

Instructions for Use

1.0 EU/mL Sensitivity

Intended Use: Pyrosate is a rapid endotoxin test specially designed for water, dialysate or other testing in applications that do not require use of a *Limulus* Amebocyte Lysate (LAL) reagent licensed by the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration.

SET-UP

1

Preheat incubator (dry or wet bath) to $37 \pm 1^\circ\text{C}$.

Verify the temperature by using a thermometer or digital display.

2

Collect the sample in a pyrogen-free container.

Be careful not to contaminate sample with fingers, instruments, sneezing, etc.

3

Use a permanent marker to label Sample (SPL) and Positive Product Control (PPC) tubes with test location or other sample identification.

4

Remove and discard stoppers of one SPL (blue capped tube) and one PPC (red capped tube). Do not touch the tube rims while removing stoppers.

TEST SAMPLES

5

Open one sterile transfer pipette* without contaminating the tip or neck of the pipette.

Touch only the bulb end of the pipette.

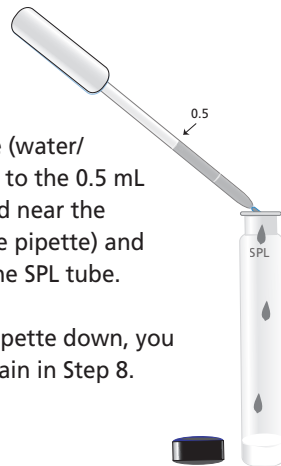


* 10 Test Kit - pipettes included
25 Test Bulk Pack - pipettes sold separately

6

Draw sample (water/ dialysate) up to the 0.5 mL mark (located near the middle of the pipette) and transfer to the SPL tube.

Do not lay pipette down, you will use it again in Step 8.



7

Gently mix the contents of the tube by lightly tapping the bottom several times with your finger.

The contents of the tube should completely dissolve within 20-60 seconds.



8

Using the same pipette, remove 0.25 mL of the liquid from the SPL tube and transfer it to the PPC tube (the 0.25 mL level is the unlabeled ring-mark below 0.5 mL on the pipette).

Discard the pipette.



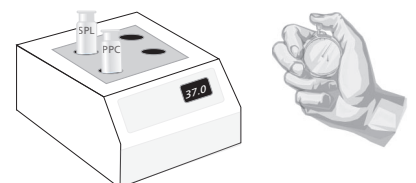
9

Gently mix the contents of the PPC tube by lightly tapping the bottom several times with your finger (10-20 seconds).



10

Immediately place both tubes in the wet or dry bath incubator. Incubate at $37 \pm 1^\circ\text{C}$ for the amount of time indicated on the Certificate of Compliance included with the kit.



READ RESULTS

NOTE: INCUBATION TIMES MAY NOT BE THE SAME FOR EVERY KIT. BE CERTAIN TO CHECK THE CERTIFICATE OF COMPLIANCE THAT WAS INCLUDED WITH THE KIT YOU ARE USING.

Read

When time is up, immediately and carefully remove the tubes one by one from the incubator. Gently invert the tubes until the absence of a solid gel-clot is confirmed or a 180 degree inversion is reached. Do not shake the tubes when reading the test.

If a solid clot has formed the result is positive (+). If no clot has formed, i.e. mixture remains liquid or the clot breaks, the result is negative (-).

PPC

PPC (Positive Product Control) tube

This tube **SHOULD** clot.

If it does not, you have an invalid test. Repeat the test. A failure of the PPC tube to clot indicates either inhibition of the assay by the sample or improper performance of the assay.

SPL

SPL (Sample) tube

This tube **SHOULD NOT** clot.

Absence of a clot means you have less than 1.0 EU/mL of endotoxin in the sample. If the SPL tube clots, your sample has endotoxin at or greater than 1.0 EU/mL.



Clot (+)



No Clot (-)

CONTROL (PPC)	SAMPLE (SPL)	RESULT
Clot (+)	Clot (+)	Sample contains \geq 1.0 EU/mL endotoxin
Clot (+)	No clot (-)	Sample contains < 1.0 EU/mL endotoxin
No clot (-)	Clot (+)	Assay is NOT valid. Repeat the test.
No clot (-)	No clot (-)	Assay is NOT valid. Repeat the test.

Caution: The silicone lubricant in syringes is known to inhibit the assay/test if the sample is held in a syringe.



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