Fungitell STAT®

Rapid (1→3)-β-D-Glucan Detection Assay

Quick Visual Guide for use with PKF08 and BG Analytics® (BGA) 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 Certificates of Compliance.

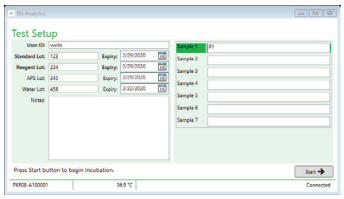
STD lot#:_____ STD lot# specific LRW volume:_____ STD lot# specific APS vol.:_____

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 marked Standard well in PKF08
- Do not over vortex RGT tubes
- Vortex settings not to exceed 2000 RPM

1 STANDARD/SAMPLE PREPARATION

BGA Test Setup Screen



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

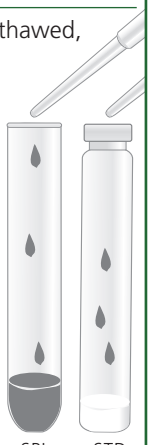
– one STD + one RGT tube

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

Add 200 µL APS to each TB240, **vortex 15 sec. and cover**

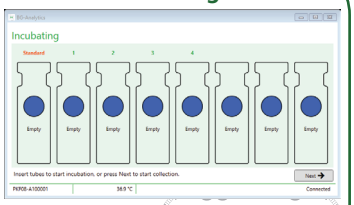
Reconstitute STD with _____ µL **LRW, vortex 15 sec.**

Add _____ µL APS to STD, **vortex 15 sec.**

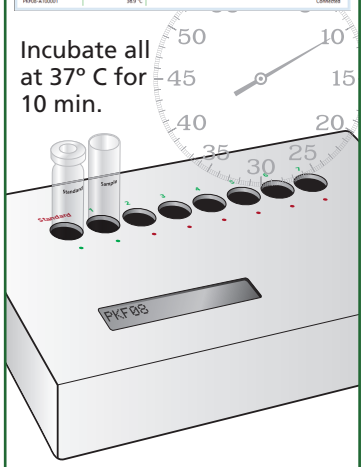


2 INCUBATE/REAGENT RECONSTITUTION

BGA Incubating Screen



Incubate all at 37° C for 10 min.

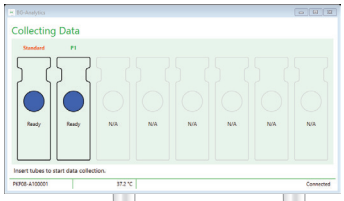


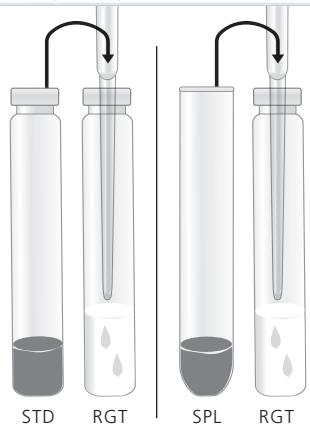
During incubation, reconstitute **RGT** with 300 µL LRW, vortex for 1-2 seconds at NMT 2000 RPM.

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

3 PREPARE REACTION MIXTURE

BGA Collecting Data Screen





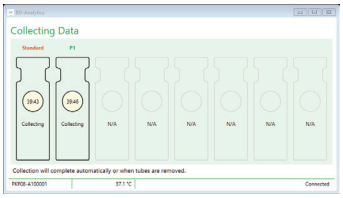
Use a Toxipet to transfer 75 µL STD directly on top of RGT

Use a Toxipet to transfer 75 µL SPL from TB240 to respective RGT tubes, directly on top

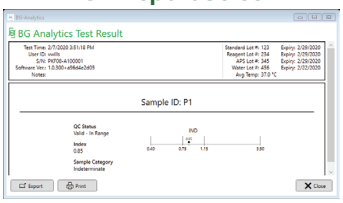
Vortex each RGT for 1-2 seconds at NMT 2000 RPM

4 READ/REPORT

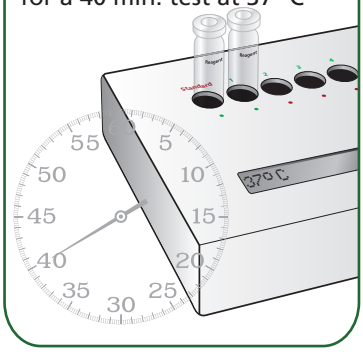
BGA Collecting Data Screen



BGA Report Screen



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



Key:

BGA: BG Analytics® Software

SPL: Patient Serum Sample

LRW: LAL Reagent Water

APS: Alkaline Pretreatment Solution

NMT: No More Than

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

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

TB240: Depyrogenated Dilution Tube
(**Note:** always use a new tube to prepare SPL)

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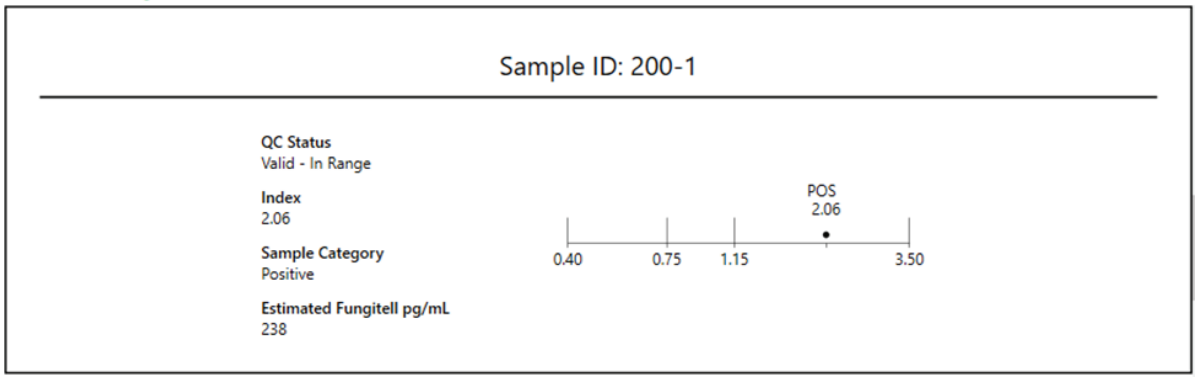
The Quality Control (QC) criteria mentioned in the Fungitell STAT® IFU are automatically reviewed by the PKF08-BGA system and lead to two types of reports one for valid results and one for invalid results.

- 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.

- Note: When using PKF08 with BG Analytics® Software, the Fungitell STAT® index result is used to determine the categorization. An estimated pg/mL value is provided for reference only

BG Analytics® Test Result



- 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 will be displayed allowing for manual review of sample characteristics against 'Section 10: Quality Control' of the IFU. Note that no index value or category will be provided.

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

Note: *All sample results should be interpreted in accordance with 'Section 11: Interpretation of Results' and 'Section 12: Limitation of the Test' as outlined in the Fungitell STAT® IFU.*

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