

Alkaline Pretreatment Solution

Instructions for Use

Manufactured by:



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Alkaline Pretreatment Solution FOR *IN VITRO* DIAGNOSTIC USE.

The Alkaline Pretreatment Solution is intended for use with the Fungitell® STAT protease zymogen-based colorimetric assay (Fungitell® STAT, Cat # FT007, from Associates of Cape Cod, Inc).

Reagent Provided

Each vial contains 2.5mL of 0.125 M KOH and 0.6 M KCl solution. This product is certified free of interfering glucans.

Precautions

1. For Professional users.
2. Establish a clean environment in which to perform the assay. Use materials and reagents that are certified to be free of detectable background levels of (1→3)-β-D-glucan. Note that glucan as well as fungal contamination from the human body, clothes, containers, water and airborne dust may cause interference with the Fungitell® STAT assay. Cellulosic materials such as gauze, paper wipes, and cardboard may contribute (1→3)-β-D-glucan to the environment where the assay is performed.
3. Products with damaged contents should not be used.
4. Do not use this product beyond its expiry date.
5. Use suitable protective clothing to avoid contact with eyes and skin. It is recommended to use this product within a biological safety cabinet to avoid inhalation as well as to increase the operator safety while working with patient samples and to reduce the potential for contamination by environmental (1→3)-β-D-glucan during the procedure. Materials exposed to potentially contaminated (pathogen-containing) fluids must be disposed of in a manner consistent with local regulation.
6. A Safety Data Sheet is available on the company website at www.acciusa.com.

Procedure

The Alkaline Pretreatment Solution is a ready to use solution. The Alkaline Pretreatment Solution converts triple-helix glucans into single-stranded glucans^{1, 2},

which are more reactive in the Fungitell® STAT assay. Additionally, the alkaline pH serves to inactivate serum proteases and inhibitors that can interfere with the assay³. Only the steps associated with the use of the Alkaline Pretreatment Solution are presented below. Refer to the Fungitell® STAT IFU (PN002603) for the complete assay procedure.

- Prepare patient sample tubes
 - a. Vortex patient samples for at least 20 seconds to ensure homogeneity.
 - b. To the appropriate labeled empty tube, add the patient sample and Alkaline Pretreatment Solution in a ratio of 1:4. The recommended volumes are 50 µl of patient sample and 200 µl of Alkaline Pretreatment Solution.
 - c. Vortex for 15 seconds and cover.
- Prepare Fungitell® STAT Standard tube
 - a. Reconstitute one vial of the Fungitell® STAT Standard with the Lot# specific volume of LAL Reagent Water and vortex for 15 seconds.
 - b. Add the Lot# specific volume of Alkaline Pretreatment Solution.

Note: *The Lot# specific reconstitution and pretreatment solution volumes are stated on the Fungitell® STAT Standard package label, on the Fungitell® STAT product Certificate of Analysis, and are available on the company website.*
 - c. Vortex for 15 seconds and cover.
- Pretreatment Incubation
Incubate the patient sample tubes and the Fungitell® STAT Standard vial for 10 minutes at 37°C.

Storage and Disposal

Store at 2-30°C. It is recommended to discard the open vials in accordance with your laboratory procedures. It is recommended not to use an open vial for more than one run to avoid potential contamination.

References

1. Saito, H., Yoshioka, Y., Uehara, N., Aketagawa, J., Tanaka, S., and Shibata, Y. 1991. Relationship between conformation and biological response for (1→3)-β-D-Glucans in the activation of coagulation factor G from *Limulus* amoebocyte lysate and host-mediated antitumor activity. Demonstration of single-helix conformation as a stimulant. *Carbohydrate Res.* 217:181-190.
2. Aketagawa, J., Tanaka, S., Tamura, H., Shibata, Y., and Saito, H. 1993. Activation of *Limulus* coagulation factor G by several (1→3)-β-D-Glucans: Comparison of the potency of glucans with identical degree of polymerization but different conformations. *J. Biochem* 113:683-686.
3. Ogawa, M., Hori, H., Niiguchi, S., Azuma, E., and Komada, Y. 2004. False positive plasma (1→3)-β-D-Glucan following immunoglobulin product replacement in adult bone marrow recipient. *Int. J. Hematol.* 80: 97-98.