

GLUCASHIELD®

INTENDED USE

Glucashield is a buffer intended for reconstitution of *Limulus* Amebocyte Lysate (LAL) reagent. It is formulated to block interference by (1→3)-β-D-glucans in endotoxin assays. Neutralization of interference with the LAL assay by glucans is addressed in the USP Bacterial Endotoxins Test¹.

PURPOSE

Endotoxin test false positives have been associated with the presence of (1→3)-β-D-glucans^{2,3}. The cause of the false positive is the activation of a glucan sensitive factor (Factor G) in LAL⁴. Glucan contamination may occur from product contact with cellulosic materials or from products derived from fungi. Certain bacterial or algal products may also contribute to glucan-derived interference. Additionally, when interfering glucans are present, test results may be elevated due to enhancement of the response to endotoxin². Glucashield may be used to block interference caused by glucan concentrations of up to 100 ng/mL (determined with Pachyman, a relatively potent glucan). To determine whether or not the samples are subject to (1→3)-β-D-glucan interference, compare endotoxin levels reported with non-Glucashield reconstituted LAL to those levels obtained with Glucashield reconstituted LAL. If the sample values are significantly lower with Glucashield reconstituted LAL product then it is likely the samples contain (1→3)-β-D-glucans. By blocking these and ensuring that all other required parameters of endotoxin testing are met, it should be possible to successfully measure endotoxin in products that would otherwise be difficult to assay accurately.

REAGENT COMPOSITION

Glucashield consists of an endotoxin-free Factor-G blocking reagent in a 0.2 M Tris-buffered formulation with a pH of approximately 7.4 at 37°C.

STORAGE CONDITIONS AND WARNINGS

Store Glucashield at 2-8°C.

Store lysate products reconstituted with Glucashield as described in the package insert for the specific product.

Use aseptic technique when using this product.

Glucashield is uniquely formulated to be compatible with LAL products manufactured by Associates of Cape Cod. Use of this buffer with LAL products from other manufacturers is not recommended.

For *in-vitro* use only. Glucashield is not to be used for the detection of endotoxemia.

INSTRUCTIONS FOR USE

- 1) Use of a decrimping tool or pliers is recommended for removal of the metal crimp seal from the vial of Glucashield. Carefully remove the stopper from the vial, taking care not to contaminate the contents.
- 2) Reconstitute the LAL Product with Glucashield following the package insert for the specific product using aseptic technique.
- 3) Allow the reconstituted LAL product to equilibrate to room temperature prior to use.
- 4) Perform the assay following the instructions in the package insert for the specific product.

PRODUCT NOTES

- 1) Consult the package inserts for the times and conditions for storage of reagents after reconstitution.
- 2) When using Glucashield in place of Pyrochrome® Buffer with Pyrochrome in a kinetic chromogenic test, it may be necessary to extend the incubation time to 75 minutes. This incubation time may need to be determined in your laboratory due to varying incubation conditions.
- 3) Glucashield is not intended for use with Pyrotell® Single Test Vials (STVs).

REFERENCES

1. Bacterial Endotoxins Test, United States Pharmacopeia (current revision), United States Pharmacopeial Convention, Rockville, MD.
2. Roslansky, P. F. and T. J. Novitsky. 1991. Sensitivity of *Limulus* Amebocyte Lysate (LAL) to LAL-Reactive Glucans. J. Clinical Microbiology 29:2477-2483.
3. Kakinuma, A., T. Asano, H. Torii, and Y. Sugino. 1981. Gelation of *Limulus* amebocyte lysate by an antitumor (1→3)-β-D-glucan. Biochem. Biophys. Res. Commun. 101:434-439.
4. Morita, T., S. Tanaka, T. Nakamura, and S. Iwanaga. 1981. A new (1→3)-β-D-glucan-mediated coagulation pathway found in *Limulus* amebocytes. FEBS Lett. 129:318-321.

Glucashield®

Glucan Inhibiting Buffer

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