

December 31, 2024

Notification RE: Important information regarding the Fungitell STAT® Quick Visual Guide (QVG)

Dear Valued Customer:

You are receiving this notification to advise you of changes to the Fungitell STAT® QVG. These changes are being implemented to better align the QVG with the Instructions for Use (IFU).

The changes are as follows:

- Increasing the vortex time from 10 to 15 seconds in Step 1
“Add 200 µL APS to each TB240, vortex 15 sec. and cover”
- The pipette has been repositioned vertically into the vial to emphasize that the liquid must be expelled directly into the vial as illustrated in Step 3
- “at NMT 2000 RPM” has been added to Step 3 “Vortex each RGT for 1-2 seconds at NMT 2000 RPM”

This change was implemented on 20 November 2024. Lot FK24024 was the first FT007 kit which contained the updated information.

For additional information, please contact me at cjones@acciusa.com or your local representative. A digital copy of this letter along with all other product notifications can be found on our corporate website at www.acciusa.com under the “News & Notices” section. In addition, the updated QVG is available on our website at www.fungitell.com/fungitell_stat.

We appreciate your business and will continue to provide you with industry-leading products and services to meet your current and future needs.

Sincerely,



Celeste P. Jones
Clinical Diagnostic Product Manager

MKT# 25-275