0.1 M TRIS BUFFER SOLUTION (TRIS {HYDROXYMETHYL} AMINOMETHANE)

Catalog #: BT105

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INTENDED USE:

The Tris 0.1 M Buffer Solution is used as an adjunct for endotoxin testing by Limulus Amebocyte Lysate (LAL) methods. The principle use of this solution is to provide pH buffering to test-materials prior to LAL testing[1]. The USFDA Guideline for LAL test applications allows the use of adjuncts to overcome inhibitory LAL-test conditions[2].

EXPLANATION OF TEST:

The LAL test is the most sensitive and specific means available to detect and measure bacterial endotoxin. The LAL reaction is an enzyme mediated process which requires a neutral pH environment and a proper balance of monovalent and divalent cations[1,2]. A pH-related inhibition is likely when the pH is lower than the optimum range and when there is a failure to recover the positive product control (PPC) in the LAL test.

The most common type of LAL-test interference is a sub-optimum pH condition[1]. All gel-clot and kinetic (chromogenic and turbidimetric) LAL reagents from Charles River Endosafe are highly buffered so that minor pH disparity is satisfied by the reagent. The ideal method to resolve chemical inhibition is to use permissible dilution. However, when levels of interfering components in the test sample are high and the MVD is low, the use of additives and dilution are the only option to testing within the permissible dilution. The best way to neutralize test specimen and raw materials for LAL testing is to make the initial dilutions of the test material with the Tris 0.1 M Buffer Solution.

COMPOSITION:

Each vial contains 5.5 mL of a buffering solution containing 0.1 Molar Tris(hydroxymethyl)-aminomethane at pH 7.4. The buffer is terminally sterilized under validated conditions and is endotoxin-free.

WARNINGS AND PRECAUTIONS:

1. For in vitro use only. Not to be used in humans or animals.
2. Only use this reagent for pH neutralization of solutions or raw materials being prepared for LAL testing using an Endosafe® LAL Reagent. This buffer solution may be used to rehydrate Endosafe®-KTA reagent which is designated for assay with the LAL-5000 kinetic turbidimetric instrument where a 1:4 LAL-to-sample ratio is applied.
3. Do not use this reagent unless it is clear and colorless.
4. Use pH electrodes that are compatible with Tris solutions.

STORAGE CONDITIONS:

Store all vials at 2-to-30°C. Do not freeze.

PROCEDURES:

Determination of the pH of the sample-LAL mixture.

1. Dilute the material to be tested to the desired concentration.
2. Mix equal parts of diluted test solution and Endosafe® LAL in a depyrogenated tube.
3. Check the pH of the mixture with a Tris-compatible system. The test material may be incompatible with LAL methods if the pH is not in the acceptable range of 6.5 to 8.0.
4. The optimum method for using this 0.1 M Tris Buffer solution to make at least the first 1:10 dilution of the test material with the buffer. The 0.1 M Tris Buffer should be used to make dilutions to the extent that the LAL-sample mixture is neutralized to the acceptable pH range and is compatible with the selected LAL method.

Routine LAL-test application.

1. Ideally, use the 0.1 M Tris solution for the first dilution step to maximize the effect of buffering and dilution.
2. If pH adjustment is required for routine LAL testing, conduct a validation study to confirm that the neutralization procedure resolves the interference condition.

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REFERENCES:

1. Cooper, J.F. "Resolving LAL Test Interferences." J. Parent. Sci. & Tech., 44:1, p.13 (1990).

2. 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. Dept. of Health & Human Services, FDA, December 1987.

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