

February 23, 2017

Notification RE: Pyrosate® Kit Update. Please note, this is for your information only. No action is required.

Dear Valued Customer:

The Pyrosate® Kit was FDA licensed in 2014 for use per the USP BET. In the current kit configuration, a compliant test must be performed using Reference Standard Endotoxin (RSE). This option is more expensive and provides a shorter reconstitution expiry date when performing the Bacterial Endotoxin Test (BET).

As we transition into Q1 2017, Associates of Cape Cod, Inc. (ACC) is excited to now offer you a more user-friendly alternative which will allow the use of the 2λ* Positive Product Control (PPC) included in the Pyrosate® Kit as a replacement for the RSE. This will result in a more cost effective and economically viable test.

Additionally, due to the shortened expiration date of the disposable transfer pipettes, they will no longer be sold in the 10 Test Pyrosate® Kit configurations (PSD030-10, PSD125-10, PSD250-10). They will however continue to be sold separately under catalog #PPT50.

The product instructions For Use (IFU) have been updated to include four (4) new Pyrosate CSE Quick Guides to supplement the current IFU. These guides now illustrate how to properly perform the test using the **Product Positive Controls** included in the kit (also referred to as CSE). These CSE Quick Guides and updated IFU are available for download at www.acciusa.com/lal/productinserts/index.html.

The Pyrosate® Kit will still be available in the following sensitivities in both 10 pack (*minus the disposable transfer pipettes*) and 30 pack formats:

- 0.03 EU/mL (catalog numbers PSD030-10 or PSD030-30)
- 0.125 EU/mL (catalog numbers PSD125-10 or PSD125-30)
- 0.25 EU/mL (catalog numbers PSD250-10 or PSD250-30)

The Pyrosate® line offers several key advantages for our customers including:

- Shorter assay time for 0.125 and 0.25 EU/mL sensitivities
- Endotoxin specific – no glucan interference
- No dilutions may be necessary
- No refrigeration required
- Matched positive product controls
- Easy, convenient testing with no waste

If you have any questions, need any additional information, or wish to order Pyrosate® or any other products or services from ACC, please contact your local representative, call ACC at 1-888-395-ACC1(2221) or email us at custservice@acciusa.com.

We appreciate your business, and will continue to provide you with leading BET products and services to meet your current and future needs.

Sincerely,

Vann

Vann Jones
Senior Manager, Marketing

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

PR # PR-17-004