



Weekly Bulletin

week ending September 29, 2023

Most Recent Topics Covered in PMFList

Sterility test area

TAMC and TYMC test for probiotic sample.

Most Recent Content Added to PMF Website

FDA Regulatory Actions

most recent: <http://www.microbiologyforum.org/content/file/Regulatory%20Actions/RA%20August%2025%202023.pdf>

Compendial Updates

most recent: [two entries] <http://www.microbiologyforum.org/content/file/Compendial%20Updates/CU%20August%2018%202023.pdf>

Articles/White Papers

most recent: http://www.microbiologyforum.org/content/file/White%20Papers/Trend%20Analysis_2.pdf

YouTube Videos

most recent: Micro Lab GMP Requirements [<https://youtu.be/cyy-TkFolpQ>]

Most Recent Content Added to PMF Website

E-Books/Training

this week: the 2010 PMFList Yearbook is available! A sample (pages 1-127 out of 388) of the Yearbook is at <http://www.microbiologyforum.org/content/file/E-Books/Book%20for%20Sponsor%202010%20v3%20sample.pdf>

Events

most recent: [Pharmig Events \(see note at linked page\)](#) [3]

Sponsors page

most recent: Icons and sponsor information added to webpage <http://www.microbiologyforum.org/sponsors.asp>

PMF “Cartoons” [\[click here\]](#)

this week: a sample question and a reply from the 2010 PMFList Yearbook is presented.

New Subscribers: 2

PMF Sponsorship Information and General Information (click link) **[revised]**

<http://www.microbiologyforum.org/content/file/Sponsorship/PMF%20Sponsorship%20full%20form%202023%20September%2021%202023%20A.pdf>

New Sponsor(s)

none this week

Thank You, Current Sponsors!



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Giles Scientific, Inc.

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PMF “Cartoons”



A question with one of the several replies from the 2010 PMFLIST Yearbook:

I am encountering back order issues with our BET (Bacterial Endotoxin Testing) supplier. They have recommended an alternative method to BET testing besides using Limulus ameocyte lysate (LAL). Called the PyroGene® Recombinant Factor C Endotoxin Detection System by [name redacted]. Have you all any experience with it? Is this an acceptable alternative test to BET by the USP, EP.... or regulatory bodies like the FDA, EU, TPD

Reply:

There is no regulatory significance in the fact that the recombinant Factor C assay is not licensed. The only reason that LAL reagents are licensed is because they originate from the blood of the horseshoe crab and the these reagents are still classified as 'blood products'. Licensing has nothing whatsoever to do with their suitability to perform the Bacterial Endotoxins test (BET). PyroGene was approved for sale several years ago and prior to its release, we specifically asked the FDA if this product required a license. The answer was 'No' because it is not derived from blood as a raw material starting point.

Feel free to email suggestions relevant to the Yearbooks to:

dporter@microbiologyforum.org

Thank you!

