



# USP BET Compliant Endotoxin Testing for Compounding Pharmacies by Associates of Cape Cod, Inc.

Associates of Cape Cod, Inc. (ACC) is an industry innovator and global supplier of endotoxin and glucan detection products and services.

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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 and our Beacon Diagnostics® laboratory is CLIA certified.

## Product Overview

### Pyros Kinetix® Flex Incubating Tube Reader

*Designed Specifically For Endotoxin Testing*

The Pyros Kinetix® Flex is an optical tube reader that runs both chromogenic and turbidimetric assays in compliance with the USP, EP, and JP bacterial endotoxin test chapters. Designed with flexibility and efficiency in mind, the PK Flex is available in three configurations: 32, 64 and 96 wells. The test capacity of a 32 well system can be doubled by connecting another unit. Data acquisition, analysis and reporting is performed by our 21 CFR Part 11 compliant Pyros® EQS Software.

## Features & Options

- **Compliance:** Meets USP BET Requirements
- **Cost-Effective:** Significant Cost Savings Available
- **Rapid Turn-Around:** Results Possible in Under 60 Minutes
- **Ease of Use:** 1 Part Product, 1 Part Reagent – The System Does the Rest
- **Operating Environment:** Non-Sterile (No Satellite Laboratory or Hood Required)
- **Low Start-up Costs:** Rapid Return On Investment
- **Technical Support:** Telephone, e-mail and Onsite Services

## Why Test For Endotoxin?

USP <797> requires that Compounding Pharmacists test certain high risk Compounded Sterile Preparations (CSPs).

## What Are Your Options?

Either send out to a contract lab, or test in-house. Associates of Cape Cod's Pyros Kinetix® Flex Endotoxin Detection System provides a cost-effective, in-house endotoxin testing solution.