

August 15, 2022

To the attention of:

**Urgent Field Safety Notice**

Re: Fungitell STAT<sup>®</sup> FT007 Lot # FK22008 and Package Control # 113041

Dear Valued Customer:

You are receiving this letter because you are a customer of record for the above listed product, Fungitell STAT<sup>®</sup> cat# FT007, Lot # FK22008 and Package Control # 113041.

The Fungitell STAT<sup>®</sup> assay is a protease zymogen-based colorimetric assay for the qualitative detection of (1→3)-β-D-glucan in the serum of patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infection. The serum concentration of (1→3)-β-D-glucan, a major cell-wall component of various medically important fungi, can be used as an aid in the diagnosis of deep-seated mycoses and fungemias. (1→3)-β-D-glucan index values should be used in conjunction with other diagnostic procedures, such as microbiological culture, histological examination of biopsy samples and radiological examination.

Associates of Cape Cod, Inc., have been informed that a customer has received incorrect information on the Fungitell STAT<sup>®</sup> clamshells containing the Fungitell STAT<sup>®</sup> Standard. This relates to printed information for reconstitution and pretreatment volumes. No accessories to the Fungitell STAT kit (including pretreatment) are affected.

The incorrect information is:

Reconstitution water volume 480 μL  
Pretreatment volume 120 μL

The correct information is:

Reconstitution water volume 120 μL  
Pretreatment volume 480 μL

A complaint has been opened and we request the return of all unused FK22008 - Package Control # 113041 products in your inventory to Associates of Cape Cod, Int., Inc, Deacon Park, Moorgate Road, Liverpool, L33 7RX, United Kingdom.

Since the overall volume from the correct and incorrect information is the same, the risk for a significant impact on the product performance is very low. Initial testing shows that the Fungitell STAT Standard values remain within the acceptable range described within the Fungitell STAT Instructions for Use when using the incorrect reconstitution volumes. However, the product was not validated for use with the incorrect information and Associates of Cape Cod, Inc., made the decision to request the return of the Fungitell STAT<sup>®</sup> FT007 Lot # FK22008 and Package Control # 113041. Authorized representative/registration holder and competent authority in regions where the FK22008 kit was distributed will be informed of this field safety notification.

**Actions required from you:**

1. **Immediately discontinue the use of the Fungitell STAT Lot # FK22008 and Package Control # 113041.**
2. Please complete the attached Acknowledgement of Notification form.
  - a. Include the total number of unused FK22008 kits still in your inventory on the form.
  - b. Coordinate the return of all unused FK22008 kits following the instructions on the formThe completed form should be forwarded to Customer Services (customerservices@acciuk.co.uk)

We are sorry for this inconvenience. We continue to appreciate your business.

Thank you for your [REDACTED] tion to this matter. If you have any questions or concerns, please contact me.

Sincerely,

[REDACTED]  
Associate Director of Customer Operations for UK and EU

Tel: [REDACTED]

Email: [REDACTED]

COMPANY CONFIDENTIAL



15 August 2022

### Acknowledgement of Notification

Re: Fungitell STAT<sup>®</sup> FT007 Lot # FK22008 and Package Control # 113041

Please complete this form acknowledging receipt of notification of the issue described in the attached letter and return it to ACC by email as indicated below.

I acknowledge receipt of notification regarding Fungitell STAT<sup>®</sup> FT007 Lot # FK22008

**Number of unused FK22008 kits still in your inventory:** \_\_\_\_\_

Company Name: \_\_\_\_\_

Telephone: \_\_\_\_\_

Email: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_

Post/Zip Code: \_\_\_\_\_

Country: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Signature: \_\_\_\_\_

A Return Authorization (RA) form will be issued for the return of these products.

Email a PDF of the completed form to **[customerservices@acciuk.co.uk](mailto:customerservices@acciuk.co.uk)**.

If you have any questions or concerns, please contact Customer Services ([customerservices@acciuk.co.uk](mailto:customerservices@acciuk.co.uk)) or Technical Services ([techservice@acciusa.com](mailto:techservice@acciusa.com))

Thank you for your attention to this matter.

COMPANY CONFIDENTIAL