Time-Course-Graph & Standard Curve

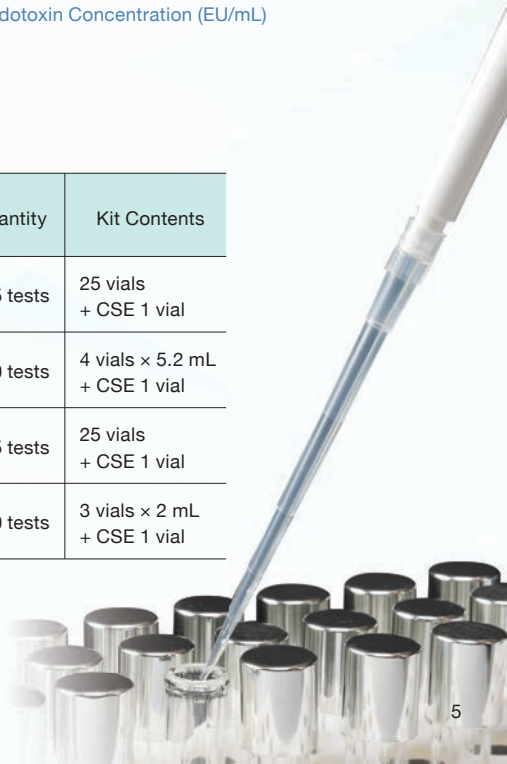
Example: Using Limulus Color KY Single Test Wako



Reagent Examples for Toxinometer

Technique	Code No.	Product Name	Quantitative Range (EU/mL)	Gel-clot Sensitivity (EU/mL)	Quantity	Kit Contents
Turbidimetric & Gel-clot	WPESK-0015	PYROSTAR™ ES-F Single Test, 0.015 EU/mL	0.001-10	0.015	25 tests	25 vials + CSE 1 vial
	WPEK4-50015	PYROSTAR™ ES-F Multi Kit, 0.015 EU/mL	0.001-10	0.015	200 tests	4 vials × 5.2 mL + CSE 1 vial
Chromogenic	291-53601	Limulus Color KY Single Test Wako	0.0002 - 5	-	25 tests	25 vials + CSE 1 vial
	291-53101	Limulus Color KY Test Wako	0.0005 - 5	-	60 tests	3 vials × 2 mL + CSE 1 vial

* CSE : Control Standard Endotoxin
* A wide variety of other reagents are available. Please contact us for the other reagents.

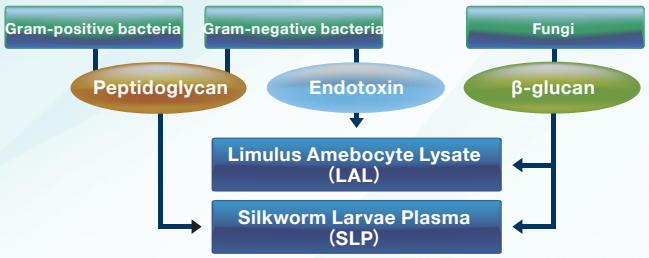


Application

Wide range of Applications

Bacteria are broadly divided into two categories: Gram-negative and Gram-positive bacteria. Every bacterium has peptidoglycan as a component of the cell wall. A Gram-negative bacterium contains endotoxin in the outer membrane of the cell wall. The cell wall of a fungus contains β-glucan.

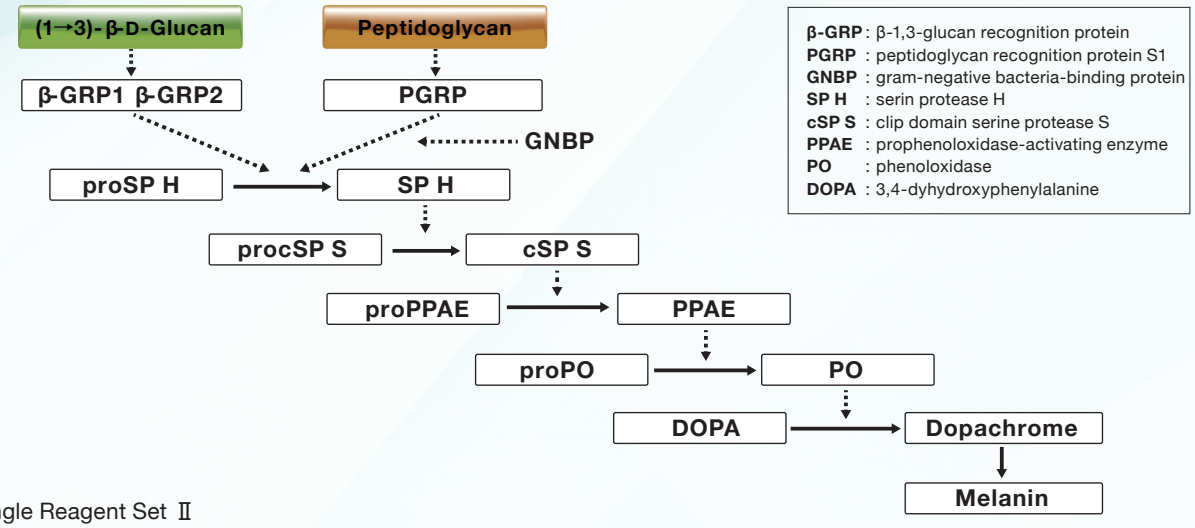
In combination with dedicated reagents, the Toxinometer® can be used for a wide range of applications such as research and monitoring of microbial contamination.



SLP Reagents

SLP reagent is a freeze-dried product prepared from silkworm larvae plasma. The reaction mechanism is shown in the following figure. When the reagent reacts with peptidoglycan and β-glucan, it eventually forms meranin, resulting in a black coloration of the sample. As when utilizing lysate reagent, a highly-sensitive measurement of this coloration is possible with the Toxinometer®.

SLP Reagent reaction mechanism



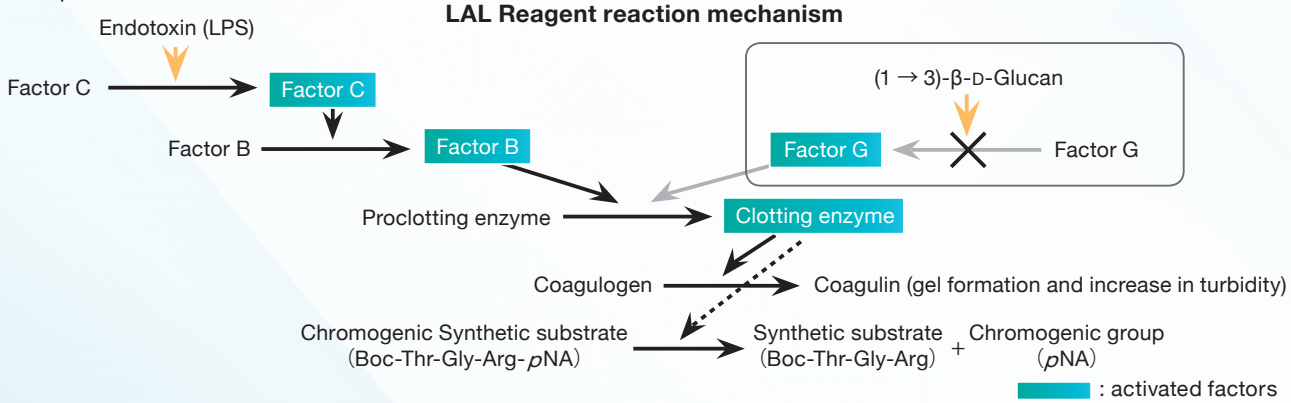
SLP-HS Single Reagent Set Ⅱ

Code No.	Product Name	Quantity tests	Kit Contents
296-81001	**SLP-HS Single Reagent Set Ⅱ**	20	• SLP-HS Regent Ⅱ (Lyophilized reagent containing Silkworm Larvae Plasma and DOPA) 0.1 mL × 20 vials Sensitivity : 10 pg/mL for PG, 1 pg/mL for β-glucan in 120 minutes. • SLP-Diluent 5 mL × 2 vials • Standard (Digested Peptidoglycan from Staphylococcus aureus) 0.5 mL × 1 vials

LAL Reagent Bacterial Endotoxin Test (BET)

A lysate reagent prepared from the amebocytes of the Atlantic horseshoe crab (Limulus polyphemus) is used to detect bacterial endotoxins. As shown in the Figure below, the cascade reactions begin due to the presence of endotoxin, whereby Factor C, a serine protease precursor, is initially activated. There follows the sequential activation of Factor B, also a serine protease precursor and a pro-clotting enzyme, which hydrolyzes coagulogen into coagulin, forming an insoluble gel. In the Bacterial Endotoxin Test, endotoxin can be quantified in three ways: measurement of gel formation, increased turbidity, or release of a yellow chromogen due to cleavage of a synthetic substrate. Endotoxin-specific LAL reagents are not activated by (1 →3)-β-D-glucan, as opposed to other BET compliance tests.

LAL Reagent reaction mechanism

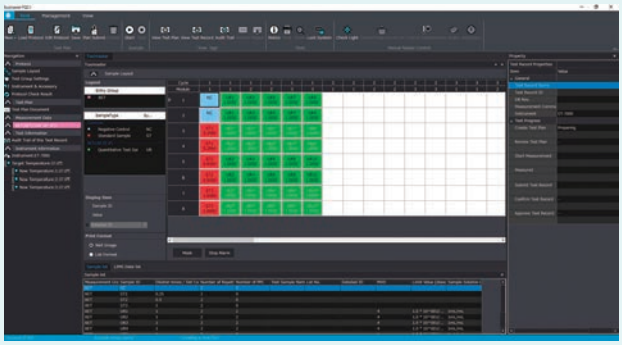


The "Welcome Screen" helps navigate you where you need to go!

Toximaster® Software

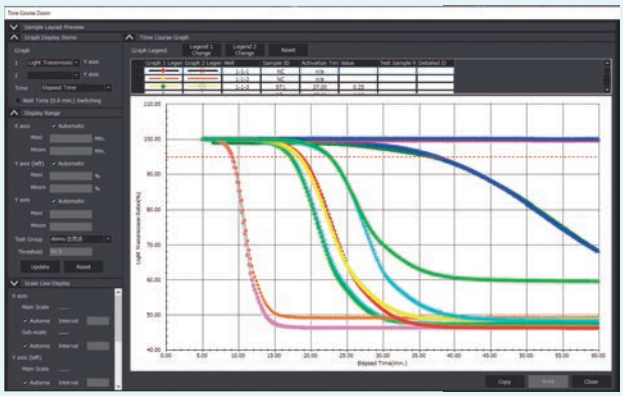
Exclusive software for efficient routine work & high quality analysis.

Protocol Settings



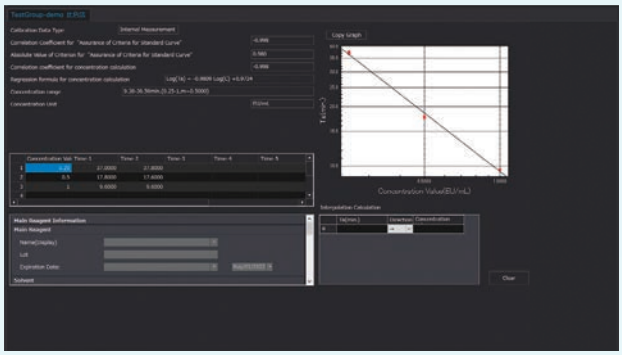
Easy to edit!
Once you create a protocol, you can start a measurement immediately.

Time Course Graph



Enables visual confirmation of measurement status.
You can predict results and prepare the next steps.

Standard Curve



Conveniently monitored!
All information can be seen on one screen.

Part 11 Functions

※Ensure data integrity

Electronic Signature

All measurement records are linked to signatures
Never allows for manipulation and falsification

Audit Trail

Major procedures are recorded automatically
History of operation can be confirmed as a log file

Operation Authorities

Each account belongs to a specific group and each group can define its own authorities for operation.

- Modify System Preferences
- Register Instrument
- Register Protocol
- Register Reagent
- Register Accessory
- Register Standard Curve Data
- Register Product
- Load Protocol into Test Record
- Star Measurement
- Load Test Record
- Review Test Plan
- Confirm Test Record
- Approve Test Record
- Submit Test Record

Etc ..

※"Toximaster®FQC1 Lite" doesn't comply with FDA 21 CFR Part11.

21 CFR Part11 System Product Composition

Item	Code No.	Product Name	Contents
Analysis System	293-36061	**Toxinometer® ET-7000**	• 1 Toxinometer® ET-7000 (1unit)
Software	290-36831	**Toximaster® FQC1 PC Set E**	• 1 Personal computer • Toximaster® FQC1 Software • System Validation Doc
Accessories (*1)	295-36761	**Toxinometer® 240V power cord**	• Toxinometer® 240V power cord (1unit)

Specification(*2)

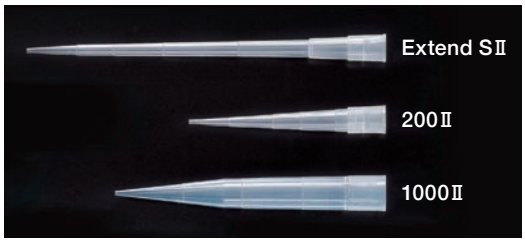
Item	Explanation
Functions	Transmitted light quantity measuring function (capable of measuring 16 samples simultaneously) Temperature control function Automatic light quantity check function
Light source	High intensity blue LED Central wavelength: 430 nm
Detector	Silicon photocell
Temperature control	Dry bath: 30±1.0 degrees C/37±1.0 degrees C (can be changed by software for ET-7000) Warmup time: 20 minutes (when preset temperature is 37 degrees C and surrounding temperature is 25 degrees C)
Display	The LED indicates measurement The LED indicates errors and information during checking
Weight	6.3 kg (±10%)
Size	W 190 mm × D 420 mm × H 130 mm (protrusions not included)

Item		Explanation
Power source		AC100-240 V (±10%)
Frequency		50/60 Hz
Power consumption		Max 120 W
Environment	During operation	When temperature is set at 37 degrees C Ambient temperature: 15 to 30 degrees C Humidity: 30 to 85%, non-condensing When temperature is controlled at 30 degrees C Ambient temperature: 15 to 25 degrees C Humidity: 30 to 85%, non-condensing
	During stored	Ambient temperature: -20 to 60 degrees C Humidity: 30 to 85%, non-condensing
	Location	Indoor
	Altitude	2000 m or lower

Related products

Endotoxin-free tip **BioCleanTip Wako®**

Code No.	Product Name		Package
294-35011	**BioCleanTip Wako® Extend S Ⅱ**	**200µL**	100 pcs
291-35021	**BioCleanTip Wako® 200 Ⅱ**	**200µL**	100 pcs
298-35031	**BioCleanTip Wako® 1000 Ⅱ**	**1000µL**	100 pcs



Endotoxin-free, Test Tube for Endotoxin Test and Aluminum Cap

Code No.	Product Name	Size	Quantity
292-32751	**Limulus Test Tube-S with Aluminum Cap**	ϕ 12 × 75 mm	10 pcs × 8
293-26551	**Limulus Test Tube-S**	ϕ 12 × 75 mm	10 pcs × 10
293-28251	**Aluminum Cap-S**	ϕ 15 × 18 mm	10 pcs × 10

(*1) It's required when using in the 200～240V area.
(*2) Up to 8 measurement modules can be connected to the unit to enable simultaneous measurement of 128 samples.

Listed products are intended for laboratory research use only, and not to be used for drug, food or human use. / Please visit FUJIFILM Wako Laboratory Chemicals site: https://labchem-wako.fujifilm.com/ / This leaflet may contain products that cannot be exported to your country due to regulations. / Bulk quote requests for some products are welcomed. Please contact us.

FUJIFILM Wako Laboratory Chemicals site
https://labchem-wako.fujifilm.com

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wkgz.info@fujifilm.com

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Endotoxin Measurement System

Toxinometer® ET-7000

- Supports "the Bacterial Endotoxin Test" in the United States / European / Japanese Pharmacopoeias
- Compliant with FDA 21 CFR, Part 11
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Since 1985

State-of-the-art analysis system configured to ensure data integrity*

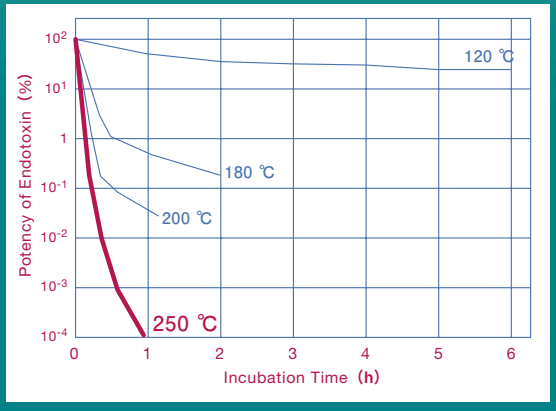
* Data integrity refers to the completeness, accuracy, and consistency of data.

Endotoxin

What is Endotoxin?

Endotoxin is a lipopolysaccharide (LPS) that comprises the cell wall of Gram-negative bacteria. Endotoxin induces various biological reactions, such as fever, when even a small amount (i.e. pg) enters the bloodstream. Endotoxins exist in environments where gram-negative bacteria reside and remain even after the bacteria die. They cannot be deactivated completely by autoclaving because of their resistance to heat. According to the Pharmacopoeia, dry heat sterilization for at least 30 minutes at a temperature equal to 250°C or higher is required for complete deactivation of endotoxins.

Heat stabilization of endotoxin (LPS: 500 ng/vial)



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High Reliability

High quality specialized glass tubes make it possible to maintain...

- **Complete Sterilization**
- **Endotoxin Free Environment**
- **No Cross Contamination**

High Sensitivity

When combined with our Chromogenic reagent can offer...

- **A maximum sensitivity of 0.0002 EU/mL.**
- **More than 3 digits dynamic range of 0.0002 - 0.5 EU/mL.**

(when using Limulus Color KY single test.)

Flexibility

ALL 3 methods available in just one system.

- **Gel-clot technique**
- **Turbidimetric technique**
- **Chromogenic technique**

Allows for continuous sample measurement
Measures Max. 128 samples simultaneously

Expandability to Support Future Growth

- **Controlled remotely from a Windows® PC**
- **Up to eight measurement modules can be additionally installed**

Wako's Toxinometer®, Highly Advanced Technology for Bacterial Endotoxin Testing

Gel-clot technique

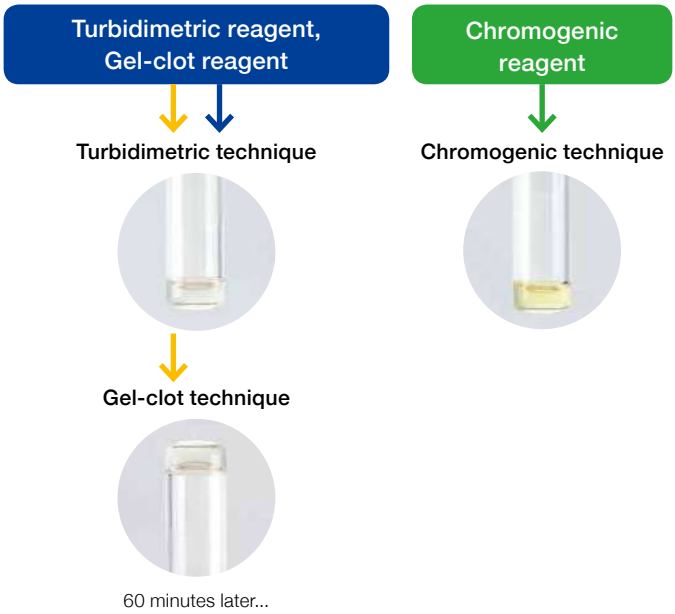
Chromogenic technique

Turbidimetric technique

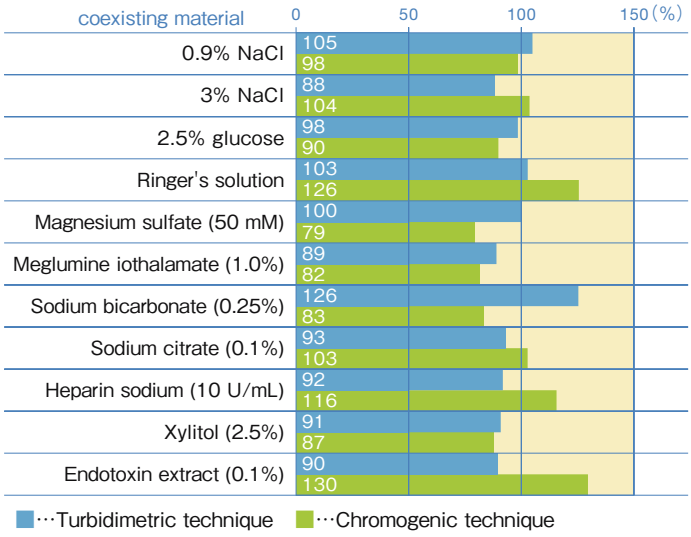
Offering reliable systems that satisfy global needs

- Meets Global Standards (C-UL (CSA) / CE).
- Pre-installed BET compliant software

All 3 techniques for BET are available on one system



Recovery of Spiked-Endotoxin in Products



Single Test Reagent for More Specific Measurements

The easiest and most beneficial way to use the Toxinometer® is by utilizing our Single Test Reagent vials, which allow you to just spike your sample and go!

Principal of Measurement

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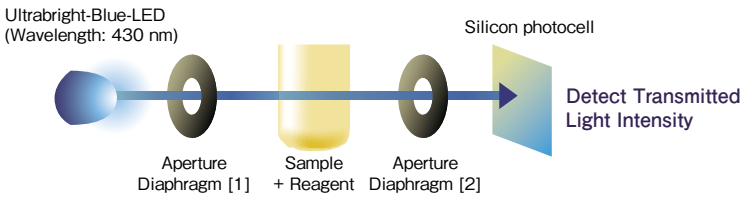
The light passes through the reaction mixture and then, while coming through aperture diaphragm 2, is detected by the silicon photocell.**



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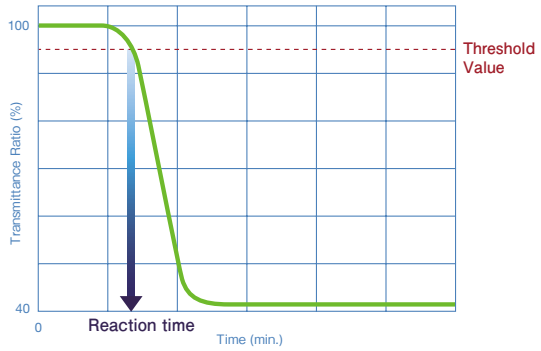
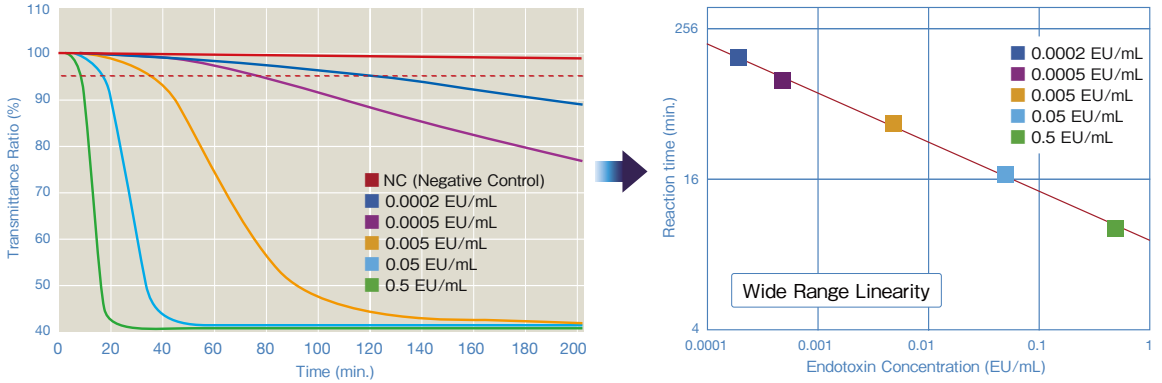


Time-Course-Graph & Standard Curve

Example: Using Limulus Color KY Single Test Wako



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Wide range of Applications

Bacteria are broadly divided into two categories: Gram-negative and Gram-positive bacteria. Every bacterium has peptidoglycan as a component of the cell wall. A Gram-negative bacterium contains endotoxin in the outer membrane of the cell wall. The cell wall of a fungus contains β-glucan.

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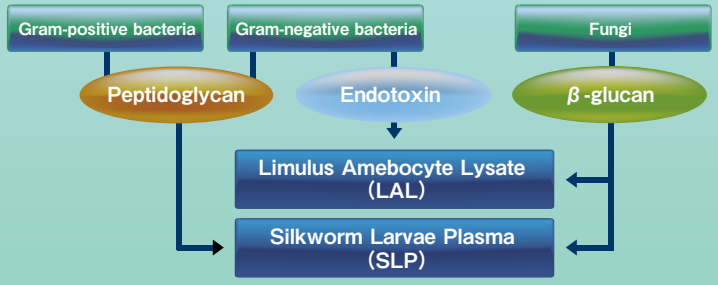

SLP Reagents

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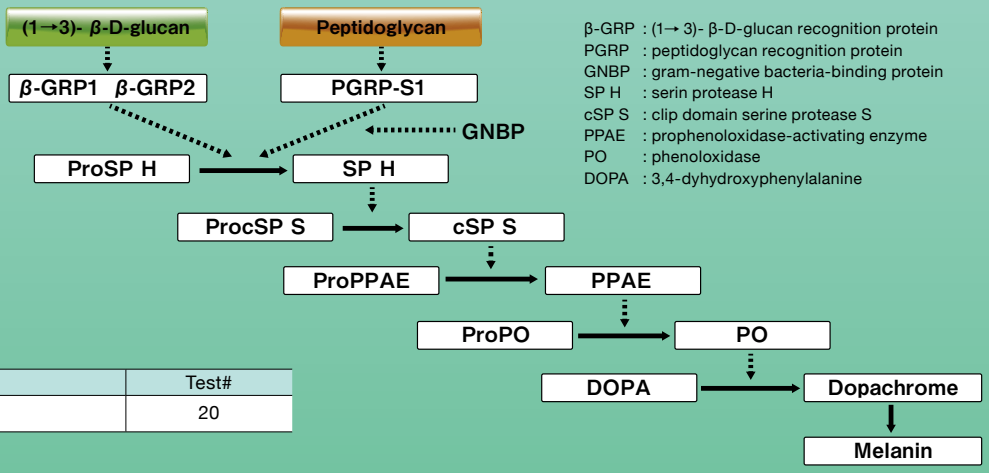
SLP-HS Single Reagent Set II

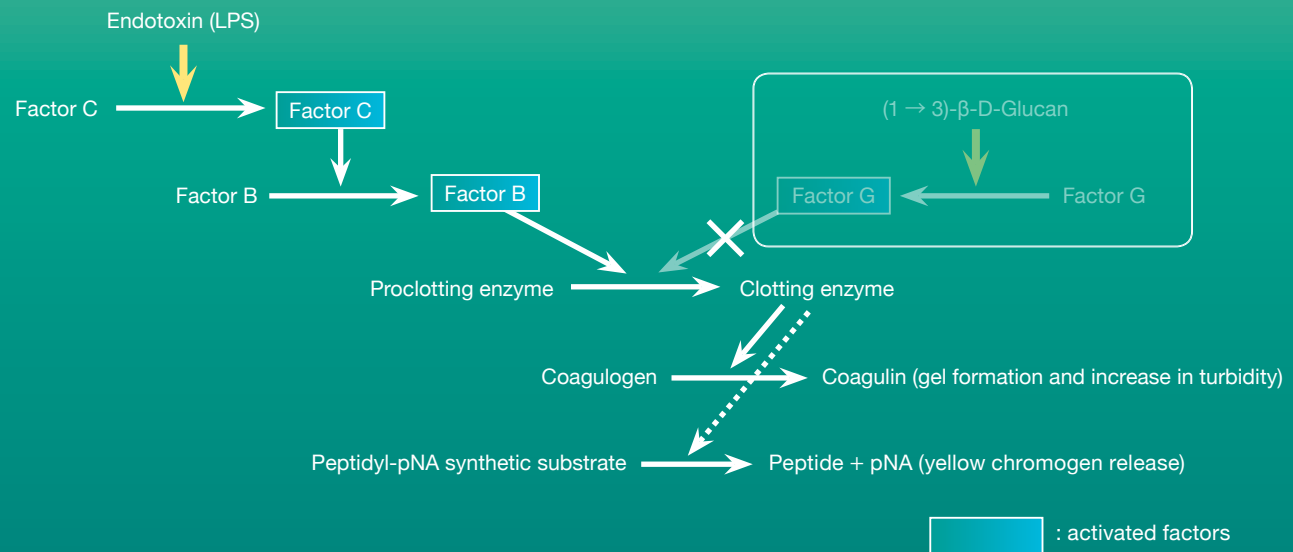
Code No.	Product name	Test#
296-81001	**SLP-HS Single Reagent Set II**	20



SLP Reagent reaction mechanism

LAL Reagent Bacterial Endotoxin Test (BET)

A lysate reagent prepared from the amebocytes of the Atlantic horseshoe crab (Limulus polyphemus) is used to detect bacterial endotoxins. As shown in the Figure below, the cascade reactions begin due to the presence of endotoxin, whereby Factor C, a serine protease precursor, is initially activated. There follows the sequential activation of Factor B, also a serine protease precursor and a pro-clotting enzyme, which hydrolyzes coagulogen into coagulin, forming an insoluble gel. In the Bacterial Endotoxin Test, endotoxin can be quantified in three ways: measurement of gel formation, increased turbidity, or release of a yellow chromogen due to cleavage of a synthetic substrate. Endotoxin-specific LAL reagents are not activated by (1 → 3)-β-D-glucan, as opposed to other BET compliance tests.



LAL Reagent reaction mechanism

The "Welcome Screen" helps navigate you where you need to go!

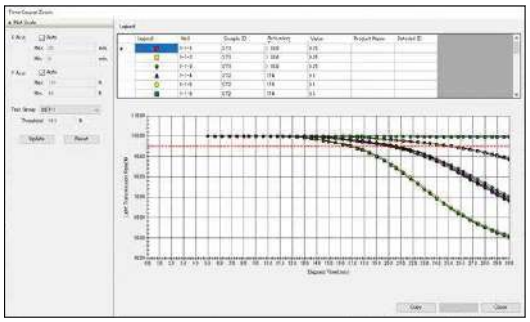
Toximaster® Software

Exclusive software for efficient routine work & high quality analysis.

Protocol Settings

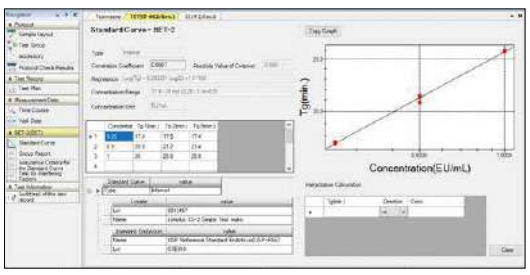
Easy to edit! Once you create a protocol, you can start a measurement immediately.

Time Course Graph



Enables visual confirmation of measurement status.
You can predict results and prepare the next steps.

Standard Curve



Conveniently monitored!
All information can be seen on one screen.

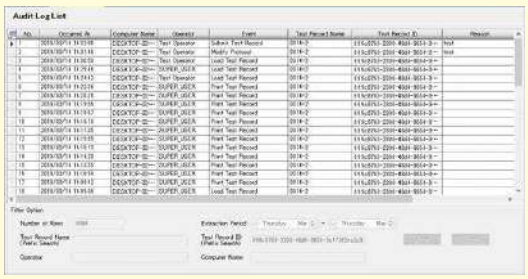
Part 11 Functions

※ Ensure data integrity

Electronic Signature

All measurement records are linked to signatures
Never allows for manipulation and falsification

Audit Trail



Major procedures are recorded automatically
History of operation can be confirmed as a log file

Operation Authorities

Each account belongs to a specific group and each group can define its own authorities for operation.

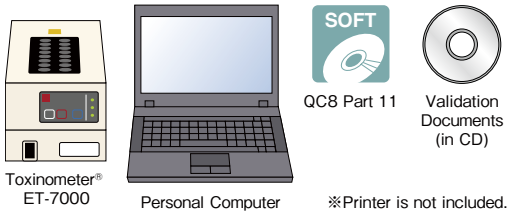
- Modify System Preferences
- Register Instrument
- Register Protocol
- Register Reagent
- Register Accessory
- Register Standard Curve Data
- Register Product
- Load Protocol into Test Record
- Star Measurement
- Load Test Record
- Review Test Plan
- Confirm Test Record
- Approve Test Record
- Submit Test Record

Etc ..

Basic configuration

Toxinometer® ET-7000/E Part 11 Set [Code No. 299-35821]
Toxinometer® ET-7000/U Part 11 Set [Code No. 294-35871]

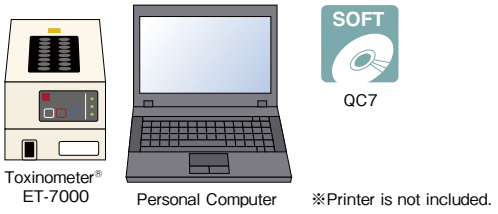
[Contents]
- Toxinometer® ET-7000 (1 unit)
- Toximaster® QC8 Part 11 (5 licenses)
- Personal Computer (1 unit)
- Toxinometer® ET-7000 Part 11 System Validation Documents



The system complies with FDA 21 CFR, Part 11.

Toxinometer® ET-7000/E Non Part 11 Set [Code No. 296-35831]
Toxinometer® ET-7000/U Non Part 11 Set [Code No. 291-35881]

[Contents]
- Toxinometer® ET-7000 (1 unit)
- Toximaster® QC7
- Personal Computer (1 unit)



The system dosen't comply with FDA 21 CFR, Part 11.

Options

Toxinometer® ET-7000/E [Code No. 292-35811]
Toxinometer® ET-7000/U [Code No. 297-35861]

※ Additional module for Part 11 Set or Non-Part 11 Set.

Specification (*1)

Item	Explanation
Functions	Transmitted light quantity measuring function (capable of measuring 16 samples simultaneously) Temperature control function Automatic light quantity check function
Light source	High intensity blue LED Central wavelength: 430 nm
Detector	Silicon photocell
Temperature control	Dry bath: 30±1.0 degrees C/37±1.0 degrees C (can be changed by software for ET-7000) Warmup time: 20 minutes (when preset temperature is 37 degrees C and surrounding temperature is 25 degrees C)
Display	The LED indicates measurement The LED indicates errors and information during checking
Weight	6.3 kg (±10%)
Size	W 190 mm × D 420 mm × H 130 mm (protrusions not included)

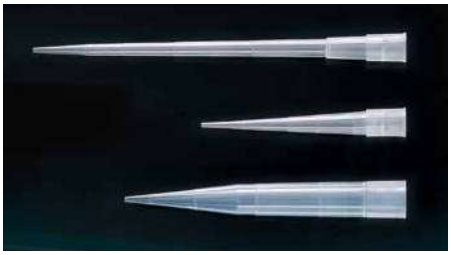
Item		Explanation
Power source		220-240 (±10%) VAC (Model: ET-7000/E) 100-120 (±10%) VAC (Model: ET-7000/U)
Frequency		50/60 Hz
Power consumption		Max 120 W
Environment	During operation	When temperature is set at 37 degrees C Ambient temperature: 15 to 30 degrees C Humidity: 30 to 85%, non-condensing When temperature is controlled at 30 degrees C Ambient temperature: 15 to 25 degrees C Humidity: 30 to 85%, non-condensing
	During stored	Ambient temperature: -20 to 60 degrees C Humidity: 30 to 85%, non-condensing
	Location	Indoor
	Altitude	2000 m or lower

(*1) These specifications are common to the Toxinometer® ET-7000 Non Part 11 Set and Part 11 Set. Up to 8 measurement modules can be connected to the unit to enable simultaneous measurement of 128 samples.

Related products

Endotoxin-free tip **BioCleanTip Wako®**

Code No.	Product Name		Package
291-35021	**BioCleanTip Wako® 200 II**	**200 µL**	100 pcs
298-35031	**BioCleanTip Wako® 1000 II**	**1000 µL**	100 pcs
294-35011	**BioCleanTip Wako® Extend S II**	**200 µL**	100 pcs



Endotoxin-free, Test Tube for Endotoxin Test and Aluminum Cap

Code No.	Product Name	Size	Quantity
292-32751	**Limulus Test Tube-S with Aluminum Cap**	ϕ 12 × 75 mm	10 pcs × 8
293-26551	**Limulus Test Tube-S**	ϕ 12 × 75 mm	10 pcs × 10
293-28251	**Aluminum Cap-S**	ϕ 15 × 18 mm	10 pcs × 10

FUJIFILM Wako Pure Chemical Corporation
http://ffwk.fujifilm.co.jp/en/index.html
1-2, Doshomachi 3-Chome, Chuo-ku, Osaka 540-8605, Japan
Tel: +81 6 6203 3741 Fax: +81 6 6203 1999
ffwk-cservice@fujifilm.com Online Catalog: www.e-reagent.com

FUJIFILM Wako Chemicals U.S.A. Corporation
www.wakousa.com
1600 Bellwood Road, Richmond, VA 23237, U.S.A.
Toll-Free (U.S. only): +1 877 714 1920
Tel: +1 804 714 1920 Fax: +1 804 271 7791
wkuslabchem@fujifilm.com

FUJIFILM Wako Chemicals Europe GmbH
www.wako-chemicals.de
Fuggerstr 12, D-41468 Neuss, Germany
Tel: +49 2131 311 0 Fax: +49 2131 311 100
labchem@wako-chemicals.de

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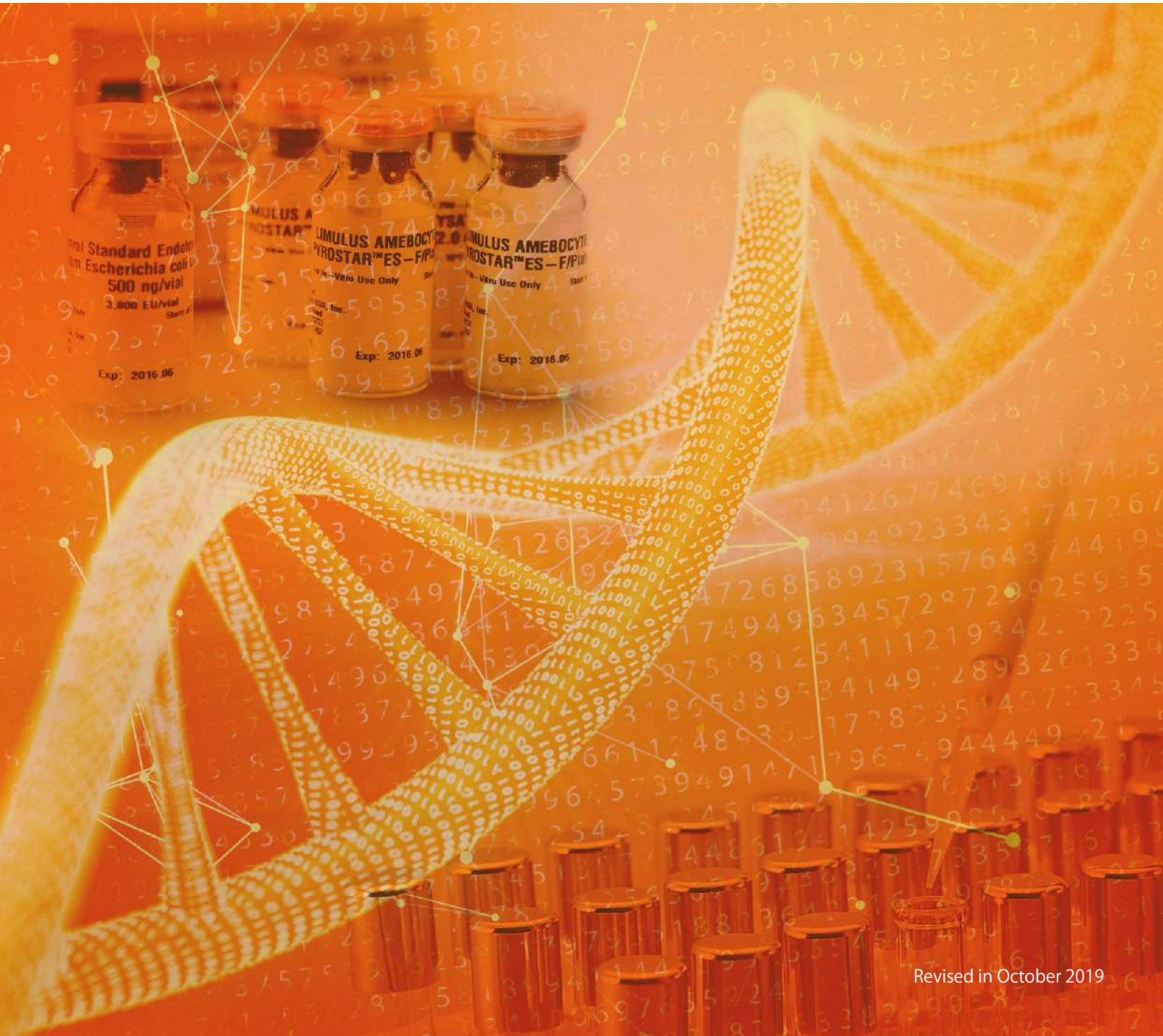
FUJIFILM
Value from Innovation

Wako

Reagents and Related Products for Detection of Microbial Cell Components

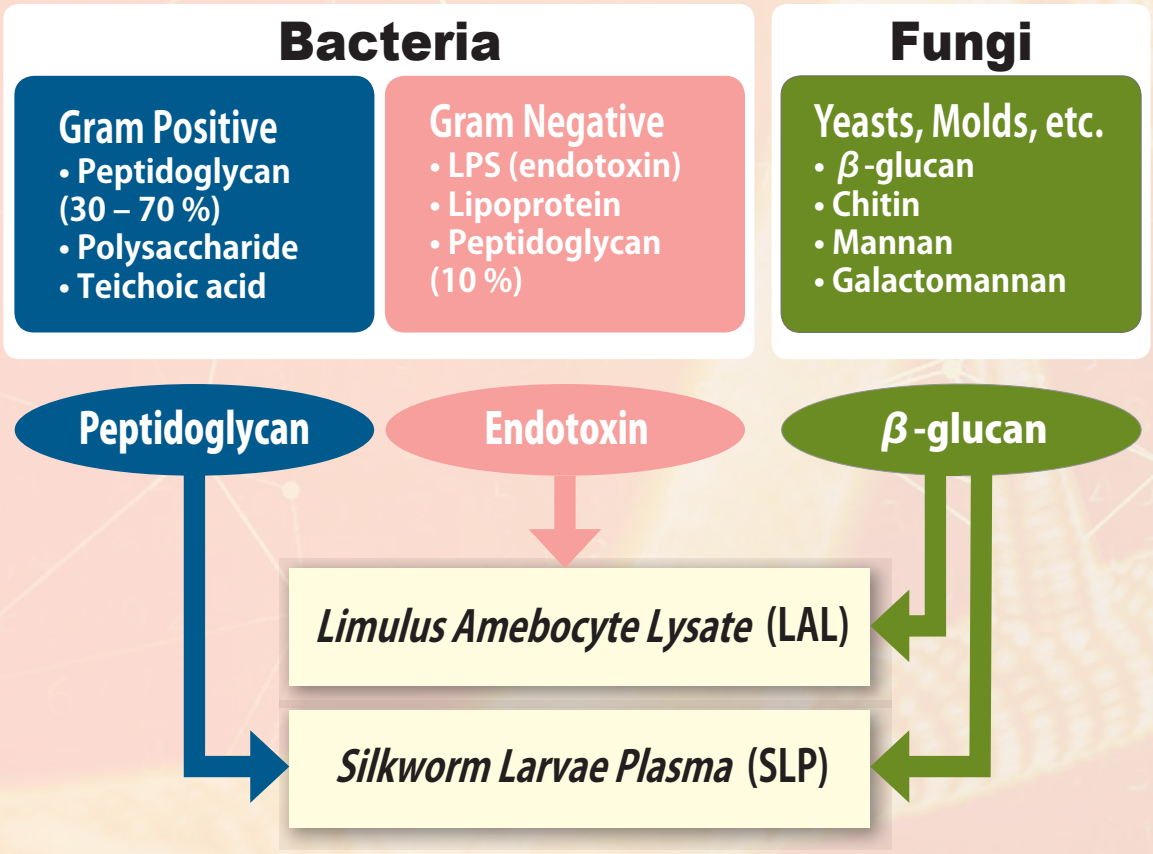
Endotoxin **Peptidoglycan** **(1 → 3)-β-D-glucan**



Revised in October 2019

Contents

Microbial Cell Wall Components



LAL Gel-clot Reagents

Bland Name	Type	Product Name	Gel-clot Sensitivity	Quantity	Page
PYROSTAR™	SINGLE TEST	PYROSTAR™ ES-F SINGLE TEST	0.015, 0.03 EU/mL	• 25 tests + 1 vial CSE (500ng/vial)	6～8p
	MULTI TEST	PYROSTAR™ ES-F MULTI KIT	0.015, 0.03, 0.06, 0.125, 0.25 EU/mL	• 80 tests + 1 vial CSE (500ng/vial) • 200 tests + 1 vial CSE (500ng/vial)	
		PYROSTAR™ ES-F MULTI KIT, BULK	0.015, 0.03, 0.06, 0.125, 0.25 EU/mL	• 2,000 tests • 5,000 tests	

LAL Turbidimetric Reagents

Bland Name	Type	Product Name	Quantitative Range	Quantity	Page
PYROSTAR™	SINGLE TEST For Toxinometer	PYROSTAR™ ES-F SINGLE TEST	0.001-10 EU/mL	• 25 tests + 1 vial CSE (500ng/vial)	6～8p
	MULTI TEST For Toxinometer	PYROSTAR™ ES-F MULTI KIT	0.001-10 EU/mL	• 80 tests+ 1 vial CSE (500ng/vial) • 200 tests+ 1 vial CSE (500ng/vial)	
		PYROSTAR™ ES-F MULTI KIT, BULK	0.001-10 EU/mL	• 2,000 tests • 5,000 tests	
	MULTI TEST For Microplate Reader	PYROSTAR™ ES-F/Plate with CSE	0.01-10 EU/mL	• 160 tests + 1 vial CSE (500ng/vial)	9p
		PYROSTAR™ ES-F/Plate without CSE	0.01-10 EU/mL	• 200 tests	

LAL Chromogenic Reagents

Bland Name	Type	Product Name	Quantitative Range	Quantity	Page
Color KY	SINGLE TEST For Toxinometer	Limulus Color KY Single Test wako	0.0002-5 EU/mL	• 25 tests + 1 vial CSE (500ng/vial)	10p
	MULTI TEST For Microplate Reader and Toxinometer	Limulus Color KY Test Wako	0.0005-5 EU/mL	• 60 tests※ + 1 vial CSE (500ng/vial)	

※120 tests with microplate reader

SLP Reagent

Bland Name	Type	Product Name	Sensitivity	Quantity	Page
SLP	SINGLE TEST For Toxinometer	SLP-HS Single Reagents Set Ⅱ	10 pg/mL (PG), 1 pg/mL (β-glucan)	• 20 tests + 2 vial (5.0mL) Diluent + 1 vial (0.5mL) Standard	11～12p

Basics of Bacterial Endotoxins Test

1. What is an endotoxin?

An endotoxin is a lipopolysaccharide (LPS) found in the cell wall of gram-negative bacteria. It is a typical pyrogen, which induces various biological reactions when even a small amount of pg (10^{-12} g) or ng (10^{-9} g) enters the bloodstream. Due to its heat resistance and stability, complete inactivation of endotoxin is not possible with autoclaving and dry heat sterilization for at least 30 minutes is required, at a temperature of 250 °C or more. It exists in the environment (e.g. water, air) inhabited by gram-negative bacteria, and bacterial endotoxins (LPS) remain even after the bacteria die.

Figure 1 shows the LPS structure schematic, which illustrates lipid A as the component responsible for the bioactivity. The molecular weight of this portion is approx. 2000. The entire molecular weight, including the sugar chain moiety, is usually approx. 5000 to 8000. However, since an LPS consists of a hydrophilic region (sugar chain) and hydrophobic region (lipid A), it associates in an aqueous solution to form a micellar structure with apparent molecular weight of hundreds of thousands to several millions. A change in the micellar structure reportedly influences the strength of bioactivity.

Figure 2 illustrates the structures of *Salmonella*-type and *E. coli*-type lipid A, which indicate that the basic structure of the lipid A is maintained fairly well, regardless of the strain variation.

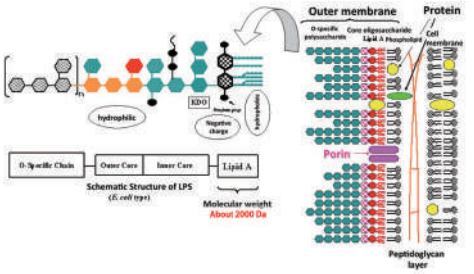


Figure 1: Lipopolysaccharide Structure Schematic Diagram

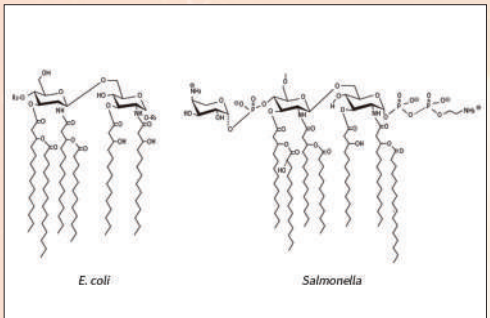


Figure 2. Lipid A Structure (*E.coli* and *Salmonella* types)

2. Various Endotoxin Test Methods using LAL Reagents

A lysate reagent prepared from the amebocytes of horseshoe crab (*Limulus polyphemus*) is used to detect bacterial endotoxins. As shown in Figure 3, the cascade reactions start by the presence of an endotoxin, whereby Factor C, a serine protease precursor, is initially activated. There follows the subsequential activation of Factor B, also a serine protease precursor and a proclotting enzyme, which hydrolyzes coagulogen into coagulin, forming an insoluble gel. In LAL tests, endotoxin can be quantified in three ways: measurement of gel formation, increased turbidity, or a yellow chromogen released due to the synthetic substrate cleavage.

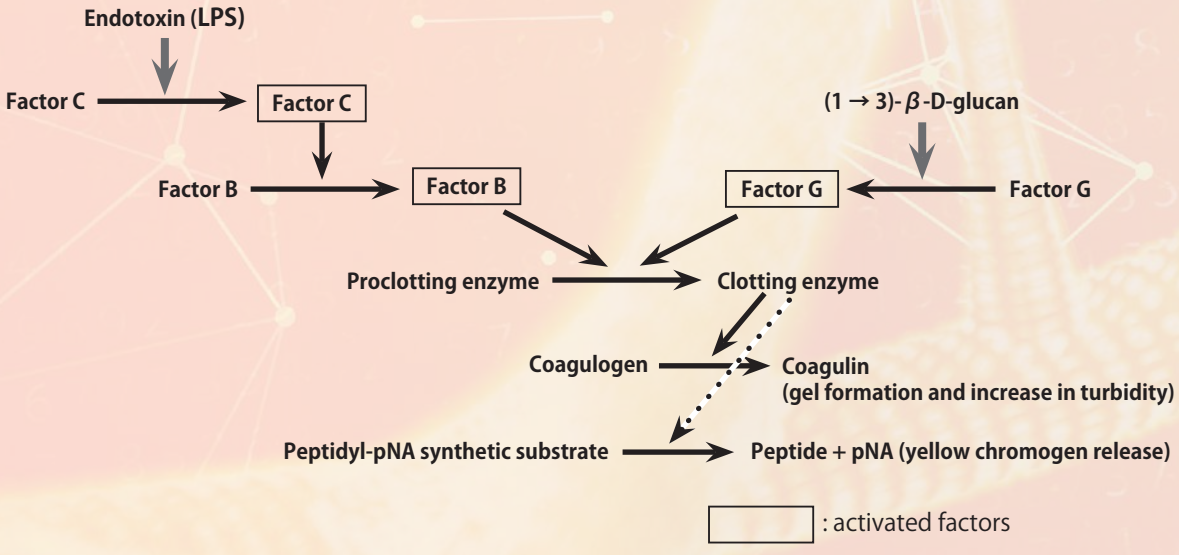


Figure 3: LAL Reagent Reaction Mechanism

Ordinary LAL reagents react not only with the endotoxin but also (1→3)-β-D-glucan (a fungal cell wall component), since the Factor G pathway can be activated in the reagents. To eliminate this (1→3)-β-D-glucan activation, various endotoxin-specific reagents are being developed in industry by removing Factor G or inhibiting its activation.
Various LAL reagents are commercially available, as well as measuring systems based on the Figure 3 reaction mechanism. It is essential to select the most appropriate product depending on the required accuracy, test frequencies, number of samples and other relevant factors.
Pharmacopoeias in the U.S., Europe and Japan refer to three means of endotoxin detection, namely the gel-clot technique, chromogenic and turbidimetric techniques, which are detailed in the following sections while introducing the characteristics and application examples of our relevant LAL reagents.

(1) Gel-clot Technique

Mix a sample with LAL reagent in a test tube and incubate it using a block heater at 37 ± 1 °C, 60 ± 2 minutes, without subjecting to vibration. Upon completion of heating, immediately but slowly tilt the tube through 180°. If a gel has formed and maintains its integrity without deformation or collapse, the result can be determined positive, while it is negative if no gel has formed. During the test, a series of samples is diluted multiple times (usually 2-fold) to check if the result is positive in each sample. The maximum valid dilution or the minimum concentration determined positive is referred to as the endpoint.

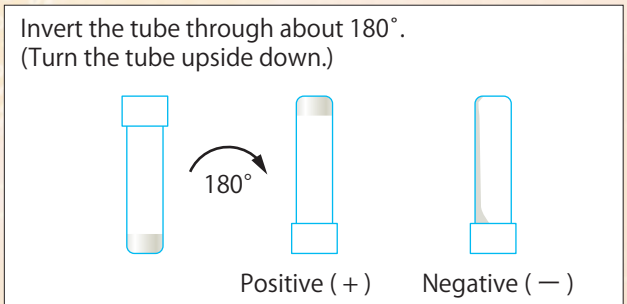


Figure 4. Gel-clot Technigue

Corresponding Reagent:

The reagent is available in a single-type kit with reaction vials containing pre-dispensed reagent for a single measurement, and a multi-type kit for dispensing the required amount of the dissolved reagent into reaction vials. The single-type kit is ideal for an assay with a few samples, and the multi-type kit for a larger number of samples.
A multi-type kit is used by dispensing 0.1 mL of dissolved LAL reagent into reaction tubes, which is then mixed after having 0.1 mL of the sample added. A single-type kit can be used by adding 0.2 mL of the sample to the reaction vial with pre-dispensed, lyophilized LAL reagent.

ES-F Series

Endotoxin-specific LAL reagents (not activated by (1→3)-β-D-glucan), compatible with the BET (USP) compliance tests U.S Food and Drug Administration (FDA) approved. They have various gelation sensitivities, and are available in both single- and multi- type kits.

*BET: Bacterial Endotoxins Test

(2) Chromogenic Technique

This technique uses synthetic chromogenic substrate cleavage to detect the activation of LAL reagent induced by endotoxin. Since the yellow color of p-nitroaniline is measured by absorbance at approx. 405 nm, the technique is not applicable if the sample has considerable absorbance at approx. 405 nm.

Corresponding Reagent:

Color KY Series

Endotoxin-specific chromogenic technique LAL reagents, compatible with the BET* (JP) compliance testing. A single-type kit combined with a Toxinometer® and a multi-type kit for use in combination with a microplate reader and Toxinometer® are available for kinetic chromogenic testing. These series also feature measurements at the lowest concentration (highest sensitivity) among our reagent products: detection limit of 0.0002 EU/mL (single-type) and 0.0005 EU/mL (multi-type).

(3)Turbidimetric Technique

This technique uses the change in gel turbidity to detect the activation of LAL reagent induced by endotoxin. It cannot be applied to samples with considerable turbidity.

Corresponding Reagent:

ES-F Series

Kinetic turbidimetric measurement is available by combining the ES-F series and Toxinometer® or a microplate reader.These reagent kits can provide gel-clot results while obtaining kinetic turbidimetric data, with the measurement time specified as 60 minutes.

3. Tools Used for Testing

All tools used for endotoxin detection must be free from endotoxin and β-glucan. Dry-heating at 250 °C for more than 30 minutes is required to deactivate endotoxin. The use of glassware treated by dry heat sterilization is recommended. Avoid metal tools, since even a small amount of eluted metal ions (e.g. Fe, Al, Ga, Cr) may affect testing. When using disposable plastic tools (not guaranteed by its manufacturer for use for testing purposes), check if they satisfy the requirements: 1) Not contaminated by endotoxin; 2) No adsorption of endotoxin; and 3) No eluted substance; in comparison with glassware.

4. Reference Standard Endotoxin

Use the appropriate type of standard endotoxin based on the testing purpose.

- Tests in compliance with BET (USP/EP/JP) such as final product inspection of pharmaceuticals and medical devices
  → Reference Standard Endotoxin of USP, EP or JP must be used.
- Tests for inspecting materials, processes and other related subjects
  → Control Standard Endotoxin (CSE) can be used.

*BET: Bacterial Endotoxins Test

5. Interference of Sample

Precautions are required against the potential impact (reaction interferences) of samples on endotoxin tests. These interferences are categorized into the following two types:

❶ Influence on LAL Reagent

- Protein denaturants (e.g. acids, alkalis, urea, surfactants, organic solvents)
- Protease and protease inhibitors
- Chelating agents (whereby Ca and Mg required for reactions are scavenged)
- For the chromogenic technique: coloring matter (substance with considerable absorbance at approx. 405 nm)
- For the turbidimetric technique: turbidity

❷ Influence on Endotoxin

- Metal ions (e.g. Fe, Al, Ga and Cr ions. Influential even at a micromole level)
- Surfactants

The effect of samples can be judged by a test referred to as the test for interference factors by Pharmacopoeias: namely, it is conducted by measuring a sample which has been spiked with a known amount of endotoxin and obtaining the recovery of the spiked endotoxin. If the recovery is within the 50 to 200 % range, then the sample is determined as not influential, in other words, the measured endotoxin concentration is correct. If any sample influence is found, it can be reduced by diluting the sample solution for measurement. However, dilution of the sample solution raises the endotoxin concentration value obtained through the conversion to the concentration of the original solution (pre-dilution solution). The possible dilution multiple (maximum valid dilution) is determined based on the desired endotoxin concentration to be detected and the detection sensitivity of the LAL reagent to be used (refer to the Bacterial Endotoxins Test by the Pharmacopoeia for details of the reaction interference factors and maximum valid dilution).

6. Principle of Limulus ES (Endotoxin Specific Reagent)

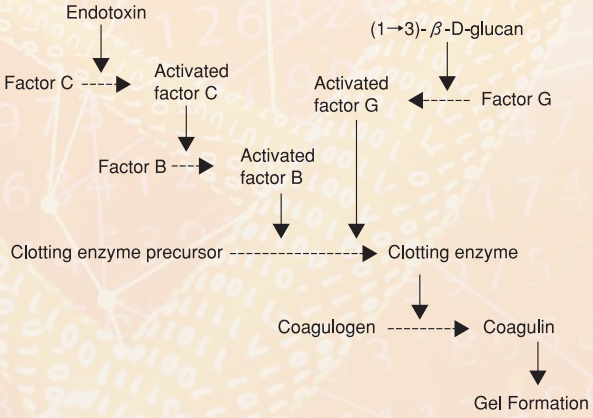
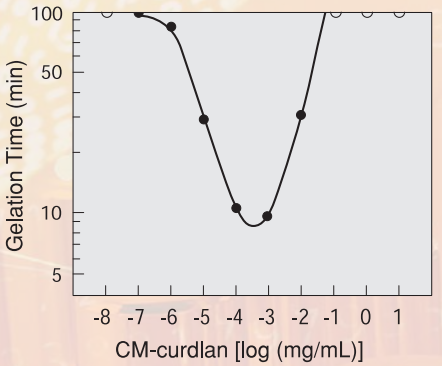


Figure 5: Limulus Test Reaction Cascade

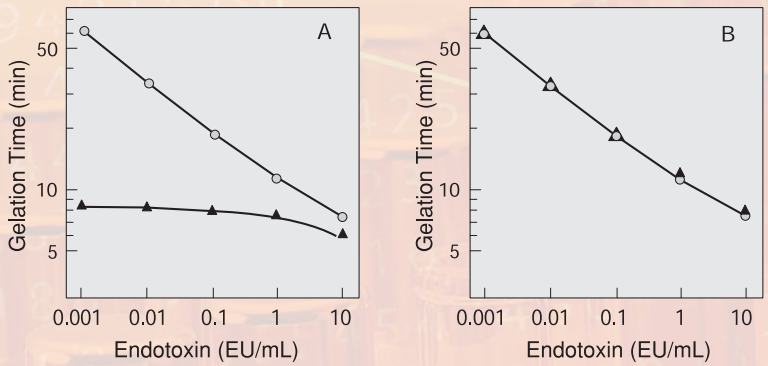
The reaction cascade mechanism of the LAL reagent and endotoxin is shown in Figure 5. If (1 → 3)-β-D-glucan* exists in the reaction system, it activates Factor G, causing a false positive reaction in which gelation occurs. This happens regardless of the presence of endotoxin, meaning endotoxin specific detection is not available. Wako's Limulus ES has been developed to inhibit the interference of (1 → 3)-β-D-glucan, by making an excessive amount of (1 → 3)-β-D-glucan (carboxymethylated curdlan) coexistent in the reaction system. Thus, the activation of LAL reagent by β-glucan is inhibited, enabling endotoxin specific detection.
The reason why an excessive amount of β-glucan can inhibit its own reaction is shown in Figure 6: the reaction range between the β-glucan and LAL reagent is too narrow for reaction. On the other hand, the reaction of endotoxin and Limulus occurs over a wide range of concentration and is not subject to any interference from the large amount of coexisting β-glucan. Wako's Limulus ES use this principle (see Figure 7).

*(1 → 3)-β-D-glucan derived from mold (fungus) or cellulosic membrane filter.



Measured by using a Toxinometer® (with the measurement time set to 99 minutes) and Limulus HS
○ : Gelation was not determined within 99 minutes
● : Gelation was determined

Figure 6: CM-curdlan and LAL Reaction



A: Limulus HS
B: Limulus ES
○ : Endotoxin dilution series
▲ : Endotoxin dilution series containing 1 μg/mL CM-curdlan

Figure 7: Effect of CM-curdlan on Endotoxin Measurement Using Limulus HS and Limulus ES

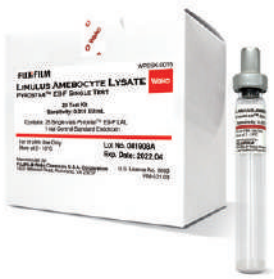
PYROSTAR™ ES-F Series

Turbidimetric Technique | Endotoxin Specific | FDA approved

Intended Use: Limulus amebocyte lysate (LAL) is intended for the detection of gram-negative bacterial endotoxins. PYROSTAR™ ES-F is intended for the qualitative detection of endotoxins by gel-clot or quantitative detection by kinetic turbidimetric methods.

- Endotoxin-specific lysate, avoids false positive results from glucans
- Available in multi-tests vials or single-test vials
- Can be used as either a gel-clot or Kinetic-Turbidimetric Assay (KTA) reagent
- (KTA) assays can be performed in tube reader or microplate reader
- Gel-Clot lysate sensitivities range from 0.015 to 0.25 EU/mL
- Available with matched control standard endotoxin (CSE)
- PYROSTAR™ ES-F reagents are available with a KTA quantitative range of either 0.001 EU/mL to 10 EU/mL. The KTA quantitative range is related to the Gel-Clot sensitivity.
- 100uL sample size when used with tube reader; 50uL sample size when used with microplate reader

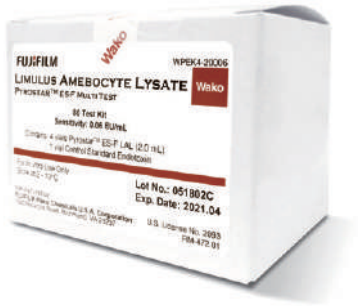
PYROSTAR™ ES-F Single Test Vial



Gel-clot Sensitivity (EU/mL)	KTA Quantitative Range (EU/mL)
0.015	0.001 to 10
0.03	0.01 to 10

	Catalog Number	Product Name	Quantity
with CSE	295-72301	Limulus Amebocyte Lysate PYROSTAR™ ES-F SINGLE TEST 0.015	25 tests
with CSE	292-81601	Limulus Amebocyte Lysate PYROSTAR™ ES-F SINGLE TEST 0.03	25 tests

PYROSTAR™ ES-F (2 ML) Multi Test Vials with CSE



Gel-clot Sensitivity (EU/mL)	KTA Quantitative Range (EU/mL)
0.015	0.001 to 10
0.03 to 0.25	0.01 to 10

	Catalog Number	Code	Product Name	Quantity
with CSE	548-10141	WPEK4-20015	PYROSTAR™ ES-F MULTI KIT (2ML), 0.015 EU/ML	2mL x 4vials
with CSE	541-10131	WPEK4-20003	PYROSTAR™ ES-F MULTI KIT (2ML), 0.03 EU/ML	2mL x 4vials
with CSE	545-10151	WPEK4-20006	PYROSTAR™ ES-F MULTI KIT (2ML), 0.06 EU/ML	2mL x 4vials
with CSE	542-10161	WPEK4-20125	PYROSTAR™ ES-F MULTI KIT (2ML), 0.125 EU/ML	2mL x 4vials
with CSE	549-10171	WPEK4-20025	PYROSTAR™ ES-F MULTI KIT (2ML), 0.25 EU/ML	2mL x 4vials

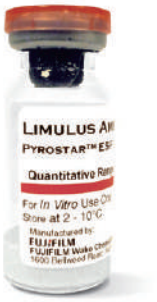
CSE：1 vial(500ng/vial)

PYROSTAR™ ES-F (2 ML) Multi Test Vials without CSE

Gel-clot Sensitivity (EU/mL)	KTA Quantitative Range (EU/mL)
0.015	0.001 to 10
0.03 to 0.25	0.01 to 10

Catalog Number	Code	Product Name	Quantity
546-10201	WPEM-20015	PYROSTAR™ ES-F MULTI KIT (2ML), BULK, 0.015 EU/ML	2mL x 100vials
546-10181	WPEM-20003	PYROSTAR™ ES-F MULTI KIT (2ML), BULK, 0.03 EU/ML	2mL x 100vials
543-10191	WPEM-20006	PYROSTAR™ ES-F MULTI KIT (2ML), BULK, 0.06 EU/ML	2mL x 100vials
540-10221	WPEM-20125	PYROSTAR™ ES-F MULTI KIT (2ML), BULK, 0.125 EU/ML	2mL x 100vials
543-10211	WPEM-20025	PYROSTAR™ ES-F MULTI KIT (2ML), BULK, 0.25 EU/ML	2mL x 100vials

PYROSTAR™ ES-F (5.2 ML) with CSE



Gel-clot Sensitivity (EU/mL)	KTA Quantitative Range (EU/mL)
0.015	0.001 to 10
0.03 to 0.25	0.01 to 10

	Catalog Number	Code	Product Name	Quantity
with CSE	543-10071	WPEK4-50015	PYROSTAR™ ES-F MULTI KIT (5.2ML), 0.015 EU/ML	5.2mL x 4vials
with CSE	542-10041	WPEK4-50003	PYROSTAR™ ES-F MULTI KIT (5.2ML), 0.03 EU/ML	5.2mL x 4vials
with CSE	547-10111	WPEK4-50006	PYROSTAR™ ES-F MULTI KIT (5.2ML), 0.06 EU/ML	5.2mL x 4vials
with CSE	544-10125	WPEK4-50125	PYROSTAR™ ES-F MULTI KIT (5.2ML), 0.125 EU/ML	5.2mL x 4vials
with CSE	549-10025	WPEK4-50025	PYROSTAR™ ES-F MULTI KIT (5.2ML), 0.25 EU/ML	5.2mL x 4vials

CSE：1 vial(500ng/vial)

PYROSTAR™ ES-F (5.2 ML) without CSE

Gel-clot Sensitivity (EU/mL)	KTA Quantitative Range (EU/mL)
0.015	0.001 to 10
0.03 to 0.25	0.01 to 10

Catalog Number	Code	Product Name	Quantity
547-10231	WPEM-50015	PYROSTAR™ ES-F MULTI KIT (5.2ML), BULK, 0.015 EU/ML	5.2mL x 100vials
544-10241	WPEM-50003	PYROSTAR™ ES-F MULTI KIT (5.2ML), BULK, 0.03 EU/ML	5.2mL x 100vials
541-10251	WPEM-50006	PYROSTAR™ ES-F MULTI KIT (5.2ML), BULK, 0.06 EU/ML	5.2mL x 100vials
548-10261	WPEM-50125	PYROSTAR™ ES-F MULTI KIT (5.2ML), BULK, 0.125 EU/ML	5.2mL x 100vials
545-10271	WPEM-50025	PYROSTAR™ ES-F MULTI KIT (5.2ML), BULK, 0.25 EU/ML	5.2mL x 100vials

PYROSTAR™ ES-F/Plate

Turbidimetric Technique | Endotoxin Specific | FDA approved

PYROSTAR ™ ES-F / Plate is a specific Turbidimetric lysate reagent specifically for 96-well microplates.
By using an absorbance microplate reader, simultaneous measurement of multiple samples is easily made possible.
The quantitative range is wide, from 0.01 to 10 EU / mL, and it can be applied to water type tests, as well as to the testing of name drugs that require dilution.

■ Product Features

- It is possible to specifically detect endotoxin without it being affected by (1 → 3) - β-D - Glucan in the sample.
- US Food and Drug Administration (FDA) approved .
- Regarding U.S. exports, it can also be applied to the final product testing.
- Since it can be measured with a sample volume of 50 μL per well, even a precious sample can be measured in a small amount.
- Stable endotoxin measurement is possible, due to the minor pH impact of the measurement sample on testing.

Multi-test

	Catalog Number	Product Name	Quantitative Range (EU/mL)	Quantity
with CSE	293-75401	Limulus Amebocyte Lysate PYROSTAR™ ES-F/Plate with CSE	0.01-10	160 tests (2.0mL×4vials)
	297-75301	Limulus Amebocyte Lysate PYROSTAR™ ES-F/Plate without CSE	0.01-10	200 tests (2.0mL ×5vials)

CSE：1 vial(500ng/vial)

The Limulus Color KY Series Endotoxin Specific Limulus Reagent

Chromogenic Technique | Endotoxin Specific

The Limulus Color KY Series includes both a multi-test kit and a single-test kit, each designed for time-based chromogenic analysis, using a synthetic substrate which produces a yellow color and can specifically detect endotoxin with high sensitivity.

■Product features

- Endotoxin-specific lysate, avoids false positive results from glucans
- Available in multi-tests vials or single-test vials
- Quantitative Kinetic-Chromogenic Assay (KCA) reagent
- KCA assays can be performed in tube reader or microplate reader
- KCA quantitative range detection limit of 0.0002 EU/mL (single-type) and 0.0005 EU/mL (multi-type).
- Available with matched control standard endotoxin (CSE※)
- 100uL sample size when used with tube reader; 50uL sample size when used with microplate reader

※CSE：1 vial(500ng/vial)

Single-test

	Catalog Number	Product Name	Quantity
with CSE	291-53601	Limulus Color KY Single Test Wako	25 tests

CSE：1 vial(500ng/vial)

Multi-test

	Catalog Number	Product Name	Quantity
with CSE	291-53101	Limulus Color KY Test Wako	60 tests

CSE：1 vial(500ng/vial)

SLP-HS Single Reagent Set Ⅱ Silkworm Larvae Plasma Reagent

Research Use only, Not for use in diagnostic procedures

■ Principle

The hemolymph of the silkworm (Bombyx mori) contains a self-defense mechanism termed "the prophenoloxidase cascade system (ProPO)," which is triggered by peptidoglycan (PG) and (1 → 3)-β-D-glucan (β-glucan), consequently activating prophenoloxidase (PO) in the system. It is postulated that serial serine proteases are involved in the PO activation; however, this has not yet been elucidated. This cascade system is believed to participate in the melanin formation observed in the insect's body fluids as a self-defense mechanism.

SLP reagent is a lyophilized product prepared under sterile conditions from the silkworm hemolymph, which contains all the ProPO factors involved in the cascade system. The reagent, activated by PG and β-glucan, oxidizes the DOPA (L-3,4- dihydroxyphenylalanine) in the substrate and forms a melanin pigment. Since PG is a component found in most bacterial cell walls and β-glucan, in many fungal cell walls, SLP enables the detection of various microorganisms by measuring the melanin pigment formation.

The activation mechanism of SLP is shown in Figure 1. PG or β-glucan binds to the respective recognition protein (PGRP or GRP), which initiates the ProPO cascade reactions, and consequently activates prophenoloxidase. The activated prophenoloxidase then oxidizes the DOPA in the substrate, thus forming black melanin pigment. Since endotoxin, which can be detected by horseshoe crab (Limulus polyphemus) amebocytes (LAL reagent), does not activate the SLP cascade system, it cannot be detected with SLP. However, it can detect PG, which cannot be detected by the LAL reagent (Figure 1). The SLP reagent strongly reacts with PG and β-glucan with β-1,3-glucoside bond, derived from various bacteria. However, it is barely activated by lipopolysaccharide (LPS) (endotoxin), a cell wall component of gram-negative bacteria.

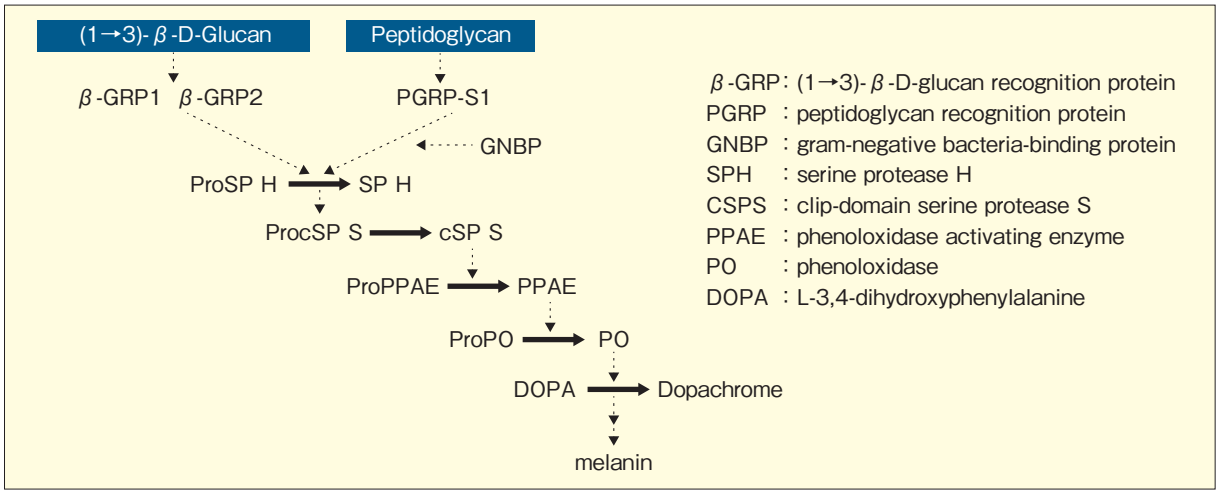


Figure 1. Phenoloxidase precursor cascade of Bombyx mori blood

Since PG is found not only in gram-positive but also gram-negative bacteria, the SLP reagent responds to a wide range of bacteria, regardless of their gram-staining classification. It also reacts with fungus-derived β-glucan, which suggests that it can respond widely to general microorganisms. Therefore, the concurrent use of LAL and SLP reagents, which are activated by endotoxin and β-glucan respectively, enable the type of microorganism in a sample to be predicted.

■ Product Features

1.High sensitive detection of PG and β-glucan
2.Accurate and sensitive quantification of PG and β-glucan with Toxinometer

■ Applications

1.Study of the structure-activity relationship, biosynthesis, metabolism and etiological significance of PG
2.Investigation of water pollution
3.Microbial contamination testing of the dialysate
4.Detection for fungal compounds in pharmaceuticals and medical devices, biologics and genetically-engineered products
5.Elucidation of the biological defense mechanism of insects

■ Kit Contents

1.SLP-HS Reagent Ⅱ (Lyophilized reagent containing *Silkworm Larvae* Plasma and DOPA)	for 0.1mL x 20 vials
2.SLP Diluent	for 5mL x 2 vials
3.Standard (Digested Peptidoglycan from Staphylococcus aureus)	for 0.5mL x 1 vial

■ Measurement Method

PG and β-glucan can be detected using SLP-HS Single Reagent Set and an instrument of Toxinometer.
The measurement principle is the same with endotoxin detection method using Toxinometer (Figure 2).
The absorbance change (melanin production) generated by the activation are detected using Toxinometer.
The correlation between the PG(or β-glucan) concentration and Ta is obtained (Figure 3), and the PG (or β-glucan) concentration is calculated from Ta of each sample.

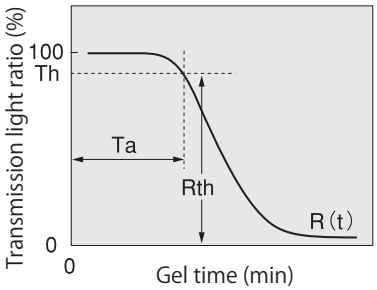


Figure 2. Measuring principles: It measures time (Ta) of index moving from R(t) to threshold (Rth). (Th: decision threshold)

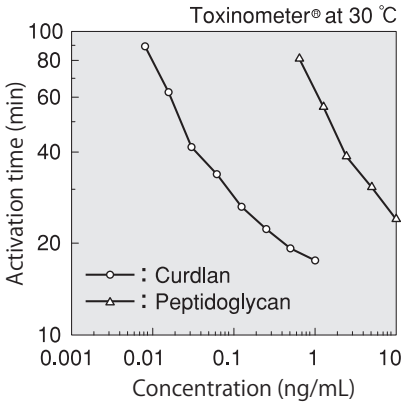


Figure 3. Measuring example using Toxinometer®

Catalog Number	Product Name	Quantity
296-81001	SLP-HS Single Reagent Set Ⅱ	20 tests

Related Products		
Catalog Number	Product Name	Quantity
030-09903	Curdlan	1g
162-18101	Peptidoglycan, from Micrococcus luteus	2 mL

Toxinometer® ET-7000

The Toxinometer® ET-7000 is our computer-operated kinetic incubating tube reader, which is exceptionally user-friendly and easily expandable. Depending on the number of samples to be processed, our state of the art expansion modules can be connected to allow for endotoxin testing in a wide range of fields and sample quantities.

■ Product Features

- Kinetic Incubating Tube Reader
- Single-test configuration avoids “Hot Wells”
- For use in Kinetic-Turbidimetric, Kinetic-Chromogenic, and Gel-Clot assays
- A single assay module can simultaneously measure up to 16 samples
- Expansion modules are available to extend number of samples in multiples of 16
- Temperature settings at both 30℃ and 37℃
- Endotoxin determination in compliance with FDA guidelines as well as withPharmacopeal (USP/EP/JP) BET monographs

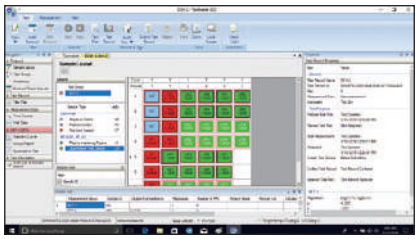
Catalog Number	Model	Power Source	Contents
Part 11 System　※The system complies with FDA21 CFR, Part 11.			
294-35871	Toxinometer® ET-7000/U Part11 Set	100-120 +/- 10% VAC (USA)	1　Toxinometer®　ET-7000 Toximaster® QC8 Software w/5User Licenses 1　Personal Computer System Validation Documents（in CD）
299-35821	Toxinometer® ET-7000/E Part11 Set	220-240 +/- 10% VAC (Europe)	
Non-Part 11 System　※The system doesn’t comply with FDA21 CFR, Part 11.			
291-35881	Toxinometer® ET-7000/U Non-Part11 Set	100-120 +/- 10% VAC (USA)	1　Toxinometer®　ET-7000 Toximaster® QC7 Software w/1User Licenses 1　Personal Computer
296-35831	Toxinometer® ET-7000/E Non-Part11 Set	220-240 +/- 10% VAC (Europe)	
Expansion Module　※Additional Module for Part 11 Set or Non-Part 11 Set.			
297-35861	Toxinometer® ET-7000/U	100-120 +/- 10% VAC (USA)	16 well expansion unit
292-35811	Toxinometer® ET-7000/E	220-240 +/- 10% VAC (Europe)	

The "Welcome Screen" helps navigate you where you need to go!

Toximaster® Software

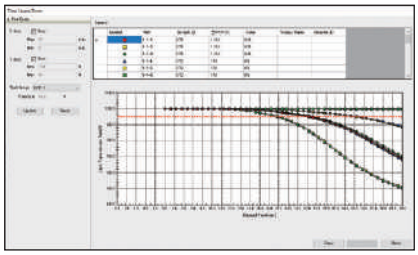
Exclusive software for Efficient routine work & High quality analysis.

■ Protocol Settings



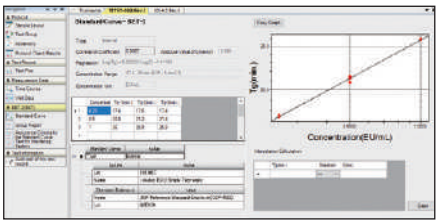
Easy to edit! Once you create a protocol, you can start a measurement immediately.

■ Time Course Graph



Enables visual confirmation of measurement status.
You can predict results and prepare the next steps.

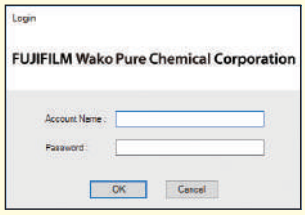
■ Standard Curve



Conveniently monitored!
All information can be seen on one screen.

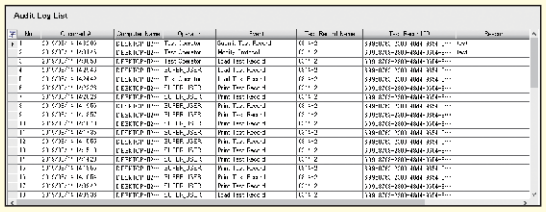
Part 11 Functions ※Ensure data integrity

■ Electronic Signature



All measurement records are linked to signatures.
Never allows for manipulation and falsification.

■ Audit Trail



Major procedures are recorded automatically.
History of operation can be confirmed as a log file.

■ Operation Authorities

Each account belongs to a specific group and each group can define its own authorities for operation.

- Modify System Preferences
- Register Instrument
- Register Protocol
- Register Reagent
- Register Accessory
- Register Standard Curve Data
- Register Product
- Load Protocol into Test Record
- Star Measurement
- Load Test Record
- Review Test Plan
- Confirm Test Record
- Approve Test Record
- Submit Test Record

Etc ..

MPR Endotoxin Measurement System for BT

It is a system dedicated to endotoxin measurement using absorbance Microplate Reader ELx808IU and standard equipment"Toximaster® MPR" software. It can be used for various endotoxin tests such as quality control tests on pharmaceuticals and medical equipment. It enables you to arrange samples and input sample information on one software screen,and supports accurate multi-sample processing with simple and small software operation.

■ Product Features

- Combined with the appropriate LAL reagent, two testing techniques: turbidimetric and chromogenic are usable with a single system.
- Simultaneous measurement of up to 96 samples is possible with 96 well plate.
- Systems comply with the FDA21 CFR Part 11 are also available.
- The software supports to BET (USP/EP/JP).
- Prepare dedicated software "Toximaster® MPR Part11" or "Toximaster® MPR Non- Part11"

Catalog Number	Product Name	Contents
Part 11 system		
292-35931	Toximaster® QC8 MPR Part 11 PC Set	Toximaster® QC8 MPR Part 11 Software Personal Computer System Validation Documemt(in CD)
Non-Part 11 system		
-	Toximaster® QC7 MPR Non-Part 11 PC Set	Toximaster® QC7 MPR Non-Part 11 Software Personal Computer

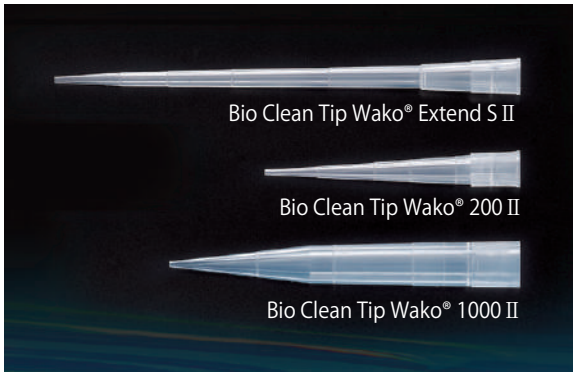
Endotoxin Test Related Accessories

BioClean® Series

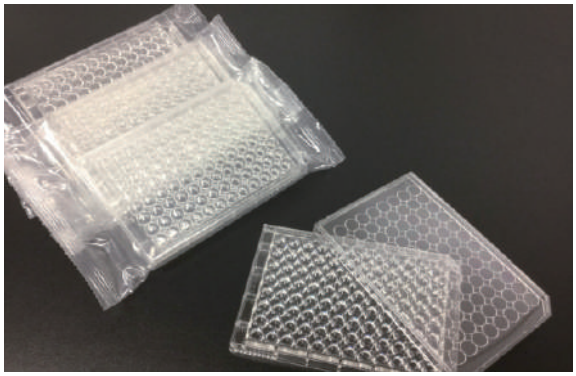
■ Product Features

- Endotoxin-free pipette tip (<0.005 EU/tip)
- Individually packaged, ideal for use in clean rooms
- Packaging film features dust-free protection
- Sterilized by gamma irradiation (25kg ray)
- Tips fit Finnpipette digital micro pipetters (20-200uL or 100-1000uL sizes)
- Endotoxin-free tubes and caps sterilized at 250 ℃
- For use with Toxinometer® measurement system

Bio Clean Tip Wako®



Bio Clean Plate Wako®



Endotoxin-free Pipette Tips and Microplates			
Catalog Number	Product Name	Volume Size	Quantity
294-35011	BioClean Tip Wako® Extend S II	200 μL	100 tips
291-35021	BioClean Tip Wako® 200 II	200 μL	100 tips
298-35031	BioClean Tip Wako® 1000 II	1000 μL	100 tips
293-35221	Bio Clean Plate Wako® Microplate	96 well	50 pcs/pk

Limulus Test Tube-S with Aluminum Cap

Endotoxin-free Test Tubes and Caps/ Gel-clot Reaction Tubes			
Catalog Number	Product Name	Volume Size	Quantity
292-32751	Limulus Test Tube-S with Aluminum Cap	12 x 75mm	80 pcs
293-26551	Limulus Test Tube-S	12 x 75mm	100 pcs
293-28251	Aluminum Cap-S	14.7 x 18mm	100 pcs

Gel-clot Reaction Tubes

■ Product Features

- Endotoxin-free test tubes (<0.001 EU/tube)
- Designed for Gel-clot testing
- Made with Borosilicate glass

Made with borosilicate glass

Catalog Number	Product Name	Volume Size	Quantity
CT-1075	Gel-clot Reaction Tube	10×75mm	200 tubes/pk
CT-1075B	Gel-clot Reaction tube,Bulk	10×75mm	1250 tubes/pk
542-10281	Depyrogenated Dilution Tube	13 x 100mm	50 pcs/pk

Endotoxin Test Related Accessories

Control Standard Endotoxin

■ Product Features

- Endotoxin derived from *E.Coli* UKT-B
- Can be used to prepare controls and standard curves
- RSE/CSE ratios supplied to match specific lots of LAL
- Reconstituted CSE can be stored at 2-10℃ for 1 month

Catalog Number	Code	Product Name	Quantity
638-01021	-	Japanese Pharmacopoeia Endotoxin Reference Standard	1 vial (10,000~ 25,000 EU/vials)
546-10061	CSE 4037-5006	Control Standard Endotoxin	6 vials (500 ng/vial)

LAL Reagent Water

Wako proudly provides high-quality, endotoxin free water ideal for all of your LAL testing needs.

■ Product Features

- Endotoxin-free water (<0.001 EU/mL)
- Steam sterilized by USP standards
- Derived from water for injection, USP
- Non LAL reactive

Catalog Number	Code	Product Name	Quantity
540-10081	LRW-12100	Lysate Reagent Water, 100mL	12 x 100mL vials
547-10091	LRW-2030	Lysate Reagent Water, 30mL	20 x 30mL vials

Endotoxin Extracting Solution

Endotoxin Extracting Solution for LAL Test

Traditionally, water or saline solution has been used to extract endotoxin in tests on medical devices and equipment; however, the efficacy of this extraction method has recently come into question. In order to provide our customers with a more reliable method for medical device testing,
FUJIFILM Wako has developed an endotoxin-free extracting solution containing human serum albumin (HSA) that is capable of extracting endotoxins which cannot be extracted in water or saline solution.

■ Product Features

- Capable of extracting endotoxins from surfaces which cannot be extracted in water or saline
- Recommended for use in endotoxin testing on equipment and devices which may come into contact with fluids containing blood or protein.

Catalog Number	Product Name	Quantity
293-51601	Endotoxin Extracting Solution for LAL Test	4 x 10 mL vials

Endotoxin Indicator

Endotoxin Indicator Vial (>1,000 EU/vial)

■ Product Features

Intended Use: The Endotoxin indicator is intended for performing validation for depyrogenation processes of dry heat oven cycles. To ensure that a cycle is effectively inactivating and/or destroying endotoxin, an analysis comparing the endotoxin concentration before and after the depyrogenation process is completed. The United States Pharmacopeia (USP) describes preparing endotoxin indicators of a sufficient concentration to allow recovery of a minimum 1,000 Endotoxin Units (EU) in order to accurately demonstrate at least a 3-log reduction in endotoxin levels during the depyrogenation process challenge. The Endotoxin indicator is intended to demonstrate a minimum 3-log reduction after depyrogenation when used with PYROSTAR™ ES-F series by gel clot and kinetic methods

Catalog Number	Code	Product Name	Quantity
549-10291	EIV-025	Endotoxin Indicators, >1,000 EU/vial	25 vials

Contribution to Measurement Technology - Acquisition of FDA approval

Endotoxin is a potent toxin contained in cell wall components of Gram-negative bacteria. Since it brings about the fever or lethal shock when entering the blood of a person, it is necessary to confirm that medicines are not contaminated with endotoxin. We have strived to evolve the endotoxin measurement technology by manufacturing lysate reagents and developing the measurement system"Toxinometer", and supported medicines from behind for over 30 years.

From sales of lysate reagents to the development of endotoxin measurement system

Our US Plant (Location: Richmond, Virginia)

IInitially, the rabbit pyrogen test was used for the endotoxin test method. After injecting the sample into the rabbit, the amount of endotoxin contamination was measured from the increasing degree of its body temperature. However, with this test method, there were drawbacks such as taking time to get results, being unable to maintain the reliable results because of using animals.

In 1956 in the United States, F.B.Bang discovered a phenomenon that the blood of horseshoe crabs solidified in a gel state with endotoxin, and then the endotoxin measurement reagent (Limulus reagent, renamed as lysate reagent later) prepared from the blood extract of horseshoe crabs and "Gel-clot technique" using this were developed. Gel-clot technique were listed in the US Pharmacopoeia in 1980, but we also began importing and selling the reagent prior to this. However, in the gel-clot technique, problems remained such as being the semi-quantitative method and the judgment accuracy depending on the proficiency of the measurer.

We challenged to solve these problems, then in 1985, developed the measurement method "Turbidimetric time analysis method" based on the different principle from the conventional one and released its measurement system "Toxinometer" for the first time in the world. At the same time, in the United States, ACC company (Associates of Cape Cod, .INC) developed a system using the same measurement principle. In response to this situation, the turbidimetric time analysis method was listed in the US FDA Guideline in 1987.

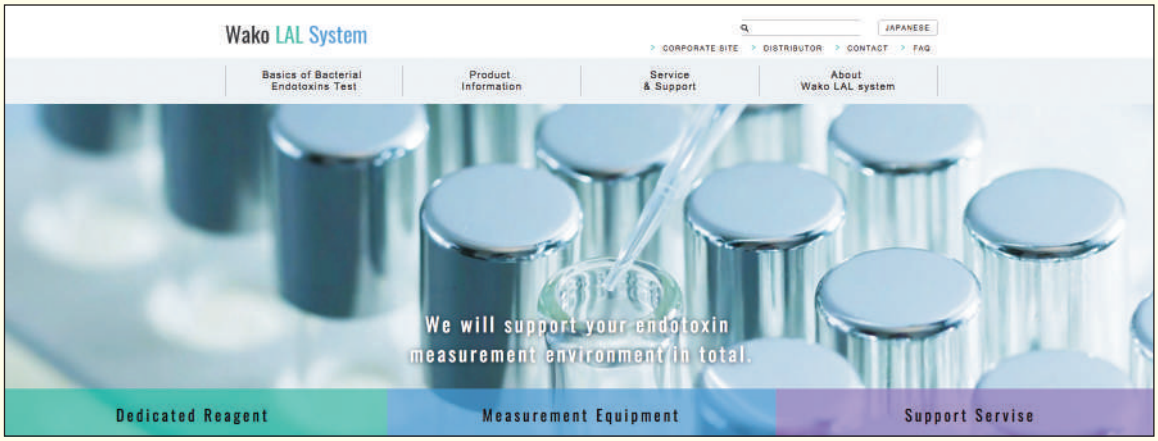
Currently, Toxinometers corresponding to the turbidimetric, chromogenic and gel-clot technique are provided along with numerous reagents. Meanwhile, also offering "MPR Endotoxin Measurement System" corresponding to the chromogenic and turbidimetric techniques using plate readers, we are contributing to the safety of pharmaceutical production and quality control of pharmaceuticals as a pioneer of endotoxin measurement.

Establishment of the FDA approved plant and development of the world's only specific reagent for endotoxin

The world's first lysate reagent was developed in the United States, and we initially handled only imported items from the United States. As the market expanded and the needs of reagents increased, we established a plant in the United States.
First of all, we bought Hemakem Inc. in St. Louis in 2003 and made it a foothold for entering the United States.
After that, we built a new plant in Richmond, received FDA approval, and began shipping reagents. Incidentally, the endotoxin specific reagents with FDA approval are only our products worldwide.

Also, there is a convenient single type reagent that is lyophilized in a test tube beforehand and can be measured simply by putting the sample. Even in this category, the company having the endotoxin specific reagents with FDA approval is only us in the world.
As described above, our company, which has been involved in endotoxin reagents for more than 30 years and making efforts on the improvement of measurement methods and the development of "Toxinometer", has tried hard to develop the pharmaceutical industry and others, as one of pioneers of endotoxin measurement.

Wako LAL System
Web Site for Endotoxin Analysis



http://www.wako-chem.co.jp/lal/en/index.html

Contact
http://ffwk.fujifilm.co.jp/en/contact/index.html

FUJIFILM Wako Pure Chemical Corporation

http://ffwk.fujifilm.co.jp/

1-2,Doshomachi 3-Chome
Chuo-Ku,Osaka 540-8605,Japan

FUJIFILM Wako Chemicals U.S.A. Corporation

www.wakousa.com
E-mail：wkuspyrostarinfo@fujifilm.com

FUJIFILM Wako Chemicals Europe GmbH

www.wako-chemicals.de
E-mail：info_wkeu@fujifilm.com

FUJIFILM
Value from Innovation

LAL REAGENT PRODUCTS

For the Detection of Bacterial Endotoxin

Wako

TABLE OF CONTENTS

The FUJIFILM Wako Chemicals bleeding facility in Cape Charles, Virginia, is a companion site where we harvest amebocytes from the Atlantic horseshoe crab, *Limulus polyphemus*, for our FDA-licensed manufacturing headquarters located in Richmond, Virginia.

WELCOME TO FUJIFILM WAKO CHEMICALS U.S.A. CORPORATION

FUJIFILM Wako Chemicals U.S.A. Corporation (FUJIFILM Wako) is recognized around the world as a trusted supplier of pure chemicals and reagents. After establishing a sales office in Dallas, Texas, in 1981, we grew significantly in the U.S. and in 1989, relocated our corporate headquarters and manufacturing facility to Richmond, Virginia.

In 2012, we culminated three decades of research and development by introducing our PYROSTAR™ ES-F series to the market. The PYROSTAR™ ES-F series offers a simple, accurate platform for the detection of bacterial endotoxin. This endotoxin-specific LAL reagent is accompanied by a suite of complementary products to offer a complete solution for your endotoxin testing needs.

Like all FUJIFILM Wako businesses, our LAL division is committed to manufacturing the highest-quality chemical reagents and supplies. Our commitment to delivering exceptional customer service is just as strong. When partnering with our LAL division, you receive personal attention from a team of specialists dedicated to your success. We look forward to providing you with superior service and supporting your laboratory in maintaining the utmost level of quality control.

HORSESHOE CRAB CONSERVATION

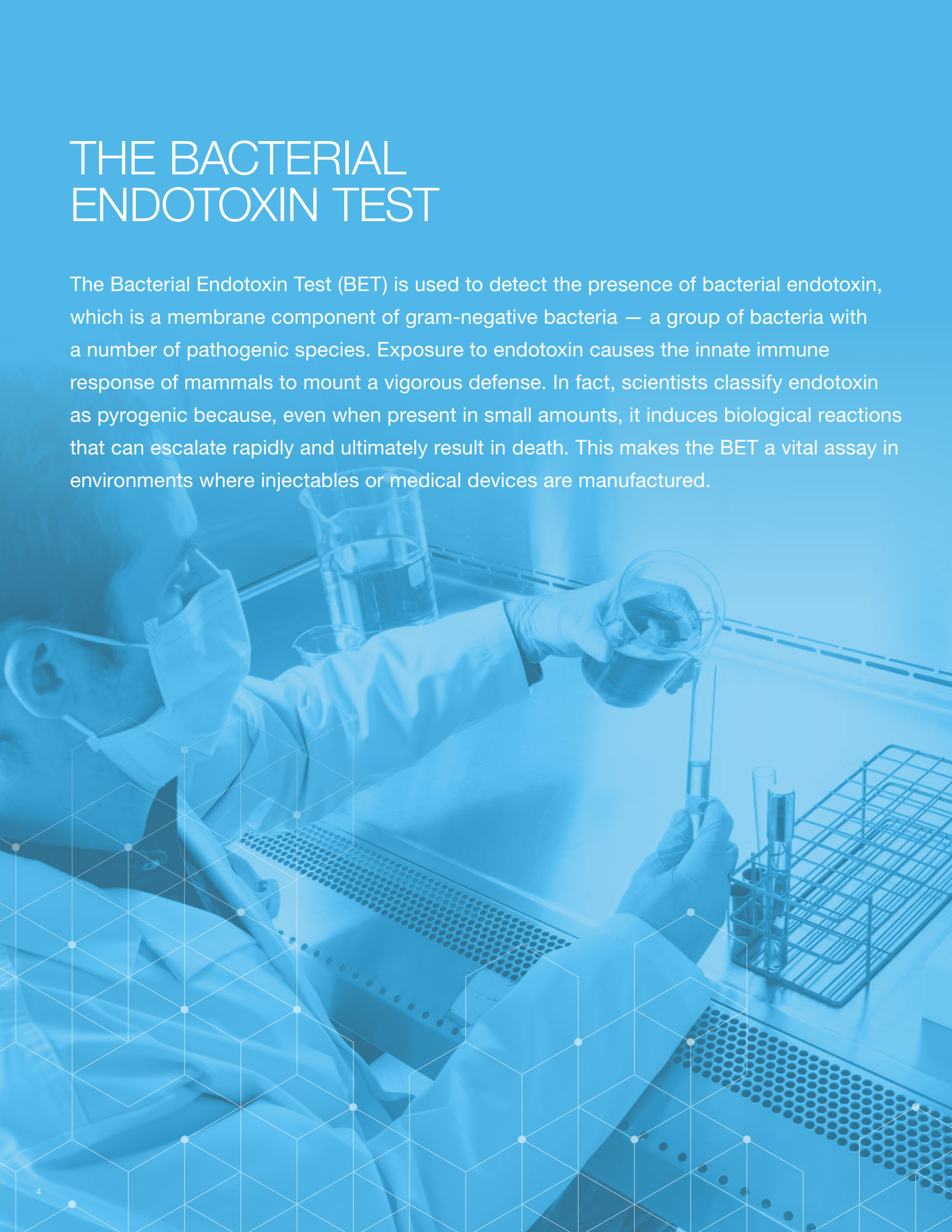
FUJIFILM Wako is committed to the sustainability of the Atlantic horseshoe crab *(Limulus polyphemus)* population. We voluntarily follow a set of best practices that involve careful handling and selection of healthy, viable animals. Our bleeding procedure is conducted with the utmost diligence to prevent any injury to the donor crabs, and our fishermen always return them to the same waters from which they were collected. FUJIFILM Wako cooperates with the U.S. Fish and Wildlife Service to tag and monitor horseshoe crabs as part of an ongoing conservation effort.

OUR PROMISE

As an FDA-licensed facility, FUJIFILM Wako is committed to ensuring that our production site and reagents comply with the rules, regulations and quality standards set forth by the FDA. We guarantee that the processes used to prepare our products adhere strictly to current Good Manufacturing Practices (cGMPs).

THE BACTERIAL ENDOTOXIN TEST

The Bacterial Endotoxin Test (BET) is used to detect the presence of bacterial endotoxin, which is a membrane component of gram-negative bacteria — a group of bacteria with a number of pathogenic species. Exposure to endotoxin causes the innate immune response of mammals to mount a vigorous defense. In fact, scientists classify endotoxin as pyrogenic because, even when present in small amounts, it induces biological reactions that can escalate rapidly and ultimately result in death. This makes the BET a vital assay in environments where injectables or medical devices are manufactured.



UNDERSTANDING BACTERIAL ENDOTOXIN TESTING

ENDOTOXIN

Endotoxin is a natural component of the outer cell wall of gram-negative bacteria. It is a lipopolysaccharide (LPS), which includes a polysaccharide portion, responsible for the immune response, and a lipid portion, responsible for the biological response. Endotoxin are highly heat resistant and must be exposed to temperatures of 250°C or greater for at least thirty minutes to achieve inactivation. It should be noted that endotoxin can trigger an immune response both when the bacterial cell wall is intact and when fragments are released upon lysis.

ENDOTOXIN CONTAMINATIONS

The BET is required in a number of industries to minimize the risk of human exposure to endotoxin. The goal of testing is to ensure that manufacturing operations prevent endotoxin contamination, which can cause a febrile response to end users, in the final product. This is very important in the pharmaceutical industry, which produces a variety of drugs, biologics and devices that could expose humans to endotoxin. Though the BET is for end-product testing, it is typically performed throughout the manufacturing process. Endotoxin testing helps pharmaceutical companies avoid releasing defective products to the market. More importantly, it protects vulnerable patients with a low infection threshold.

HISTORY OF THE BET

The BET gets its secondary name — limulus amebocyte lysate (LAL) test — from its reliance on amebocytes derived from the Atlantic horseshoe crab *(Limulus polyphemus)*. The blood of this living fossil, which has existed for millions of years, possesses an interesting defense mechanism against gram-negative bacteria. When the animal becomes injured, its blood will immediately bind and form a clot around the invading foreign organisms as an immune response to prevent any additional infection to the injured area.

In 1953, Frederik B. Bang described the effects of injecting a marine bacterium into *Limulus polyphemus*. When he injected gram-negative bacteria, he observed intravascular clotting; when he injected gram-positive bacteria, no clotting occurred. Bang also observed that the clotting did not require living bacteria; dead cells also triggered the reaction. His research ultimately led to the discovery of the cells responsible for the clotting reaction and how to isolate the active material — an aqueous extract of horseshoe crab blood cells known as limulus amebocyte lysate, or LAL. In the late 1970s, the United States Food and Drug Administration (FDA) approved the LAL test as an acceptable substitution to the rabbit pyrogen test to determine the presence of endotoxin in pharmaceutical drugs, biologics and medical devices.

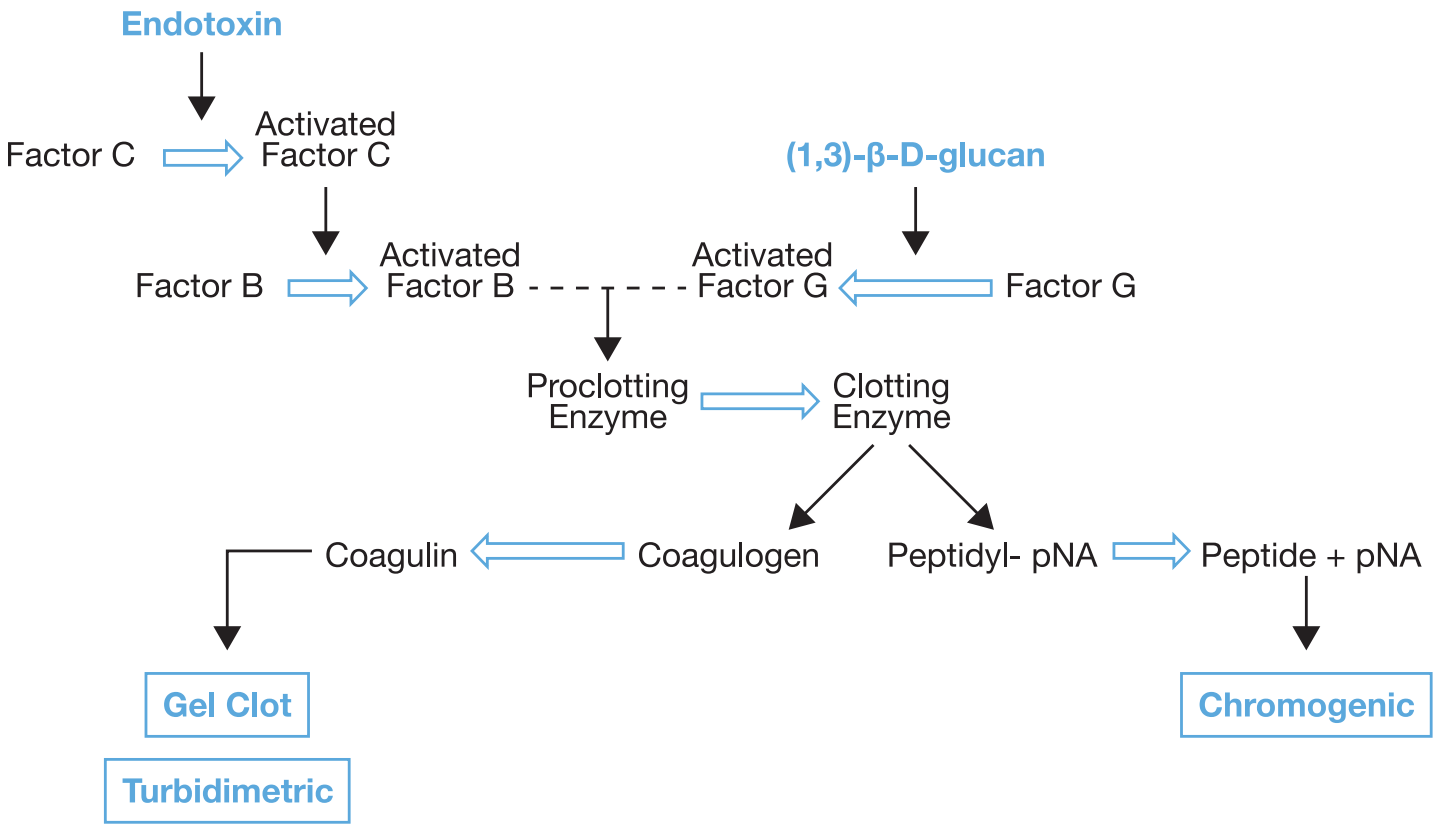
LAL BIOCHEMICAL CASCADE

There is a biochemical cascade associated with LAL that makes it possible to observe either qualitative or quantitative effects when endotoxin is present. The test itself can be conducted using one of three techniques: gel clot, turbidimetric or chromogenic.

As shown below, the endotoxin interaction initiates the first serine protease precursor (Factor C) from its inactivated form; this in turn activates the second serine protease precursor (Factor B). The activated Factor B stimulates the clotting enzyme, converting it from a proclotting enzyme. The clotting enzyme cleaves peptide bonds within coagulogen to yield coagulin, the insoluble gel-forming protein produced in the gel clot assay.

The cascade mechanism is identical in the turbidimetric assay, although it is measured differently. In the turbidimetric assay, the rate at which turbidity increases relative to the concentration of endotoxin, is the critical measurement. Although the chromogenic assay has the same protease precursors activated as in both the gel clot and turbidimetric assays, a chromogenic synthetic substrate is cleaved by the clotting enzyme to convert the chromogenic peptide into a synthetic substrate and a para nitroaniline (pNA). This releases the chromophore, yielding a yellow color whose intensity is directly proportional to the endotoxin concentration.

It should also be noted that LAL can yield a biochemical process in the presence of (1,3)-ß-D-glucan by way of an additional factor (Factor G). Because of this, most LAL reagents require buffers to block the (1,3)-ß-D-glucan from detection in order to determine the true concentration of endotoxin.



LAL TECHNIQUES

GEL CLOT

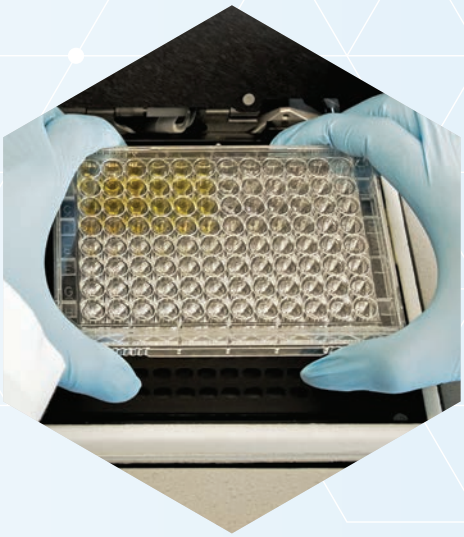
Gel clot assays function both qualitatively and semi-quantitatively. Gel clot assays are incubated at 37°C ± 1°C for 60 ± 2 minutes using a water bath, heat block or tube reader. After the incubation time has elapsed, the tube is removed and slowly inverted 180° to determine if there is a firm gel formed at the bottom of the tube. If the integrity of the gel within the tube is intact with no deformation, the result is positive. If the gel collapses, the result is negative.

TURBIDIMETRIC

Turbidimetric assays rely on turbidity change to determine the presence of endotoxin. The endpoint turbidimetric reaction is measured at a determined time after the reagent is mixed with the sample. The kinetic turbidimetric reaction measures the time it takes to reach a predetermined optical density or threshold value. Both methods can be measured around 405 nm incubated at 37°C ± 1°C in a microplate or tube reader, and a linear regression of the standards can be generated.

CHROMOGENIC

Chromogenic assays rely on color change to indicate the presence of endotoxin. The endpoint chromogenic reaction is stopped after a specific incubation period by the addition of acid; the kinetic chromogenic reaction is determined by the time it takes to reach a predetermined optical density or threshold. Regardless of the chromogenic method used, a linear regression of the standards can be generated and the yellow coloration produced can be measured around 405 nm incubated at 37°C ± 1°C in a microplate or tube reader.



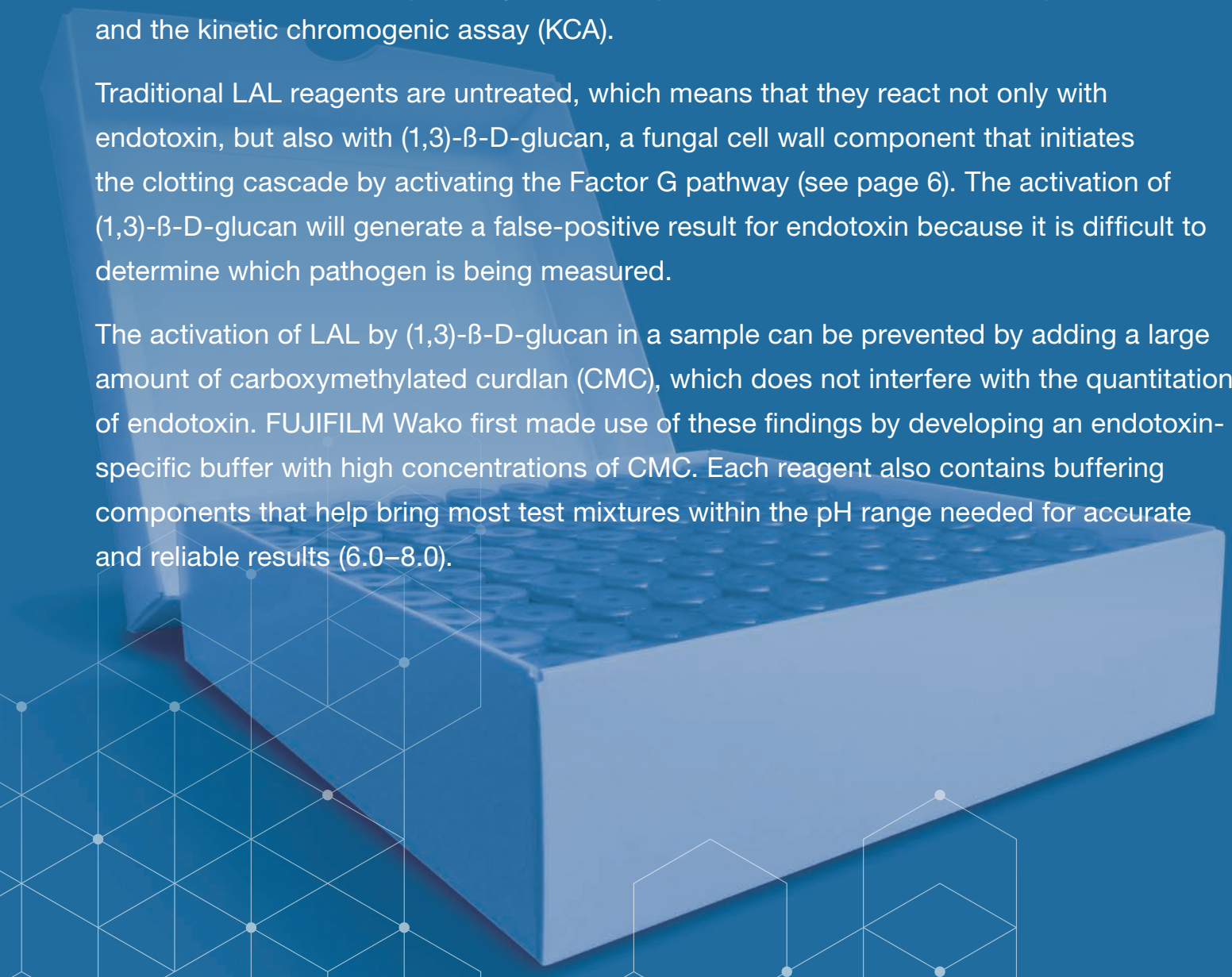
It is crucial that the user has the necessary endotoxin-free accessories to obtain reliable, reproducible and accurate results during LAL testing. Water-for-injection (WFI) or LAL Reagent Water is ideal for endotoxin testing. Reference Standard Endotoxin (RSE) should be used as a standard when testing for endotoxin, though the Control Standard Endotoxin (CSE) is an economic alternative. CSE are standardized against the RSE by each LAL manufacturer, allowing CSE to be used in place of RSE. For more detailed information, refer to regulatory guidance documents for bacterial endotoxin testing.

ENDOTOXIN-SPECIFIC LAL REAGENTS

FUJIFILM Wako provides a line of reagents formulated to perform each of the three endotoxin detection assays: the gel clot assay, the kinetic turbidimetric assay (KTA) and the kinetic chromogenic assay (KCA).

Traditional LAL reagents are untreated, which means that they react not only with endotoxin, but also with (1,3)-ß-D-glucan, a fungal cell wall component that initiates the clotting cascade by activating the Factor G pathway (see page 6). The activation of (1,3)-ß-D-glucan will generate a false-positive result for endotoxin because it is difficult to determine which pathogen is being measured.

The activation of LAL by (1,3)-ß-D-glucan in a sample can be prevented by adding a large amount of carboxymethylated curdlan (CMC), which does not interfere with the quantitation of endotoxin. FUJIFILM Wako first made use of these findings by developing an endotoxin-specific buffer with high concentrations of CMC. Each reagent also contains buffering components that help bring most test mixtures within the pH range needed for accurate and reliable results (6.0–8.0).



PYROSTAR™ | ES-F Series

The PYROSTAR™ ES-F series of reagents are endotoxin-specific and specially formulated to be unreactive to (1,3)-ß-D-glucan. In addition, these products are dual-purpose, meaning they are formulated to be used as either a gel clot or kinetic turbidimetric assay. They are available in a single-test or multi-test configuration.

These reagents require only one Certificate of Analysis (COA), regardless of whether they are used as a gel clot or kinetic turbidimetric assay. PYROSTAR™ ES-F/Plate requires a different COA. All reagent kits are matched with a specific Control Standard Endotoxin (CSE). These reagents work well with samples that have color or with samples that present difficulties in quantification by the KCA.

PYROSTAR™ ES-F SINGLE TEST

Single-test vials come with pre-dispensed LAL reagent for a single measurement. This configuration is used by adding 0.2 mL of the sample directly to the reaction vial containing the lyophilized reagent. This single-test vial is designed to be used with our Toxinometer® Measurement System (Toxinometer®) to assist labs transitioning from a gel clot to a kinetic turbidimetric methodology. The single-test configuration is ideal to assay a small number of samples or for a less-experienced user.

Key Features

- Endotoxin-specific reagent avoids false positive results from glucans
- Gel clot sensitivities include 0.015 EU/mL, 0.03 EU/mL, 0.125 EU/mL and 0.25 EU/mL
- KTA sensitivities range from 0.001 to 10 EU/mL
- Can be used with the traditional water bath or heat block
- Can be used with the Toxinometer® to facilitate easier transition from gel clot to KTA

PYROSTAR™ ES-F SINGLE TEST KIT
25 single-test vials + 1 vial CSE (500 ng/vial)

Catalog Number	Gel Clot Sensitivity (EU/mL)	Kinetic Turbidimetric Quantitative Range (EU/mL)
WPESK-0015	0.015	0.001 to 10
WPESK-0003	0.03	0.01 to 10
WPESK-0125	0.125	0.01 to 10
WPESK-0025	0.25	0.01 to 10

PYROSTAR™ ES-F MULTI-TEST

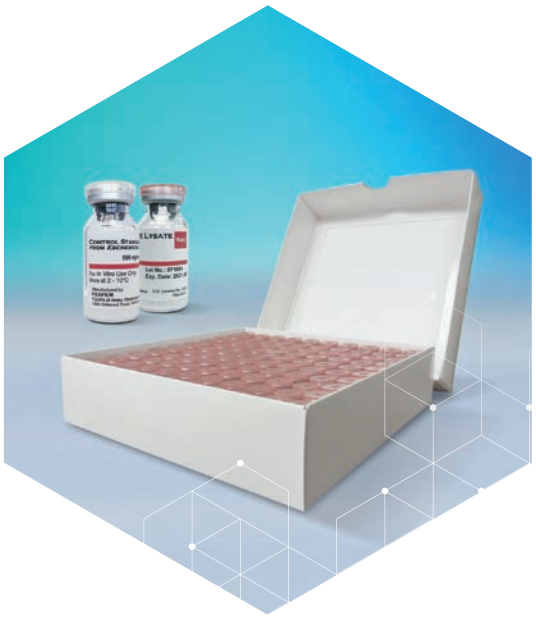
This multi-test vial is designed to be used with a water bath, heat block or the Toxinometer®. With this configuration, the user dispenses 0.1 mL of dissolved LAL reagent into the appropriate reaction tube, then adds 0.1 mL of the sample. This multi-test vial is ideal for a user testing a larger number of samples.

PYROSTAR™ ES-F 80 TEST KIT
4 multi-test vials (2.0 mL) + 1 vial CSE (500 ng/vial)

Catalog Number	Gel Clot Sensitivity (EU/mL)	Kinetic Turbidimetric Quantitative Range (EU/mL)
WPEK4-20015	0.015	0.001 to 10
WPEK4-20003	0.03	0.01 to 10
WPEK4-20006	0.06	0.01 to 10
WPEK4-20125	0.125	0.01 to 10
WPEK4-20025	0.25	0.01 to 10

PYROSTAR™ ES-F 200 TEST KIT
4 multi-test vials (5.2 mL) + 1 vial CSE (500 ng/vial)

Catalog Number	Gel Clot Sensitivity (EU/mL)	Kinetic Turbidimetric Quantitative Range (EU/mL)
WPEK4-50015	0.015	0.001 to 10
WPEK4-50003	0.03	0.01 to 10
WPEK4-50006	0.06	0.01 to 10
WPEK4-50125	0.125	0.01 to 10
WPEK4-50025	0.25	0.01 to 10



PYROSTAR™ ES-F 2.0 ML BULK KIT
100 multi-test vials (2.0 mL)

Catalog Number	Gel Clot Sensitivity (EU/mL)	Kinetic Turbidimetric Quantitative Range (EU/mL)
WPEM-20015	0.015	0.001 to 10
WPEM-20003	0.03	0.01 to 10
WPEM-20006	0.06	0.01 to 10
WPEM-20125	0.125	0.01 to 10
WPEM-20025	0.25	0.01 to 10

PYROSTAR™ ES-F 5.2 ML BULK KIT
100 multi-test vials (5.2 mL)

Catalog Number	Gel Clot Sensitivity (EU/mL)	Kinetic Turbidimetric Quantitative Range (EU/mL)
WPEM-50015	0.015	0.001 to 10
WPEM-50003	0.03	0.01 to 10
WPEM-50006	0.06	0.01 to 10
WPEM-50125	0.125	0.01 to 10
WPEM-50025	0.25	0.01 to 10

Key Features

- Endotoxin-specific reagent avoids false positive results from glucans
- Dual-purpose reagent can perform either a gel clot or kinetic turbidimetric assay (KTA)
- Gel clot sensitivities range from 0.015 to 0.25 EU/mL
- Kinetic turbidimetric sensitivities range from 0.001 to 10 EU/mL
- Due to its high sensitivity, chances of interference are reduced
- Facilitates easier transition from gel clot to KTA

PYROSTAR™ ES-F/PLATE

This multi-test vial is designed to be used with the microplate reader. To use this configuration, the user dispenses 0.05 mL of the sample into the microplate followed by 0.05 mL of dissolved LAL reagent. This assay is ideal for testing a larger number of samples in one run.

PYROSTAR™ ES-F/PLATE TEST KIT
4 multi-test vials + 1 vial CSE (500 ng/vial)

Catalog Number	Volume (mL)	Kinetic Turbidimetric Quantitative Range (EU/mL)
WPEPK4-20015	2.0	0.01 to 10
WPEPK4-50015	5.2	0.01 to 10

Key Features

- Endotoxin-specific reagent avoids false positive results from glucans
- 2.0 mL volume equates to approximately 40 tests per vial
- 5.2 mL volume equates to approximately 100 tests per vial
- The sensitivity ranges from 0.01 to 10 EU/mL

LIMULUS COLOR KY SERIES

The Limulus Color KY Series are quantitative kinetic chromogenic assays (KCA) that are endotoxin-specific and unreactive to (1,3)-ß-D-glucan. This series includes both a multi-test kit and a single-test kit, which utilize a synthetic substrate that produces a yellow color to detect endotoxin with high sensitivity. All reagent kits are matched with a Control Standard Endotoxin (CSE). These reagents work well with samples that are very turbid or show difficulty in quantification by the kinetic turbidimetric assay (KTA).

LIMULUS COLOR KY SINGLE TEST

Limulus Color KY single-test vials come with pre-dispensed LAL reagent for a single measurement. This configuration is used by adding 0.2 mL of the sample directly to the reaction vial containing the lyophilized reagent. This single-test vial is ideal for a user testing a smaller number of samples or one who is less experienced.

LIMULUS COLOR KY TEST KIT
25 single-test vials + 1 vial CSE (500 ng/vial)

Catalog Number	Kinetic Chromogenic Quantitative Range (EU/mL)	Number of Tests
291-53601	0.0002 to 5	25 tests

Key Features

- KCA quantitative range detection limit of 0.0002 to 5 EU/mL
- Reagent reacts with endotoxin over a wide range of concentrations
- High sensitivity to reduce the chance of interfering factors
- Can be used with the Toxinometer®
- Reduces the chance of contamination and no wasted reagent during testing

LIMULUS COLOR KY MULTI TEST

This multi-test vial is designed to be used with the Toxinometer® or a microplate reader. To use this configuration with a microplate reader, the user dispenses 0.05 mL of the sample into a microplate containing 0.05 mL of dissolved LAL reagent. When utilizing the Toxinometer®, the user dispenses 0.1 mL of dissolved LAL reagent into the appropriate reaction tube followed by 0.1 mL of the sample. The multi-test vial is ideal for a user with a larger number of samples that are turbid.

LIMULUS COLOR KY TEST KIT
3 multi-test vials (2.0 mL) + 1 vial CSE (500 ng/vial)

Catalog Number	Kinetic Chromogenic Quantitative Range (EU/mL)	Number of Tests
291-53101	0.0005 to 5	60 tests

Key Features

- Reagent reacts with endotoxin over a wide range of concentrations
- Reduces the chance of interfering factors due to high sensitivity
- Can be used with the Toxinometer® or microplate reader
- KCA quantitative range detection limit of 0.0005 to 5 EU/mL
- The sample size is 0.1 mL when used with tube reader; 0.05 mL sample size when used with microplate reader

LIMULUS PS SINGLE TEST

The Limulus PS Single Test contains endotoxin-specific single-test vials and an affinity resin suspension called PyroSep™, which is designed to overcome any product interference by adsorbing potential endotoxin in samples while washing away the inhibitory components.

Case Studies: Using the Limulus PS Single Test

Endotoxin Detection in Peritoneal Dialysate/Replacement Fluid

5 mL samples of commercially available dialysate (Dialysate X) and two kinds of replacement fluids for artificial kidneys (Fluids Y and Z) were spiked with two different concentrations of Reference Standard Endotoxin: 0.1 EU/mL and 1.0 EU/mL. The samples were analyzed using the PyroSep™ method. All endotoxin spikes showed recovery within the acceptable range of 50% to 200%.

Endotoxin Recovery from Peritoneal Dialysate/ Replacement Fluid Using the PyroSep™ Method

SAMPLE	ENDOTOXIN SPIKE (EU/mL)	ENDOTOXIN RECOVERY (%)
Dialysate X	0.1	80
	1.0	72
Fluid Y	0.1	144
	1.0	102
Fluid Z	0.1	108
	1.0	118

LIMULUS PS SINGLE TEST

Catalog Number	Contents	
299-54501	- 20 LAL ES single-test vials - PyroSep™ resin suspension - LAL reconstitution solution	- Wash solution - Sample diluent - 20 glass capillary columns

PS ACCESSORY KIT (OPTIONAL)

Catalog Number	Contents	
294-33311	- 12 syringes (20 mL) - 12 T-shape stopcocks R Type - 20 Dedicated adapters - 12 Bulldog clips	- 25 Polystyrene tubes (5 mL) - 25 Polystyrene tubes (14 mL) - Test tube rack

Key Features

- Endotoxin-specific reagent avoids false positive results from glucans
- This kit is in single-test configuration to avoid contamination
- KTA quantitation for this product is performed on the Toxinometer®
- Allows endotoxin-specific measurement in samples that typically have inhibitory components: ethanol, silicone oil, soybean oil, olive oil, stearic acid, egg yolk lecithin, oil-adjuvanted vaccine, albumin products, coagulation factor products (factor 8), interferon formulation, antithrombin III, immunoglobulin product and other ethanol-soluble samples

ENDOTOXIN ANALYSIS SYSTEMS

FUJIFILM Wako provides analysis systems with software that is user friendly and capable of performing all methodologies for LAL testing.

TOXIMASTER® QC8 SOFTWARE

The Toximaster® QC8 software supports data processing based on the protocols complying with three types of pharmacopeia (USP/EP/JP) for bacterial endotoxin testing. This software is compliant with FDA 21 CFR Part 11 ERES (electronic records/electronic signature), which requires the proper information from all parties involved in the testing of the sample. Toximaster® QC8 offers excellent audit trail capabilities, can provide statistical processing of means and standard deviations, and has robust data processing functions. These data processing functions can be performed by defining sample types such as standards, controls and test samples.

TOXINOMETER® ET-7000 — 21 CFR PART 11 (ERES) COMPLIANT SOFTWARE

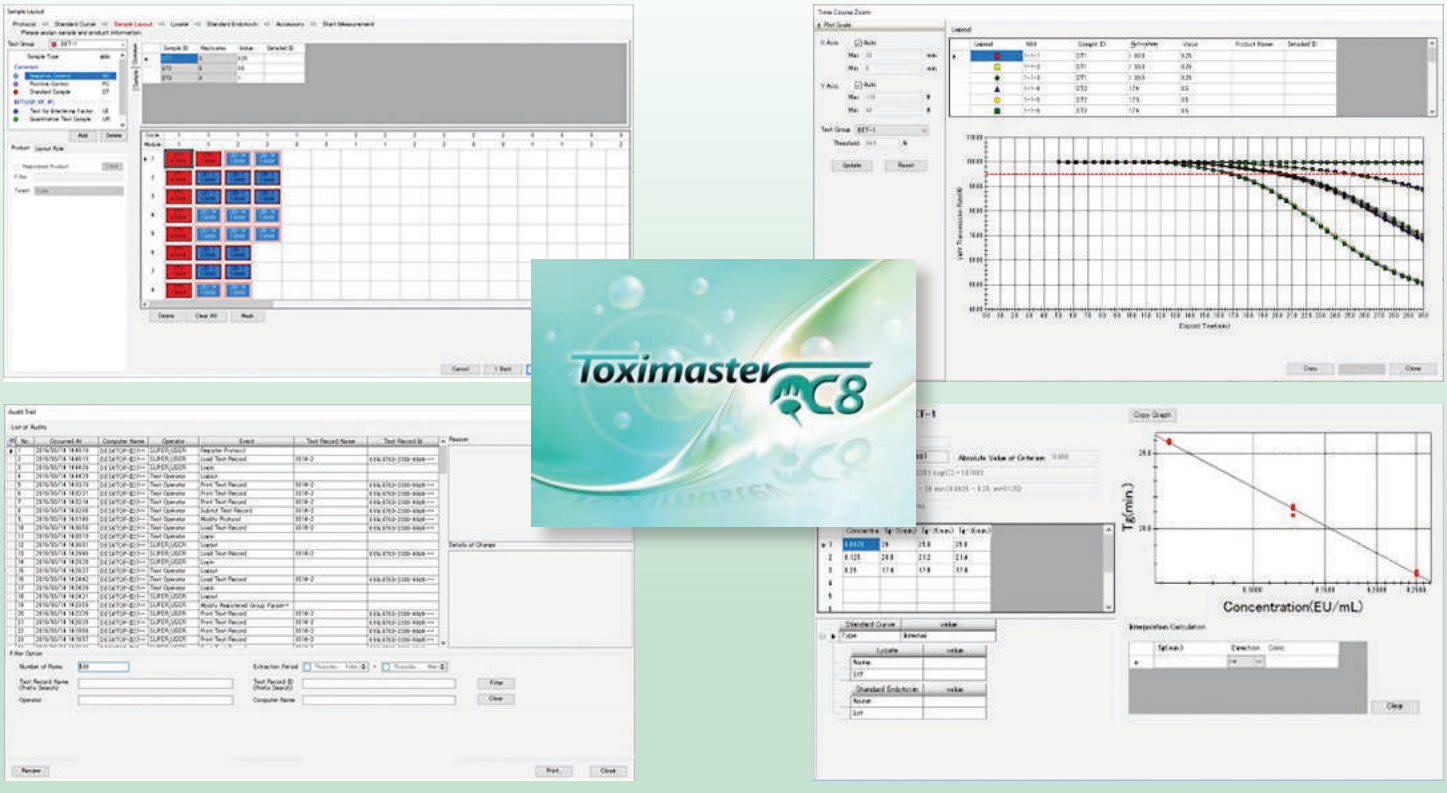
Catalog Number	Model	Contents
297-35981	Part 11 software PC set	Toximaster® QC8 Software with 1 Personal Computer
293-35961	Part 11 software only	Toximaster® QC8 Software

BIOTEK ELX808IU MICROPLATE READER — 21 CFR PART 11 (ERES) COMPLIANT SOFTWARE

Catalog Number	Model	Contents
292-35931	Part 11 software PC set	Toximaster® QC8 Software with 1 Personal Computer
290-35971	Part 11 software only	Toximaster® QC8 Software

Key Features

- FDA 21 CFR Part 11 ERES compliant
- Endotoxin determination in compliance with pharmacopoeias (USP/EP/JP) for BET
- Capable of creating three types of curves: internal standard curve, manual input curve and a measured curve
- Product endotoxin limit and MVD generation
- Allows trending of product results over time and early detection of potential product failures
- Generates hard copy printouts with all pertinent information for routine audits through three unique audit trails
- Creation of a standard workflow to be reviewed, confirmed and approved prior to operating
- Security functions to lock the application, disable an account and lock out the system
- Backup of the user management database and automatic backup of the system information database
- Improved precision and accuracy over the traditional gel clot method
- Ideal software for comparative testing and validating most LAL



Key Features

- Single assay module can simultaneously measure up to 16 samples
- Expansion modules are available (up to 8) to extend the number of samples in multiples of 16
- Single-test configuration avoids the “hot wells” phenomenon associated with microplate readers by evenly distributing the temperature in all single wells
- Reduces the chance of contamination due to the single-well formats
- Ideal for users who are converting from gel clot method to kinetic turbidimetric assays

TOXINOMETER® ET-7000 ENDOTOXIN MEASUREMENT SYSTEM

The Toxinometer® ET-7000 is a computer-operated kinetic incubating tube reader, designed to be exceptionally user-friendly. Our state-of-the-art expansion modules can be connected to allow for endotoxin testing in a wide range of fields and sample quantities.

The Toxinometer® ET-7000 can perform all LAL testing methodologies (gel clot, kinetic turbidimetric and kinetic chromogenic assays). The instrument has 16 wells for single-test configuration in order to easily detect erroneous readings or contamination associated with each well. The kinetic incubating tube reader has uniformity temperature settings of 30°C and 37°C.

TOXINOMETER® ET-7000 + 21 CFR PART 11 (ERES) COMPLIANT SET

Catalog Number	Model	Power Source	Contents
294-35871	Toxinometer® ET-7000/U Part 11 Set	100–120 ± 10% VAC (USA)	- 1 Toxinometer® ET-7000 - Toximaster® QC8 Software - 1 Personal Computer - System Validation Doc.
299-35821	Toxinometer® ET-7000/E Part 11 Set	220–240 ± 10% VAC (Europe)	

TOXINOMETER® ET-7000 ANALYSIS MODULES

Catalog Number	Model	Power Source	Contents
297-35861	Toxinometer® ET-7000/U Expansion Module	100–120 ± 10% VAC (USA)	16-well expansion unit
294-35811	Toxinometer® ET-7000/E Expansion Module	220–240 ± 10% VAC (Europe)	16-well expansion unit

BIOTEK ELX808 MICROPLATE READER

The BioTek ELx808 microplate reader provides the flexibility to manipulate and analyze your data. This multi-channel reader continues BioTek's tradition of offering the strictest specifications of any microplate reader that ensure both accurate and repeatable results. The ELx808 offers a superior 4-zone™ incubator, providing excellent stability for temperature-sensitive assays such as endotoxin analysis and long-term bacterial and yeast growth studies. FUJIFILM Wako now offers this highly reliable instrument with a convenient laptop and software package specifically dedicated to LAL testing.

Key Features

- 96-well configuration, ideal for high throughput of samples
- Superior 4-Zone™ incubation
- Fast kinetics, endpoint and linear well scanning
- Optical design eliminates crosstalk
- Extensive endotoxin analysis with Toximaster® QC8 software

BIOTEK ELX808 MICROPLATE READER

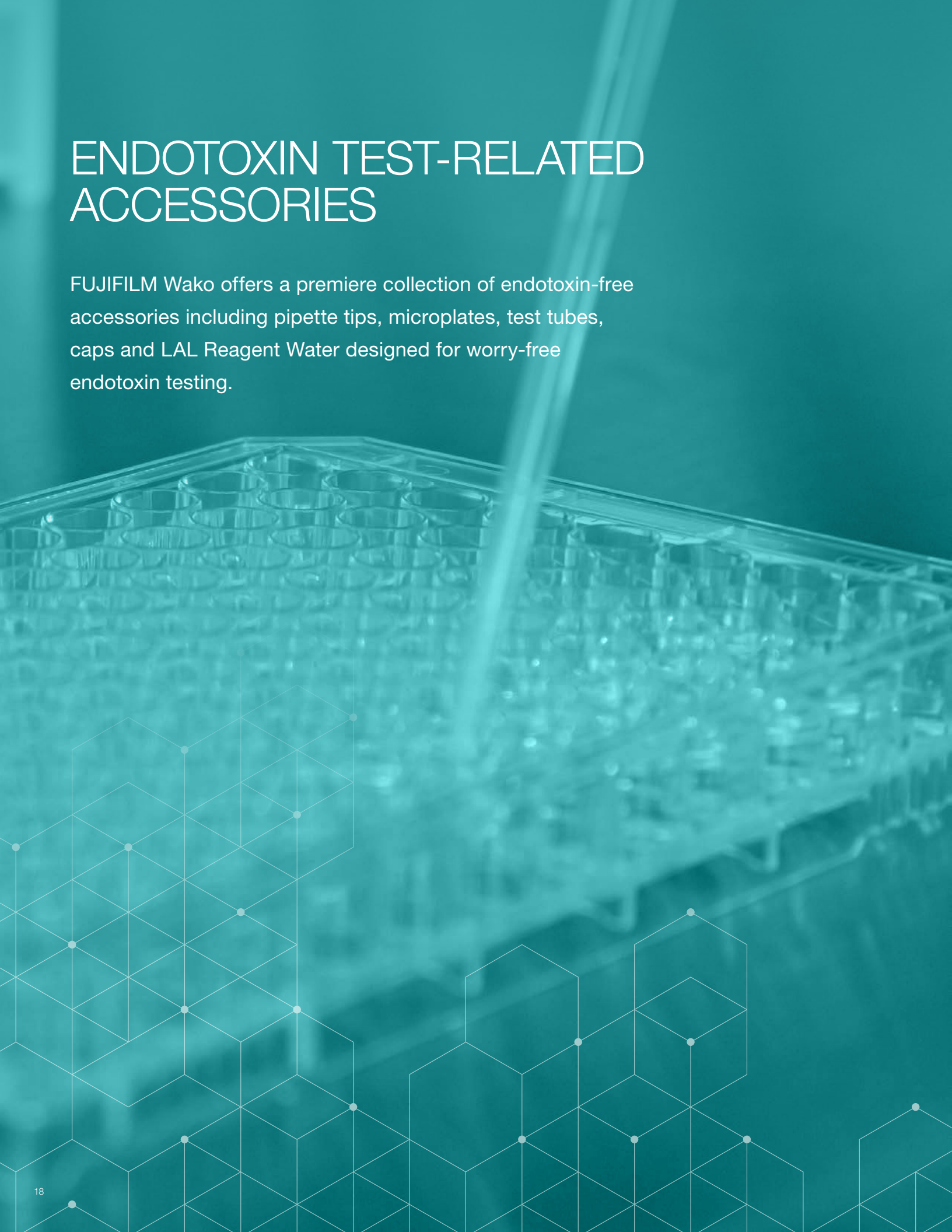
Catalog Number	Model	Contents
BIOT-808IU	ELx808	- 1 BioTek ELx808 unit

BIOTEK ELX808 MICROPLATE READER + 21 CFR PART 11 (ERES) COMPLIANT SET

Catalog Number	Model	Contents
BIOT-35931	ELx808	- 1 BioTek ELx808 unit - 1 Personal Computer - Toximaster® QC8 Software

ENDOTOXIN TEST-RELATED ACCESSORIES

FUJIFILM Wako offers a premiere collection of endotoxin-free accessories including pipette tips, microplates, test tubes, caps and LAL Reagent Water designed for worry-free endotoxin testing.



BIOCLEAN SERIES

BioClean Series pipette tips and microplates are endotoxin-free. These micropipette tips and microplates are individually wrapped to reduce the chance of contamination and are for all types of LAL testing. BioCleanTip Wako® are available in both 200 µL and 1000 µL volumes, with the 200 µL volume tips being offered in standard and extended sizes. The Extend S tips are used for aliquoting multi-test reagent into Gel Clot Reaction Tubes, Limulus Test Tube-S or BioCleanPlate Wako™. This pipette tip can deliver the reagent to the bottom of the tubes/wells without introducing contamination.

Catalog Number	Product Name	Volume Size	Quantity
291-35021	BioCleanTip Wako® 200 ll	200 µL/tip	100 tips
298-35031	BioCleanTip Wako® 1000 ll	1000 µL/tip	100 tips
294-35011	BioCleanTip Wako® Extend S	200 µL/tip	100 tips
293-35221	BioCleanPlate Wako™	96 wells/plate	50 plates

Key Features

- Endotoxin-free pipette tip (<0.005 EU/tip)
- Endotoxin-free 96-well microplate (<0.01 EU/plate)
- Individually packaged, ideal for use in clean rooms
- Packaging film features dust-free protection
- Pipette tips fit most micropipettes
- Plates are designed for use with microplate readers

LAL REAGENT WATER

LAL Reagent Water can be used to fulfill all aspects of endotoxin testing. From reconstitution of both the CSE and LAL for creation of standard curves to the making of product dilutions, LAL Reagent Water provides reliable and reproducible data when paired with our endotoxin-specific LAL reagents.

Catalog Number	Product Name	Quantity
LRW-12100	LAL Reagent Water, 100 mL	12 x 100 mL glass bottles
LRW-2030	LAL Reagent Water, 30 mL	20 x 30 mL glass bottles
LRW-12125	LAL Reagent Water, 125 mL	12 x 125 mL plastic bottles

Key Features

- Endotoxin-free water (<0.001 EU/mL)
- Steam-sterilized by USP standards
- Non-LAL reactive
- Great for reconstitution of LAL, RSE and CSE
- Used to perform dilution series of RSE and CSE
- Used for sample dilutions

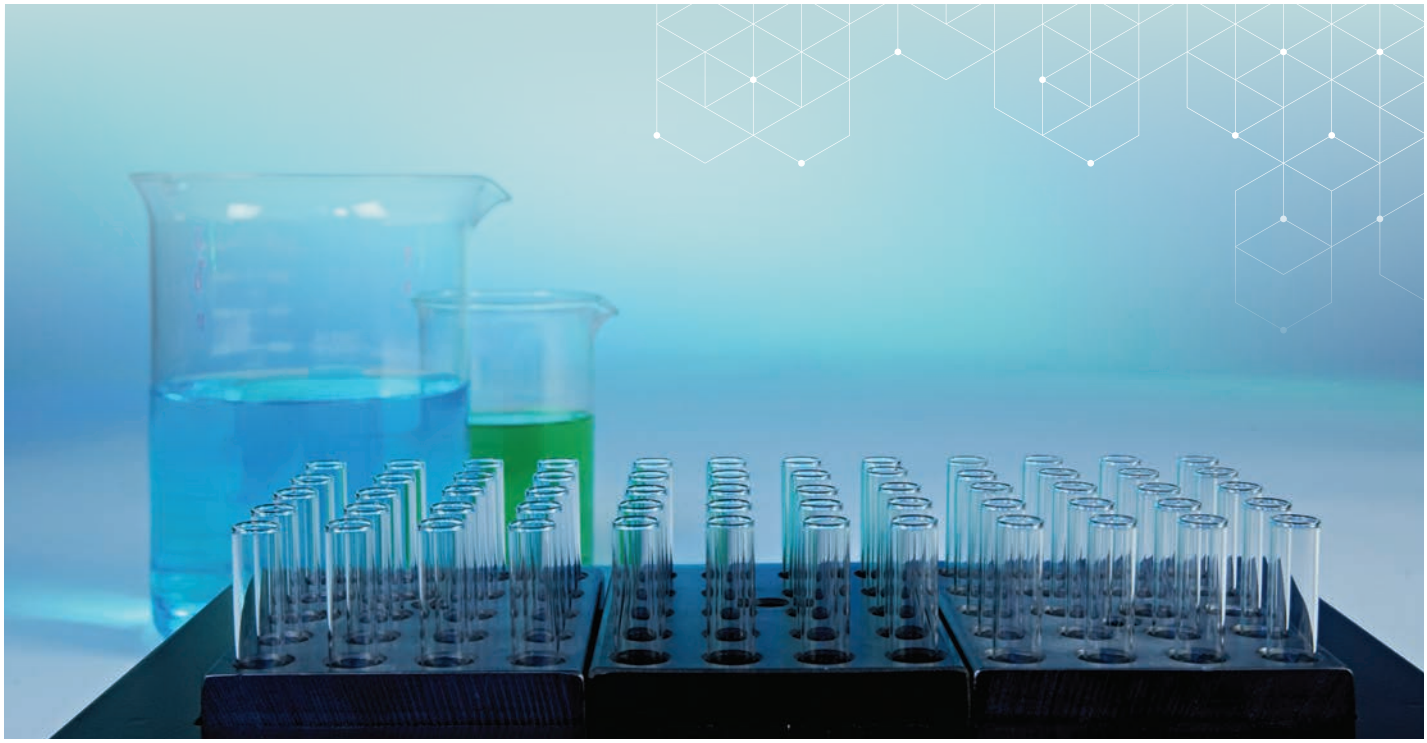
GEL CLOT REACTION TUBES

Our Gel Clot Reaction Tubes are made of high-quality borosilicate glass, depyrogenated at 250°C. This results in an endotoxin-free tube that is designed to perform successful LAL gel clot assays with heat blocks and water baths.

Key Features

- Endotoxin-free test tubes (<0.001 EU/tube)
- Endotoxin-free tubes depyrogenated at 250°C
- Made with borosilicate glass and designed for gel clot testing

Catalog Number	Product Name	Quantity
CT-1075	10 x 75 mm Borosilicate Test Tubes	200 tubes/pkg
CT-1075B	10 x 75 mm Borosilicate Test Tubes, Bulk	1250 tubes/pkg



LIMULUS TEST TUBE-S

Our specialized Limulus Test Tube-S are made of high-quality borosilicate glass depyrogenated at 250°C. These tubes have a special curvature that allows the appropriate amount of light to transmit through the sample to measure the endotoxin concentration based on the method used. This glass tube is designed for the Toxinometer® Measurement System.

Key Features

- Endotoxin-free test tubes (<0.001 EU/tube)
- Designed for gel clot, KTA and KCA testing on the Toxinometer®
- Made with borosilicate glass

Catalog Number	Product Name	Dimensions	Quantity
292-32751	Limulus Test Tube-S with Aluminum Cap	12 x 75 mm	80 caps/tubes
293-26551	Limulus Test Tube-S	12 x 75 mm	100 tubes

DEPYROGENATED DILUTION TUBES

Our Depyrogenated Dilution Tubes are made of high-quality borosilicate glass depyrogenated at 250°C. This results in endotoxin-free tubes that can perform successful LAL dilution series, from creating the standard curve to sample dilutions, with minimal chance of potential contamination.

Key Features

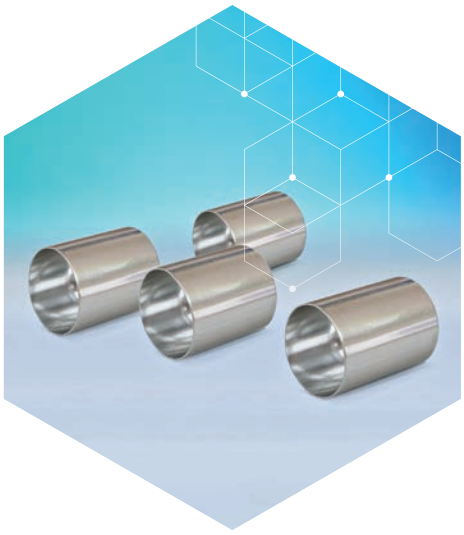
- Endotoxin-free test tubes (<0.001 EU/tube)
- Made with borosilicate glass

Catalog Number	Product Name	Quantity
DL-13100	13 x 100 mm Borosilicate Test Tubes	50 tubes

ALUMINUM CAP-S

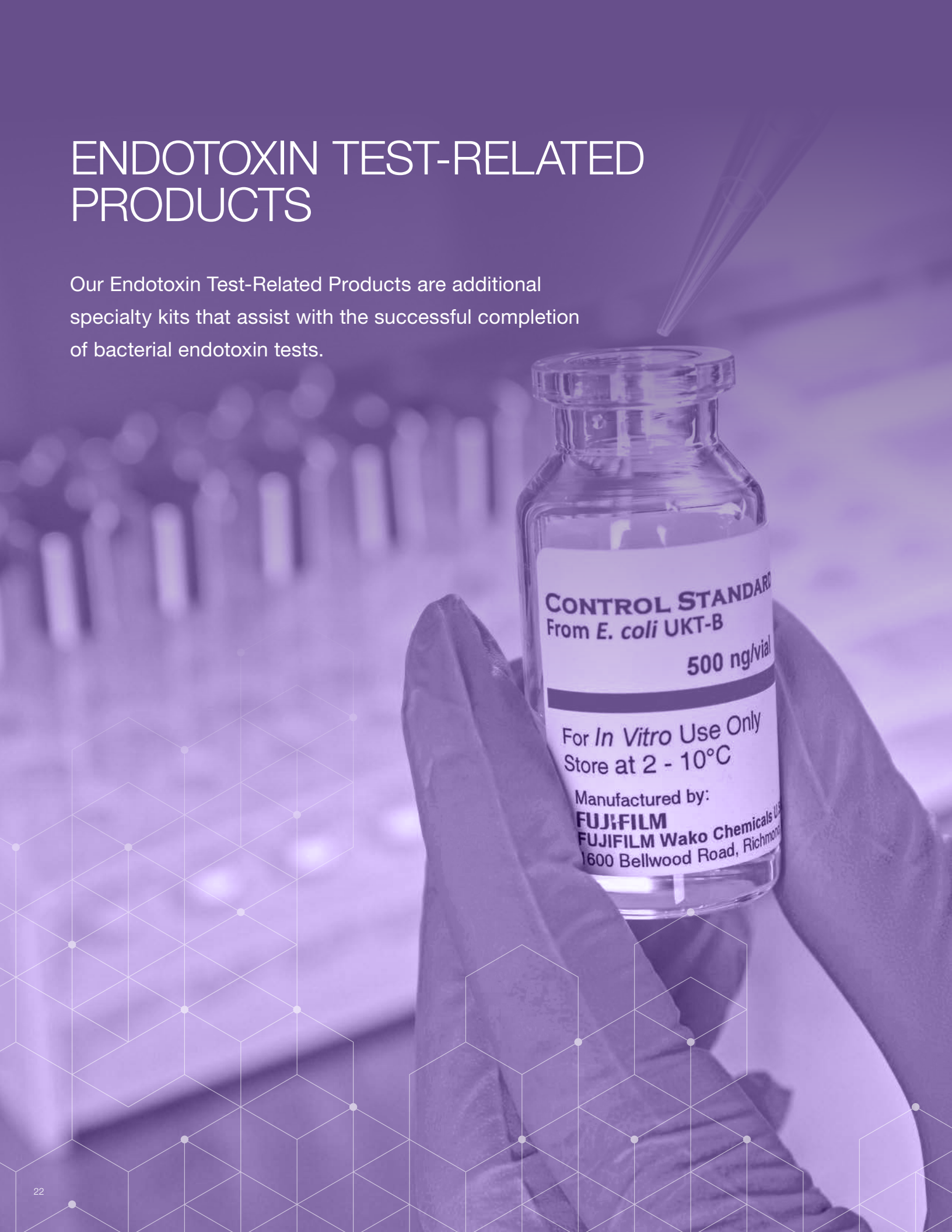
Our Aluminum Cap-S assist in reducing the chance of contamination, preventing any additional substances or material from entering the testing tubes.

Catalog Number	Product Name	Dimensions	Quantity
293-28251	Aluminum Cap-S	14.7 x 18 mm	100 caps/pkg



ENDOTOXIN TEST-RELATED PRODUCTS

Our Endotoxin Test-Related Products are additional specialty kits that assist with the successful completion of bacterial endotoxin tests.



CONTROL STANDARD ENDOTOXIN

Our Control Standard Endotoxin (CSE) is a lyophilized product composed of a 500 ng vial of endotoxin, purified from *E. coli* UKT-B strain that serves as an accurate and dependable standard for endotoxin testing.

Catalog Number	Contents
CSE4037-5006	6 vials (500 ng/vial)

Key Features

- Endotoxin derived from *E. coli* UKT-B
- Can be used to prepare controls and standard curves
- Potency of CSE supplied to match each lot of LAL
- Reconstituted CSE can be stored at 2°C–10°C for one month

ENDOTOXIN INDICATOR VIALS

The Endotoxin Indicator Vials are ready-to-use vials composed of *E. coli* O55:B5 (>1000 EU/vial) for performing depyrogenation validation studies to ensure that a process is effectively inactivating and/or destroying endotoxin. These vials may be tested using reagents from our PYROSTAR™ ES-F series.

Catalog Number	Contents
EIV-025	25 vials (>1000 EU/vial)

Key Features

- *E. coli* O55:B5 (>1000 EU/vial)
- Ready-to-use vials, no preparation needed
- Used for validation studies

LPS FOR ENDOTOXIN INDICATOR

The LPS for Endotoxin Indicator is composed of *E. coli* O55:B5 (>100,000 EU/vial) and serves as a stock solution to prepare multiple endotoxin indicators for depyrogenation validation studies. The prepared endotoxin indicators may be tested using reagents from our PYROSTAR™ ES-F series.

Catalog Number	Contents
WLPS-0100K	6 vials (>100,000 EU/vial)

Key Features

- *E. coli* O55:B5 (>100,000 EU/vial)
- Can make multiple endotoxin indicators from one vial
- Used for validation studies

ES BUFFER

The ES Buffer is an endotoxin-specific buffer that is ideal for untreated LAL. Though all LAL reagents produced by FUJIFILM Wako are endotoxin-specific, other commercially available LAL reagents are not. Without this buffer, tests can activate (1,3)-ß-D-glucan when trying to determine the endotoxin concentration in the sample.

Catalog Number	Contents
ESB-0006	6 vials x 5.2 mL

Key Features

- Each vial has solution for use in reconstituting a maximum of 5.2 mL of reagent
- Ideal for LAL that has the potential to react with glucans, thus making an endotoxin-specific reagent

ENDOTOXIN EXTRACTING SOLUTION

Traditionally, water or saline solution has been used to extract endotoxin in tests involving medical devices and equipment; however, the efficacy of this extraction method is debated. In order to provide our customers with a more reliable method, FUJIFILM Wako has developed a solution containing human serum albumin (HSA) that is capable of extracting endotoxins that cannot be extracted in water or saline solution.

Catalog Number	Contents
293-51601	4 vials x 10 mL

Key Features

- Capable of extracting endotoxins that are unable to be extracted in water or saline
- Recommended for use in endotoxin testing on equipment and devices that may come into contact with fluids containing blood or protein

THE EXPERTS BEHIND THE PRODUCTS

Our team at FUJIFILM Wako would like to thank you for your interest, and we look forward to working with you!

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