



Specialists in **(1→3)-β-D-Glucan Analysis** to aid the **Diagnosis** of
Invasive Fungal Disease

CLIA Certified

Information Guide



Beacon
Diagnostics[®]
Laboratory

Fungitell[®] Kit



Beacon Diagnostics® Laboratory

About Beacon

The Beacon Diagnostics® Laboratory is a fully CLIA-certified reference laboratory specializing in (1→3)-β-D-glucan analysis services to support the diagnosis of Invasive Fungal Disease (IFD). Serving clinical and reference laboratories, we offer a rapid, cost-effective alternative to in-house testing.

Patients at High Risk For IFD

Immunosuppressed patients are at high risk for developing invasive fungal disease, which is often difficult to diagnose. Affected patient populations include:

- Cancer patients undergoing chemotherapy
- Stem Cell and Organ Transplant patients
- Burn patients
- HIV patients
- ICU patients

Our laboratory also tests veterinary samples.

The laboratory is a division of Associates of Cape Cod, Inc. 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 disease. We currently hold certifications and licenses in Massachusetts, California, Florida, Maryland, New York, Pennsylvania and Rhode Island. An updated list can be found on our website at www.BeaconDiagnostics.com.

Additional information concerning the applications and latest findings of (1→3)-β-D-glucan testing in patients can also be found on our website.

Hours of Operation

Testing

Monday-Friday, 8:00 a.m. to 5:00 p.m. EST

Sample Receiving

Monday-Saturday, 8:00 a.m. to 7:00 p.m. EST

CLIA License Number

22D1021258

Test Information and 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.

1.



Testing and Turn-around Time

Testing is performed Monday through Friday. Typical turnaround time is 48 hours from receipt of sample at our facility.

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 www.BeaconDiagnostics.com.

- Please provide at least 0.5 mL of serum separated from the clot and shipped cold or frozen on ice packs or dry ice. Secure the vial closure with Parafilm® or tape. Next day shipping is required.
- Serum should be shipped in a sterile, clean, screw-cap plastic vial (most cryogenic vials certified DNase and RNase free are typically suitable for use). Do not send serum in glass tubes. Samples not separated from the clot prior to shipment may incur an additional handling and preparation fee.
- Avoid contact between the serum and potential sources of (1→3)-β-D-glucan contamination including cellulosic filters, gauze, and cotton swabs.
- Hemolyzed, lipemic, and icteric samples are not suitable for testing.
- Samples must be shipped in accordance with federal shipping requirements for Clinical Diagnostic Specimens.
- Use Red Top Tubes
- Heel and finger stick samples are inappropriate

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 or dry ice when shipping samples.

Clinical Significance

Normal human serum contains low levels of (1→3)-β-D-glucan, typically 10-40 pg/mL, presumably from commensal yeasts present in the alimentary canal. Most pathogenic fungi have (1→3)-β-D-glucan in their cell walls and minute quantities are sloughed into the circulation during the life cycle. Thus, (1→3)-β-D-glucan appears in the serum in most cases of invasive fungal disease (IFD). Monitoring serum (1→3)-β-D-glucan for evidence of elevated and rising levels provides a convenient surrogate marker for IFD. Levels above 80 pg/mL, in at-risk patients, are considered positive. Because a fungal disease is a dynamic process, repeat testing, typically 2-3 times per week, improves sensitivity. Time courses of serum (1→3)-β-D-glucan levels through the course of the disease have been shown to exhibit a rising level which often falls in response to efficacious therapy.¹

The Fungitell® assay is indicated for presumptive diagnosis of fungal disease and should be used in conjunction with other diagnostic procedures. It does not detect certain fungal species such as the genus *Cryptococcus*, which produces very low levels of (1→3)-β-D-glucan. The assay also does not detect the Zygomycetes, such as *Absidia*, *Mucor*, and *Rhizopus*, which are not known to produce (1→3)-β-D-glucan. The invasive form of *Blastomyces dermatitidis* produces very little (1→3)-β-D-glucan and has been demonstrated not to yield positive serum glucan values.²

Contact Information

Beacon Diagnostics® Laboratory

124 Bernard E. Saint Jean Drive
East Falmouth, MA 02536-4445, USA

For technical information and sample submission call:

Tel: (800) 568-0058

Fax: (508) 444-1481

E-mail: info@beacondiagnostics.com

1. Kondori N., Edebo L., and Mattsby-Baltzer I. Circulating (1→3)-β-D-glucan and Immunoglobulin G subclass antibodies to *Candida albicans* cell wall antigens in patients with systemic candidiasis. *Clinical and diagnostic Laboratory Immunology*. 11(2):344-350 (2004)

2. Girouard, G., Lachance, C., and Pelletier, R. Observations on (1→3)-β-D-glucan detection as a diagnostic tool in endemic mycosis caused by *Histoplasma* or *Blastomyces*. *Journal of Medical Microbiology*. 56:101-1002 (2007).



Fungitell® Kit

Glucan Assay for (1→3)-β-D-glucan in Serum

FDA 510(k) cleared Diagnostic Kit

General Product Description

The Fungitell® kit is a highly sensitive, rapid diagnostic test that detects (1→3)-β-D-glucan in serum in as little as one hour. (1→3)-β-D-glucan is a cell wall constituent of most medically important fungi including *Candida* and *Aspergillus*.^{*} The assay is based upon a modification of the *Limulus* Amebocyte Lysate (LAL) pathway (see Figure 1). The Fungitell® reagent is modified to eliminate Factor C and does not react to endotoxin. It is specific for (1→3)-β-D-glucan and does not react to other polysaccharides, including beta-glucans with different glycosidic linkages.

The Fungitell® assay's ability to detect picogram levels of (1→3)-β-D-glucan in serum assists clinicians in identifying Invasive Fungal Disease (IFD) early in the disease process.

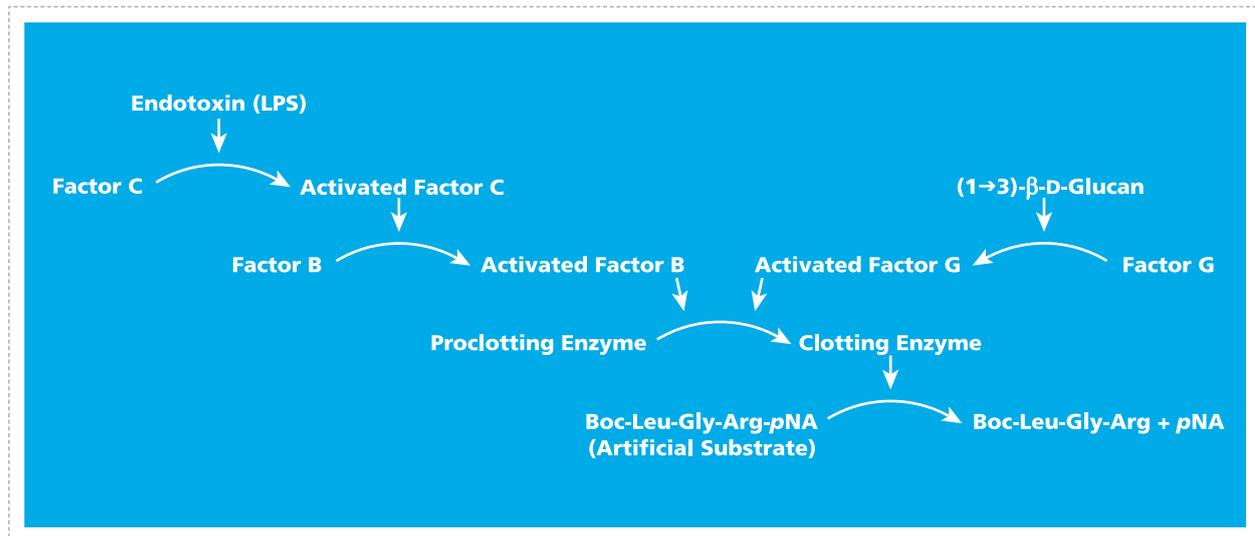
Normal human serum contains low levels of (1→3)-β-D-glucan, typically 10–40 pg/mL, presumably from commensal yeasts present in the digestive tract. Most pathogenic fungi have (1→3)-β-D-glucan in their cell walls and minute quantities are sloughed into the circulation during the life cycle. Thus, (1→3)-β-D-glucan appears in the serum in most cases of IFD. Monitoring serum glucanemia for evidence of elevated and rising levels provides a convenient surrogate marker for IFD. Levels above 80 pg/mL, in at-risk patients, are considered positive.

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Test Performance

The sample / pretreatment mixture is incubated in at 37°C ± 1°C in a microplate reader or heat block for 10 minutes. Then 100 µL of reagent is added to the sample and standard curve wells and the microplate is placed in a microplate reader at 37°C ± 1°C. The microplate reader must be equipped with a 405 nm filter and is analyzed over time by a suitable software program.

FIGURE 1



^{*}Fungi that do not synthesize (1→3)-β-D-glucan, such as Zygomycetes, will not produce positive results with this assay.

[‡]Girouard, G., Lachance, C., and Pelletier, R. Observations on (1→3)-β-D-glucan detection as a diagnostic tool in endemic mycosis caused by *Histoplasma* or *Blastomyces*. *Journal of Medical Microbiology*. 56:101-1002 (2007).

Stability

Store all reagents as supplied 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 up to 20 days, thawed once and used.

Packaging

The Fungitell® assay is packaged in kit form, which includes (2) vials of Fungitell reagent, (2) vials of Glucan standard, (2) bottles of Reagent grade water, (2) vials of Pyrosol® buffer, (1) vial each of the serum pretreatment reagents, and (2) 96 well microplates.

Product Applications

Diagnosis of invasive fungal disease, including patients in the following categories:

- Cancer patients undergoing chemotherapy
- Transplant patients
- HIV patients
- Burn patients
- Long term intensive care unit patients
- Other immuno-suppressed patient groups

Mycotic diseases research

- Serum and plasma glucan analysis
- Tissue glucan analysis
- Anti-fungal drug efficacy

(1→3)-β-D-glucan experimental drug therapy

- Pharmacokinetics and (1→3)-β-D-glucan tissue distribution

Accessory Products

1. Pyroplate® (CA961), 96-well microplate
2. 250 µL Pipette tips (PPT25), endotoxin and glucan-free
3. 1000 µL Pipette tips (PPT10), endotoxin and glucan-free
4. Pyrotubes® (TB013), 13 x 100 mm borosilicate glass dilution tubes
5. Incubating microplate readers: ELx808™ (PPS04) and VersaMax™ (VERSAMAX)

Note: High quality repeating pipettes are recommended

For more information please visit our website at www.acciusa.com or contact technical services at (800) 848-3248.

Fungitell® Kit

#FT001- - - - - (1→3)-β-D-glucan detection in serum (110 test wells)-FDA 510(k) cleared for use as an adjunct to diagnosis of deep-seated mycosis and fungemia.





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LABORATORY

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