

WAY 18

Associates of Cape Cod – Delivering Rapid Endotoxin Testing Results for Compounding Pharmacies

Pyrosate® has been developed as an easy-to-use Limulus Amebocyte Lysate (LAL) gel-clot test that enables rapid testing and does not require special laboratory supplies. The Pyrosate kit provides rapid results and is especially convenient for research, testing water, and dialysate.

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Company Background

Associates of Cape Cod, Inc. (ACC), is one of the world's largest manufacturers of products developed to detect and quantify gram-negative bacterial endotoxins and (1→3)-β-D-glucans. Our products are used worldwide by leading pharmaceutical and medical device companies to ensure the safety of their parenteral drugs, biological products, and medical devices. Our goal is to provide the best products and services, as well as the best technical support and customer service in our industry, to enhance the productivity and efficiency of all our customers. We are ISO 13485: 2003 certified, our laboratories are FDA inspected and DEA licensed. Our Beacon Diagnostics® laboratory is CLIA certified.

Product Overview

Associates of Cape Cod, Inc., (ACC) is pleased to introduce Pyrosate®, a new FDA licensed version of our rapid endotoxin detection kit. Pyrosate is well suited for performing endotoxin assays in full compliance with the Bacterial Endotoxins Test, USP chapter <85>. Pyrosate has been developed as an easy-to-use Limulus Amebocyte Lysate (LAL) gel-clot test that enables rapid testing and does not require special laboratory supplies. The easy-to-follow, step-by-step illustrated instructions allow the user to set up assays within minutes.

In addition to FDA licensure, the Pyrosate® Kit is now available in sensitivities of 0.03 EU/mL, 0.125 EU/mL and 0.25 EU/mL, in both 10-pack and 30-pack formats. With the introduction of this licensed version, in addition to research and water testing, Pyrosate is ideal for dialysis centers, compounding pharmacies, and pharmaceutical and medical device companies.

Performing the Test

The Pyrosate® kit is a rapid gel-clot test that contains a 2λ* endotoxin tube (PPC) matched to the sample (SPL) tube for each sensitivity. This feature is unique to the Pyrosate assay. The endotoxin tube (PPC) assures that the sample does not interfere with the test, ruling out false negatives. Pyrosate is formulated to eliminate false positives due to (1→3)-β-D-glucans. This endotoxin specific reagent does not require additional blocking buffers.

Reconstitution

Pyrosate® is reconstituted directly with the sample by adding 0.5 mL to the sample tube (SPL). After approximately 60 seconds of gentle mixing, 0.25 mL is transferred to the endotoxin tube (PPC). The lot-specific incubation time at 37±1°C is given on the Certificate of Compliance.

Stability

Pyrosate® is stable at room temperature and does not require refrigeration for shipping or storage.

Product Applications

- Hemodialysis
- Water and Water Systems
- Filter Industry
- Research
- Final Product Release

Product Benefits

- Shorter Assay Time
- Endotoxin Specific
- No Dilutions Required
- No Refrigeration Required
- Matched Positive Product Control

*λ (lambda) is the lowest concentration of endotoxin to cause a positive test result under standard conditions.