



PYROSTAR™

LAL Reagent Products for Detection of
BACTERIAL ENDOTOXIN



Toxinometer® Measurement System

FUJIFILM Wako Chemicals U.S.A. Corp.

FUJIFILM
Value from Innovation

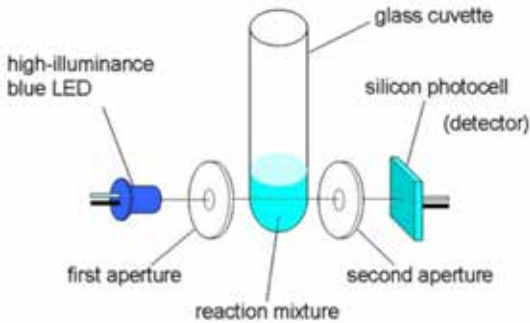
Toxinometer® ET-6000 - Endotoxin Measurement System

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.



Toxinometer® Measurement Principle

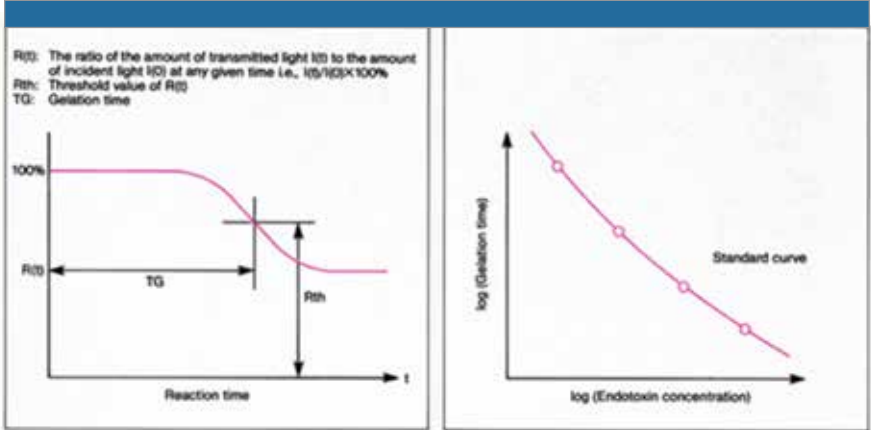
The Toxinometer® ET-6000 measurement system translates the reaction of the LAL reagent with endotoxin into changes in the light intensity transmitted through two specialized apertures at 430nm, which are then detected by a silicon photocell. The light intensity remains constant for a while after the start of the reaction, but gradually decreases as the reaction proceeds, and stops upon completion of the reaction.



Toxinometer® Measurement Principle

$$R(t) = [I(t)/I_0] \times 100\%$$

The ratio of the light intensity $I(t)$ to the light intensity at an early stage of the reaction $I(0)$ is defined as $R(t)$, and the threshold $R(th)$ of $R(t)$ is determined. Based on this, the Toxinometer® reads the period from the start of the reaction to the point at which $R(t)$ reaches $R(th)$ as the gelation time (T_g) or the activation time (T_a). The standard curve is generated based on the log of the gelation time plotted against the log endotoxin concentration in the sample.



Measure the time period TG from the start of the reaction to the end-point when $R(t) = R(th)$.

Plot gelation time against endotoxin concentration on log-log paper.



Toximaster[®] QC7 Software

The Toxinometer[®] ET-6000 measurement system is supplied with our exclusive, state of the art QC7 software package that allows for efficient routine work and high-quality data analysis. The software comes pre-loaded on the Toxinometer[®] system for immediate use and is fully compliant with FDA 21CFR, Part 11 requirements.



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 21CFR, 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 |
| 290-33519 | Toxinometer® ET-6000/E Part 11 Set | 220-240 +/- 10% VAC (Europe) | 1 Personal Computer System Validation Doc. |
| 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 |
| 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 |



FUJIFILM Wako Chemicals U.S.A. Corp.

FUJIFILM Wako Chemicals U.S.A. Corp. is a wholly owned subsidiary of FUJIFILM Wako Pure Chemical Corp. of Japan; a company world renowned for its high purity chemicals.

As a central theme in our management philosophy, FUJIFILM Wako Chemicals U.S.A. Corp. 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, FUJIFILM Wako Chemicals U.S.A. Corp. 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, FUJIFILM Wako Chemicals U.S.A. Corp. participates in organizations with this goal in mind. FUJIFILM Wako Chemicals U.S.A. Corp. 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. FUJIFILM Wako Chemicals U.S.A. Corp. 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 - 2017



FM 582849



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

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 fishermen 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. Corporation participates in a horseshoe crab tagging and monitoring program coordinated by the U.S. Fish and Wildlife Service.



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