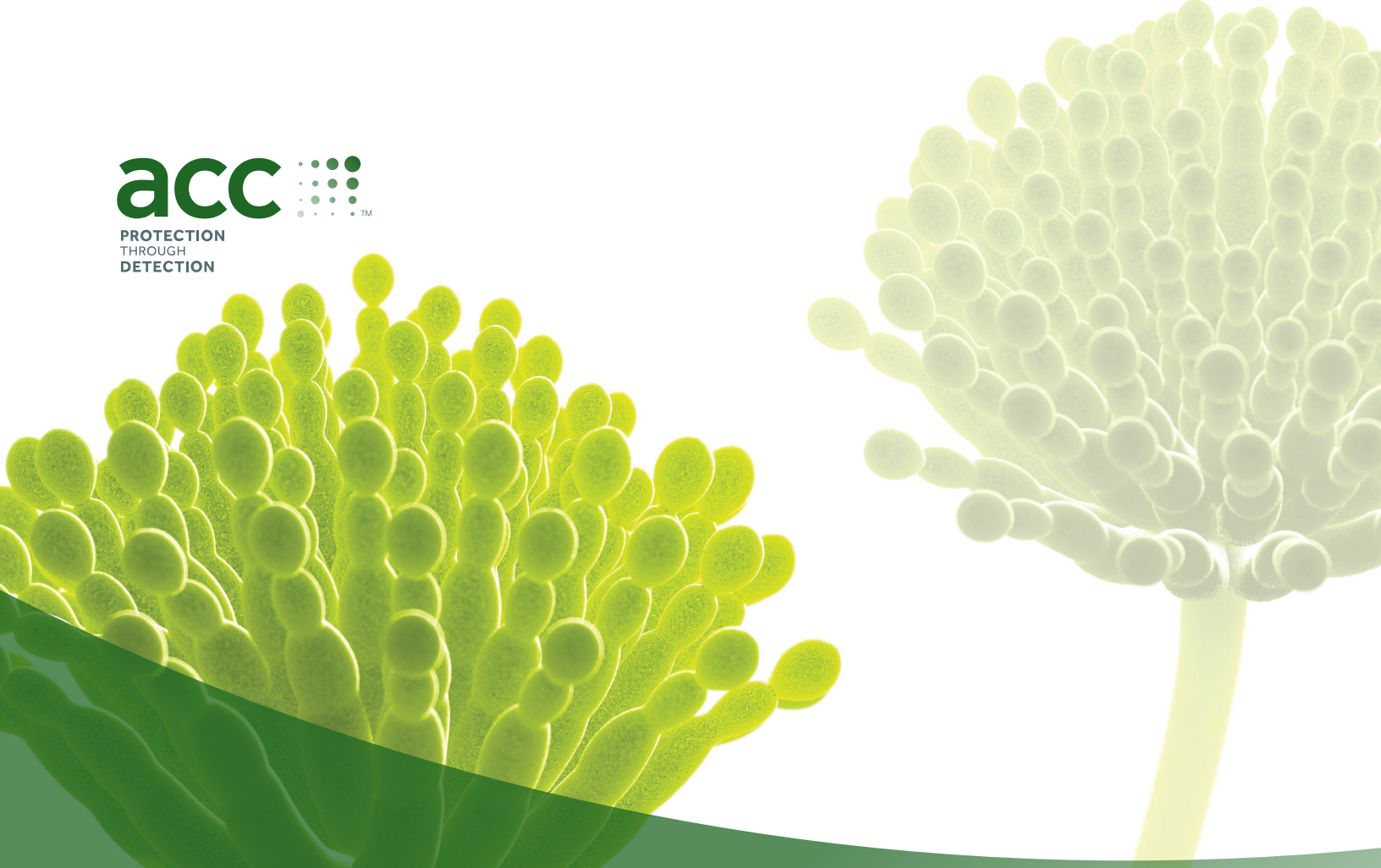
acc™
PROTECTION
THROUGH
DETECTION



Fungitell® / FungitellSTAT®

(1→3)-β-D-Glucan Detection Assay

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

The only FDA-cleared and CE-marked 510(k) *in vitro* diagnostic screening test for Invasive Fungal Infection (IFI)

CE

MEDICAL DEVICES ISO 13485:2016 NSAI Certified

www.acciusa.com

In House. In Lab. In Minutes.

A Better IFI Test, No Matter Where You Test.

More aggressive medical care, including immunosuppressive therapy and ICU care, has greatly increased the population of patients at risk of invasive fungal infection (IFI). Researchers estimate that more than 6.55 million people are affected by invasive fungal infections annually.[1] *Candida* and *Aspergillus* species are among the most prevalent fungal pathogens responsible for invasive fungal infections (IFIs). Given the low sensitivity and prolonged incubation times associated with microbial culture—the most widely used diagnostic method—there is a critical need for faster, more sensitive techniques to save lives.

Why Test for (1→3)-β-D-Glucan?

Most pathogenic fungi* contain (1→3)-β-D-glucan in their cell walls, and minute, but detectable quantities are released into circulation during infection. Detection of elevated levels of (1→3)-β-D-glucan is an aid to the diagnosis of invasive fungal infection (IFI) in at-risk patients.

Multiple studies[3,4,5,6,7] have shown glucan to become elevated well in advance of conventional clinical signs and symptoms. Early diagnosis and therapy for invasive fungal infection are associated with improved clinical outcomes; delayed diagnosis and therapy are associated with increased mortality.[8]

Conversely, the elevated morbidity and mortality associated with invasive fungal infection drive potentially inappropriate systemic antifungal therapy. Research has demonstrated the utility of the >95% / high negative predictive value of Fungitell® and Fungitell STAT® to support decisions to withhold or withdraw inappropriate antifungals with excellent patient safety.[9,10,11] Hence, there is significant utility in the application of a reliable diagnostic test in at-risk patients.

AT-RISK PATIENTS

Invasive fungal infection is increasing in at-risk populations[12] such as:

- ICU patients
- Cancer patients undergoing chemotherapy
- Stem cell and organ transplant patients
- HIV patients
- Burn patients
- Patients with uncontrolled diabetes
- Patients with chronic lung diseases
- Patients on long-term corticosteroid therapy
- Patients with prolonged neutropenia
- Patients undergoing gastrointestinal surgery

*_Cryptococcus_, Zygomycetes (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.

Fungitell® & Fungitell STAT®

Fungitell®, the gold standard in rapid screening for invasive fungal infection, is used for the detection of (1→3)-β-D-glucan in serum. It offers high sensitivity and results within an hour.

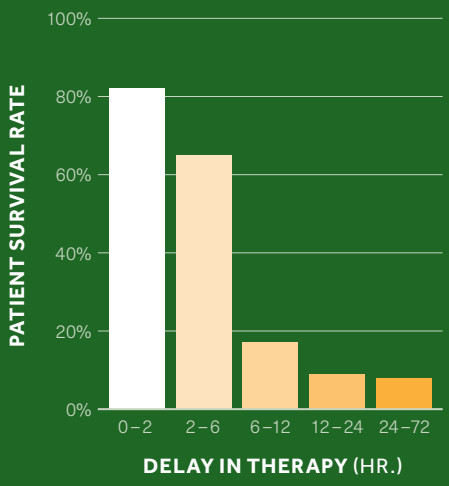
Features and Benefits of Fungitell®:

- Provides earlier support for diagnosis of IFI
- Detects glucan from most fungi, including *Candida* and *Aspergillus**
- Rapid results within an hour
- FDA-cleared
- CE-marked

Fungitell® is also available in a single sample format. Fungitell STAT® makes it possible to test from 1 to 7 samples in a single run using an incubating 8-well tube reader and Beta-Glucan (BG) Analytics® software.

EARLY DETECTION IS CRUCIAL

Early diagnosis and treatment have been proven to significantly improve survival rates in cases of septic shock caused by *Candida* infection.[2]





Fungitell® Assay
Product Information

PRINCIPLE OF THE FUNGITELL® ASSAY

Fungitell® is a (1→3)-β-D-glucan specific Limulus amebocyte lysate (LAL) reagent containing a chromogenic peptide substrate. (1→3)-β-D-glucan in the sample causes activation of serine proteases. An activated protease cleaves p-nitroaniline (pNA) from the peptide substrate and the free pNA is measured at 405 nm. The test is performed in a standard incubating plate reader.

MATERIALS SUPPLIED WITH THE KIT

FT001 Fungitell® Kit — 110 test wells

- 2 vials Fungitell® Reagent
- 2 vials Pyrosol® Reconstitution Buffer[a]
- 2 vials Glucan Standard
- 2 bottles Reagent Grade Water,[a] 20 mL
- 2 vials Alkaline Pretreatment Solution[a]

STORAGE CONDITIONS

Store all reagents at 2–8°C in the dark. Reconstituted Fungitell® reagent should be stored at 2–8°C and used within 2 hours. Alternatively, reconstituted Fungitell® reagent can be frozen at -20°C for 20 days, thawed once and used.

MATERIALS REQUIRED BUT NOT SUPPLIED

All materials and glassware must be free of interfering glucan. Dry heat depyrogenation is effective in eliminating interfering levels of (1→3)-β-D-glucan from glass surfaces. Purchase supplies from a supplier that will certify the materials free of interfering glucan.

- 96-well microplate[b]
- Repeating pipette and tips (250 mL; 1000 mL)[b]
- Test tubes for sample dilution (13 x 100 mm)[b]
- Glass pipettes — not plastic
- Parafilm®
- Incubating plate reader capable of reading at 405 and 490 nm with appropriate kinetic software for determination of V_{mean}[b]
- Vortex mixer

WARNINGS, PRECAUTIONS & LIMITATIONS

See Instructions For Use for details.

i. The tissue locations of fungal infection and encapsulation may affect the serum concentration of (1→3)-β-D-glucan.

ii. Some individuals have elevated levels of (1→3)-β-D-glucan that fall into the indeterminate zone of 60–79 pg/mL. In such cases, additional testing is recommended.

iii. Test levels were established in adult subjects. Infant and pediatric normal levels approach those of adults. Data for neonates and infants less than six months are lacking.

iv. Off-color or turbid samples such as those that are grossly hemolyzed, lipemic, or contain excessive bilirubin may cause interference.

v. Samples obtained by heel or finger stick methods are unacceptable as the alcohol-soaked gauze used to prepare the site and/or blood pooling on the skin surface may contaminate the specimens.

vi. Surgical gauzes and sponges can leach high levels of (1→3)-β-D-glucan and may contribute to a transient positive result in the Fungitell® assay.

vii. The serum of hemodialysis patients may contain high levels of (1→3)-β-D-glucan when certain cellulose dialysis membranes are used.

viii. In performing the test, great care must be taken to avoid contamination.

ix. The use of Fungitell® for purposes other than those described in the Intended Use section of the Instructions For Use is neither recommended nor supported by ACC.

Fungitell® — Trustworthy & Proven

Highly Sensitive & Predictive

The Fungitell® assay is a highly sensitive, microplate-based test that detects (1→3)-β-D-glucan in serum. (1→3)-β-D-glucan is a cell wall constituent of most medically important fungi, including *Candida* and *Aspergillus*.* (1→3)-β-D-glucan is normally found at low levels in the blood of healthy humans.

In at-risk patients, serum (1→3)-β-D-glucan values of at least 80 pg/mL are highly associated with invasive fungal infection. Conversely, low levels of (1→3)-β-D-glucan have a high negative predictive value for invasive fungal infection.

(1→3)-β-D-glucan detection is not suppressed by anti-fungal therapy, nor is the test cross-reactive with other polysaccharides.

Diagnostic Performance

Multiple studies[3,4,5,6,7] in diverse patient groups have shown sensitivities from 70–100% and high negative predictive values. A variety of studies also demonstrate diagnostic utility in *Pneumocystis jirovecii* pneumonia.[13,14]

Rapid Results

The Fungitell® assay is performed entirely within a microplate well without washing steps and provides results within an hour.

Antimicrobial Stewardship

Studies have shown that early discontinuation of empirical therapy in high-risk ICU patients based on consecutive negative (1→3)-β-D-glucan tests may be a reasonable strategy, with great potential to reduce the overuse of antifungals.[12]

Marketplace Longevity

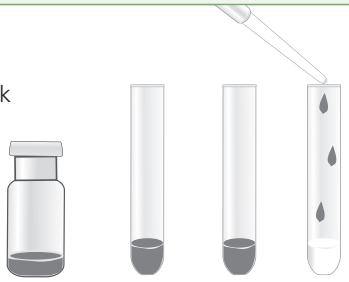
Fungitell® has over two decades of proven clinical use and has been referenced in over 200 peer-reviewed clinical papers.

Test Procedure Outline

SET UP

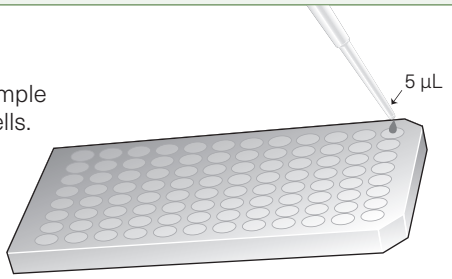
1

Reconstitute glucan stock and make standards.



2

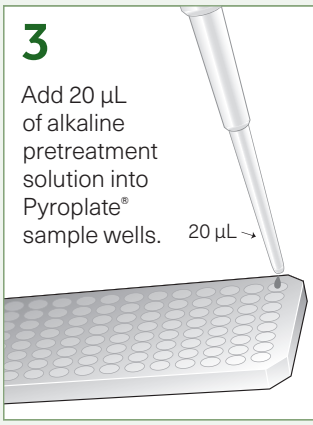
Pipette 5 µL of sample into Pyroplate® wells.



TEST SAMPLES

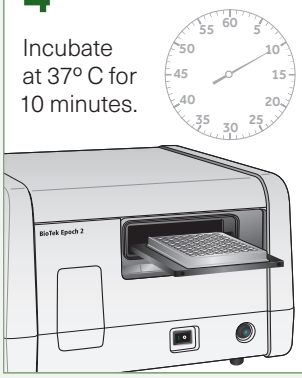
3

Add 20 µL of alkaline pretreatment solution into Pyroplate® sample wells.



4

Incubate at 37° C for 10 minutes.



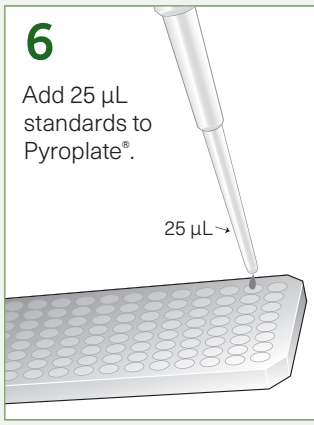
5

Reconstitute Fungitell® Reagent.



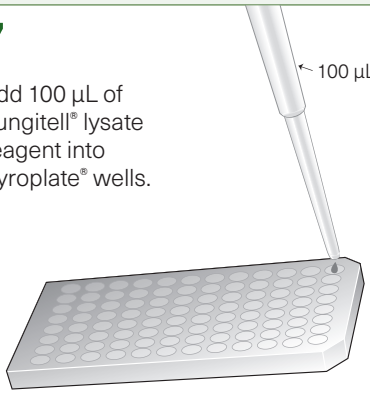
6

Add 25 µL standards to Pyroplate®.



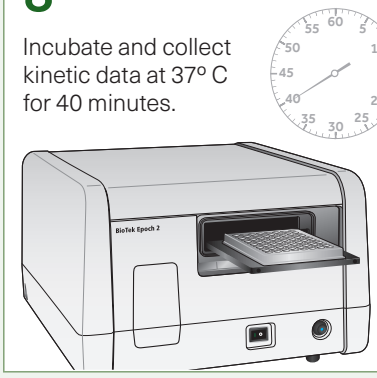
7

Add 100 µL of Fungitell® lysate reagent into Pyroplate® wells.



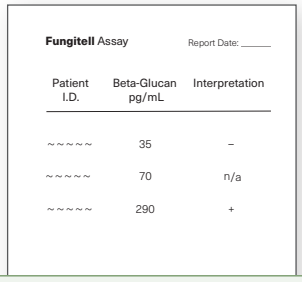
8

Incubate and collect kinetic data at 37° C for 40 minutes.



9

Read report data.



Fungitell Assay Report Date: _____

Patient I.D.	Beta-Glucan pg/mL	Interpretation
~~	35	–
~~	70	n/a
~~	290	+

Note: For complete test procedure, refer to Fungitell® Instructions For Use (IFU).

a. Products are free of interfering glucans
b. Available from ACC

**Cryptococcus*, Zygomycetes (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.

Fungitell STAT® Assay
Product Information

PRINCIPLE OF THE FUNGITELL STAT® 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 them to IFI. Users can test from 1 to 7 samples in a single run using an 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 that is both familiar to the infectious disease community and 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, Beta-Glucan Index index (BGI) result using a reference control provided with the reagent kit. 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 Fungitell®. 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%.[15]

THE FUNGITELL STAT KIT®

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.

- 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)*
  - » *17.45 cm x 11.84 cm x 3.81 cm (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

BG Analytics® Software

BG Analytics® is a unique, easy-to-use, intuitive software application designed to deliver qualitative measurements of (1→3)-β-D-glucan, specifically for use with the Fungitell STAT® kinetic assay.

BG Analytics® collects and processes data from the 8-well incubating tube reader, stores the information in a database, and produces test result reports.

- 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*
  - » *4 GB minimum physical memory (8 GB recommended)*
  - » *10 GB minimum hard disk space (at least 15 GB recommended)*
  - » *At least 1 free USB port (2 USB ports needed when using the barcode scanner)*
- Additional Computer Requirements:
  - » *Connection to a printer*
  - » *Connection to a barcode scanner*

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

MATERIALS SUPPLIED WITH THE KIT

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

STORAGE CONDITIONS

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 BUT NOT SUPPLIED

All materials and glassware 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.

- Pipettes capable of delivering 20–200 µL and 100–1000 µL volumes
- Sterile, glucan-free, screw-cap storage tubes for aliquoting 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 techniques.

Caution: Glass pipettes with cotton plugs and micropipette tips with cellulosic filters are potential sources of glucan contamination.

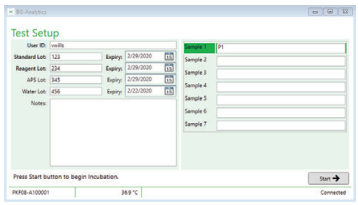
Test Procedure Outline

STANDARD & SAMPLE PREPARATION

1

Reconstitute Fungitell STAT® Standard and prep sample.





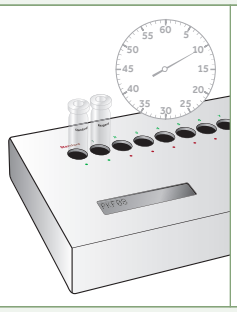
BGA TEST SETUP SCREEN

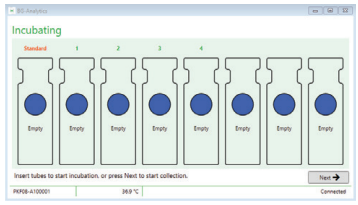
INCUBATE & REAGENT RECONSTITUTION

2

Incubate at 37º C for 10 minutes.

Reconstitute reagent during incubation.



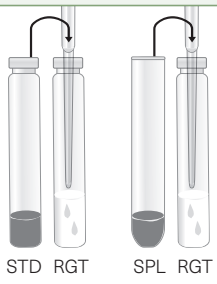


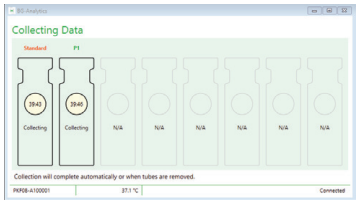
BGA INCUBATION SCREEN

PREPARE REACTION MIXTURE

3

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





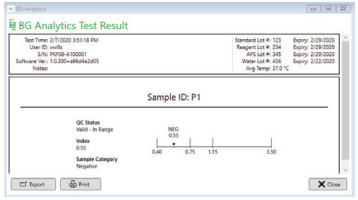
BGA DATA COLLECTION SCREEN

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).

Ordering Information

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



Fungitell®

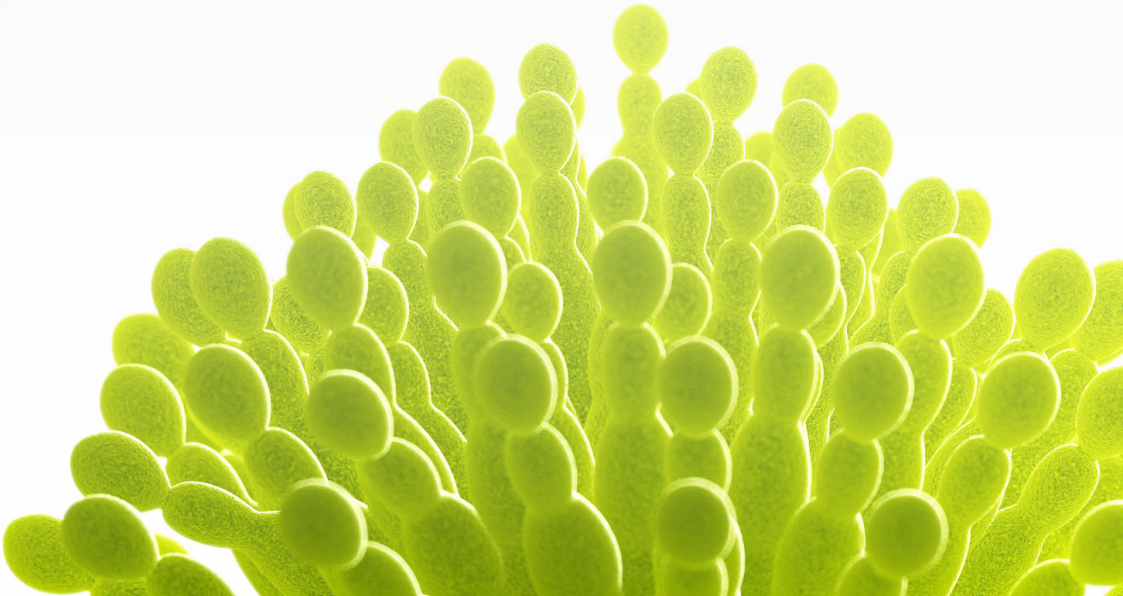
Product Code	Description
#FT001	Fungitell® Kit — 110 test wells
	2 vials Fungitell® Reagent
	2 vials Pyrosol® Reconstitution Buffer*
	2 vials Glucan Standard
	2 bottles Reagent Grade Water,* 20 mL
	2 vials Alkaline Pretreatment Solution*



Fungitell STAT®

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

*These products, supplied by ACC, Inc., are certified free of interfering glucans.



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Beacon Diagnostics® Laboratory is a fully CLIA-certified reference laboratory specializing in (1→3)-β-D-glucan analysis services as well as Galactomannan testing (invasive aspergillosis) to support the diagnosis of invasive fungal infection (IFI). Serving clinical and reference laboratories, we offer a rapid, cost-effective alternative to in-house testing.

The laboratory is a division of ACC. The expert staff at Beacon Diagnostics® Laboratory provides clients with rapid diagnostic and analytical service to assist in the medical evaluation of patients suspected of having invasive fungal infection. Our laboratory also tests veterinary samples.

We currently hold certifications and licenses in Massachusetts, California, Maryland, Pennsylvania and Rhode Island. An updated list can be found on our website at BeaconDiagnostics.com.

Contact Information

Beacon Diagnostics® Laboratory | 124 Bernard E. Saint Jean Drive | Falmouth, MA 02536

TECHNICAL INFORMATION & SAMPLE SUBMISSION
t 800.568.0058 | **f** 508.444.1481 | **e** info@beacondiagnostics.com



Beacon Diagnostics®
LABORATORY

TEST INFORMATION & SAMPLE REQUIREMENTS

Pricing and Current Procedure Terminology (CPT) Coding

- Call for pricing
- The Fungitell® assay does not have an assigned CPT code. Commonly accepted laboratory practice for coding a diagnostic test is to seek an existing CPT code that exactly describes the test—i.e., the organism, methodology, analyte and sample, as appropriate. If there is no exact match, then a code is chosen that most closely describes the laboratory procedure on the basis of methodology. Based on comparison of the test characteristics to the CPT code description, commonly accepted coding practice may allow coding for Fungitell® using 87449. The coding preferred by individual payers may vary. Please check with your payer for specific billing instructions.
- The CPT code for the Galactomannan test is 87305.

TESTING & TURNAROUND TIME

Testing is performed Monday through Friday. Typical turnaround time is about 48 hours from receipt of sample at our facility, but most results are available the same day they are received.

SPECIMEN REQUIREMENTS

Each sample sent to Beacon Diagnostics® Laboratory for testing must be accompanied by a completed Sample Submission Form. Forms can be obtained by calling 800.568.0058 or by visiting our website at BeaconDiagnostics.com.

1. **Use Serum Gel Tubes (Avoid Gauze and Cotton Swabs)**
   - Centrifuge and send entire specimen in original serum gel collection tube.
   - Do not aliquot or open tube to avoid exposure of specimen to environmental contaminants.
   - Provide 2 mL (min. of 1 mL) of serum if requesting both assays.
2. Heel and finger stick samples will be rejected.
3. Grossly hemolyzed, lipemic, and icteric samples are not suitable for testing.
4. Our laboratory also tests veterinary samples.

SPECIMEN SHIPPING INSTRUCTIONS

1. Ship the specimen refrigerated (preferred) or frozen well packaged to prevent breakage during shipping.
2. Serum should be shipped in the serum gel tube.
3. Ship specimens to:

   Beacon Diagnostics Laboratory
   124 Bernard E. St. Jean Drive
   East Falmouth, MA 02536 USA

Note: *To maintain optimal sample temperatures during transit, especially during the warm summer months, it is advisable to use insulated shipping containers (e.g., Styrofoam liners) and extra cold packs when shipping samples.*



PROTECTION THROUGH DETECTION

CORPORATE HEADQUARTERS

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