ASSOCIATES OF
CAPE COD
INCORPORATED

Specialists in Endotoxin and Glucan Detection

December 20, 2012

Re: Lot Change in USP Endotoxin Reference Standard

Dear Customer:

The purpose of this letter is to inform our customers of a change in lots of the USP Endotoxin Reference Standard (RSE) and other issues related to RSE. You are receiving this letter because in the past your organization has purchased *Limulus* amebocyte lysate (LAL) reagent manufactured by from Associates of Cape Cod, Inc. (ACC).

USP Endotoxin Reference Standard lot G3E069 had been replaced by a new lot, number H0K354. (The previous lot, G3E069, can be used through February 2013; then it will cease to be a valid USP standard[1].) The USP has conducted a multi-laboratory collaborative study and established that the new standard (H0K354) is equivalent in potency to the former standard (G3E069).

In addition, the FDA has ceased providing its own RSE, of which the last lot was EC6-3, to licensed LAL manufacturers for release of lysate reagent lots. Manufacturers now have to use USP endotoxin reference standard. Consequently, the vial labels on recent (and future) lots of ACC's multi-test vials of gel-clot reagent bear the RSE lot number H0K354. In addition, lot H0K354 is now the RSE used for potency determinations and will be listed on certificates of analysis (Cs of A).

This controlled change in reference standards is not expected to cause any performance issues. If you have any concerns please contact our Technical Services staff at techservice@acciusa.com or on (508) 540-3444.

Sincerely,

Michael Dawson

Michael E. Dawson, Ph.D., RAC
Director of Regulatory Affairs

[1] http://store.usp.org/OA_HTML/ibeCCtpItmDspRte.jsp?item=18789&section=10552&beginIndex=20&sitex=10020:22372:US).

124 Bernard E. Saint Jean Drive ■ East Falmouth, Massachusetts 02536 ■ Tel: (800) 848-3248 ■ (508) 540-3444 ■ Fax: (508) 540-8680