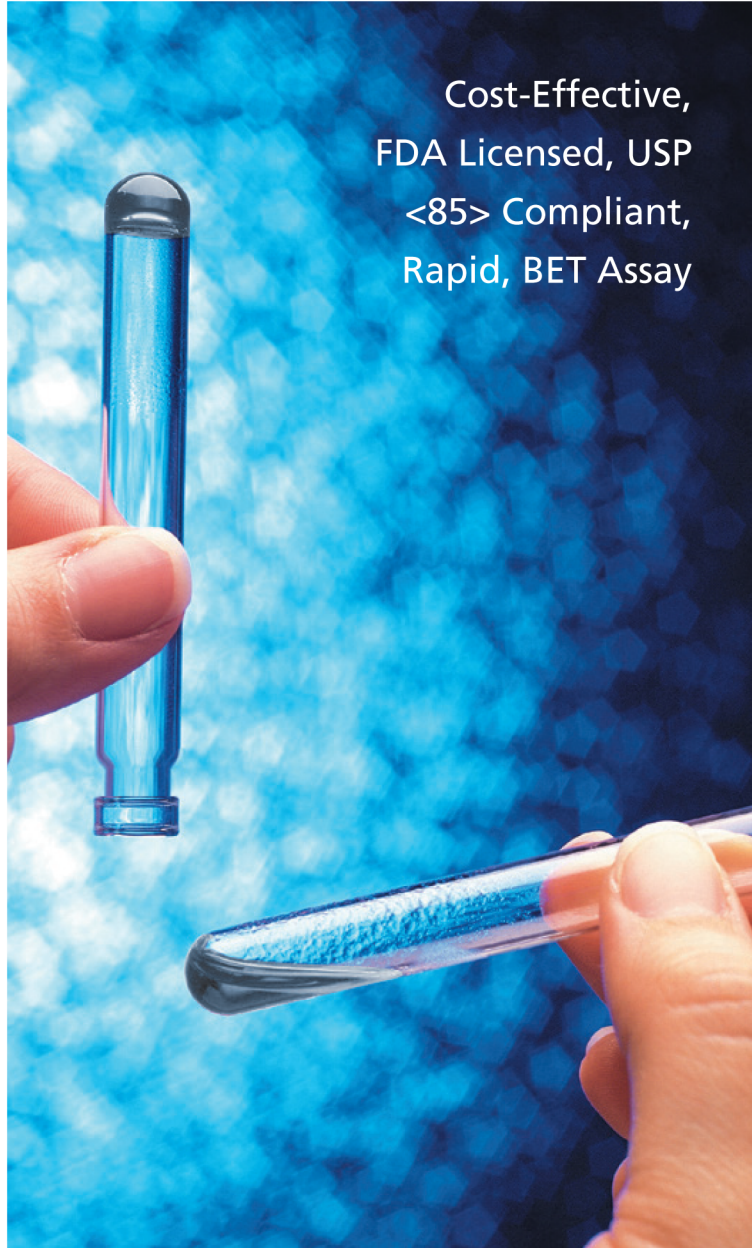


PYROSATE® KIT



Cost-Effective,
FDA Licensed, USP
<85> Compliant,
Rapid, BET Assay

 **Associates of Cape Cod, Inc.**
Your Endotoxin & Glucan Experts

www.acciusa.com

Available in Canada from...

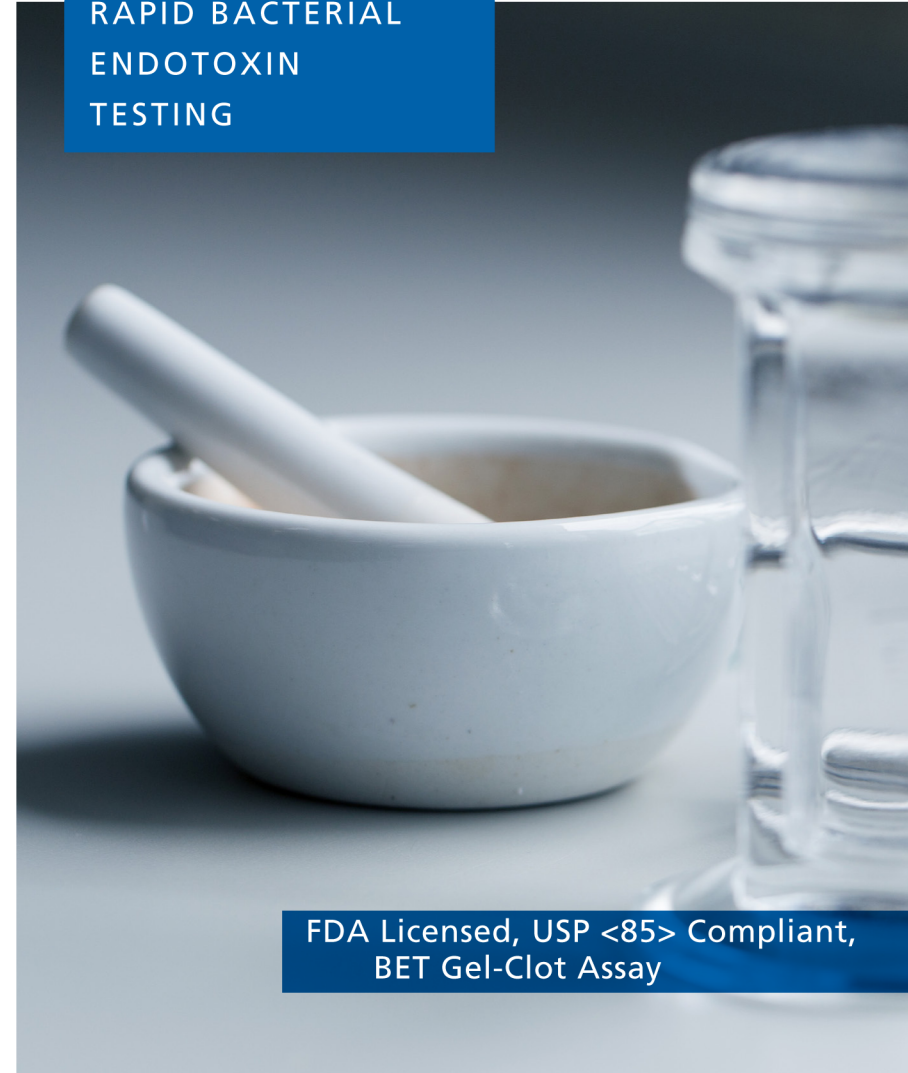
MJS
BioLynx
INC.

1-888-593-5969
www.biolynx.ca
tech@biolynx.ca



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PYROSATE® KIT
RAPID BACTERIAL
ENDOTOXIN
TESTING



FDA Licensed, USP <85> Compliant,
BET Gel-Clot Assay

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PR18-012

PYROSATE® RAPID ENDOTOXIN DETECTION KIT

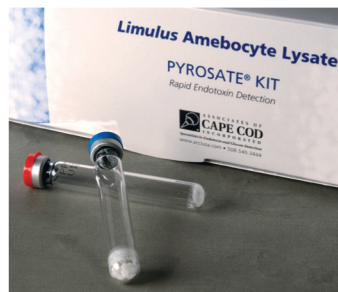
FDA LICENSED, USP <85> COMPLIANT, BET GEL-CLOT ASSAY

Sample Positive Product Control (PPC)

Pyrosate® is a rapid, easy to use and cost effective compliant BET test. The positive product control is provided within the kit to simplify setup. Pyrosate® is reconstituted directly with the sample by adding 0.5 mL to the sample tube (SPL). This feature is unique to the Pyrosate® assay and ensures the validity of the test.

Robust Gel-Clot Assay That Is Less Susceptible To Product Interference

Pyrosate® is formulated to eliminate false positives due to (1→3)-β-D-glucans. This endotoxin specific reagent does not require additional blocking buffers.



Results In About 30 Minutes

- Increase your turnaround time
- Increase efficiency and save money

Minimal Startup Cost

Get started for around \$500 with incubating heat block.

Low Per Sample Cost (~\$10/sample)

The low cost-per-sample amount and rapid turn-around time provides for a rapid return on your investment.

FDA Licensed Product That Can Be Run As A Fast Check Or As A Fully USP <85> Compliant Assay

Using the Pyrosate® Kit provides flexibility and ensures your compounding requirements for compliance with USP 797 are fully met.

Room Temperature Storage

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

Sensitive Down To 0.03 EU/mL

The Pyrosate® kit is available in sensitivities of 0.03 EU/mL, 0.125 EU/mL and 0.25 EU/mL. The test may be as short as 30 minutes, depending on the sensitivity.

Endotoxin Specific Reagent

There is no need to be concerned about false positive results due to Beta Glucan contamination.

QC Laboratory Skills Not Needed

The Pyrosate® kit is developed as an easy-to-use LAL gel-clot test. The assay does not require special QC training or laboratory supplies. The step-by-step illustrated instructions allow the user to perform assays within minutes. The test utilizes a simple bulb pipetting technique that is straight forward and high levels of precision are not needed for successful tests.

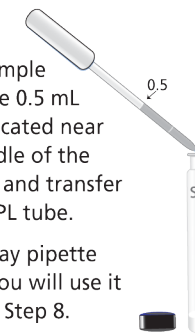


Process Overview

1

Draw sample up to the 0.5 mL mark (located near the middle of the pipette) and transfer to the SPL tube.

Do not lay pipette down, you will use it again in Step 8.



2

Gently mix the contents of the tube by lightly tapping the bottom several times with your finger.

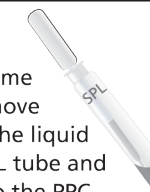
The contents of the tube should completely dissolve within 20-60 seconds.



3

Using the same pipette, remove 0.25 mL of the liquid from the SPL tube and transfer it to the PPC tube (the 0.25 mL level is the unlabeled ring-mark below 0.5 mL on the pipette).

Discard the pipette.



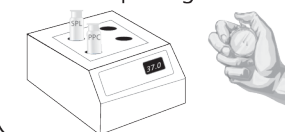
4

Gently mix the contents of the PPC tube by lightly tapping the bottom several times with your finger (10-20 seconds).



5

Immediately place both tubes in the wet or dry bath incubator. Incubate at 37 ± 1°C for the incubation time indicated on the 10 vial clamshell package labels.



For a complete guide to performing the Pyrosate® test please refer to the product IFU.