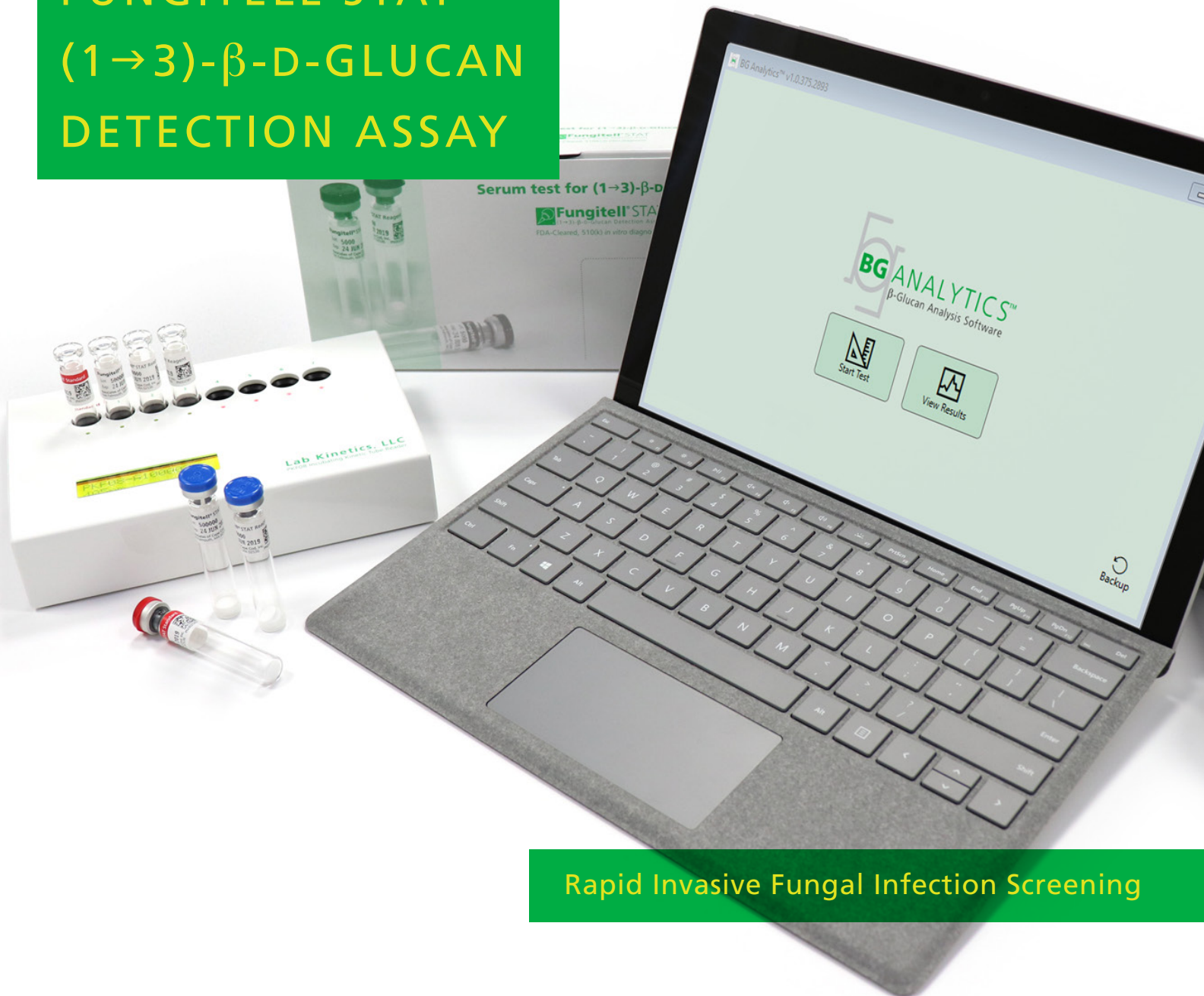


**FUNGITELL STAT™
(1→3)-β-D-GLUCAN
DETECTION ASSAY**



Rapid Invasive Fungal Infection Screening

Single Sample Format For Rapid Invasive Fungal Infection (IFI) Screening

Fungitell STAT™ is the first and only single sample format **FDA-cleared and CE marked** rapid *in vitro* diagnostic screening test for IFI (including *Candida*, *Aspergillus* and *Pneumocystis*) that detects (1→3)-β-D-Glucan in serum

FUNGITELL STAT™ (1→3)-β-D-GLUCAN DETECTION ASSAY



Introducing Fungitell STAT™

Fungitell®, The Gold Standard in Rapid Screening for Invasive Fungal Infection (IFI), is now available in a single sample format.

Fungitell®, the gold standard in (1→3)-β-D-Glucan testing, has been providing reliable laboratory support for IFI diagnosis, or rule-out since 2004.

Why test for (1→3)-β-D-Glucan?

Most pathogenic fungi¹ have (1→3)-β-D-Glucan in their cell walls and minute, but detect-

able quantities are released into the circulation during infection. Detection of elevated levels of (1→3)-β-D-Glucan is an aid to the presumptive diagnosis of IFI in at risk patients.

IFIs cause severe illness in the critically ill and immunocompromised patients and are associated with high morbidity and mortality. More aggressive medical care, including immunosuppressive therapy and ICU care has greatly increased the population of patients at risk of IFI.

Immunocompromised and at-risk populations

Aggressive Care (SICU/MICU/NICU)

Hemodialysis

Cancer Treatment

HIV

Central Venous Catheters

Mechanical Ventilation

Diabetes

Stem Cell and Organ Transplants

Gastrointestinal Surgery

Total Parenteral Nutrition

FUNGITELL STAT™ (1→3)-β-D-GLUCAN DETECTION ASSAY

The Fungitell STAT™ 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, IFI. Fungitell STAT™ is a design modification to the Fungitell assay format. The Fungitell STAT™ assay was developed to answer the need for a single use test format and smaller kit size relative to the 96-well plate format of the Fungitell assay.

Fungitell STAT™ offers the convenience of either a single sample or a small number of patient samples test run with a minimal footprint. Test from 1-7 samples in a single run using the Lab Kinetics Incubating 8-well Tube Reader and Beta Glucan (BG) BG Analytics™ software.

Fungitell STAT™ presents qualitative information concerning patient serum BG levels, using an index value result format that is both familiar to the infectious disease community and which allows the rapid stratification of patients as diagnostically positive, negative or indeterminate relative to serum BG burden.

Fungitell STAT™ is designed to provide an easy-to-interpret, computer-generated index result using a reference control provided with the reagent kit. Beta-Glucan Index (BGI) interpretive zones are as follows:

Fungitell STAT™ Index Ranges

Result	Index Value
Negative	≤0.74
Indeterminate	0.75 -1.1
Positive	≥1.2

Fungitell STAT™ was developed and tested using the Fungitell® (1→3)-β-D-Glucan Assay predicate device and its results track closely to the familiar pg/mL output of that kit. The concordance testing of Fungitell STAT™ BGI results to the original Fungitell pg/ml results provided a Positive Percent Agreement of 99% and a Negative Percent Agreement of 98%.²



Fungitell STAT™ Assay

Features & Benefits

- Test a single sample at a time – Flexibility of testing when you need it
- Rapid in-house results – within 1 hour eliminating the need for expensive send out services
- The first and only FDA-Cleared and CE Marked single test (1→3)-β-D-Glucan assay – Reliable cut off values
- Detects glucan from most fungi including *Candida*, *Aspergillus* and *Pneumocystis*²
- Decreased turn-around-time – no more waiting for large, batched sample runs or send outs

FUNGITELL STAT™ (1→3)-β-D-GLUCAN DETECTION ASSAY



8-well Tube Reader Instrument

Features & Benefits

Lab Kinetics Incubating 8-well Tube Reader *Incubating (37°C) tube reader capable of reading at 405 nm and 495 nm with a range of at least 0 – 1.0 Absorbance Units and accommodates vials of 12 mm diameter*

- Incubating absorbance tube reader equipped with 8 wells (1 standard and up to 7 sample positions)
- Minimal footprint:
6.87" x 4.65" x 1.5" (W x D x H)
17.45cm X 11.84cm X 3.81cm (W x D x H)
- Solid State Design: Low instrument maintenance
- Each well is individually timed for immediate data collection upon insertion of a reaction tube into the tube reader
- Uses disposable depyrogenated glass tubes

FUNGITELL STAT™ (1→3)-β-D-GLUCAN DETECTION ASSAY

BG Analytics™ Software

Features & Benefits

BG Analytics™ is a unique, easy-to-use, intuitive software application that provides a qualitative measurement of (1→3)-β-D-Glucan for use with the Fungitell STAT™ kinetic assay.

BG Analytics™ software collects and processes data from the Lab Kinetics 8-well incubating tube reader, stores the information in a database and produces reports of the test results.

- Comes standard with a local SQLite 10 GB database
- Allows for backup
- Is LIMS compatible
- Software System Requirements:
 - Operating System: Microsoft® Windows® 10 64 bit, v1809 or newer
 - Physical Memory: Minimum: 4 GB Recommended: 8 GB
 - Hard Disk Space: Minimum: 10 GB Recommended: 15 GB or more
 - Communication Ports: at least one free USB port (or two USB ports needed when using barcode scanner)

The image displays four screenshots of the BG Analytics software interface. The top screenshot shows the main menu with the BG ANALYTICS logo and buttons for 'Start Test' and 'View Results'. The second screenshot is the 'Test Setup' window, which includes fields for 'User ID', 'Standard Lot', 'Reagent Lot', 'APS Lot', and 'Water Lot', each with an 'Expiry' date. It also has a list for 'Sample 1' through 'Sample 7' and a 'Start' button. The third screenshot is the 'Collecting Data' window, showing a row of eight wells. The first two wells, labeled 'Standard' (39.43) and 'P1' (39.46), are marked 'Collecting'. The other six wells are marked 'N/A'. The bottom screenshot is the 'BG Analytics Test Result' window, displaying test time, user ID, S/N, software version, and various lot numbers. It features a graph for 'Sample ID: P1' showing an index of 0.55, which is within the 'Valid - In Range' (NEG) zone. The sample category is 'Negative'.

NOTE: ACC strongly recommends that Microsoft Windows updates are performed on a regular basis to ensure the latest security fixes and critical updates.

FUNGITELL STAT™ (1→3)-β-D-GLUCAN DETECTION ASSAY

Additional Computer Requirements:

- At least one (1) USB port
- Connection to a printer
- Connection to a barcode scanner

MATERIALS SUPPLIED WITH THE FUNGITELL STAT™ PRODUCT

1. Fungitell STAT™ Reagent, a lyophilized (1→3)-β-D-Glucan specific LAL (10 vials)
2. Fungitell STAT™ Glucan Standard (5 vials), with the (1→3)-β-D-Glucan content stated on the labeling
3. Instructions for Use
4. Quick Visual Guide

REAGENT STORAGE

Store all reagents, as supplied, at 2-8°C in the dark. Fungitell STAT™ Reagent and Fungitell STAT™ Standard should be used within 1 hour following reconstitution.

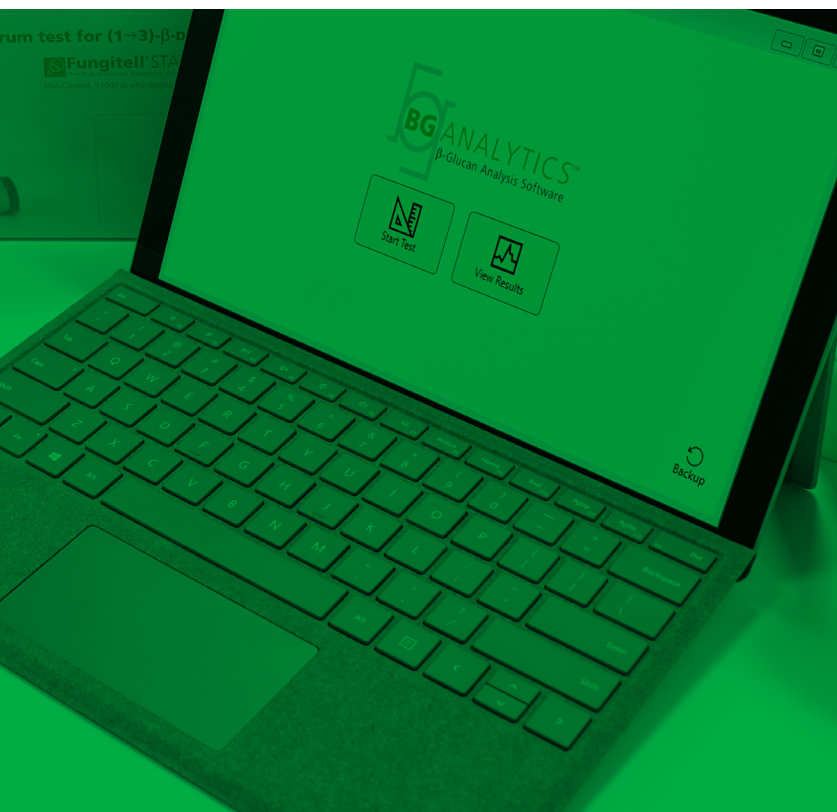
MATERIALS REQUIRED

All materials must be free of interfering glucans. Glassware must be dry-heat depyrogenated for at least 7 hours at a minimum of 235°C (or a validated equivalent) to be considered suitable for use.

ORDER INFORMATION

Description	Catalog Number
Fungitell STAT™, (10 vials of STAT Reagent and 5 vials of STAT Standard)	#FT007
Lab Kinetics Incubating 8-well Tube Reader with BG Analytics™ Software	#PKF08-PKG
LAL Reagent Water (5.5 mL vial, 10 Pack) ³	#W0051-10
Alkaline Pretreatment Solution (2.5 mL vial, 5 Pack) ³	#APS51-5
Toxipet Long Pipette tips (20-200 µL, Box of 50) ³	#TPT50
Pipette tips (250 µL, 96/Box, 10 Boxes /Pack)	#PPT25
Pipette tips (1000 µL, 96/Box, 8 Boxes/Pack)	#PPT10
Test tubes for patient sample preparation and combining serum pretreatment solution. (12 x 75 mm, 42/Pack, 5 Packs) ³	#TB240-5

For product pricing and ordering details, please refer to your local representative.



FUNGITELL STAT™ (1→3)-β-D-GLUCAN DETECTION ASSAY

Additional items not supplied by ACC.

- Pipettes capable of delivering 20-200 μL and 100-1000 μL volumes Sterile, glucan-free, screw-cap storage tubes for aliquotting samples (most tubes that are certified to be RNase, DNase, and pyrogen-free are free of interfering levels of (1→3)-β-D-Glucan).
- Parafilm®
- BG Analytics™ is designed to be compatible with any barcode scanner configured in USB HID Points of Sale scanner mode. For example, Honeywell healthcare corded barcode scanners Honeywell PN1950HHD and Honeywell 1950HSR are compatible.

Refer to the barcode scanner's user manual for proper scanning technique.

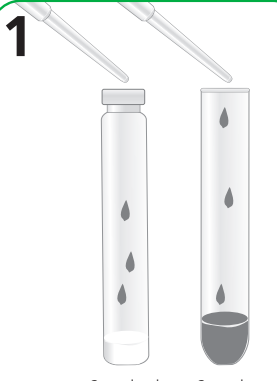
1. Cryptococcus, Mucorales (such as Absidia, Mucor and Rhizopus) and Blastomyces dermatitidis (infective yeast form) are known to have little or no (1→3)-β-D-Glucan and thus, glucan is not detected during infection with these organisms.
2. D'Ordine, R.L.; Garcia, K.A.; Roy, J.; Zhang, Y.; Markley, B.; and Finkelman, M.A. Performance Characteristics of Fungitell™ STAT, A Rapid (1→3)-β-D-Glucan Single Patient Sample *in vitro* Diagnostic Assay. Medical Mycology: In Press.
3. These products, supplied by Associates of Cape Cod, Inc., are certified free of interfering glucans.

Caution - glass pipettes with cotton plugs and micro-pipette tips with cellulosic filters are potential sources of glucan contamination.

Fungitell STAT™ ASSAY Test Procedure Outline

STANDARD/SAMPLE PREPARATION

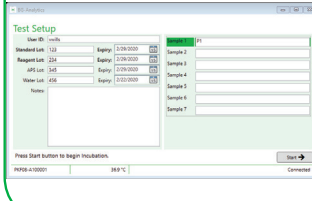
1



Standard Sample

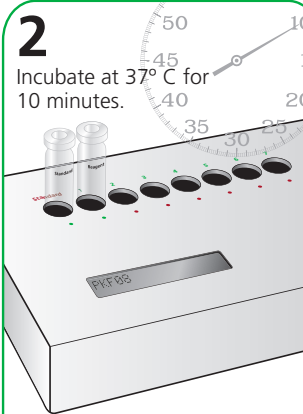
Reconstitute Fungitell STAT™ Standard and prep sample.

BGA Test Setup Screen



INCUBATE/REAGENT RECONSTITUTION

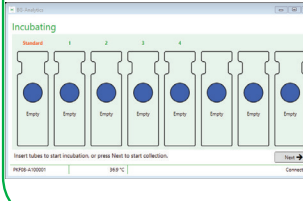
2



Incubate at 37° C for 10 minutes.

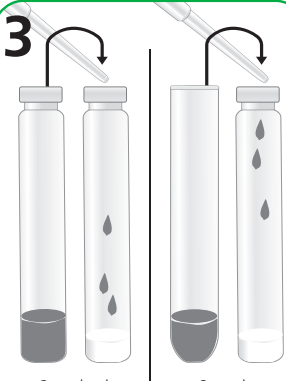
Reconstitute reagent during pretreatment incubation.

BGA Incubation Screen



ADD TO REAGENT

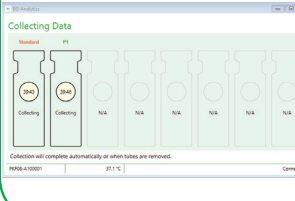
3



Standard Sample

Add sample and standard to reconstituted Fungitell STAT™ reagent tubes.

BGA Data Collection Screen



READ/REPORT

4

Place vials in instrument to initiate data collection.



BGA Report Screen



NOTE: For complete test procedure refer to Fungitell STAT™ Instructions For Use (IFU).



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