Invasive Fungal Disease

(1→3)-β-D-Glucan in Pathogenic Fungi

Most pathogenic fungi* have (1→3)-β-D-Glucan in their cell walls. Minute 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 invasive fungal disease in at risk patients.

Earlier Support for Diagnosis

Multiple studies1,2,3,4,5 have shown glucan to become elevated well in advance of conventional clinical signs and symptoms. Delayed diagnosis and therapy of invasive fungal disease is associated with increased mortality8.

Rapid Results

The Fungitell® assay is performed entirely within a microplate well without washing steps. The assay provides results within 2 hours.

Diagnostic Performance

Multiple studies1,2,3,4,5 in diverse patient groups have shown sensitivities from 70 – 100% and high negative predictive values. Recent studies suggest diagnostic utility in Pneumocystis jirovecii pneumonia6,7.

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 disease. Conversely, low levels of (1→3)-β-D-Glucan have a high negative predictive value for invasive fungal disease.

(1→3)-β-D-Glucan detection is not subject to the usual interferences. It is not suppressed by anti-fungal therapy, nor is the test cross-reactive with other polysaccharides.

*See item i under Warnings, Precautions and Limitations (on reverse)
Fungitell® Assay
Serum test for (1→3)-β-D-Glucan
FDA-Cleared, 510(k) in vitro diagnostic

The mortality rate for patients with invasive fungal infections (IFI) is especially high in immunosuppressed patient populations.

Barnes J.A.C. 61: Suppl. 1, i3-i6 (2008)

Product Information

Principal of the Fungitell® Reagent
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.

Materials Supplied with the Kit

- 2 vials Fungitell® Reagent
- 2 vials Pyrosol® Reconstitution Bufferb
- 2 vials Glucan Standard
- 2 bottles Reagent Grade Water,b 20 mL
- 1 vial KCPC
- 1 vial KOHb
- 2 96-well microplatesb

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.

- Pipette tips (250 μL; 1000 μL)c and repeating pipette & tips
- Test tubes for sample dilution (13 x 100 mm)c
- Glass pipettes – not plastic
- Parafilm®
- Incubating plate reader capable of reading at 405 nm with appropriate kinetic software for determination of Vmean,c
- Vortex mixer

Order Information
FT001 Fungitell® Kit-110 test wells

Warnings, Precautions and Limitations (see instructions for use for details):

i. 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.

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

iii. 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.

iv. 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.

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

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

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

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

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

x. The use of Fungitell® for purposes other than those described in the Intended Use section of instructions for use of the product is neither recommended nor supported by Associates of Cape Cod, Inc.