

Wako

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**PYROSTAR™**

LAL Reagent Products for Detection of  
**BACTERIAL ENDOTOXIN**



**Limulus PS Single Test**

Wako

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**Pyrosep™ Endotoxin Specific Measurement Kit****Overcomes Product Inhibition**

Allows endotoxin specific measurement in samples inhibitory in traditional LAL assays by first removing any interfering substances in the sample. Even fat-soluble vitamins, oils and fats can be tested if they can be dissolved in ethanol. LAL reagent is supplied in pre-dispensed individual vials.

**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
- 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 can be tested

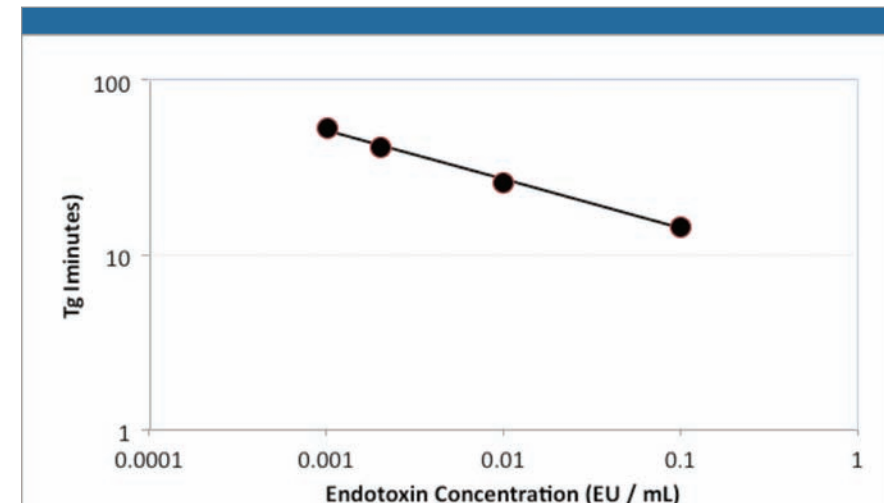
**Measurement Principle**

The endotoxin in the sample is adsorbed onto a capillary column filled with Pyrosep™ (an affinity adsorbent with histidine bound to a water-insoluble support via a spacer, designed to specifically adsorb endotoxin). Inhibitory substances contained in the sample are washed away allowing the adsorbed endotoxin to be measured with PYROSTAR™ ES-F single test LAL reagent.

**Endotoxin extracted using PyroSep™ Method**

Typical Standard Curve (sample volume 5.0 mL).

Standard	Concentration (EU / mL)	Tg (min)	Average Tg (min)
1	0.001	53.0	53.60
		53.4	
		54.4	
2	0.002	41.6	41.53
		41.2	
		41.8	
3	0.01	26.6	26.07
		26.0	
		25.6	
4	0.1	14.6	14.60
		14.8	
		14.4	



Slope = -0.279

Y Intercept = 0.875

|Coefficient of Correlation| = 0.998

### Applications

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

**Table 1: 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

### Endotoxin Detection in Fat Soluble Vitamins

Fat-soluble vitamins D, E, and K were dissolved in ethanol at the concentration indicated in Table 2. The samples were spiked with Reference Standard Endotoxin to yield a final concentration of 0.05 EU/mL. The samples were analyzed using the PyroSep™ method. All endotoxin spikes showed recovery within the acceptable range of 50 – 200 %.

**Table 2: Endotoxin Recovery from Fat-soluble Vitamins Dissolved in Ethanol using the Pyrosep™ Method**

Vitamin	Vitamin Concentration (mg/mL)	Endotoxin Recovery (%)
D <sub>2</sub>	10	170
E	10	91
	20	83
K	10	99
	20	68

### 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





### Wako Chemicals USA, Inc.

Wako Chemicals USA, Inc. is a wholly owned subsidiary of Wako Pure Chemical Industries, Ltd. of Japan; a company world renowned for its high purity chemicals.

As a central theme in our management philosophy, Wako Chemicals strives to fulfill our social obligations to both our employees and the community while providing products that meet or exceed our customer's requirements; thus consistently aiming to create a company whose products are trusted by our customers worldwide. Today, Wako Chemicals USA, Inc. consists of the following divisions: Specialty Chemicals, Clinical Diagnostics, Laboratory Reagents, Automation, and LAL, all of which strive to maintain excellence in product quality, customer service, and customer satisfaction.

### Community and Involvement

As a company dedicated to protecting the environment and to providing a safe and healthy work place for our valued employees, Wako participates in organizations with this goal in mind. Wako is an active participant in "Business for the Chesapeake Bay" organization, which aims to reduce the release of chemicals into the Chesapeake Bay and its rivers.

Wako is also involved in several organizations within the community and industries that are related to our products. These organizations are The Virginia Biotechnology Association, The American Institute of Chemical Engineers, and The Greater Richmond Technology Council.

In addition, the employees' band together to participate in several charitable events in our community throughout the year. These include Chesterfield Christmas Mother, Susan G. Komen Race for the Cure, and the American Heart Association Heart Walk.

Virginia wastewater excellence award 2010, 2011, 2012, 2013



FM 582849



Member of Virginia SHARP  
(Safety and Health Achievement  
Recognition Program)

### 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.



Wako Chemicals USA, Inc. - Cape Charles Bleeding Facility: Cape Charles, Virginia 23310