

Pyrosol® LAL Reconstitution Buffer with pH Indicator Instructions for Use

Intended Use

Pyrosol® LAL Reconstitution Buffer with phenol red indicator is free of interfering endotoxin, intended as a reconstitution solution for multitest vials of Pyrotell® gel-clot *Limulus* Amebocyte Lysate (LAL). Multitest vials of Pyrotell lysate reconstituted with Pyrosol buffer may be used to test samples or sample dilutions that may otherwise require prior adjustment of pH with acid or base or which precipitate on adjustment of pH. For convenience, a pH indicator, phenol red, has been included in the Pyrosol buffer formulation to indicate by the color of the reaction mixture whether or not the mixture is grossly within the range of pH over which gelation can occur. A red reaction mixture indicates a suitable range and the mixture should gel in the presence of endotoxin. A yellow (acid) or purple (basic) color means that the sample is either at the extremes of the range or out of range.

Storage

Recommended storage temperature for Pyrosol buffer is 2-30°C.

Use

Follow the instructions in the insert included with Pyrotell lysate for reconstitution of the LAL, substituting Pyrosol buffer for LAL Reagent Water (LRW). LRW is recommended for the dilution of standard endotoxin or samples for assay.

Multitest vials of Pyrotell lysate reconstituted with Pyrosol buffer should have the same sensitivity as reagent reconstituted with LRW, within the error of the test. Confirm the sensitivity of Pyrotell lysate reconstituted with Pyrosol buffer as indicated in the appropriate pharmacopeial reference (1, 2) or U.S. FDA guideline (3).

Discard any Pyrosol buffer remaining in opened containers at the end of the working day.

Precautions

Pyrosol buffer is not intended for use in humans or animals either alone or as a vehicle for other substances.

Pyrosol buffer is not intended for use as a diluent for

endotoxin or test samples, however if such use cannot be avoided, observe the following precautions.

Because the buffer inhibits the gel-clot test at concentrations greater than 0.1M in the reaction mixture, it may be necessary to dilute the buffer with LRW before use. Make sure that the concentration is the same in all samples, including the endotoxin standard series and inhibition/enhancement controls.

Pyrosol buffer may not bring the pH of all samples into the range necessary for successful performance of the LAL test, especially at greater sample concentrations. See the appropriate insert included with Pyrotell lysate for information concerning the pH of the reaction mixture.

References

1. Bacterial Endotoxins Test. USP current revision, United States Pharmacopeial Convention, Rockville, MD.
2. European Pharmacopoeia, current revision, Section 2.6.14. Bacterial Endotoxins. European Pharmacopoeia Secretariat, Strasbourg.
3. Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, December 1987.

LAL Reconstitution Buffer

PYROSOL®

with pH indicator

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