ASSOCIATES OF CAPE COD INCORPORATED
Specialists in Endotoxin and Glucan Detection

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Walk us through recent developments in your LAL product offerings.

Associates of Cape Cod, Inc.'s (ACC) fourth generation tube reader, the Pyros® Kinetix Flex, offers the most sensitive bacterial endotoxin test (BET) available for both turbidimetric and chromogenic kinetic methods. In addition to flexibility of test method, ACC offers a choice of 32, 64 and 96 well readers. All of these readers provide the flexibility to add tubes at any time. Unlike a microplate reader, additional samples can be added after a test has been started. Also, we shall soon have an exciting new offering in the area of endotoxin testing.

Discuss techniques for overcoming inhibition and enhancement.

There are a range of strategies for overcoming interference. The most common technique is dilution. The test method is usually substantially more sensitive than is necessary to detect the endotoxin limit, which allows the sample to be diluted to overcome interference. For example, if the sensitivity is 100 times greater than the endotoxin limit (i.e. the maximum valid dilution is 100), the sample can be diluted by a factor of up to 100. In some cases, a particular test method may be less susceptible to interference by a particular product. ACC's Contract Test Service can develop and validate a test method.

What are the core strengths of your Contract Test Services?

Our Contract Test Services group has more than 30 years of experience with products ranging from classic and novel drugs to biological products, medical devices of very different configurations as well as biologically-based medical devices.

In addition to routine testing, CTS has extensive expertise and the ability to:

- Develop methods for difficult samples such as liposomes, oligonucleotides and nanoparticles
- Work closely with clients to customize endotoxin testing to the individual clients' needs
- Provide same day test for rapid turnaround
- Training and transfer of BET test methods developed
- Design and produce custom depyrogenation controls for oven validations.

CTS is GMP compliant, ISO 13485: 2003/2012 certified and licensed by the DEA as a laboratory capable of handling controlled drug substances other than those included in Schedule I. Endotoxin testing is performed in accordance with FDA guidance and USP, EP and JP requirements, as is appropriate for the customer's needs.

What are the benefits of attending one of your BET workshops?

Our workshops are attended by people ranging from those who have never performed an endotoxin test to those with many years of experience. The workshops are educational, interactive and give hands-on experience conducting LAL tests and learning to read and interpret results.

The benefits of attending our BET workshops include:

- A better understanding of endotoxin and the BET through detailed demonstrations of the test methods including a discussion of laboratory set-up, materials, aseptic techniques, and sample handling/preparation, which can assist in developing a strategy to overcome interference.
- A clear understanding of the regulations and standards applicable to endotoxin testing and the rationale behind them. This helps assure that the appropriate procedures and controls are in place for compliant testing.

ACC also offers a Bioburden, Endotoxin and Sterility Testing (BEST) training program in collaboration with EMD Millipore.

What does the future hold for LAL testing?

The future of endotoxin testing is bright, given the importance of QC testing of injectable products and non-pyrogenic medical devices. It is likely that new technology will become available and replace the current dominant technologies. However, the conservative nature of Pharma means that adoption of such new technologies will be slow. Any new technologies will need to be thoroughly validated and proven before they will be accepted by this highly regulated industry. LAL technology has protected and helped improve the quality of a wide range of critical healthcare products. The industry and the regulators will not want to leave behind this proven technology without the confidence of knowing the alternatives offer the highest levels of assurance of product integrity and patient safety. ACC is working towards this end.