

PYROSTAR™ ES-F Single-Test on the Toxinometer® - Gel Clot Method

This is a guide to explain how to perform the Gel Clot method with PYROSTAR™ ES-F Single-Test on the Toxinometer® Measurement System. Prior to performing the assay, allow the reagent to come to room temperature and the Toxinometer® to reach 37°C±1°C.

Step 1:

Select "Start Measurement" on the Toxinometer® QC8 software prior to testing.



Step 2:

Reconstitute the Control Standard Endotoxin (CSE) with the LAL Reagent Water (LRW) to yield a concentration of 1000 EU/mL based on the Certificate of Analysis.



Step 3:

Vortex the reconstituted CSE for 2 minutes.

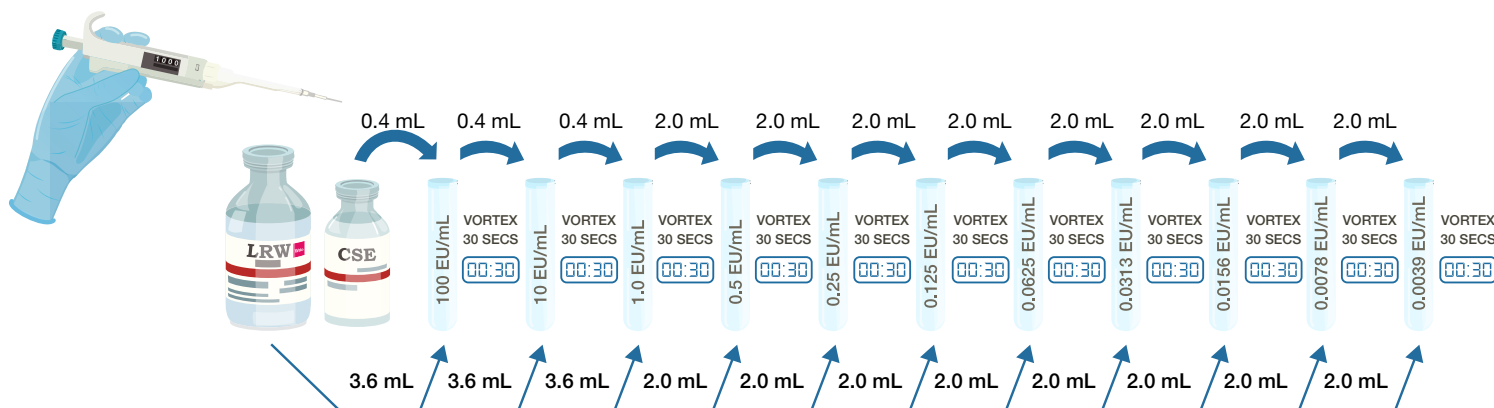


Step 4:

Label the endotoxin concentration for each dilution tube and then add the appropriate volume of LRW. Using the reconstituted CSE, prepare a 2-fold dilution series to bracket the lysate labeled sensitivity.

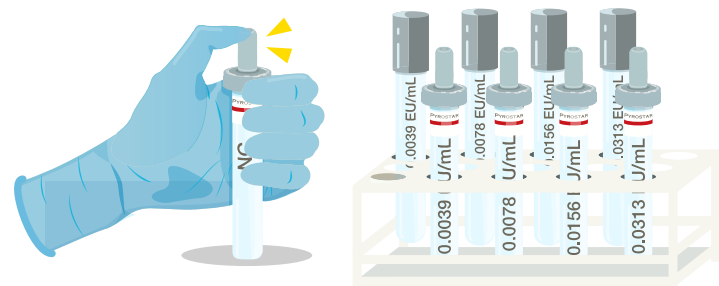
Dilutions may be prepared in different volumes if the same ratios are maintained.

Dilution series for labeled sensitivity: 0.015 EU/mL



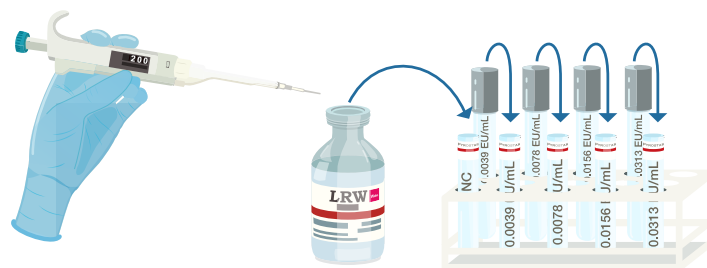
Step 5:

Label each PYROSTAR™ ES-F Single-Test vial and bring all contents to the bottom by gently tapping the bottom of the vial on a surface.



Step 6:

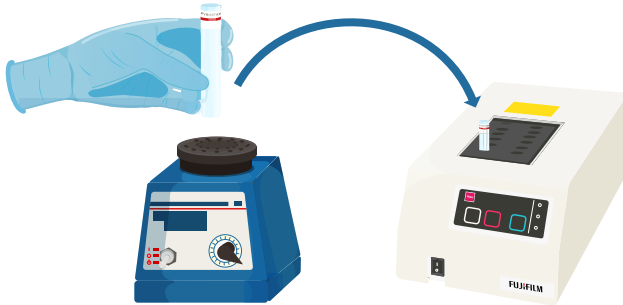
Open each single test vial. Add 200 µL of the endotoxin standards, controls, samples, etc., to the appropriate single test vials to reconstitute the lyophilized product.



Step 7:

Quickly vortex the content in each vial for a few seconds and immediately place in the Toxinometer® at 37°C ±1°C for 60 minutes (± 2 minutes).

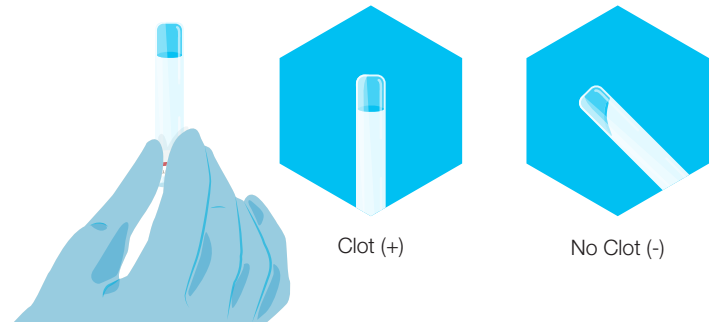
Remember to have laboratory equipment in an area with no vibration.



Step 8:

After incubation, remove each vial and carefully invert 180°.

Record if the reaction is positive (+) or negative (-).



For more detailed information, refer to the PYROSTAR™ ES-F Single-Test package insert.

Materials needed for Gel Clot Method

Offered at FUJIFILM Wako

	Name of Products	Contents	Catalog Number
Depyrogenated Test Tubes	13 x 100 mm Borosilicate Test Tubes	13 x 100 mm (50 test tubes)	DL-13100
	Aluminum Cap S	14.7 x 18 mm (100 caps/pkg)	293-28251
	LAL Reagent Water, 30 mL	20 x 30 mL glass bottle	LRW-2030
Endotoxin-free consumables	LAL Reagent Water, 100 mL	12 x 100 mL glass bottle	LRW-12100
	BioCleanTip Wako® 200 II	200 µL/tip (100 tips/pkg)	291-35021
	BioCleanTip Wako® Extend S	200 µL/tip (100 tips/pkg)	294-35011
	BioCleanTip Wako® 1000 II	1000 µL/tip (100 tips/pkg)	298-35031
LAL Reagents	PYROSTAR™ ES-F Single Test	Sensitivity: 0.015 EU/mL	WPEK4-0015
		Sensitivity: 0.03 EU/mL	WPEK4-0003
		Sensitivity: 0.125 EU/mL	WPEK4-0125
		Sensitivity: 0.25 EU/mL	WPEK4-0025
	Toxinometer® ET-7000/U Part 11 Set	1 Toxinometer® ET-7000/ Toximaster® QC8 Software	294-35871
Measurement Systems	Toxinometer® ET-7000/E Part 11 Set	1 Toxinometer® ET-7000/ Toximaster® QC8 Software	299-35821
	Toxinometer® ET-7000/U Expansion Module	100 - 120 ± 10% VAC (USA)	297-35861
	Toxinometer® ET-7000/E Expansion Module	220 - 240 ± 10% VAC (Europe)	294-35811

Not offered at FUJIFILM Wako

- Pipettes
- Test Tube Rack
- Vortex Mixer