FUJIFILM
Value from Innovation

LAL REAGENT PRODUCTS

For the Detection of Bacterial Endotoxin

Wako

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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

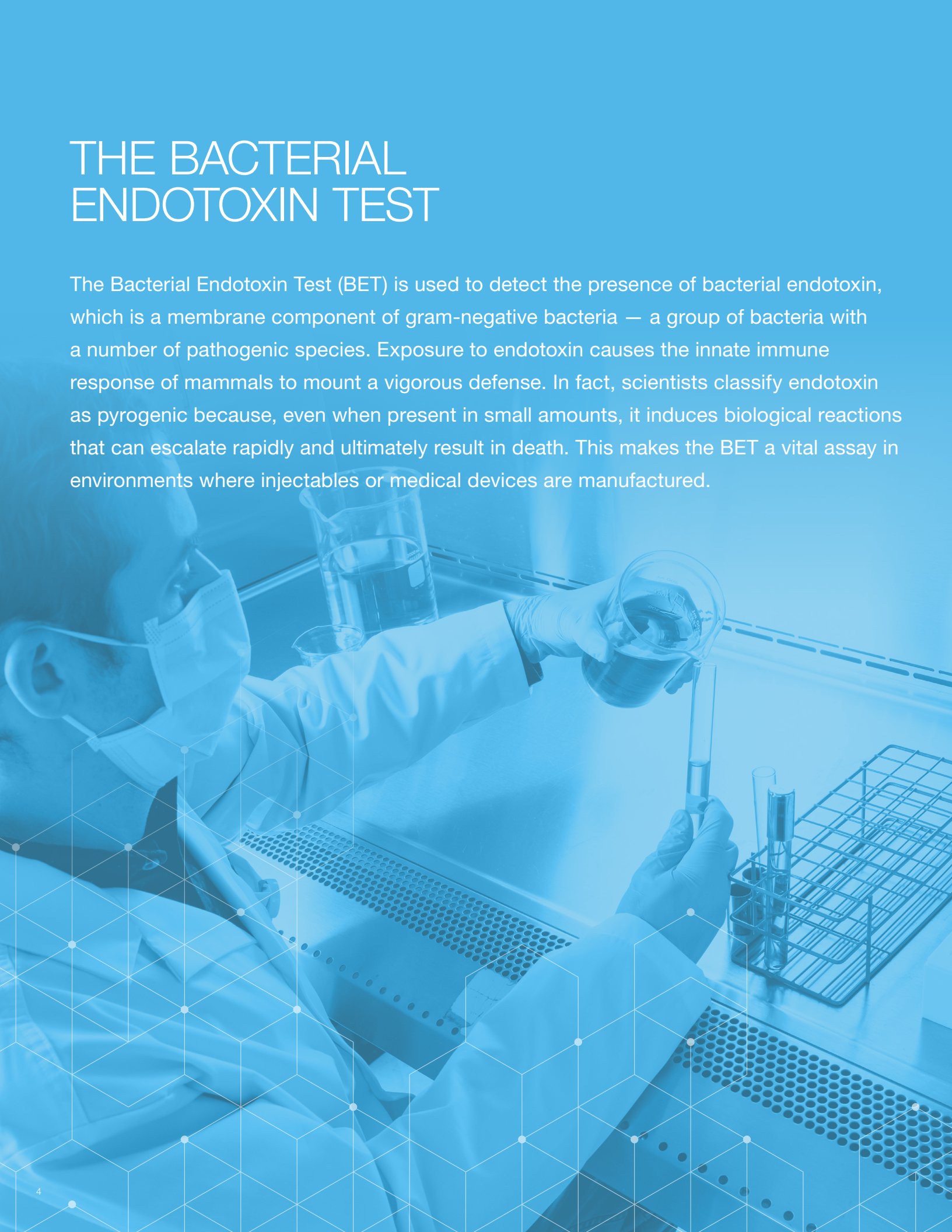
FUJIFILM Wako is committed to the sustainability of the Atlantic horseshoe crab *(Limulus polyphemus)* population. We voluntarily follow a set of best practices that involve careful handling and selection of healthy, viable animals. Our bleeding procedure is conducted with the utmost diligence to prevent 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.

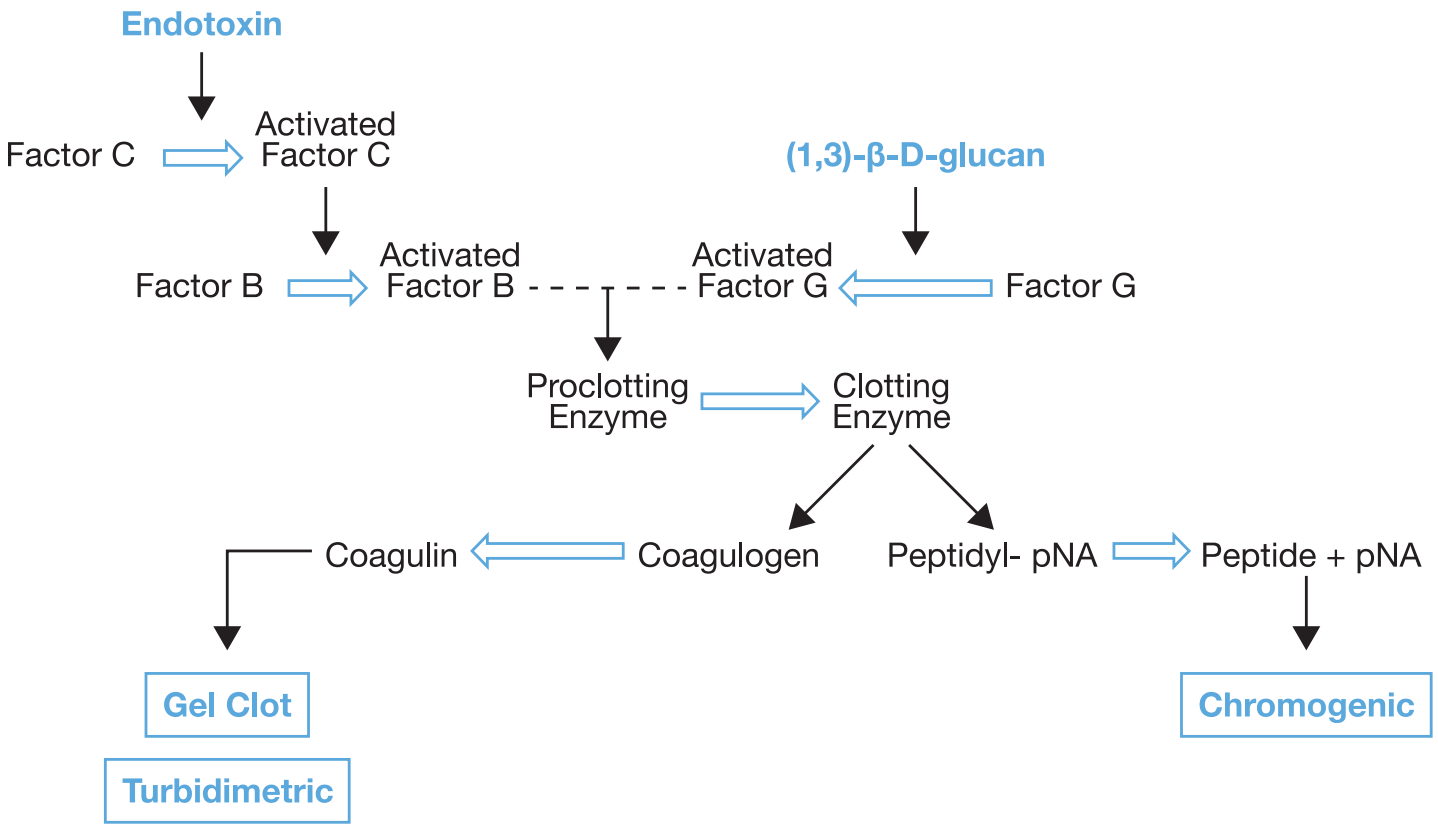
LAL BIOCHEMICAL CASCADE

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.

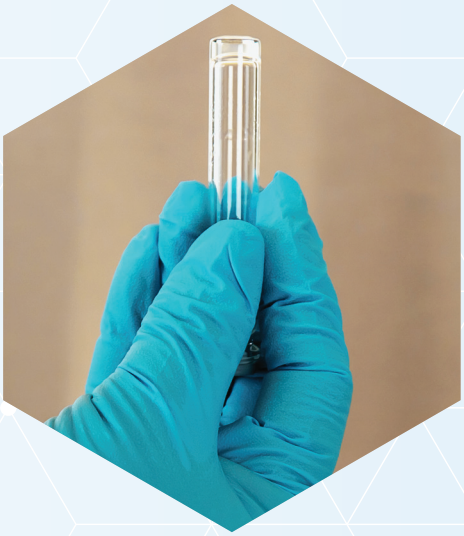
It should also be noted that LAL can yield a biochemical process in the presence of (1,3)-ß-D-glucan by way of an additional factor (Factor G). Because of this, most LAL reagents require buffers to block the (1,3)-ß-D-glucan from detection in order to determine the true concentration of endotoxin.



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.

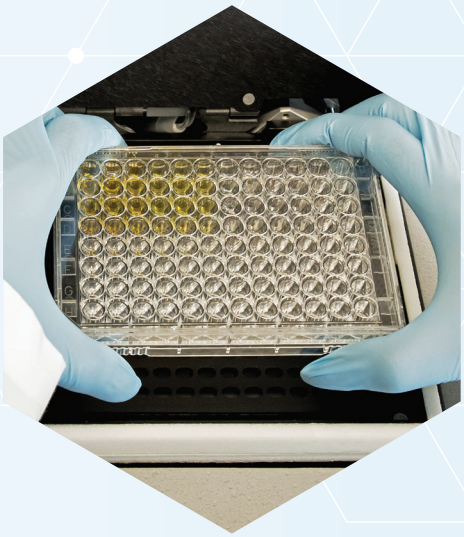


TURBIDIMETRIC

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.



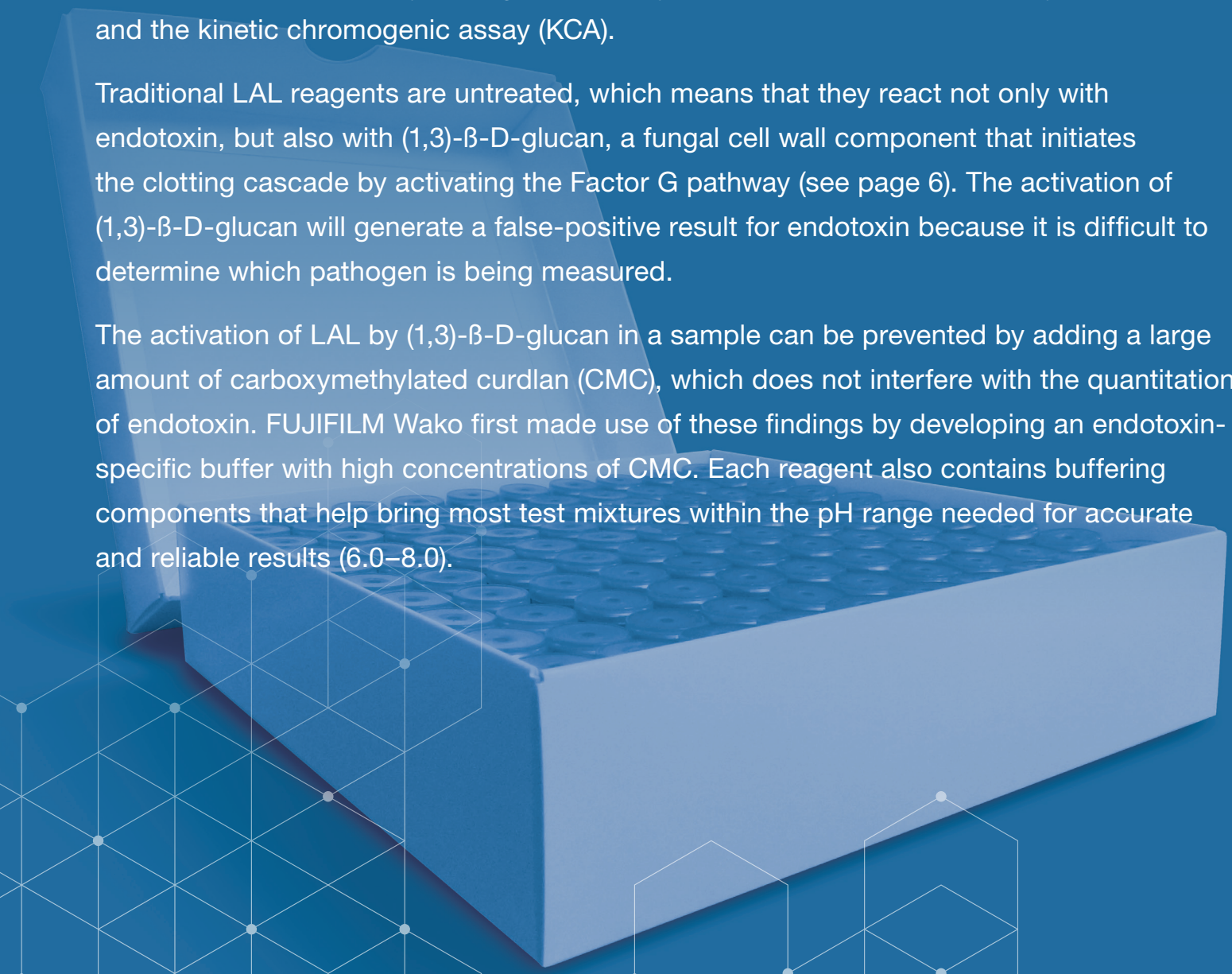
It is crucial that the user has the necessary endotoxin-free accessories to obtain reliable, reproducible and accurate results during LAL testing. Water-for-injection (WFI) or LAL Reagent Water is ideal for endotoxin testing. Reference Standard Endotoxin (RSE) should be used as a standard when testing 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 quantitative 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

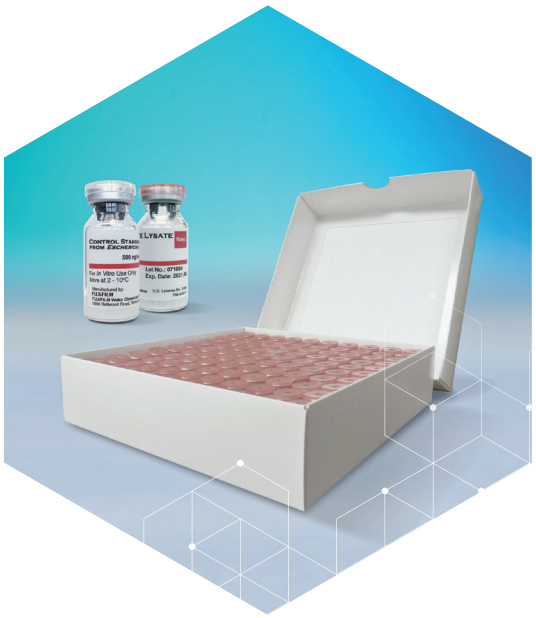
This multi-test vial is designed to be used with a water bath, heat block or the Toxinometer®. With this configuration, the user dispenses 0.1 mL of dissolved LAL reagent into the appropriate reaction tube, then adds 0.1 mL of the sample. This multi-test vial is ideal for a user testing a larger number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

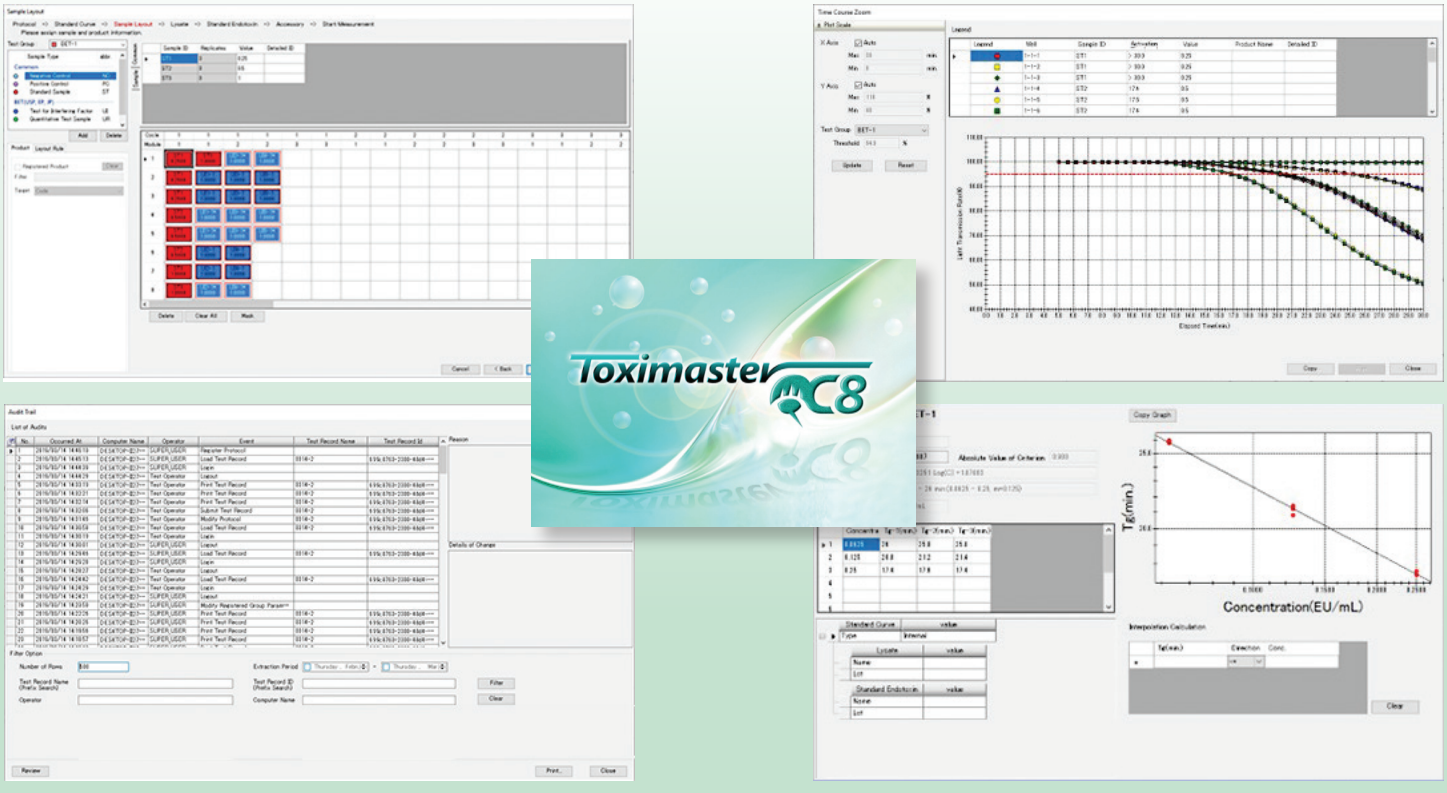
Catalog Number	Model	Contents
297-35981	Part 11 software PC set	Toximaster® QC8 Software with 1 Personal Computer
293-35961	Part 11 software only	Toximaster® QC8 Software

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

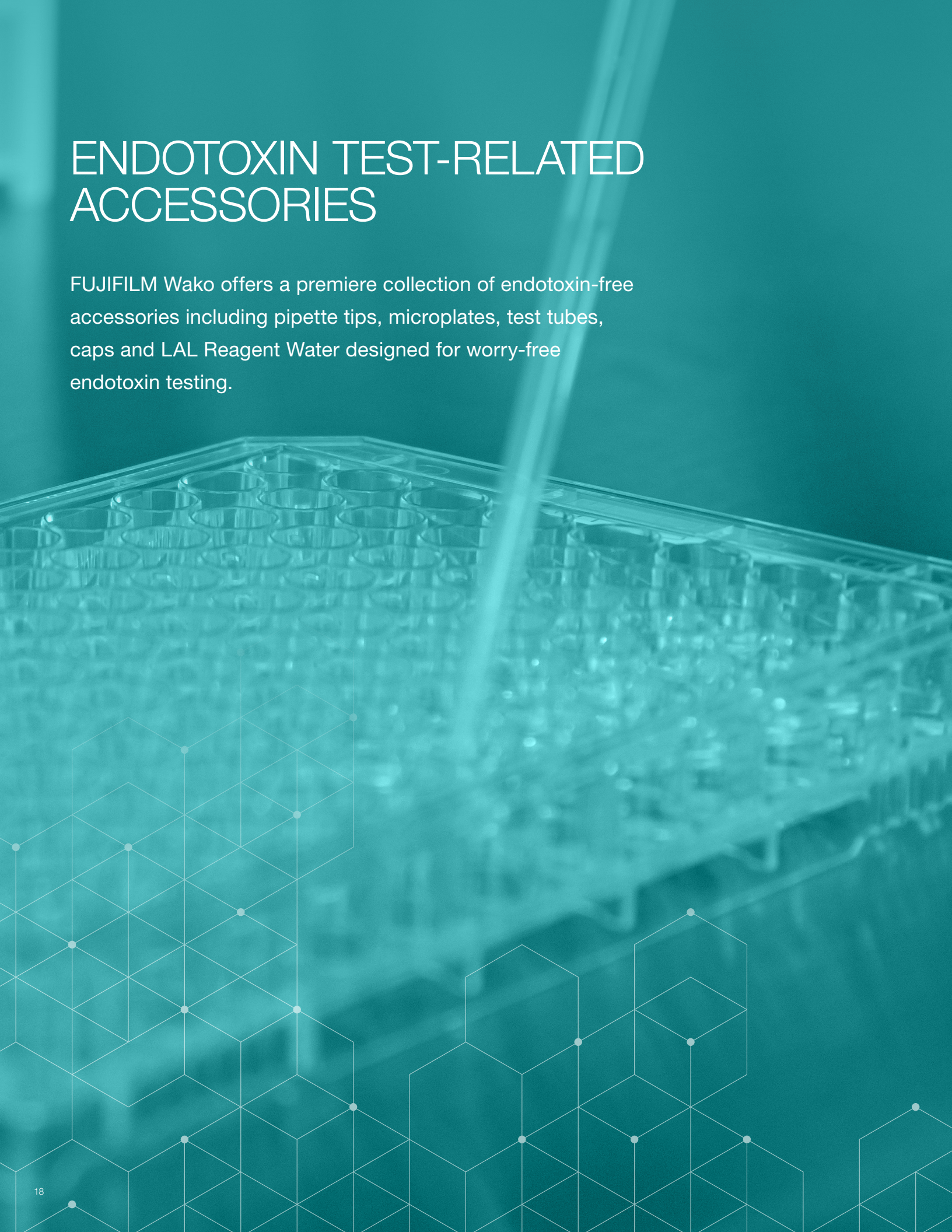
Catalog Number	Model	Contents
BIOT-808IU	ELx808	- 1 BioTek ELx808 unit

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.

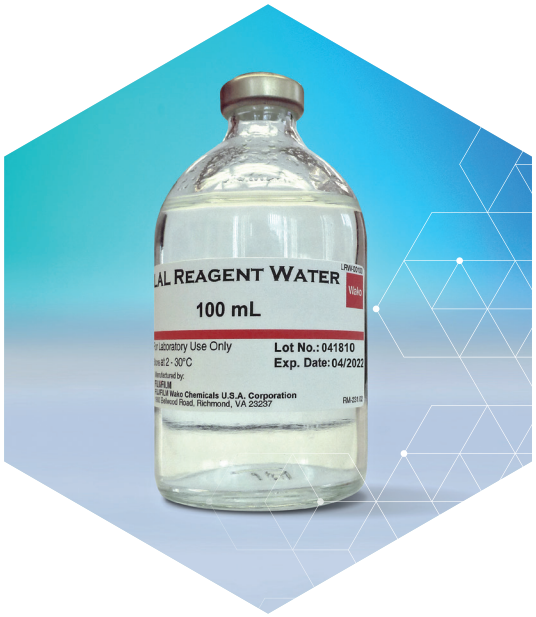
Catalog Number	Product Name	Volume Size	Quantity
291-35021	BioCleanTip Wako® 200 ll	200 µL/tip	100 tips
298-35031	BioCleanTip Wako® 1000 ll	1000 µL/tip	100 tips
294-35011	BioCleanTip Wako® Extend S	200 µL/tip	100 tips
293-35221	BioCleanPlate Wako™	96 wells/plate	50 plates

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

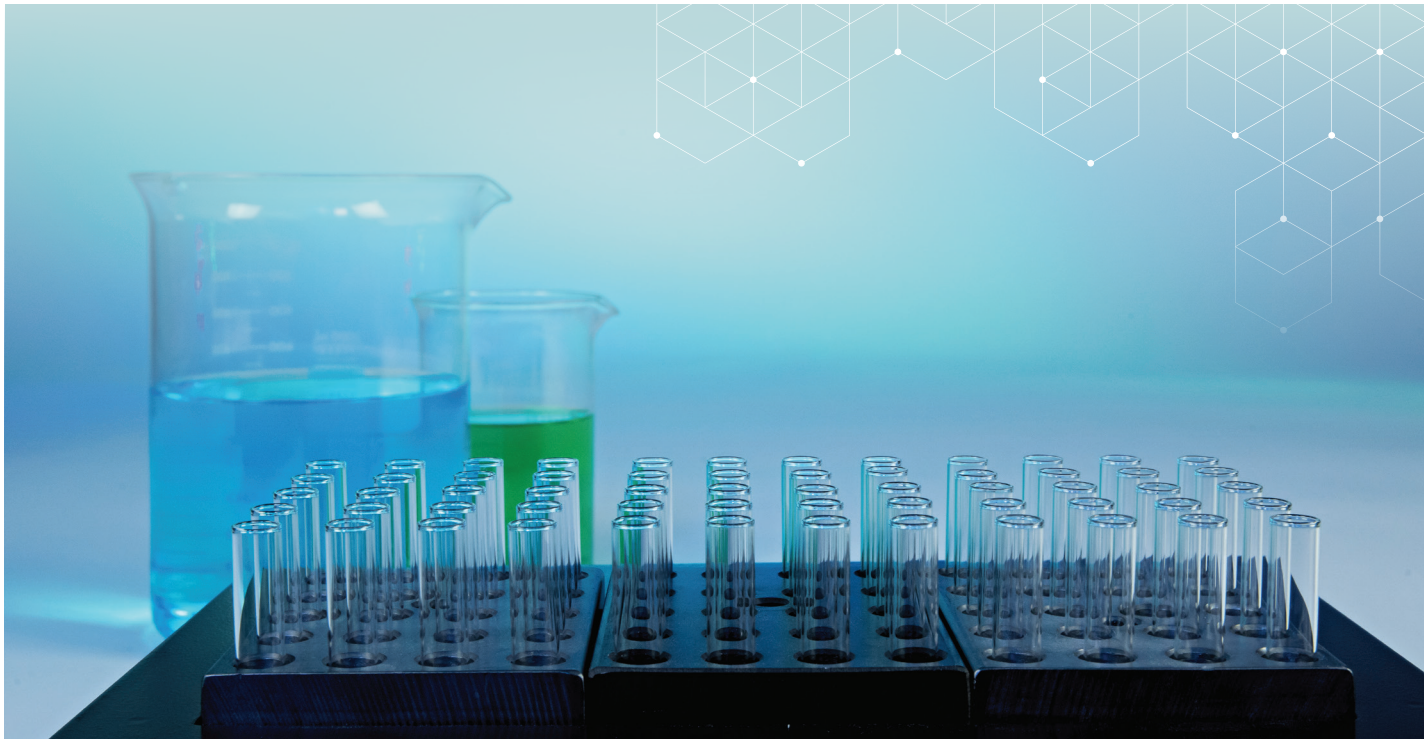
GEL CLOT REACTION TUBES

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

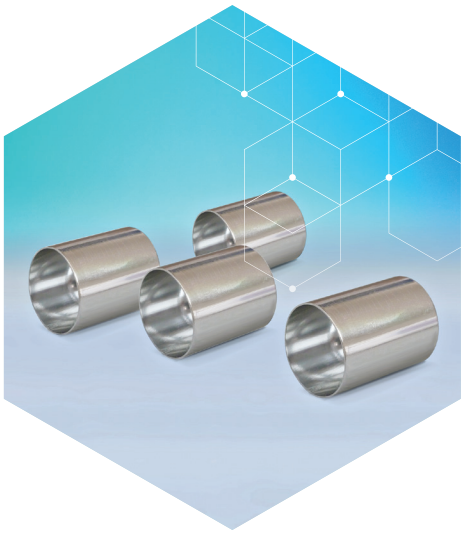
- Endotoxin-free test tubes (<0.001 EU/tube)
- Made with borosilicate glass

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

ALUMINUM CAP-S

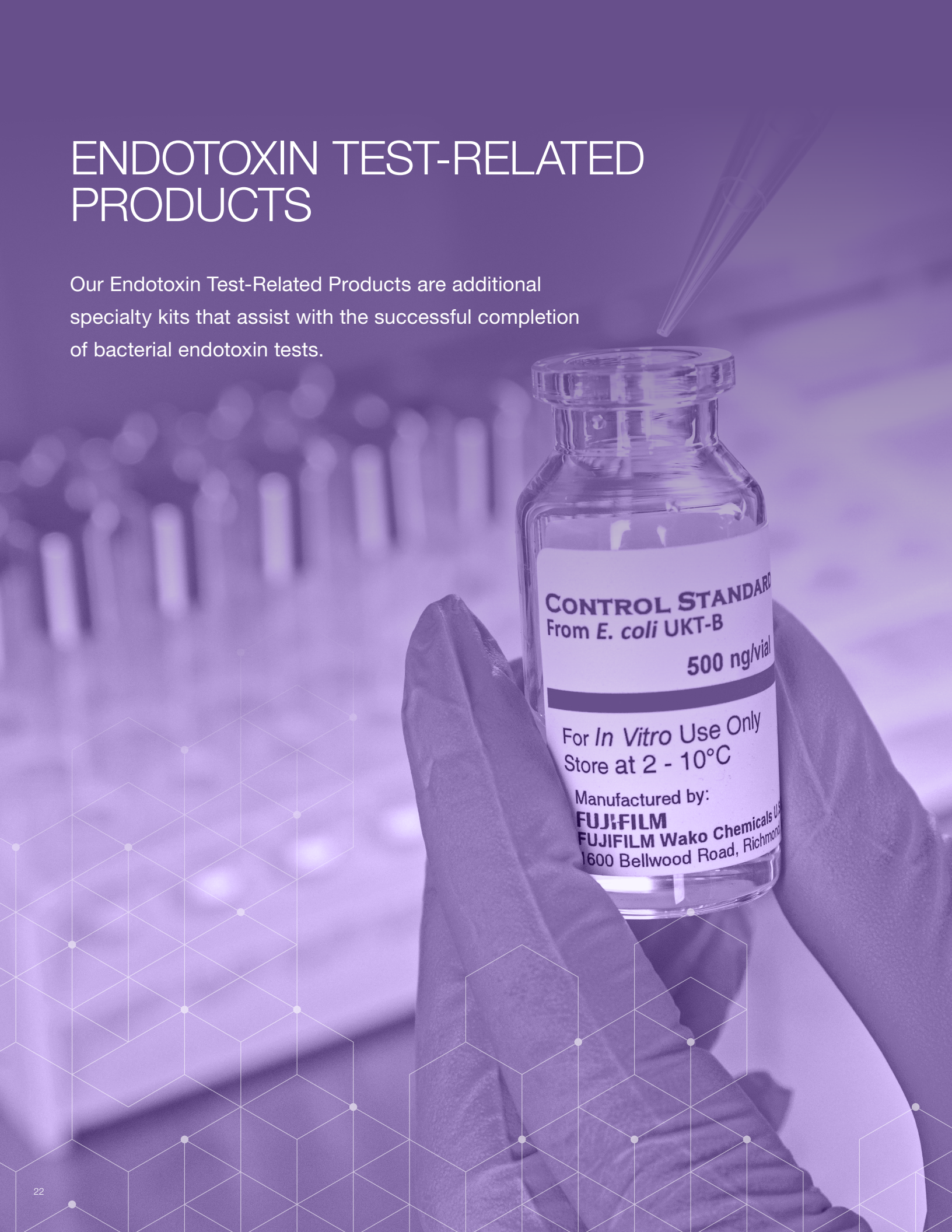
Our Aluminum Cap-S assist in reducing the chance of contamination, preventing any additional substances or material from entering the testing tubes.

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 6 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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