

## ENDOSAFE™ RAPID LAL SINGLE-TEST VIALS\*

Endosafe™ Rapid LAL Single-Test Vials (STV) are single-use vials containing gel-clot limulus amebocyte lysate (LAL) for the quantitative detection of bacterial endotoxin. Endotoxins are produced by Gram negative bacteria commonly found in water purification systems. LAL is a sensitive and specific way to measure the presence of bacterial endotoxins as the reagent develops an opaque gel in the presence of sufficient levels of endotoxin. Endosafe™ Rapid LAL STVs are routinely used for endotoxin detection in research samples, renal dialysis process water, and dialysate solutions.

### Endotoxin and Water Systems

Endotoxin, also known as pyrogen, is a large molecular complex that makes up the cell wall of Gram negative bacteria. Endotoxin is stable and difficult to destroy using sanitizing agents. In a dialysis setting, reverse osmosis (RO) membranes are used to remove both the chemical impurities and the bacterial endotoxins that are typically found in water supplies. However, RO membranes are not capable of removing all bacteria and cannot prevent the proliferation of bacteria at downstream sites. Fouling (the formation of biofilm) can occur at locations downstream of the RO membrane. The gelatinous biofilm matrix is difficult to remove once established in a water distribution system. The Rapid LAL STV can be used to test water from specific points of use to monitor the adequacy of RO purification and sanitization processes that are in place.

### Test Technology

The gel-clot LAL test is a simple, reproducible test that involves mixing a sample of dialysis fluid or water with LAL reagent. After incubating at 37°C for a specific amount of time, the test is complete and results can be interpreted. In a positive gel-clot test, a firm gel forms in the tube, indicating that the concentration of endotoxin in the sample is equal to or greater than the labeled sensitivity of the reagent. In a negative test, a firm gel does not form and the sample contains less endotoxin than the labeled sensitivity.

### Endosafe™ Rapid LAL STV Applications

- R&D samples
- Renal dialysis process water
- Dialysate solutions

### Rapid LAL STV Procedure

- Collect samples
- Dispense 0.2 mL of sample into tube of LAL
- Dispense 0.2 mL of sample into PPC tube
- Place tubes in 37°C water or dry bath and incubate according to sensitivity desired
- Invert tubes 180 degrees to read firmness of gel
- Interpret results





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### Hemodialysis Use

The Association for the Advancement of Medical Instrumentation (AAMI) provides Standards and Recommended Practices which are approved by the American National Standards Institute. The AAMI guidelines recommend that water for use with dialysate has an endotoxin limit of 2.0 EU/mL. The limit for ultrapure dialysate is 0.03 EU/mL.

The voluntary standards established for hemodialysis water by the European Pharmacopoeia are a bioburden limit of 100 CFU/mL and an endotoxin limit of 0.25 IU/mL for water used to dilute concentrated hemodialysis fluids. The Expert Committee on Biological Standardization of WHO has assigned a potency of the International Standard endotoxin such that 1 IU=1 EU and 0.25 IU/mL is equivalent to 0.25 EU/mL.

It has been recommended by the European Dialysis and Transplant Nurses Association and European Renal Care Association (EDTNA/ERCA) that the frequency of microbiological testing should be based on the historical data and maintenance procedures for the water system in place. Monthly evaluation of endotoxin levels is usually sufficient, unless there is a history of elevated endotoxin levels or a lack of historical data available. In those cases, weekly endotoxin testing is recommended.

The guideline also recommends that facilities have in-house capabilities for endotoxin testing. With in-house testing, results are known rapidly and investigation into unsafe conditions can be identified and corrected quickly.

**For additional information on the Endosafe™ Rapid Single-Test Vials, please visit our web site at [www.criver.com](http://www.criver.com) or call Technical Assistance at 1-800-762-7016.**

*\*Endosafe™ Rapid Single-Test Vials are not licensed by the FDA and are not to be used for end-product release of pharmaceutical drugs, devices, or biologics that are regulated by the FDA.*