

September 27, 2018

Notification RE: Important information regarding the newly configured Fungitell[®] Assay Kit. We recommend that customers evaluate the impact of the kit changes on their operating protocols.

Dear Valued Customer:

You are receiving this notification as a follow up to our letter dated 25 January 2018. As you may be aware, Associates of Cape Cod, Inc. (ACC) has modified the kit configuration and packaging for the Fungitell[®] Assay. To recap, the changes are outlined as follows:

- ✓ Two (2) vials of pre-combined Alkaline Pretreatment Solution are included in the kit in lieu of one (1) vial of KCl and one (1) vial of KOH* – eliminating the mixing step
- ✓ Pyroplates[®] have been removed from kit packaging due to expiration date concerns impacting the life of kits
- ✓ IFU (*Instructions for Use*) are now printed in English only, additional languages are available online
- ✓ Newly designed box to accommodate new configuration
- ✓ New carrier inserts for product integrity during shipping and storage
- ✓ Recyclable packaging

In July, we began shipping the new kit configuration. Pyroplates[®] will now need to be ordered separately. You may purchase Pyroplates[®] from ACC as follows:

- CA961-10 96-well microplate - 10 pack
- CA961-50 96-well microplate - 50 pack

Failure to use Pyroplates[®] or equivalent may lead to invalid test results as other plates may contain interfering glucans.

For additional information, please contact our Clinical Diagnostic Product Manager Celeste Jones at +1 (508) 444-1469, or your local representative. We appreciate your business, and will continue to provide you with industry leading products and services to meet your current and future needs.

Sincerely,



Vann Jones
Senior Manager, Marketing

*The combined solution is equivalent in performance to the previous two component pre-treatment system. It does not change either the performance specifications or the operating principle of the IVD.