

# LAL REAGENT PRODUCTS

For the Detection of Bacterial Endotoxin



# TABLE OF CONTENTS

## 03 FUJIFILM WAKO CHEMICALS U.S.A. CORPORATION

## 04 THE BACTERIAL ENDOTOXIN TEST

- 05 UNDERSTANDING BACTERIAL  
ENDOTOXIN TESTING
- 06 LAL BIOCHEMICAL CASCADE
- 07 LAL TECHNIQUES

## 08 ENDOTOXIN-SPECIFIC LAL REAGENTS

- 09 PYROSTAR™ ES-F SERIES
- 12 LIMULUS COLOR KY SERIES
- 13 LIMULUS PS SINGLE TEST

## 14 ENDOTOXIN ANALYSIS SYSTEMS

- 15 TOXIMASTER® QC8
- 16 TOXINOMETER® ET-7000
- 17 BIOTEK ELX808

## 18 ENDOTOXIN TEST-RELATED ACCESSORIES

- 19 BIOCLEAR SERIES
- 19 LAL REAGENT WATER
- 20 GEL CLOT REACTION TUBES
- 20 LIMULUS TEST TUBE-S
- 21 DEPYROGENATED DILUTION  
TUBES
- 21 ALUMINUM CAP-S

## 22 ENDOTOXIN TEST-RELATED PRODUCTS

- 23 CONTROL STANDARD  
ENDOTOXIN
- 23 ENDOTOXIN INDICATOR VIALS
- 23 LPS FOR ENDOTOXIN INDICATOR
- 24 ES BUFFER
- 24 ENDOTOXIN EXTRACTING  
SOLUTION

## 25 THE EXPERTS BEHIND THE PRODUCTS

## 26 FUJIFILM WAKO LAL DISTRIBUTORS



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 ameocyte lysate (LAL) test — from its reliance on ameocytes 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 ameocyte 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.

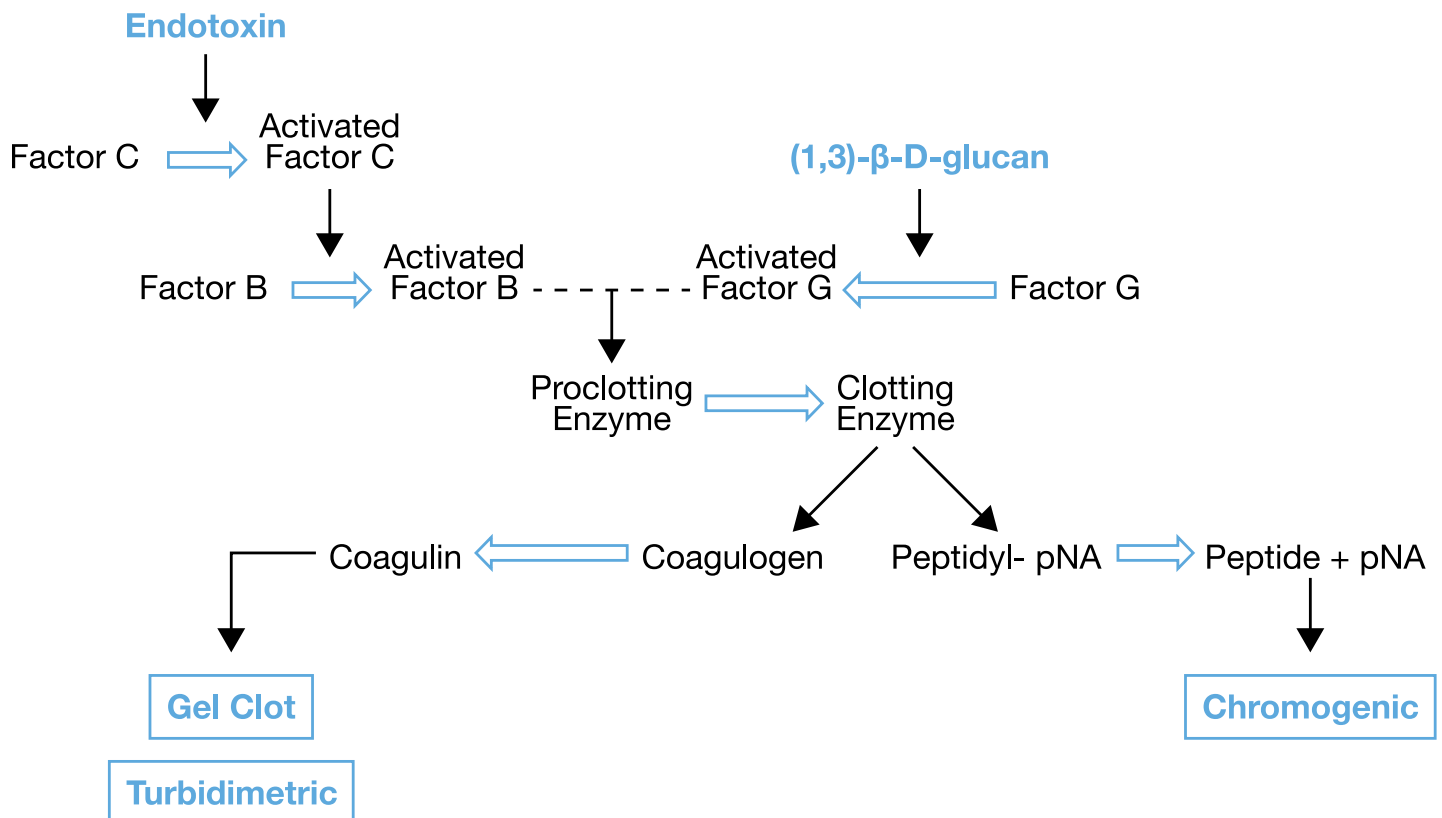
As shown below, the endotoxin interaction initiates the first serine protease precursor (Factor C) from its inactivated form; this in turn activates the second serine protease precursor (Factor B). The activated Factor B stimulates the clotting enzyme, converting it from a proclotting enzyme. The clotting

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)- $\beta$ -D-glucan by way of an additional factor (Factor G). Because of this, most LAL reagents require buffers to block the (1,3)- $\beta$ -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  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  for  $60 \pm 2$  minutes using a water bath, heat block or tube reader. After the incubation time has elapsed, the tube is removed and slowly inverted  $180^{\circ}$  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.



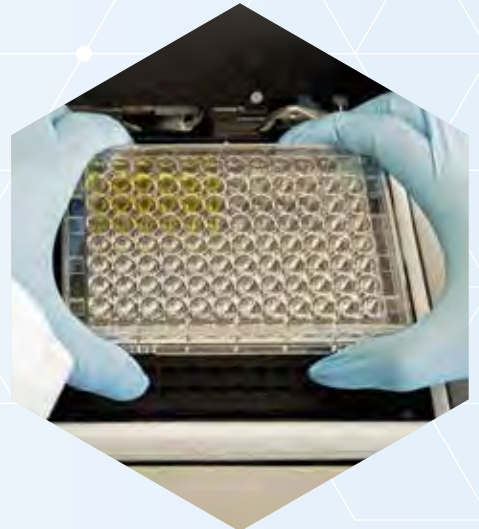
## TURBIDIMETRIC

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  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  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  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  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)- $\beta$ -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)- $\beta$ -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)- $\beta$ -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)-β-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)- $\beta$ -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	<ul style="list-style-type: none"> <li>- 20 LAL ES single-test vials</li> <li>- PyroSep™ resin suspension</li> <li>- LAL reconstitution solution</li> <li>- Wash solution</li> <li>- Sample diluent</li> <li>- 20 glass capillary columns</li> </ul>

## PS ACCESSORY KIT (OPTIONAL)

Catalog Number	Contents
294-33311	<ul style="list-style-type: none"> <li>- 12 syringes (20 mL)</li> <li>- 12 T-shape stopcocks R Type</li> <li>- 20 Dedicated adapters</li> <li>- 12 Bulldog clips</li> <li>- 25 Polystyrene tubes (5 mL)</li> <li>- 25 Polystyrene tubes (14 mL)</li> <li>- Test tube rack</li> </ul>

## 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

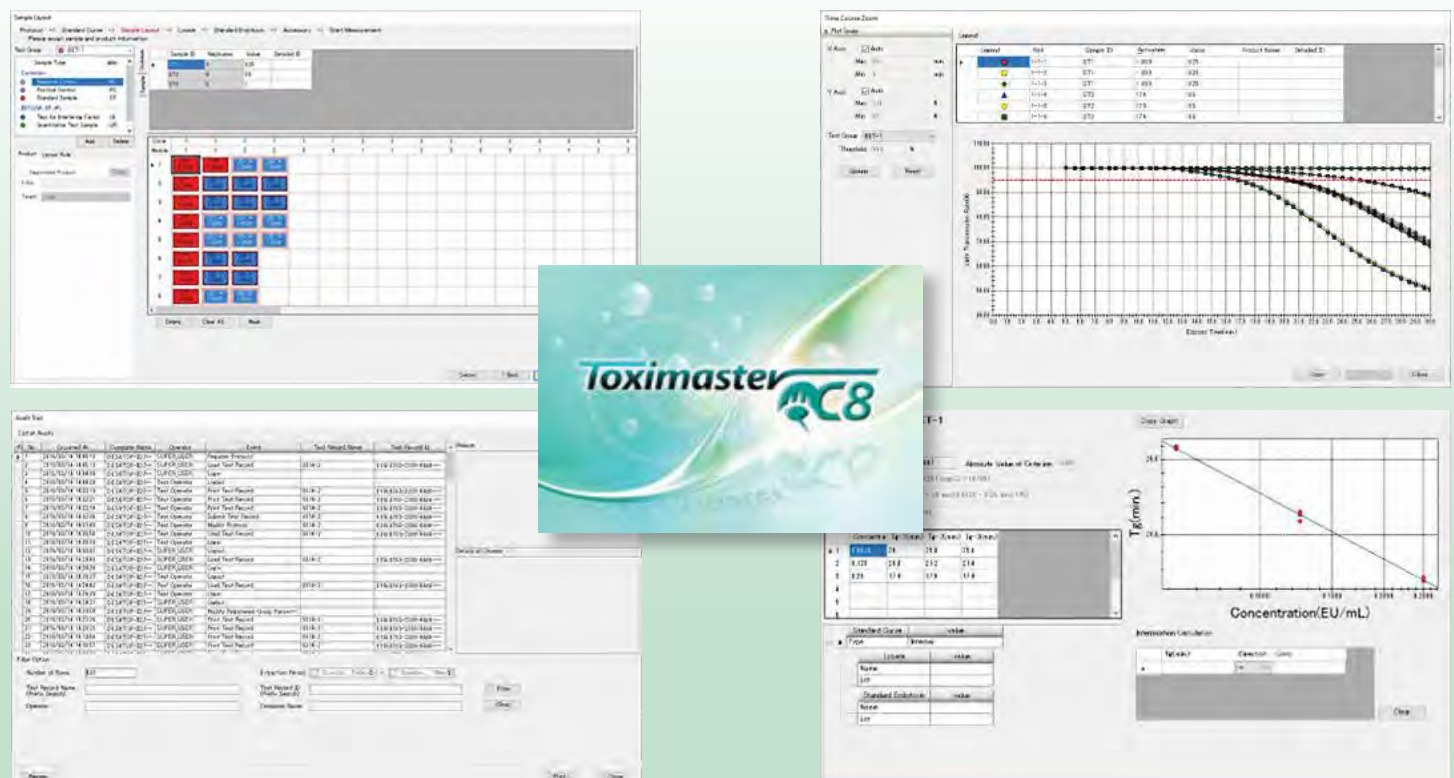
Catalog Number	Model	Contents
297-35981	Part 11 software PC set	Toximaster® QC8 Software with 1 Personal Computer
293-35961	Part 11 software only	Toximaster® QC8 Software

### 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
299-35821	Toxinometer® ET-7000/E Part 11 Set	220–240 ± 10% VAC (Europe)	- System Validation Doc.

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 II	200 µL/tip	100 tips
298-35031	BioCleanTip Wako® 1000 II	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

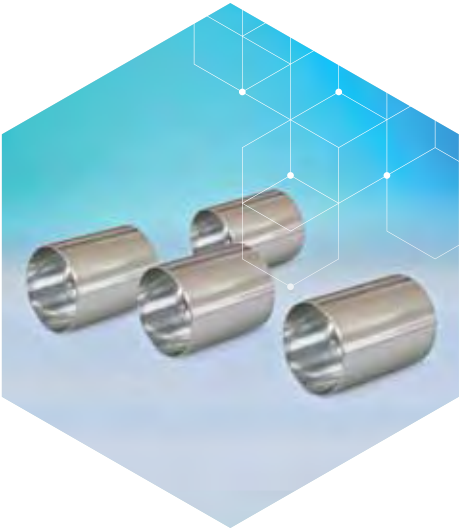
Catalog Number	Product Name	Quantity
DL-13100	13 x 100 mm Borosilicate Test Tubes	50 tubes



## 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)- $\beta$ -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!



# FUJIFILM WAKO LAL DISTRIBUTORS

## CONTACT OUR DISTRIBUTORS

Looking for a distributor in your region?

Please see our list of distributors around the globe:

### ARGENTINA

#### Endolab S.A.

Emilio Lamarca 381/397  
Buenos Aires, Argentina

Contact: Osvaldo Fernandez Poblet  
Phone: +54 011 4733 4047  
+54 011 4792 7820

Email: ventas@endolabsa.com.ar  
Website: www.endolabsa.com.ar

#### 2MS S.R.L.

Llerena 3192  
CABA  
CP 1427.  
Argentina

Contact: Dr. Marcelo Madeo  
Phone: +5491145247878/7979  
Email: 2ms@2ms.com.ar  
Website: www.2ms.com.ar

### BANGLADESH

#### Bioaid

1/B/1 (Flat A1) Road#01,  
Shyamoli, Dhaka-1207, Bangladesh

Contact: Md. Abdul Latif  
Phone: +880 29134673  
Email: bioaidbd@gmail.com

#### M/S RIFA Enterprise

51 North Goran, Dhaka-1219  
Bangladesh

Contact: AKM Faizur Rahman  
Phone: +880 1911 367920  
+880 2 934250  
Email: faizur7@dhaka.net

### BELARUS AND RUSSIA

#### DP Unilab

220094 Minsk, Gorovtse str.24, Apartment 3,  
Office 4  
Republic of Belarus

Contact: Eugene Kostoglod  
Phone: +375 29 395 25 90  
Fax: +375 17 319 57 91  
Email: info@unilab.by  
Website: www.unilab.by  
www.dpunilab.by

### CAMBODIA

#### Khema Scientific Co., Ltd.

01E0E1, Street 2005, Phum Dei Thmei, Sangkat  
Kok Khleang  
Khan Sen Sok, Phnom Penh, Cambodia 12101

Contact: Mr. San Sokhem  
Phone: +855 97 3035378  
Email: info@khemasci.com  
khemasci@hotmail.com

### COLOMBIA

#### Water Treatment Systems S.A.S.

Avenida Calle 24 # 51-40 Oficina 508  
Centro Empresarial Capital Towers Colombia

Contact: Jose Luis Pinzon  
Phone: +571 2574301, +571 312 3191024  
Email: gerenciawts1@gmail.com  
Website: www.wts.com.co

#### ADN Internacional

Carrera 58 #127-59 of 378  
Colombia

Contact: Sandra Cortes  
Phone: +571 9261278  
Email: gerencia@adninternacional.co  
Website: www.adninternacional.co

### COSTA RICA

#### Makol OCR S.A.

Heredia, Costa Rica

Contact: Angela Rauff  
Phone: +506 22939694  
Fax: +506 22930562  
Email: angelar@makolcr.com  
Website: www.makolcr.com

### EGYPT

#### Femto Trade Co.

25 Ibn Battota Street, Madcor Station  
Giza, 12111, Egypt

Contact: Dr. Essam Abdallah  
Phone: +20 1005126629  
Fax: +20 233928424  
Email: sales@femtotrade.com  
essamfemto@yahoo.com  
Website: www.femtotrade.com

### ETHIOPIA

#### Binocular Trading

Bole Sub City, Woreda 5, Mulugeta Zeleke,  
Building 108  
Addis Ababa, Ethiopia

Contact: Zenaw Workneh  
Phone: +251 911 733801  
Email: zenaww@gmail.com

### EUROPE

#### FUJIFILM Wako Chemicals Europe GmbH

Fuggerstr. 12, 41468 Neuss, Germany

Contact: Dr. Elisa-Charlotte Schoeneweiss  
Phone: +49 2131 311 101  
Fax: +49 2131 311 110  
Email: labchem\_wkeu@fujifilm.com  
Website: https://labchem-wako.fujifilm.com/europe/index.html

### INDIA

#### BioSolutions

102, Ashok Heights, Dr. S. Radhakrishnan Marg  
Andheri (East), Mumbai-400069, India

Contact: Mr. Prakash Bapodara  
Phone: +91 9819973583  
Email: mail@biosolutions.co.in  
biosolutions@rediffmail.com

#### Biomatiq Quality Solutions

Plot No.1386, Apuroopa Township, Pragathi Nagar  
Medchal District, Hyderabad, India 500090

Contact: Omkaranath  
Phone: +91 40 48554486  
+91 9121010201  
Email: omkar@biomatiq.com  
Website: www.biomatiq.com

### ISRAEL

#### Biotech Medical Supplies Ltd.

Issaq St, Misk Bldg, Ramallah  
West Bank, Palestine

Contact: Ayyad O. Rabi  
Phone: +972 2 2976265  
Fax: +972 2 2959414  
Email: info@biotech.ps  
Website: www.biotech.ps

### IVORY COAST, GHANA, TOGO, AND BENIN

#### African Bio-expertise Services-CI Ltd

Cocody Angre Djibi, Boulevard 8e Tranche  
28 B.P. 1080, Abidjan 28, Abidjan - Côte d'Ivoire

Contact: Stephane Damien  
Phone: +225 22 42 89 02, +225 78 69 42 26  
Email: stephane\_damien@abs-ai.com  
Website: www.abs-ai.com

### JORDAN

#### Safe Way Medical Supply

Al-Bayader, Hosni Sober Street, Randa Complex 72  
Amman, Jordan

Contact: Hamzeh Salameh  
Phone: +962 6 5811 704  
+962 797868687  
Fax: +962 6 5811 704  
Email: H.Salameh@sway-jo.com  
info@sway-jo.com

### LATVIA, LITHUANIA, AND ESTONIA

#### SIA GenMedica Baltic

Miera Street 43-3, Riga, LV-1001, Latvia

Contact: Agnese Priedite  
Phone: +371 66119593  
Fax: +371 66119594  
Email: info@genmedica.eu  
agnese.priedite@genmedica.eu  
Website: www.genmedica.eu

## MACEDONIA, KOSOVO, ALBANIA

### **Biotek DOO**

Zagrebska 28V 1000 Skopje  
Macedonia

Contact: Milena Stojanova, Aleksandra Kasapovska  
Phone: +389 02 3110106  
Fax: +389 02 3220154  
Email: mstojanova@biotek.com.mk  
sales@biotek.com.mk  
Website: www.biotek.com.mk

## MEXICO

### **Bioprocesos Farmaceuticos Integral S.A. de C.V.**

Cerro del Obispo 231 Lomas de Valle Dorado  
Tlalnepantla de Baz, 54023, Mexico

Contact: IBQ Karla Gimena Velazquez Cansino,  
Technical  
IBI Luis Alberto Valderrama Lopez, Sales  
Phone: +52 01 55 15091624  
+52 01 55 50128130  
+52 15580967253 (Mobile)  
Email: gerencia\_soporte@bpfinintegral.com  
gerencia\_comercial@bpfinintegral.com  
Website: www.bpfinintegral.com

## MOROCCO

### **MAST COMM**

2 rue Chenguiti, Et 4 N° 6,  
Belvedere, Casablanca, 20310, Morocco

Contact: Aziz Agouzzi  
Phone: +212 522 249 755/766  
Fax: +212 522 249 924  
Email: mastcomm1@gmail.com

## NEPAL

### **Rajshree Scientific Suppliers Pvt. Ltd.**

University Marga, Near Nabil Bank  
In Front of Krishi Samagri Snasthan  
Kuleshwar, Kathmandu, Nepal  
Contact: Shankar Mainali  
Phone: +977 1 4272428  
+977 9851195572  
Email: rajshreesm@yahoo.com

## PAKISTAN

### **Sind Trading Company**

3/14 Arkay Square, Shahrah-e-Liaquat,  
Karachi, 74000, Pakistan

Contact: Shujat Mohsin  
Phone: +92 300 8240578  
+92 2132410550  
Email: shujatmohsin@gmail.com  
sind\_trading\_co@yahoo.com

### **S.S. Scientific System**

Barkati Manzil No. 6 Office No. 2 S.R 7/37  
Campbell Street  
Off Ma Jinnah Road, Beside Sindh Bank, Karachi  
Contact: Sheikh M Ashhad Vohra  
Phone: +92 21 32634258  
Fax: +92 21 32634427  
Email: info@ssscientificsystem.com  
ssystem4u@yahoo.com  
Website: www.ssscientificsystem.com

## PARAGUAY, ECUADOR, AND BOLIVIA

### **Doma International LLC**

5717 NW 125 Ave., Coral Springs  
Florida, 33076 United States of America

Contact: Marcelo Madeo  
Phone: +54 91156476820  
Email: info@domainternationalllc.com  
Website: www.domainternationalllc.com

## RUSSIA

### **B/B Medical LLC**

14 Shukhova str.  
Moscow, 115162, Russia

Contact: German Yakovenko  
Phone: +7 4955443902  
Email: sales@bbmed.ru  
Website: www.bbmed.ru

## RUSSIA, KAZAKHSTAN, UZBEKISTAN

### **Algimed**

Russian Federation, Moscow  
Barklaya Street 6, Building 5, Office 622

Contact: Anna Tutnova  
Phone: +7 499 682 6109 - Russia  
+7 (700) 613 13 07 - Kazakhstan  
+7 7172 790771 - Kazakhstan  
+998 71 256 95 02 - Uzbekistan  
Email: a.tutnova@algimed.ru  
Website: www.algimed.ru  
www.algimed.kz, www.algimed.uz

## SAUDI ARABIA

### **Fuad Abduljalil Alfadhli and Sons Trading Company**

Prince Mashur Ibn Abdulaziz Street  
Mursalat, Riyadh, Saudi Arabia

Contact: Mohamed Hussin  
Phone: +966 920 002 306  
Fax: +966 920 002 406  
Email: info@fuadalfadhli.com  
mhussin@fuadalfadhli.com  
Website: www.fuadalfadhli.com

## SE ASIA

### **FUJIFILM Wako Pure Chemical Corporation**

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

Phone: +81 6 6203 3741  
Fax: +81 6 6201 5964  
Email: ffwk-cservice@fujifilm.com  
Website: https://labchem-wako.fujifilm.com/asia

## SPAIN

### **FONTLAB 2000, S.L.**

P.I. Can Magre, C/ Carles Buigues, 76  
08187 – Santa Eulalia de Ronçana  
Barcelona, Spain

Contact: Pelayo Fontsaré  
Phone: +34 93 844 60 42  
Email: info@fontlab2000.com  
website: www.fontlab2000.com

## TANZANIA

### **Total Med Lab Solutions Ltd.**

P.O. Box 15311, Block 46  
Plot No. 111 Kijitonyama, Dar Es Salaam

Contact: Muhammad Kuppa  
Phone: +255 654 948794, +255 713 631 074  
Email: info@tmls.co.tz

## TUNISIA AND ALGERIA

### **TUNLAB**

2 Rue Medenine. CP2000 Le Bardo- Tunisia  
Contact: Dr. Bankaji Mahmoud

Phone: +216 71 220 299, +216 20 317 158  
Email: mbancaji@gmail.com  
Website: www.tunlab.com

## TURKEY

### **Mikromed Medikal Paz. Ith. Ihr. San. Ve Tic. Ltd. Sti.**

Mehmet Akif Mah, Elalmis Cad. Asya Sk, No.19 D.3  
34774 Umraniye, Istanbul, Turkey

Contact: Esin Tor, Derya Kurfeyiz  
Phone: +90 216 668 00 52/42  
Fax: +90 216 526 29 43  
Email: esin@mikromedltd.com  
derya@mikromedltd.com  
info@mikromedltd.com  
Website: www.mikromedltd.com

## UKRAINE

### **Friedman-Ukraine Ltd.**

Pr. Peremogy, 68/1, r.62  
Kyiv, 03113, Ukraine

Contact: Vitaliy Melnik  
Phone: +38 067 504 20 79  
Email: vitaliy@friedman.com.ua  
Website: https://friedman.com.ua

## UNITED ARAB EMIRATES

### **Microgen Medical Equipments Trading Est.**

Office No. 10, New Industrial Area, Al Ain  
United Arab Emirates

Contact: Mr. Labeeb Abdulla  
Phone: +971 506956253  
Email: sales@microgen-me.com  
Website: www.microgen-me.com

## URUGUAY

### **KOMPASS**

Prudencio Vazquez y Vega 1112 C.P. 11300  
Montevideo, Uruguay

Contact: Guillermo Gonzalez  
Phone: +598 2 710 4373  
+598 99 167879  
Email: info@kompass.com.uy  
Website: www.kompass.com.uy



## UNITED STATES OF AMERICA

### FUJIFILM Wako Chemicals U.S.A. Corp.

1600 Bellwood Road  
North Chesterfield, VA 23237

Toll Free: 800-992-9256  
Tel: 804-714-1919  
Tel: 804-672-4655  
Fax: 804-271-7791  
Email: [wkuspyrostarinfo@fujifilm.com](mailto:wkuspyrostarinfo@fujifilm.com)  
[www.wakopyrostar.com](http://www.wakopyrostar.com)

## JAPAN

### FUJIFILM Wako Pure Chemical Corp.

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

Telephone: + 81-6-6203-3741  
Facsimile: + 81-6-6203-2029  
<http://ffwk.fujifilm.co.jp/>

## GERMANY

### FUJIFILM Wako Chemicals Europe GmbH

Fuggerstraße 12  
41468 Neuss, Germany

Telephone: + 49-2131-311-0  
Facsimile: + 49-2131-311-100  
[www.wako-chemicals.de](http://www.wako-chemicals.de)