

# Why Test For (1→3)-β-D-Glucan

Most pathogenic fungi\* have (1→3)-β-D-Glucan in their cell walls and minute, but detectable 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 (IFD) in at risk patients.

Associates of Cape Cod, Inc. (ACC) manufactures Fungitell®, an FDA cleared diagnostic test for the detection of (1→3)-β-D-Glucan. Fungitell® is a (1→3)-β-D-Glucan specific *Limulus* amoebocyte lysate (LAL) reagent containing a chromogenic peptide substrate. (1→3)-β-D-Glucan in the sample causes activation of a serine protease. The activated protease cleaves p-nitroaniline (pNA) from the peptide substrate and the free pNA is measured at 405 nm. The test is run in a standard incubating plate reader.

Multiple studies<sup>1,2,3,4,5</sup> have shown glucan to become elevated well in advance of conventional clinical signs and symptoms. The early diagnosis of and administration of therapy for invasive fungal disease is associated with improved clinical outcome; delayed diagnosis and therapy is associated with increased mortality<sup>8</sup>. Hence, there is significant utility in the application of the Fungitell® test in at risk patients.

## At Risk Patients

Invasive Fungal Disease is increasing in at risk populations\* such as:

- Aggressive Care (SICU/MICU/NICU)
- Mechanical Ventilation
- Stem Cell and Organ Transplants
- HIV
- Cancer Treatment
- Diabetes
- Central Venous Catheters
- Hemodialysis
- Gastrointestinal Surgery
- Total Parenteral Nutrition

## Opportunities

Fungitell® test is used for the detection of (1→3)-β-D-Glucan, which is frequently associated with the presence of fungal pathogens. The majority of these are *Candida* and *Aspergillus* species. The number of at risk patients is much higher than the current testing volume, representing an underdeveloped market.

There are, potentially, clinical applications that could benefit from utilizing the (1→3)-β-D-Glucan test where pneumocystosis is suspected.

## The Fungitell® Assay

### Features and Benefits

- Provides earlier support for diagnosis of IFD
- Detects glucan from most fungi including *Candida* and *Aspergillus*\*\*
- Rapid results within hours
- FDA Cleared
- CE Marked

\*Enoch et al., (2006) JMM 55:809-818.

\*\**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.

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