INTENDED USE
Fungitell® STAT assay and C. neoformans, A. fumigatus, Acremonium spp., Coccidioides immitis, Histoplasma capsulatum, Sporothrix schenckii, Exserohilum rostratum.

PRINCIPLE OF THE PROCEDURE
The Fungitell® STAT assay is a kinetic test that measures the rate of optical density increase produced by a sample. This rate is compared to the rate of optical density increase produced by a sample containing the active clotting enzyme, which in turn cleaves para-nitroanilide (Boc-Leu-Gly-Arg-pNA), creating a chromophore.

SUMMARY AND EXPLANATION
The assay is a rapid, sensitive method for the detection of β-D-glucans, which are released from yeast and fungi. This method can be used to detect fungal infections in patients with suspected fungal infections, especially in those with compromised immune systems.

MATERIALS SUPPLIED WITH THE FUNGITELL® STAT PROTOCOL
1. Fungitell® STAT Reagent: A lyophilized (1→3)-β-D-glucan-specific LAL reagent
2. Fungitell® STAT Standard: A lyophilized (1→3)-β-D-glucan-specific LAL reagent
3. Fixation volume (100 μL, catalog # F10000)
4. Pipette tips (250 μL catalog # PPT25 and 1000 μL catalog # PPT10)
5. Long Pipette tips (100 μL, catalog # PPT100)
6. A kinetic tube reader and mixing device
7. Tube reader and kinetic assay software
8. For PKF08 instrument, add 3.6 mL of 1× beta-glucan standard (lot # 00230016) to each patient sample
9. For PKF08 instrument, add 1.8 mL of 1× beta-glucan standard (lot # 00230017) to each patient sample

This product is for IN VITRO DIAGNOSTIC USE.

WARNINGS AND PRECAUTIONS
1. Certain fungal species produce very low levels of (1→3)-β-D-glucan and are not usually detected by the Fungitell assay. This includes blastomycosis and coccidioidomycosis. These species cannot be detected by the Fungitell assay.
2. In the event of an optical density (OD) peak at the end of the test, the patient sample OD must be compared to the standard curve. If the OD peak is greater than 0.07, the sample is considered positive.
3. If the OD peak is less than 0.07, the sample is considered negative.

PROPERTIES
The Fungitell® STAT assay is designed to be used in combination with other diagnostic methods, such as microbiological culture, histology, and radiology. The assay is sensitive to contamination and requires the use of sterilized equipment.

Figures 1 and 2 illustrate the steps involved in the assay. Figure 1 shows the steps involved in the test and Figure 2 shows the steps involved in the pretreatment process.
The Fungitell® assay is used to detect and quantify (1→3)-β-D-glucan, a component of the cells of filamentous fungi such as *Aspergillus* and *Rhizopus*. This assay is primarily used to help diagnose fungal infections and monitor their progression.

**Interpreting Results**

The Fungitell® test results are used in conjunction with other clinical findings to establish a diagnosis. It is important to note that a positive Fungitell® result alone does not define the presence of disease.

**Limitations of the Test**

- **Slope and rate are synonymous in this application.**
- **The frequency of patient testing will depend upon the relative risk of fungal infection.** Sampling rates of at least two to three times per week are recommended for at-risk patients.
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- **Reduced ability to contribute (1→3)-β-D-glucan to the bloodstream may affect the serum concentration of this analyte.** Reduced ability to contribute (1→3)-β-D-glucan to the bloodstream may affect the serum concentration of this analyte.
- **The following sample conditions can interfere with an accurate Fungitell® assay result:**
  - Elevated levels of Immunoglobulin G, such as may exist in the serum due to multiple melanomas, may result in false positive results.
  - Hemolysis may affect the sensitivity and specificity of the assay.
  - Precipitation in the reaction mixture upon the addition of Fungitell® STAT to the pre-treated serum may affect the test result.

**Fungitell® Sample Performance Comparisons to Fungitell®**

To ensure accuracy and reliability, the Fungitell® assay should be used in conjunction with other clinical findings to establish a diagnosis.

**NOMENCLATURE**

- **β-glucan**: A component of the cell walls of filamentous fungi such as *Aspergillus* and *Rhizopus*.
- **Fungitell®**: A diagnostic assay used to detect and quantify (1→3)-β-D-glucan.
- **(1→3)-β-D-glucan**: A component of the cell walls of filamentous fungi such as *Aspergillus* and *Rhizopus*.

**REFERENCES**