



LAL Reagent Products for Detection of BACTERIAL ENDOTOXIN



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Wako

Wako Chemicals USA, Inc.

Greetings from Wako Chemicals USA, Inc.

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), Wako Chemicals USA 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, Wako Chemicals USA, Inc. – 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

Wako Chemicals USA, Inc. 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, Wako USA participates in a horseshoe crab tagging and monitoring program coordinated by the U.S. Fish and Wildlife Service.



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Wako Chemicals USA introduces Endotoxin-Specific LAL Reagents for every user and for every method

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

WAKO 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

- Avoids false positive results
 - Endotoxin-specific lysate, avoids false positive results from glucans
 - Single-test (Tube) configuration avoids “Hot Wells”
- Available in multi-tests vials or single-test vials
- Can be used as either a gel-clot or KTA (Kinetic-Turbidimetric Assay) 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 or 0.01 EU/mL to 10 EU/mL. The KTA quantitative range is related to the Gel-Clot sensitivity.



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 Quantitative Range (EU/mL)
WPEK4-20015	0.015	0.001 to 10
WPEK4-20003	0.03	
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 Quantitative Range (EU/mL)
WPEK4-50015	0.015	0.001 to 10
WPEK4-50003	0.03	
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 Quantitative Range (EU/mL)
WPEK4-0015	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 Quantitative Range (EU/mL)
WPEM-20015	0.015	0.001 to 10
WPEM-20003	0.03	
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 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	



PYROSTAR™ ES-F PLATE

Our same reliable endotoxin specific formulation for use with microplate readers.

Product features

- Endotoxin specific testing
- Quantitative detection by kinetic turbidimetric method
- KTA Quantitative Range (EU/mL) 0.01 to 10
- For use with microplate readers
- Formulated for no interference from beta-Glucans
- No buffer required to block beta-Glucan interference



PYROSTAR™ ES-F Plate contains 4 multi-test vials of endotoxin specific lysate and 1 vial of a matching CSE.

Thermo Finnpipette, 96-well microplate, and microplate reader not included and must be purchased separately.



PYROSTAR™ ES-F/Plate 2 mL Test Kit • 4 multi-test vials (2 mL) + 1 vial CSE (500 ng/vial)		
Catalog number	Gel Clot Sensitivity EU/mL	Kinetic Turbidimetric Assay Quantitative Range (EU/mL)
WPEPK4-20015	0.015	0.01 to 10

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 colorimetric analysis, using a synthetic substrate which produces a yellow color and can specifically detect endotoxin with high sensitivity.



Product features

- Avoids false positive results
 - Endotoxin-specific lysate, avoids false positive results from glucans
 - Single-test (tube) configuration avoids “Hot Wells”
- Available in multi-tests vials or single-test vials
- Quantitative KCA reagent (kinetic-chromogenic assay) 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)

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

- Avoids false positive results
 - Endotoxin-specific lysate, avoids false positive results from glucans
 - Single-test (tube) configuration avoids “Hot Wells”
- KTA assay is performed in tube reader
- Allows endotoxin specific measurement in samples inhibitory in traditional LAL assays
- Even 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 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



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
- 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 Toximaster QC7 Software w/5 User Licenses 1 Personal Computer System Validation Documents
290-33519	Toxinometer® ET-6000/E Part 11 Set	220-240 +/- 10% VAC (Europe)	
293-33989	Toxinometer® ET-6000/U Non- Part 11 Set	100-120 +/- 10% VAC (USA)	1 Toxinometer® ET-6000 Toximaster QC7 Software w/1 User License 1 Personal Computer
299-33969	Toxinometer® ET-6000/E Non- Part 11 Set	220-240 +/- 10% VAC (Europe)	
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 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
- Can be used for depyrogenation validation
- Reconstituted CSE can be stored at 2-10°C for 1 month

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



Bio Clean® Series

Wako's premiere collection of endotoxin-free pipette tips, test tubes and caps designed for worry free endotoxin testing on our Toxinometer® ET-6000 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 pipetters (20-200ul or 100-1000ul sizes)
- For use with Toxinometer® ET-6000
- Endotoxin-free tubes and caps sterilized at 250 °C



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
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

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 for LAL Test

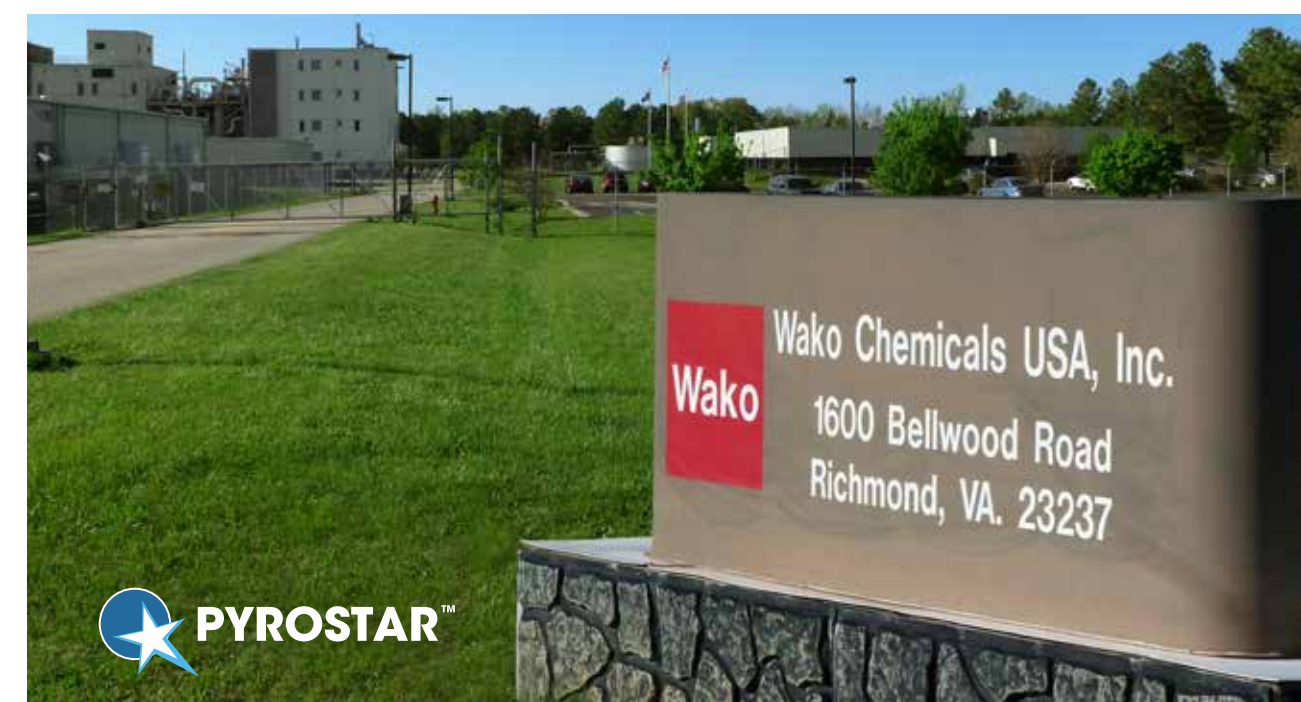
Traditionally, water or saline solution has been used to extract endotoxin in tests on medical devices and equipment; however, the efficacy of this extraction method has recently come into question. In order to provide our customers with a more reliable method for medical device testing, Wako has developed 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



Charles River Endotoxin Detection\Products and Services

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GC Apteka-95 (Distributor for Ukraine and Uzbekistan)

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