

Pyrosate™ Endotoxin Testing

0.25 EU/mL and 1.0 EU/mL

Designed for water and dialysate testing

"Everything you wanted in Endotoxin testing without the hassle."

AAMI Microbial Standards for Dialysis Water (adopted 1/26/11)

Microbiological level	2010 Standards	2010 Alert Level	New Standards	New Alert Level
Coliform Forming Units	<200 CFU/mL	<1EU/mL / <50CFU/mL	<100 CFU/mL	>50 CFU/mL
Endotoxin Units	<2 EU/mL	<1EU/mL / <50CFU/mL	<0.25 EU/mL	>0.125 EU/mL

Water systems should be tested weekly until a pattern of consistent compliance is demonstrated. It is recommended that the system be tested monthly thereafter. Testing points should include the first and last outlets of the water loop as well as the endpoints supplying the reprocessing and bicarb mixing areas.

Dialysate from machines should be tested monthly. Clinics should test at least 2 machines a month so that each machine is tested at least once per year. The dialysate to be tested should be drawn from the dialysate port of the dialyzer or a sampling port from which samples can be collected using a pyrogen-free container.

Bacterial endotoxin testing can be done using the Limulus Amebocyte Lysate (LAL) Assay. Endotoxin testing has been simplified and is now less expensive when you use Pyrosate™. Pyrosate has been designed especially for water and dialysate testing. Simple instructions will allow gel clot assay **results in less than 30 minutes.**

Pyrosate advantages are:

- No technical skills required
- Shorter assay time – 0.25 EU/mL in under 30 minutes
- Endotoxin specific
- No dilutions required / no other reagents needed
- Includes a matched 2λ positive control
- Easy open vials
- 10 Test Kit comes complete with disposable pipettes
- Bulk size available

The above product provides quicker results and a lower cost per test than current methods.

- 25 Test Package cost is \$272 ÷ 25 tests: \$10.88/test
 - Incubator: \$.67/ test
\$400.00 ÷ 5 years (should last longer) = \$80/yr. ÷ 12 mo. = \$6.67/mo.
\$6.67/mo. ÷ 10 tests/mo. (most facilities will do more)
 - Disposable pipette and sampling tubes: \$ 1.16/test
- Total cost = \$12. 71/test**
(less if higher volume)

Pyrosate 10 Test Kits – Kit contains 10 positive product control tubes, 10 sample tubes, 12 disposable pipettes, instructions for use and a Certificate of Compliance

PSD101	Pyrosate 10 kit, 1.0 EU/mL	\$122.50/kit
PSD10	Pyrosate 10 kit, 0.25 EU/mL	\$122.50/kit

Pyrosate 25 Test Bulk Packs – Pack contains 25 positive product control tubes, 25 sample tubes, instructions for use and a Certificate of Compliance – pipettes sold separately

PSD251	Pyrosate 25 kit, 1.0 EU/mL	\$272.00/kit
PSD25	Pyrosate 25 kit, 0.25 EU/mL	\$272.00/kit

Additional Supplies

PPT50	Disposable pipettes, 50 pack	\$27.00/pk
TS050	Pyrogen-free sampling tubes, 50 pack	\$31.00/pk

Dry Bath Incubator - You will need a 120 volt, dry bath incubator with digital control + block to hold tubes. Please contact us if you need information on where to purchase the incubators. **Cost is \$350 - \$450**

Written instructions, tracking charts and training charts are available via e-mail. These documents will allow you to develop a complete policy and procedure for this product. Contact us at ols.svc@gmail.com - Ph: 407-444-1066 for a full package of information and how to order.

PYROSATE INSTRUCTIONS FOR USE

Total test time ≈ 30 minutes

1. Gather needed supplies while preheating dry bath incubator to 37°C. (do not use liquid bath incubator)
2. Use a permanent marker to label sample and control tubes with test location; avoid marking over 0.5mL and 0.25 mL lines.
3. Collect sample with pyrogen-free container. Caution: some syringes contain silicone, which can inhibit the test. Tester should take measures to not contaminate sample (don gloves, mask, etc. as required)
4. Remove and discard stoppers of one SPL (blue-capped sample tube) and one PPC (red-capped Positive Product Control tube). Do not touch rim of tubes while removing stoppers.
5. Open 1 pipette without contaminating the tip or neck of the pipette.
6. Draw sample water/dialysate up to the .5 mL mark (located near the middle of the pipette) and transfer it into the SPL tube. (do not lay pipette down, you will use it again in 60 seconds)
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 60 seconds.
8. Using the same pipette, remove .25 mL (unlabeled ring-mark below .5 mL on the pipette) of the liquid from the SPL tube and transfer it to the PPC (Positive Product Control) tube. Discard pipette.
9. Gently mix contents of the tube by lightly tapping bottom several times with your finger (60 seconds)
10. Immediately place both tubes in the incubator. Incubate at $37 \pm ^\circ\text{C}$ for the amount of time indicated on the Certificate of Compliance included with the kit. **Incubation times will vary with each lot number.**
11. Do not move/bump the incubator during testing – test is movement sensitive.
12. Once incubation time is up, remove both tubes and check results (invert over a discard container to check for clot formation).

RESULTS

PPC (Positive Product Control) tube should clot. If it doesn't you have an invalid test. Repeat the test.

SPL (Sample) tube should not clot. A negative result means you have less than 1.0 EU/mL of endotoxin. If the SPL tube clots, your sample is contaminated and you should not use the water/dialysate.