BEFORE YOU START!!! Record Lot# and volumes for this specific kit.

Information is found on the Fungitell STAT® Standard (STD) clamshell or on our website www.acciusa.com under Certificate of Compliance.

STD lot#:_________ STD lot# specific LRW volume:_________ STD lot# specific APS vol.:_________

Prerequisites:
- All materials must be free of interfering glucans
- Use long pipette tips (e.g., Toxipet) to avoid cross-contamination
- One STD should always be included on every run with SPLs
- STD should always be processed at the same time as SPLs
- It is strongly recommended the assay be performed in a biosafety cabinet

1 STANDARD/SAMPLE PREPARATION

Set up and label tubes:
- one TB240 + one RGT tube per each SPL
- one STD + one RGT tube

Transfer 50 µL of thawed, vortexed (20 sec.) SPL to TB240

Add 200 µL APS to each TB240, vortex 10 sec. and cover

Reconstitute STD with _______ µL LRW, vortex 10 sec.

Add _______ µL APS to STD, vortex 10 sec.

3 ADDING REAGENT

During incubation, reconstitute RGT with 300 µL LRW, vortex NMT 5 sec.

After incubation is complete, retrieve TB240s and STD, vortex for 5 sec. each

Use a Toxipet to transfer 75 µL STD to RGT

Use a Toxipet to transfer 75 µL SPL from TB240 to respective RGT

Vortex each RGT for NMT 5 sec.

4 READ/REPORT

Place each RGT in their respective wells in PKF08 for a 40 min. test at 37º C

Key:
- SPL: Patient Serum Sample
- LRW: LAL Reagent Water
- NMT: No More Than
- TB240: Depyrogenated Dilution Tube
  (Note: always use a new tube to prepare SPL)

STD: Fungitell STAT® Standard Tube (red cap vial)

RGT: Fungitell STAT® Reagent Tube (blue cap vial)

APS: Alkaline Pretreatment Solution
Quick Visual Guide for use with PKF08 and BG Analytics® software
Refer to Fungitell STAT® IFU for full procedural details.

The Quality Control (QC) criteria mentioned in the Fungitell STAT® IFU are automatically reviewed by the PKF08-BGA instrument and lead to two types of reports one for valid results and one for invalid results.

- If the Fungitell STAT® Standard result and the Patient sample results meet the QC criteria, the QC status of the Patient sample will be reported as valid and the category (i.e. Negative/Indeterminate/Positive) will be provided (see example below). Note that an index value will not be calculated for samples with a QC Status – Valid – Above Range and Valid – Below Range.

- If the Fungitell STAT® Standard result or the Patient sample results do not meet QC criteria, the QC status will be reported as invalid and the kinetic curve and other parameters allowing for the manual review of the QC criteria will be reported. Note that no index value or category will be provided.

- Disposal guidance: dispose of all the materials in compliance with the local requirements.

**Note:** All Sample results should be interpreted in light of the Interpretation of Results and Limitation of the Test sections described in the Fungitell STAT® IFU.