FUJIFILM
Value from Innovation

Wako

Endotoxin Measurement System

Toxinometer® ET-7000

- Supports "the Bacterial Endotoxin Test" in the United States / European / Japanese Pharmacopoeias
- Compliant with FDA 21 CFR, Part 11
- Conforms to the international certification standards for C-UL(CSA) and CE

Since 1985

State-of-the-art analysis system configured to ensure data integrity*

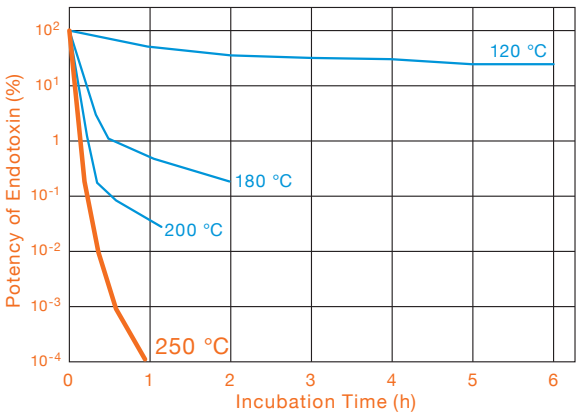
* Data integrity refers to the completeness, accuracy, and consistency of data.

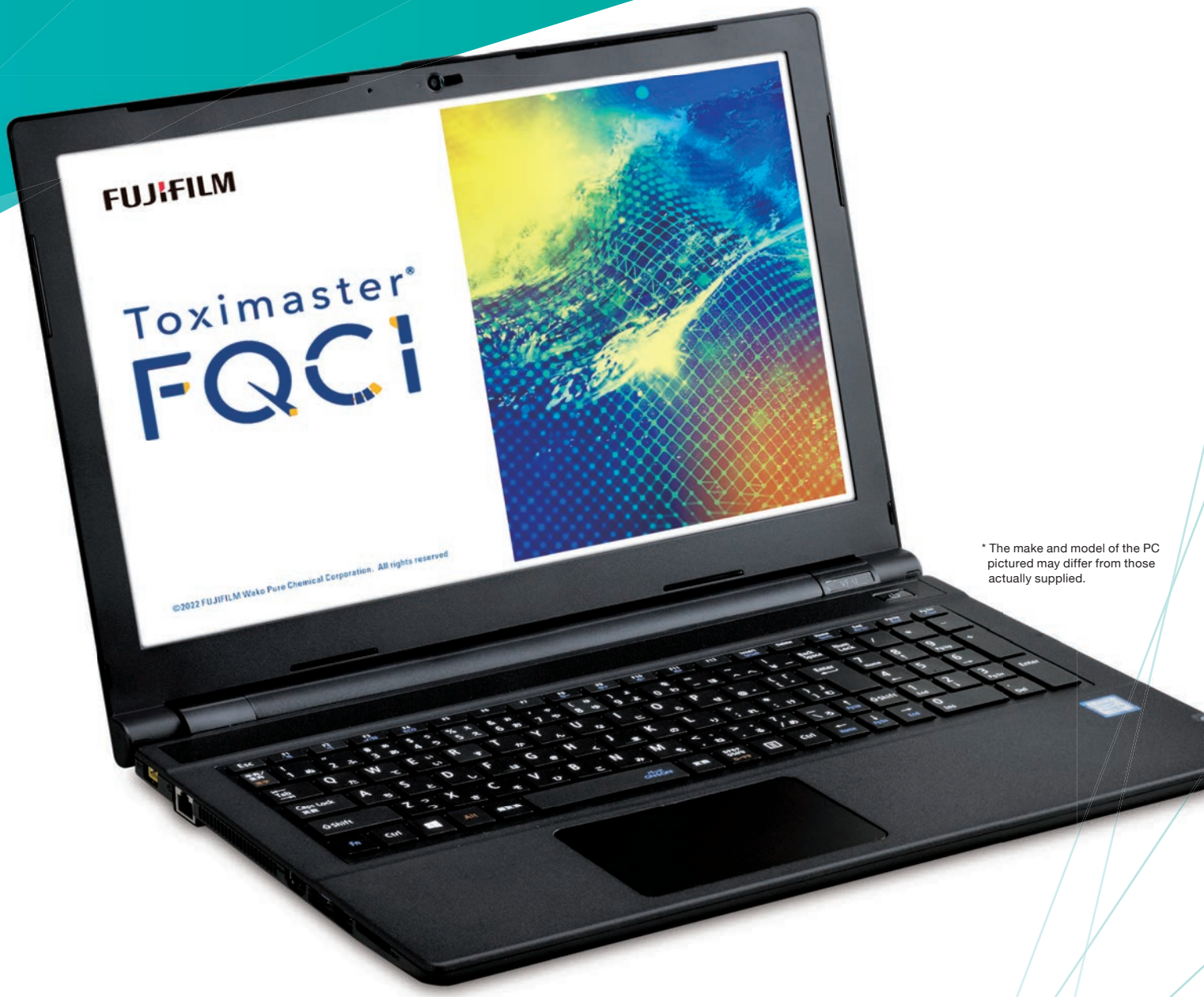
Endotoxin

What is Endotoxin?

Endotoxin is a lipopolysaccharide (LPS) that comprises the cell wall of Gram-negative bacteria. Endotoxin induces various biological reactions, such as fever, when even a small amount (ng) enters the bloodstream. Endotoxins exist in environments where gram-negative bacteria reside and remain even after the bacteria die. They cannot be deactivated completely by autoclaving because of their resistance to heat.
According to the Pharmacopoeia, **dry heat sterilization for at least 30 minutes at a temperature equal to 250 ° C or higher** is required for complete deactivation of endotoxins.

Heat stabilization of endotoxin
(LPS: 500 ng/vial)





* The make and model of the PC pictured may differ from those actually supplied.

High Reliability

High quality specialized glass tubes make it possible to maintain...

- Complete Sterilization
- Endotoxin Free Environment
- No Cross Contamination

High Sensitivity

When combined with our Chromogenic reagent can offer...

- A maximum sensitivity of 0.0002 EU/mL.
- More than 3 digits dynamic range of 0.0002 - 0.5 EU/mL.

(when using Limulus Color KY single test.)

Flexibility

ALL 3 methods available in just one system.

- Gel-clot technique
- Turbidimetric technique
- Chromogenic technique

Expandability to Support Future Growth

- Controlled remotely from a Windows® PC
- Up to 8 measurement modules can be additionally installed

Allows for continuous sample measurement Measures Max. 128 samples simultaneously

Wako's Toxinometer®, Highly Advanced Technology for Bacterial Endotoxin Testing

Gel-clot technique

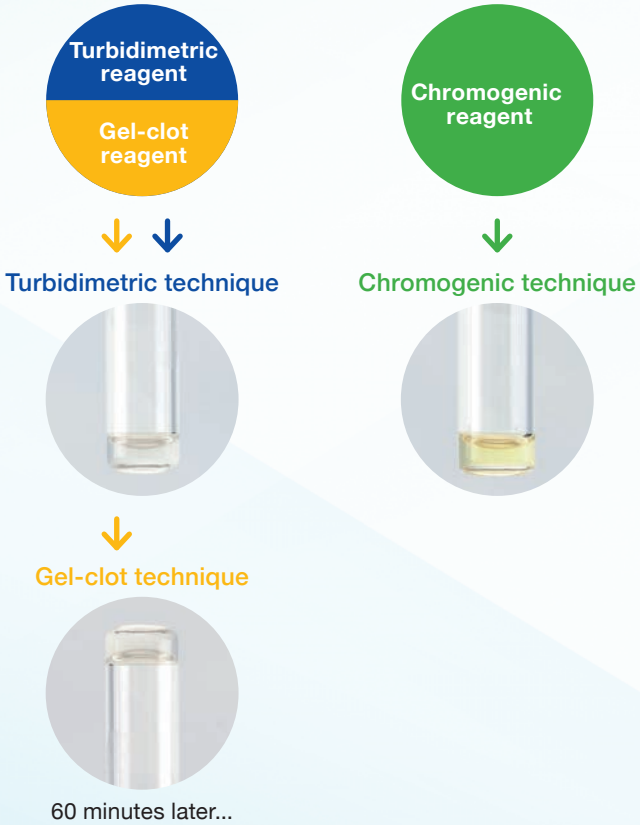
Chromogenic technique

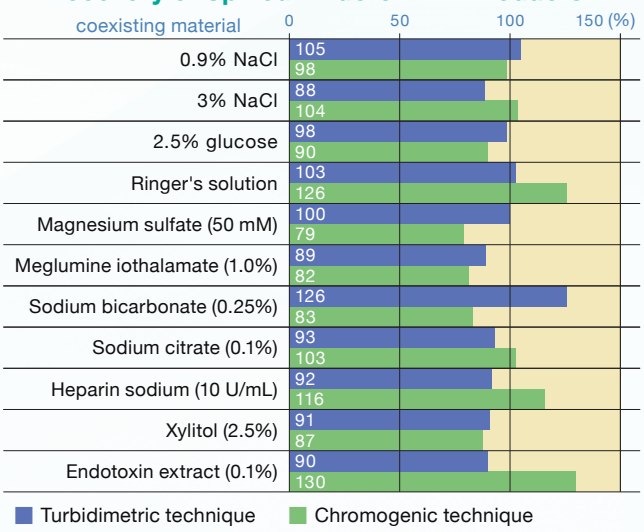
Turbidimetric technique

Offering reliable systems that satisfy global needs

- Meets Global Standards (C-UL(CSA)・CE).
- Pre-installed BET compliant software

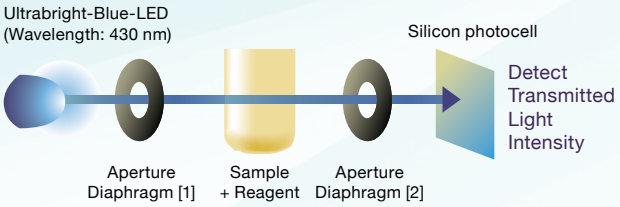
All 3 techniques for BET are available on one system





Principal of Measurement

Light from an LED goes through the reaction tube filled with reaction mixture via aperture diaphragm 1.
The light passes through the reaction mixture and then, while coming through aperture diaphragm 2, is detected by the silicon photocell.

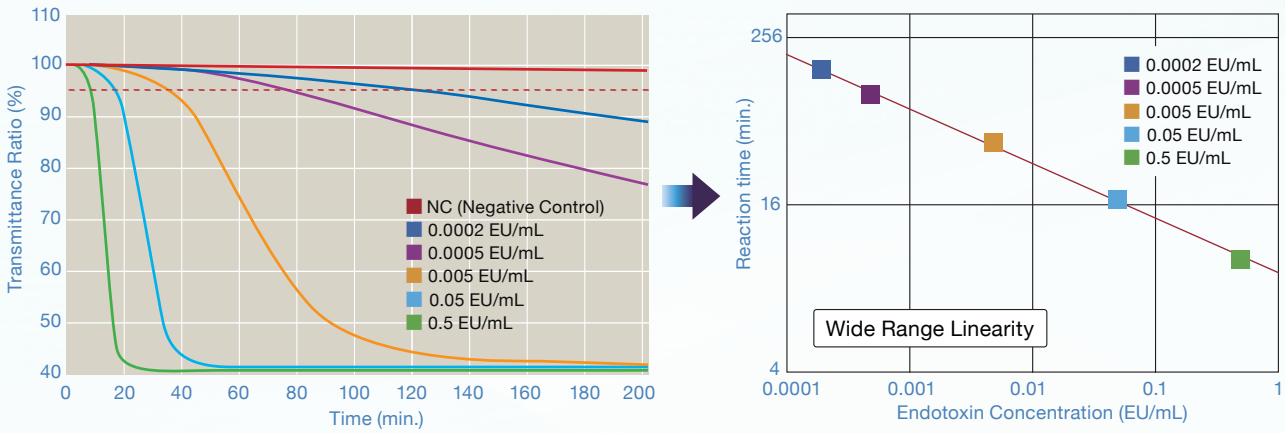


Determination of Kinetic Measurement

The Toxinometer® reports your Reaction Time as either Gelation Time (Tg for Turbidimetric technique) or Activation Time (Ta for Chromogenic technique) based on the methodology used.
The higher the concentration of endotoxin present, the shorter the reaction time.
The Toxinometer® measures the Transmittance Ratio of each well independently and simultaneously.
The Reaction Time is determined when the Transmittance Ratio falls below the Threshold value.

Time-Course-Graph & Standard Curve

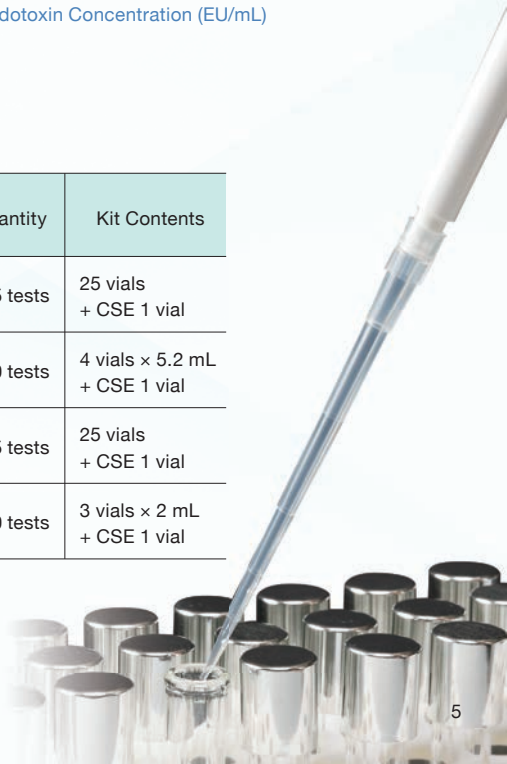
Example: Using Limulus Color KY Single Test Wako



Reagent Examples for Toxinometer

Technique	Code No.	Product Name	Quantitative Range (EU/mL)	Gel-clot Sensitivity (EU/mL)	Quantity	Kit Contents
Turbidimetric & Gel-clot	WPESK-0015	PYROSTAR™ ES-F Single Test, 0.015 EU/mL	0.001-10	0.015	25 tests	25 vials + CSE 1 vial
	WPEK4-50015	PYROSTAR™ ES-F Multi Kit, 0.015 EU/mL	0.001-10	0.015	200 tests	4 vials × 5.2 mL + CSE 1 vial
Chromogenic	291-53601	Limulus Color KY Single Test Wako	0.0002 - 5	-	25 tests	25 vials + CSE 1 vial
	291-53101	Limulus Color KY Test Wako	0.0005 - 5	-	60 tests	3 vials × 2 mL + CSE 1 vial

* CSE : Control Standard Endotoxin
* A wide variety of other reagents are available. Please contact us for the other reagents.

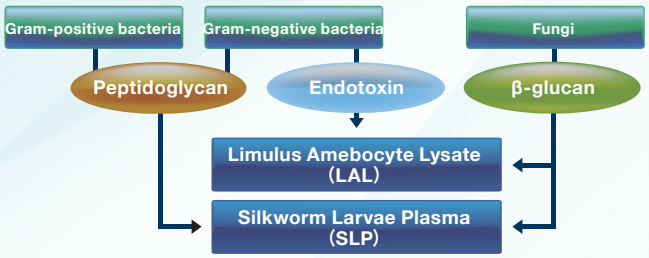


Application

Wide range of Applications

Bacteria are broadly divided into two categories: Gram-negative and Gram-positive bacteria. Every bacterium has peptidoglycan as a component of the cell wall. A Gram-negative bacterium contains endotoxin in the outer membrane of the cell wall. The cell wall of a fungus contains β-glucan.

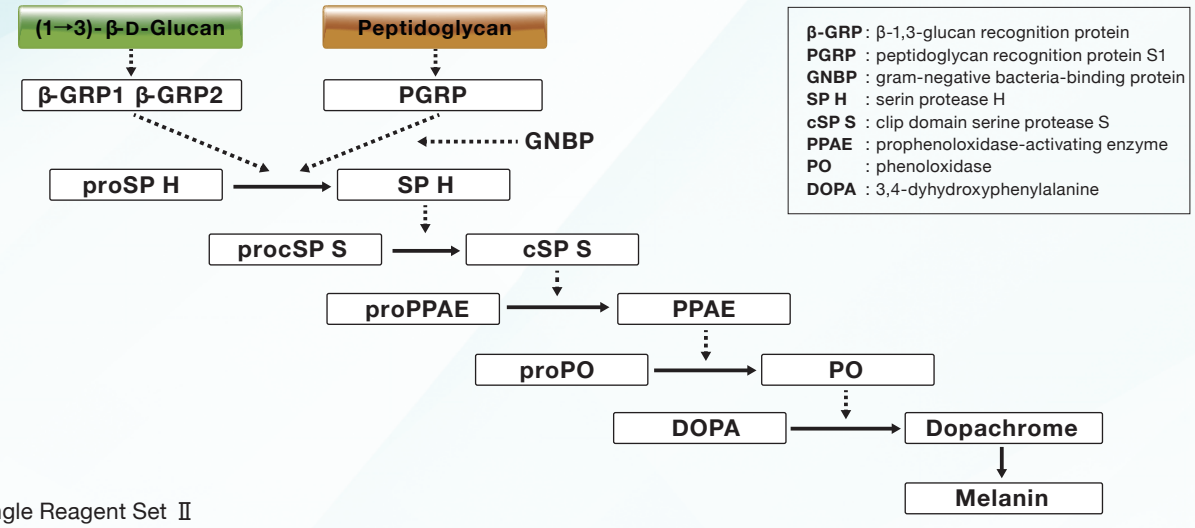
In combination with dedicated reagents, the Toxinometer® can be used for a wide range of applications such as research and monitoring of microbial contamination.



SLP Reagents

SLP reagent is a freeze-dried product prepared from silkworm larvae plasma. The reaction mechanism is shown in the following figure. When the reagent reacts with peptidoglycan and β-glucan, it eventually forms meranin, resulting in a black coloration of the sample. As when utilizing lysate reagent, a highly-sensitive measurement of this coloration is possible with the Toxinometer®.

SLP Reagent reaction mechanism



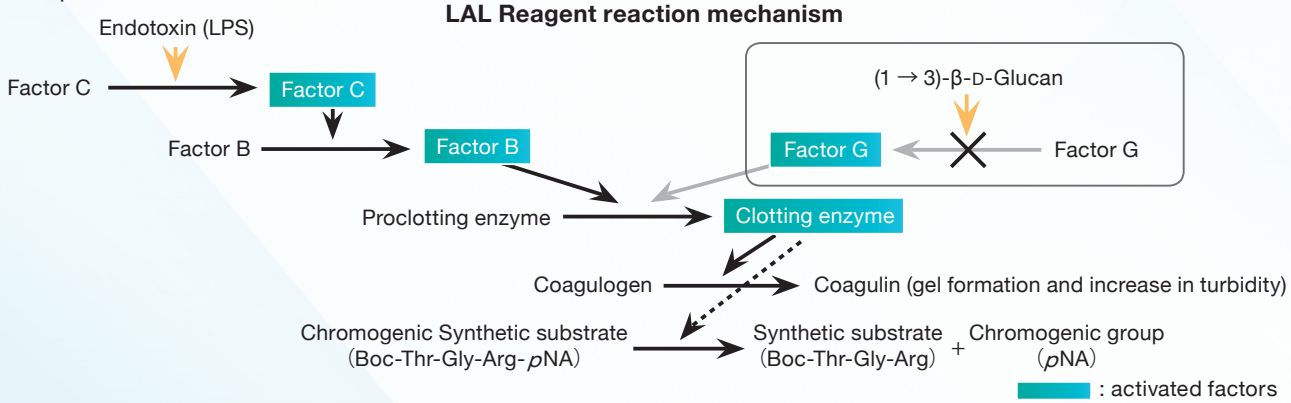
SLP-HS Single Reagent Set Ⅱ

Code No.	Product Name	Quantity tests	Kit Contents
296-81001	**SLP-HS Single Reagent Set Ⅱ**	20	• SLP-HS Regent Ⅱ (Lyophilized reagent containing Silkworm Larvae Plasma and DOPA) 0.1 mL × 20 vials Sensitivity : 10 pg/mL for PG, 1 pg/mL for β-glucan in 120 minutes. • SLP-Diluent 5 mL × 2 vials • Standard (Digested Peptidoglycan from Staphylococcus aureus) 0.5 mL × 1 vials

LAL Reagent Bacterial Endotoxin Test (BET)

A lysate reagent prepared from the amebocytes of the Atlantic horseshoe crab (Limulus polyphemus) is used to detect bacterial endotoxins. As shown in the Figure below, the cascade reactions begin due to the presence of endotoxin, whereby Factor C, a serine protease precursor, is initially activated. There follows the sequential activation of Factor B, also a serine protease precursor and a pro-clotting enzyme, which hydrolyzes coagulogen into coagulin, forming an insoluble gel. In the Bacterial Endotoxin Test, endotoxin can be quantified in three ways: measurement of gel formation, increased turbidity, or release of a yellow chromogen due to cleavage of a synthetic substrate. Endotoxin-specific LAL reagents are not activated by (1 →3)-β-D-glucan, as opposed to other BET compliance tests.

LAL Reagent reaction mechanism

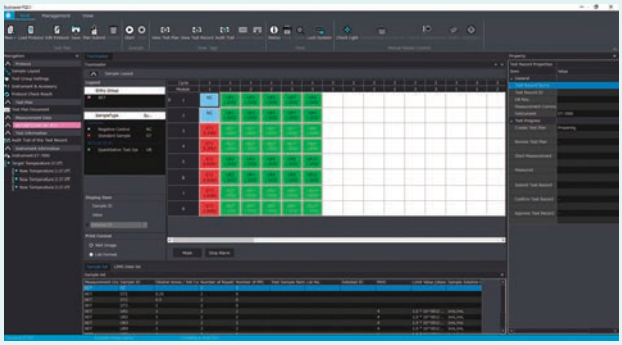


The "Welcome Screen" helps navigate you where you need to go!

Toximaster® Software

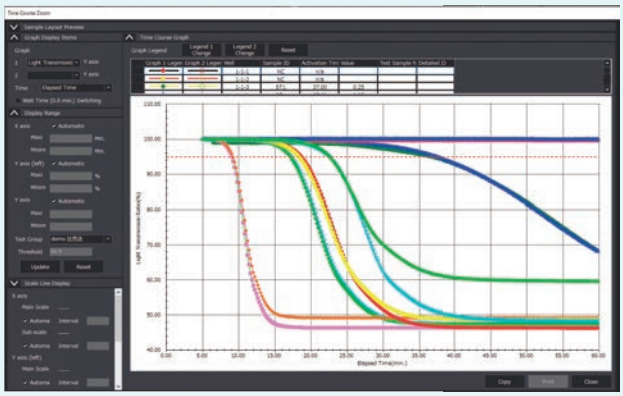
Exclusive software for efficient routine work & high quality analysis.

Protocol Settings



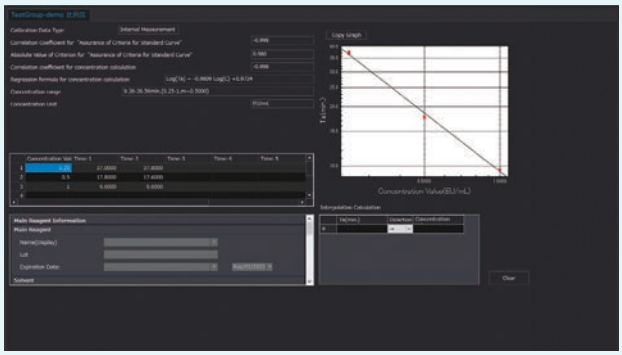
Easy to edit!
Once you create a protocol, you can start a measurement immediately.

Time Course Graph



Enables visual confirmation of measurement status.
You can predict results and prepare the next steps.

Standard Curve



Conveniently monitored!
All information can be seen on one screen.

Part 11 Functions

※Ensure data integrity

Electronic Signature

All measurement records are linked to signatures
Never allows for manipulation and falsification

Audit Trail

Major procedures are recorded automatically
History of operation can be confirmed as a log file

Operation Authorities

Each account belongs to a specific group and each group can define its own authorities for operation.

- Modify System Preferences
- Register Instrument
- Register Protocol
- Register Reagent
- Register Accessory
- Register Standard Curve Data
- Register Product
- Load Protocol into Test Record
- Star Measurement
- Load Test Record
- Review Test Plan
- Confirm Test Record
- Approve Test Record
- Submit Test Record

Etc ..

※"Toximaster®FQC1 Lite" doesn't comply with FDA 21 CFR Part11.

21 CFR Part11 System **Product Composition**

Item	Code No.	Product Name	Contents
Analysis System	293-36061	**Toxinometer® ET-7000**	• 1 Toxinometer® ET-7000 (1unit)
Software	290-36831	**Toximaster® FQC1 PC Set E**	• 1 Personal computer • Toximaster® FQC1 Software • System Validation Doc
Accessories (*1)	295-36761	**Toxinometer® 240V power cord**	• Toxinometer® 240V power cord (1unit)

Specification(*2)

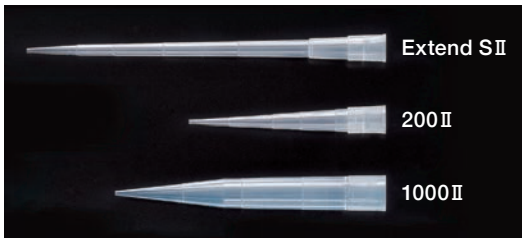
Item	Explanation
Functions	Transmitted light quantity measuring function (capable of measuring 16 samples simultaneously) Temperature control function Automatic light quantity check function
Light source	High intensity blue LED Central wavelength: 430 nm
Detector	Silicon photocell
Temperature control	Dry bath: 30±1.0 degrees C/37±1.0 degrees C (can be changed by software for ET-7000) Warmup time: 20 minutes (when preset temperature is 37 degrees C and surrounding temperature is 25 degrees C)
Display	The LED indicates measurement The LED indicates errors and information during checking
Weight	6.3 kg (±10%)
Size	W 190 mm × D 420 mm × H 130 mm (protrusions not included)

Item		Explanation
Power source		AC100-240 V (±10%)
Frequency		50/60 Hz
Power consumption		Max 120 W
Environment	During operation	When temperature is set at 37 degrees C Ambient temperature: 15 to 30 degrees C Humidity: 30 to 85%, non-condensing When temperature is controlled at 30 degrees C Ambient temperature: 15 to 25 degrees C Humidity: 30 to 85%, non-condensing
	During stored	Ambient temperature: -20 to 60 degrees C Humidity: 30 to 85%, non-condensing
	Location	Indoor
	Altitude	2000 m or lower

Related products

Endotoxin-free tip **BioCleanTip Wako®**

Code No.	Product Name		Package
294-35011	**BioCleanTip Wako® Extend S Ⅱ**	**200µL**	100 pcs
291-35021	**BioCleanTip Wako® 200 Ⅱ**	**200µL**	100 pcs
298-35031	**BioCleanTip Wako® 1000 Ⅱ**	**1000µL**	100 pcs



Endotoxin-free, Test Tube for Endotoxin Test and Aluminum Cap

Code No.	Product Name	Size	Quantity
292-32751	**Limulus Test Tube-S with Aluminum Cap**	ϕ 12 × 75 mm	10 pcs × 8
293-26551	**Limulus Test Tube-S**	ϕ 12 × 75 mm	10 pcs × 10
293-28251	**Aluminum Cap-S**	ϕ 15 × 18 mm	10 pcs × 10

(*1) It's required when using in the 200～240V area.
(*2) Up to 8 measurement modules can be connected to the unit to enable simultaneous measurement of 128 samples.

Listed products are intended for laboratory research use only, and not to be used for drug, food or human use. / Please visit FUJIFILM Wako Laboratory Chemicals site: https://labchem-wako.fujifilm.com/ / This leaflet may contain products that cannot be exported to your country due to regulations. / Bulk quote requests for some products are welcomed. Please contact us.

FUJIFILM Wako Laboratory Chemicals site
https://labchem-wako.fujifilm.com

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