



# FUJIFILM

Value from Innovation

## LAL Reagent Products for Detection of BACTERIAL ENDOTOXIN



Wako

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

Since the establishment of our first satellite sales office in Dallas, TX (1981), to the construction of our corporate headquarters and manufacturing facilities in Richmond, VA (1989), Fujifilm Wako Chemicals U.S.A. Corporation has strived to provide customers in all scientific disciplines with products of the utmost quality and dependability.

Long recognized as a world-renowned supplier of high purity chemicals and reagents, our company continues to maintain a proud history of product quality and customer service through the establishment of the LAL Division, and the introduction of our new PYROSTAR™ ES-F line for the detection of bacterial endotoxin.

This publication represents the culmination of more than 30 years of research and development, dedicated to providing our customers with endotoxin-specific reagents for “every user and for every method”.

We invite you to review our catalog and look forward to having the opportunity to serve you.

## Our Promise

As an FDA licensed facility, FUJIFILM Wako Chemicals U.S.A. Corp. – LAL Division is committed to ensuring that our production site and LAL reagents comply with all the rules, regulations, and quality standards set forth by FDA for current Good Manufacturing Practices (cGMP's).

## Horseshoe Crab Conservation

FUJIFILM Wako Chemicals U.S.A. Corp. is very much concerned with maintaining the viability of the horseshoe crab population. We are dedicated to following practices that ensure the careful handling and good quality of crabs used for LAL manufacture that both minimize injury and protect this invaluable species. After bleeding, the crabs are returned the next day by our fisherman to the same waters where they were collected. To assist in the collection of data for crab conservation studies, FUJIFILM Wako Chemicals U.S.A. Corp. participates in a horseshoe crab tagging and monitoring program coordinated by the U.S. Fish and Wildlife Service.



FUJIFILM Wako Chemicals U.S.A. Corp. - Cape Charles Bleeding Facility: Cape Charles, Virginia 23310



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## FUJIFILM Wako Chemicals U.S.A. Corp introduces Endotoxin-Specific LAL Reagents for every user and for every method

Untreated LAL reagents react not only with endotoxin but also with (1→3) β-D-glucan, a fungal cell wall component that initiates the clotting cascade by activating the Factor G pathway. To eliminate this (1→3) β-D-glucan activation, various endotoxin-specific reagents have been developed by either removing Factor G or inhibiting its activation.

FUJIFILM Wako Chemicals U.S.A. Corp now provides a new line of reagents formulated to perform each of the three endotoxin detection assays, namely the Gel-Clot Assay, Kinetic-Turbidimetric Assays (KTA) and Kinetic-Chromogenic Assays (KCA).

### The PYROSTAR™ ES-F Series

The PYROSTAR™ ES-F series of reagents represent our uniquely endotoxin specific line of Limulus Amebocyte Lysate products, which are formulated to be used either qualitatively as a gel-clot reagent or quantitatively as a Kinetic-Turbidimetric reagent.

#### Product features

- 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



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

## Multi-Test Lysate with matched CSE

| PYROSTAR™ ES-F 2.0 mL Test Kit • 4 multi-test vials (2.0 mL) + 1 vial CSE (500 ng/vial) |                            |   |
|---|----------------------------|---|
| Catalog number  | Gel-clot Sensitivity EU/mL | Kinetic-Turbidimetric Assay<br>Quantitative Range (EU/mL) |
| WPEK4-20015   | 0.015                      | 0.001 to 10   |
| WPEK4-20003   | 0.03                       | 0.01 to 10  |
| WPEK4-20006   | 0.06                       |   |
| WPEK4-20125   | 0.125                      |   |
| WPEK4-20025   | 0.25                       |   |



| PYROSTAR™ ES-F 5.2 mL Test Kit • 4 multi-test vials (5.2 mL) + 1 vial CSE (500 ng/vial) |                            |   |
|---|----------------------------|---|
| Catalog number  | Gel-clot Sensitivity EU/mL | Kinetic-Turbidimetric Assay<br>Quantitative Range (EU/mL) |
| WPEK4-50015   | 0.015                      | 0.001 to 10   |
| WPEK4-50003   | 0.03                       | 0.01 to 10  |
| WPEK4-50006   | 0.06                       |   |
| WPEK4-50125   | 0.125                      |   |
| WPEK4-50025   | 0.25                       |   |



## Single- Test Lysate with matched CSE

| 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 Assay<br>Quantitative Range (EU/mL) |
| WPESK-0015   | 0.015                      | 0.001 to 10   |



## Bulk Lysate

| PYROSTAR™ ES-F 2.0 ml Bulk Kit • 100 multi-test vials (2.0 mL) |                            |   |
|--|----------------------------|---|
| Catalog number   | Gel-clot Sensitivity EU/mL | Kinetic-Turbidimetric Assay<br>Quantitative Range (EU/mL) |
| WPEM-20015   | 0.015                      | 0.001 to 10   |
| WPEM-20003   | 0.03                       | 0.01 to 10  |
| WPEM-20006   | 0.06                       |   |
| WPEM-20125   | 0.125                      |   |
| WPEM-20025   | 0.25                       |   |



## Bulk Lysate

| PYROSTAR™ ES-F 5.2 ml Bulk Kit • 100 multi-test vials (5.2 mL) |                            |   |
|--|----------------------------|---|
| Catalog number   | Gel-clot Sensitivity EU/ml | Kinetic-Turbidimetric Assay<br>Quantitative Range (EU/mL) |
| WPEM-50015   | 0.015                      | 0.001 to 10   |
| WPEM-50003   | 0.03                       | 0.01 to 10  |
| WPEM-50006   | 0.06                       |   |
| WPEM-50125   | 0.125                      |   |
| WPEM-50025   | 0.25                       |   |



## The Limulus Color KY Series

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

## Lysate with matched CSE

| Limulus Color KY Test Kit • 3 multi-test vials (2.0 mL) + 1 vial CSE (500 ng/vial) |                 |
|--|-----------------|
| Catalog number   | Number of Tests |
| 291-53101  | 60 tests        |

| Limulus Color KY Single Test Kit • 25 single test vials + 1 vial CSE (500 ng/vial) |                 |
|--|-----------------|
| Catalog number   | Number of Tests |
| 291-53601  | 25 tests        |

## Limulus PS Single Test

The Limulus PS Single Test is a kit composed of LAL endotoxin specific reagent and an affinity resin suspension known as PyroSep™, designed to overcome any product interference by adsorbing potential endotoxin in samples while washing away the inhibitory components.



## Product Features

- Endotoxin-specific lysate, avoids false positive results from glucans
- KTA assay is performed in tube reader
- Allows endotoxin specific measurement of samples which inhibit traditional LAL assays
- Fat-soluble vitamins, oils and fats can be tested if they can be dissolved in ethanol.

| Limulus PS Single Test |  |
|------------------------|--|
| Catalog Number         | Contents   |
| 299-54501              | 20 LAL ES single test vials<br>PyroSep™ resin suspension<br>LAL reconstitution solution<br>Wash solution<br>Sample diluent<br>20 Glass capillary columns |

| PS Accessory Kit (optional) |  |
|-----------------------------|--|
| Catalog Number              | Contents   |
| 294-33311                   | 12 syringes (20 mL)<br>12 T-shape stopcocks R Type<br>20 Dedicated adapters<br>12 Bulldog clips<br>25 Polystyrene tubes (5 mL)<br>25 Polystyrene tubes (14 mL)<br>Test tube rack |



# Toxinometer® Measurement System **FUJIFILM**

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**Next generation ET-7000 to be released 4th Quarter of 2018**



## Toxinometer® ET-6000 - Endotoxin Measurement System

The Toxinometer® ET-6000 is our new 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°C and 37°C
- Endotoxin determination in compliance with FDA guidelines as well as with Pharmacopeal (USP/EP/JP) BET monographs
- Toximaster QC7 - State of the art software
  - FDA 21 Part 11 Compliant
  - Allows trending of product results over time
  - Allows early detection of potential product failures
  - Generates hard copy printouts documenting assay parameters and sample results
  - Test to completion without intervention
  - Develop automated assay systems with ease
  - Offers improved precision and accuracy over the gel-clot method



| Catalog No. | Model                                   | Power Source                 | Contents  |
|-------------|---|------------------------------|---|
| 293-33509   | Toxinometer® ET-6000/U Part 11 Set      | 100-120 +/- 10% VAC (USA)    | 1 Toxinometer® ET-6000<br>Toximaster QC7 Software w/5 User Licenses |
| 290-33519   | Toxinometer® ET-6000/E Part 11 Set      | 220-240 +/- 10% VAC (Europe) | 1 Personal Computer<br>System Validation Documents                  |
| 293-33989   | Toxinometer® ET-6000/U Non- Part 11 Set | 100-120 +/- 10% VAC (USA)    | 1 Toxinometer® ET-6000<br>Toximaster QC7 Software w/1 User License  |
| 299-33969   | Toxinometer® ET-6000/E Non- Part 11 Set | 220-240 +/- 10% VAC (Europe) | 1 Personal Computer   |
| 297-33529   | Toxinometer® ET-6000/U Expansion Module | 100-120 +/- 10% VAC (USA)    | 16 well expansion unit  |
| 294-33539   | Toxinometer® ET-6000/E Expansion Module | 220-240 +/- 10% VAC (Europe) | 16 well expansion unit  |

## Control Standard Endotoxin

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



## 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°C for 1 month

(Ready-made indicators and new high concentration LPS to launch Fall of 2018)

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



## BioClean® Series

FUJIFILM Wako's premiere collection of endotoxin-free pipette tips, test tubes and caps designed for worry free endotoxin testing on our Toxinometer® measurement system.

### 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 Finnpiquette digital micro pipettors (20-200ul or 100-1000ul sizes)
- Endotoxin-free tubes and caps sterilized at 250 °C
- For use with Toxinometer® measurement system



### Endotoxin-free Pipette Tips and Microplates

| Catalog Number | Product Name                   | Volume Size | Quantity  |
|----------------|--------------------------------|-------------|-----------|
| 291-35021      | BioClean® Tip Wako 200 II      | 200 µl      | 100 tips  |
| 298-35031      | BioClean® Tip Wako 1000 II     | 1000 µl     | 100 tips  |
| 294-35011      | BioClean® Tip Wako Extend S II | 200 µl      | 100 tips  |
| 293-35221      | Bioclean® Microplate           | 96 well     | 50 pcs/pk |



### Endotoxin-free Test Tubes and Caps

| Catalog Number | Product Name                       | Dimensions  | Quantity |
|----------------|------------------------------------|-------------|----------|
| 292-32751      | Limulus Test Tube-S w/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

Our Gel-clot Reaction Tubes are made of high quality Borosilicate glass and certified free of interfering endotoxins and glucans.

### Product Features

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



| Catalog Number | Product Name                           | Quantity      |
|----------------|--|---------------|
| CT-1075        | Gel-clot Reaction Tube                 | 200 tubes/pk  |
| CT-1075C       | Gel-clot Reaction Tube w/ Aluminum Cap | 50 pcs/pk     |
| CT-1075B       | Gel-clot Reaction tube, Bulk           | 1250 tubes/pk |
| DL-13100       | Depyrogenated Dilution Tube 13 x 100mm | 50 pcs/pk     |

## 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

(125mL in plastic bottles to launch Fall 2018)



| Catalog Number | Product Name                | Quantity         |
|----------------|-----------------------------|------------------|
| LRW-12100      | Lysate Reagent Water, 100ml | 12 x 100mL vials |
| LRW-2030       | Lysate Reagent Water, 30ml  | 20 x 30mL vials  |



# Endotoxin Extracting Solution

**FUJIFILM**  
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## 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 | Contents       |
|----------------|----------------|
| 293-51601      | 4 x 10mL vials |



## Contact Our Distributors

Looking for a distributor in your region?  
Please see our list of distributors around the globe:

### DOMA INTERNATIONAL LLC

(Distributor for Argentina, Paraguay, Ecuador, Chile, and Bolivia)

5717 NW 125 Ave.  
Coral Springs  
Florida, 33076  
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**Contact Us** Our goal is to provide you with quality customer service. Whether it is assisting with your order, providing technical information, or advising pricing on our products, the staff of Fujifilm Wako Chemicals U.S.A. Corporation is here to help. Please contact us with your inquiries directly or through our website [www.wakopyrostar.com](http://www.wakopyrostar.com)

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Email: amit.gupta@pammvi.com  
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Website: www.advansys.co.il

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