

# THE FUNGITELL® ASSAY

## THE GOLD STANDARD IN RAPID SCREENING FOR IFI

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13. Note: For complete test procedure refer to Fungitell® Instructions For Use (IFU)
14. The microplate reader must be equipped with a 405 nm filter which can be analyzed over time by a suitable software program.



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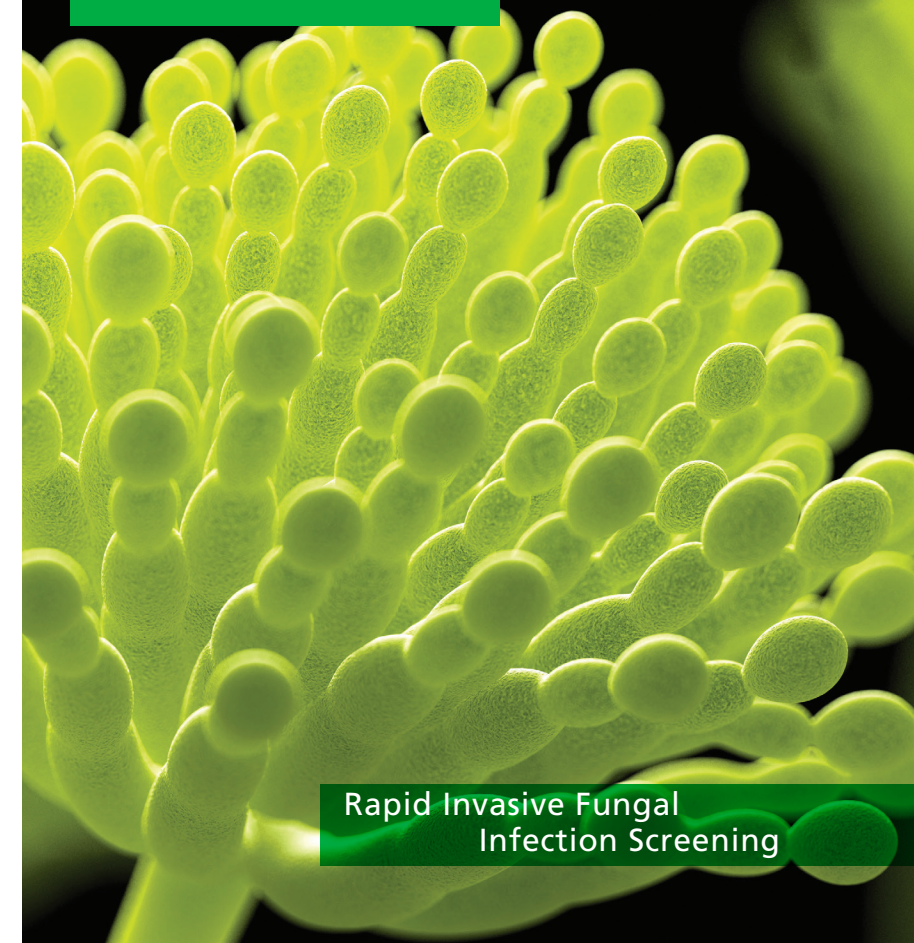
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FUNGITELL® ASSAY  
THE GOLD STANDARD  
IN (1→3)-β-D-GLUCAN  
TESTING



Rapid Invasive Fungal  
Infection Screening

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# THE FUNGITELL® ASSAY

## THE GOLD STANDARD IN RAPID SCREENING FOR INVASIVE FUNGAL INFECTION

### The Impact Of Invasive Fungal Infections

Invasive fungal infections (IFI) cause severe illness in critically ill and immunocompromised patients and are associated with high morbidity and mortality. IFI of the blood and organs are thought to cause around 1.5 million deaths worldwide each year.<sup>1</sup>

### Pathogenic Fungi

The majority of IFI are caused by *Candida* and *Aspergillus* species with *Candida* being the single most important cause of fungal infections worldwide.<sup>2</sup> In fact, *Candida* is the fourth leading hospital-acquired bloodstream infection, and with a mortality rate of 40%.<sup>3</sup>

### IFI Diagnosis

Early diagnosis is critical as delaying therapy even by a few hours greatly affects mortality (Figure 1).<sup>4</sup> Despite the severity of the issue, little has changed in the diagnostic process. Current diagnostic methods rely on blood culture which has a relatively low sensitivity and long incubation time. In fact, blood culture is estimated to be only 50% sensitive for *candidiasis*<sup>5</sup> and results can often take up to a week or even longer.<sup>6</sup>

### Fungitell® Assay - A Rapid, IFI Screening Test

Fungitell® is a rapid test that can detect the presence of invasive fungal infection-associated (1→3)-β-D-Glucan in under an hour, up to 99% faster than blood culture.

Fungitell® is the first and the **only FDA-cleared and CE marked** rapid *in vitro* diagnostic test for detecting (1→3)-β-D-glucan in serum as an adjunct to IFI diagnosis (including *Candida*, *Aspergillus* and *Pneumocystis*). (1→3)-β-D-glucan is a component of most fungal cell walls and is shed into the bloodstream during an infection rendering it an effective aid to the diagnosis of IFI in at risk patients.<sup>7</sup>

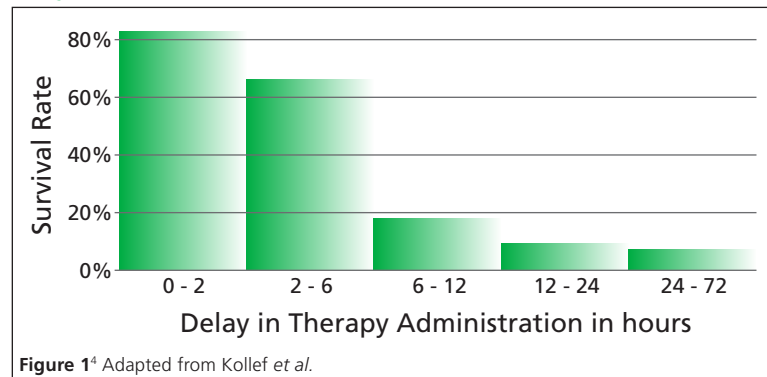
### Benefits Of The Fungitell® Assay

Compared to conventional diagnostic methods, the Fungitell® assay provides a rapid, reliable and near pan fungal<sup>8</sup> marker for early IFI screening:

- **Early Indication** – glucan becomes elevated well in advance of conventional signs/symptoms of IFI
- **Rapid Results** – assay provides results in less than 1 hour
- **Strong Negative Predictive Value (NPV)** – highly effective in ruling out the presence of IFI<sup>9,10,11</sup>

- **(1→3)-β-D-Glucan Detection** – not suppressed by anti-fungal therapy; a mycology criterion for the purposes of supporting the classification of “probable” IFD per the EORTC/MSG Consensus Group
- **Anti-Microbial Stewardship** – consecutive negative tests may reduce the overuse of antifungals, help combat the emergence of anti-fungal resistance, ensure better patient outcomes and promote cost savings. Cost savings associated with *candidaemia* alone can range from between \$25,000-\$55,000.<sup>12</sup>
- **Longevity in the Marketplace** – over a decade of proven clinical use, 100+ peer-reviewed clinical papers

### Early intervention increases survival rates in candidal shock<sup>4</sup>



### Risk Factors For IFI<sup>7</sup>

- Hematological Malignancies
- Systemic Inflammatory Diseases
- Diabetes Mellitus
- Chronic Respiratory Diseases
- Chronic Renal Failure
- Acute Renal Failure
- Morbid Obesity
- Liver Cirrhosis
- Pancreatitis (acute/chronic)
- Burns
- Surgery
- Intensive Care

### How A Fungitell® Test Is Performed

The Fungitell® assay is performed in microplates and read in an incubating reader. However, unlike standard enzyme immunoassays, the Fungitell® assay does not require any washing steps. All reagents added remain in the well and the test can be completed in approximately one hour.

### Reagent Storage

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.

### Specimen Collection

Serum is the only sample type that is currently approved for use with the Fungitell® assay.



**Note:** Serum that is hemolyzed, lipemic, or visually icteric or turbid is not suitable for use with the Fungitell® assay.

### Serum samples should be:

- collected in sterile vacuum tubes (red tops) or serum separator tubes (SST) (free from interfering levels of (1→3)-β-D-Glucan)
- allowed to clot
- then separated from the clot. If a pour-off tube is used, it should be free of interfering levels of (1→3)-β-D-Glucan

### How To Conduct The Test<sup>13</sup>

1. The sample/pretreatment mixture is incubated in a 37°C ± 1°C microplate reader or heat block for 10 minutes.
2. 100µl of reagent is then added to the sample and standard curves.
3. The microplate is then placed in a microplate reader at 37°C ± 1°C.
4. The plate reader<sup>14</sup> incubates and collects kinetic data for 40 min.

### How To Interpret Results

Result	(1→3)-β-D-Glucan Levels
Negative	(1→3)-β-D-Glucan values < 60 pg/mL
Indeterminate	(1→3)-β-D-Glucan values from 60-79 pg/mL
Positive	(1→3)-β-D-Glucan values ≥ 80 pg/mL