

# Instructions for Use

## 0.25 EU/mL Sensitivity

**Intended Use:** Pyrotell 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.

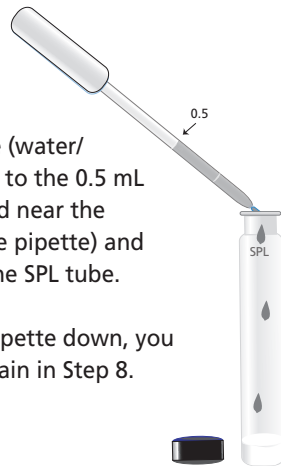


\* 10 Test Kit - pipettes included  
25 Test Bulk Pack - pipettes sold separately

# 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.



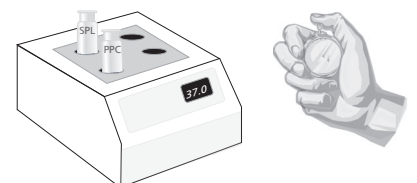
# 9

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 0.25 EU/mL of endotoxin in the sample. If the SPL tube clots, your sample has endotoxin at or greater than 0.25 EU/mL.



Clot (+)



No Clot (-)

CONTROL (PPC)	SAMPLE (SPL)	RESULT
Clot (+)	Clot (+)	Sample contains $\geq$ 0.25 EU/mL endotoxin
Clot (+)	No clot (-)	Sample contains $<$ 0.25 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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