

Quick Visual Guide for use with PKF08 and BG Analytics™ software

Refer to Fungitell[®] STAT IFU for full procedural details.

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
- Use two tube racks: one for SPL and one for RGT tubes
- Always place STD in position #1 (racks and PKF08)
- Do not over vortex RGT tubes
- Vortex settings not to exceed 2000 RPM

1 STANDARD/SAMPLE PREPARATION

Set up and label tubes:

– one TB240 + one RGT tube per each SPL

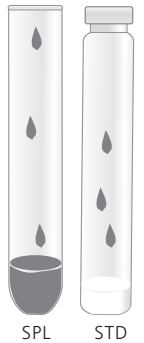
– one STD + one RGT tube

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

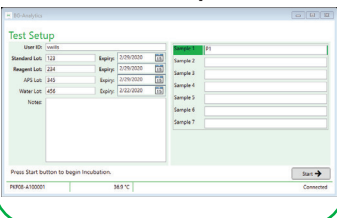
Add 200 µL APS to each TB240, vortex 10 sec. and cover

Reconstitute STD with _____ µL LRW, vortex 10 sec.

Add _____ µL APS to STD, vortex 10 sec.

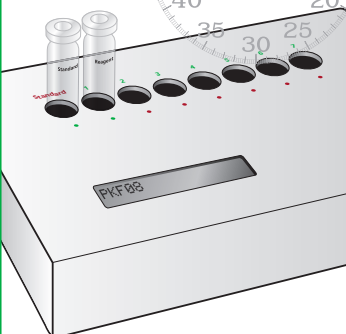


BGA Test Setup Screen



2 INCUBATE/REAGENT RECONSTITUTION

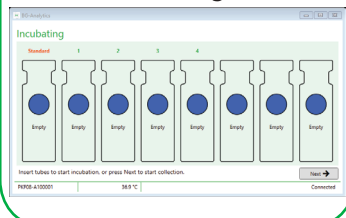
Incubate all at 37° C for 10 min.



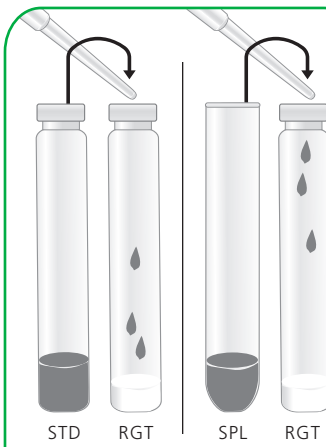
During incubation, reconstitute RGT with 300 µL LRW, vortex NMT 5 sec.

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

BGA Incubating Screen



3 ADDING REAGENT

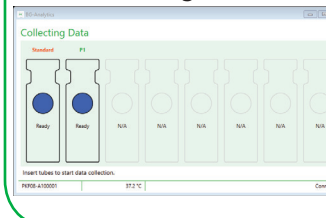


Use a Toxipet to transfer 75 µL STD to RGT

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

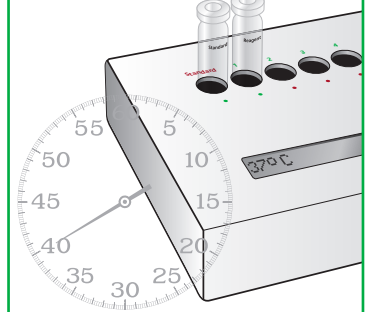
Vortex each RGT for NMT 5 sec.

BGA Collecting Data Screen

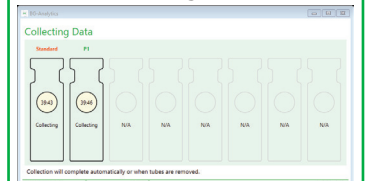


4 READ/REPORT

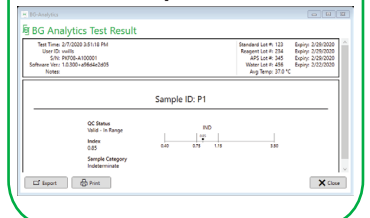
Place each RGT in their respective wells in PKF08 for a 40 min. test at 37° C



BGA Collecting Data Screen



BGA Report Screen



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

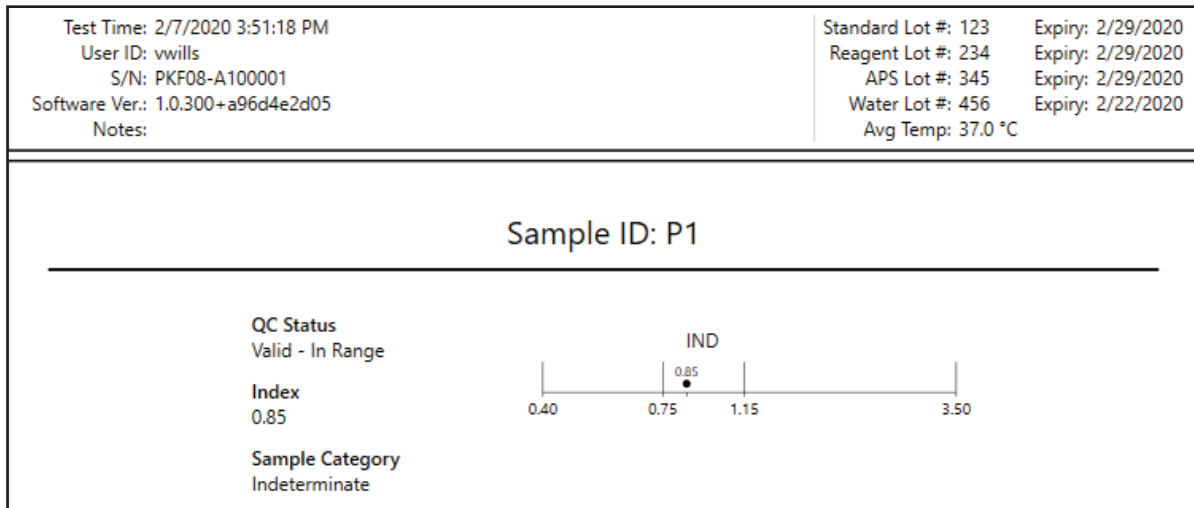


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The Quality Control (QC) criteria mentioned in the Fungitell® STAT IFU are automatically reviewed by the PKF08-BGA instrument and lead to two types of reports one for valid results and one for invalid results.

- 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.