INTENDED USE
no-compromised patients
Amebocyte Lysate (LAL) pathway15,16, Figure 1. The Fungitell® assay
zymogen. The activated Factor G converts the inactive pro-clotting
invasive fungal infection. The serum concentration of (1→3)-β-D-glucan, a major cell-wall component of
detected by the Fungitell® assay test results.

SUMMARY AND EXPLANATION
Inactivated path
taining cellulose dialysis membranes are used

WARRANTS AND PRECAUTIONS

Note 2: The correlation coefficient (r) of the standard curve (linear vs. linear) should be ≥ 0.980.

The assay measures (1→3)-β-D-glucan. The assay is based upon a modification of the
mucous membranes 11,12. Diagnosis of invasive mycoses and

- The correlation coefficient (r) of the standard curve (linear vs. linear) should be ≥ 0.980.

- Do not pipette any material by mouth. Do not smoke, eat or drink in areas where specimens or kit reagents are handled. Follow institution and local safety regulations.

- 1. Certain fungi species produce very low levels of (1→3)-β-D-glucan and are not usually detected by the Fungitell® assay. These include the genera Cryptococcus* as well as many species within the genus Rhizopus, such as R. delemar and R. delemar var. oryzae. Note that glucans from these fungi may still be detected by the Fungitell® assay, as the assay is not specific for (1→3)-β-D-glucan. However, the presence of (1→3)-β-D-glucan is not considered to affect the results of the Fungitell® assay.

- Do not reconstitute one vial of Fungitell® reagent at a time; store reconstituted samples at 4°C for 24 hours in the dark. The Fungitell® assay is stable for 24 hours at room temperature. The Fungitell® assay reagent can be frozen at

- 1. Preparation of glucan standard provided in the kit.

- 2. Open the Alkaline Pretreatment Solution. The Alkaline Pretreatment Solution contains triple-helical glutelin produced by the root of a leafy plant. The Fungitell® assay reagent is a certified reagent free of interfering glucans. A calibration curve is not provided with the Fungitell® assay.
INTERFERING SUBSTANCES

A multi-center, prospective study to validate the performance characteristics of the Fungitell PERFORMANCES

The presence of anti-fungal drugs therapy had been statistically significant effect upon assay sensitivity. 118 subjects were tested for positive or negative fungal infection. 82 were positive by the assay (sensitivity, 68.5%, 4, 2, 8-32). In third-party, many negative results were positive and false positive 18 were positive by the assay (specificity, 97.5%, 95, 2-4).

SPECIFICITY

A total of 170 subjects were negative for fungal infection and were apparently healthy individuals. The specificity was 87.5% with the assay. The specificity was 95% with the assay.

FUSARIOSE

Three subjects were positive for fungus. 2 of the 3 were positive by the assay.

ANTI-FUNGALS

The presence of visually apparent bilirubin

Sample turbidity caused by lipemia

The frequency of patient testing will depend upon the relative risk of fungal infection.

6. Test levels were established in adult subjects. Infant and pediatric normal and cut-off levels are under investigation.

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*The presence of visually apparent bilirubin

Sample turbidity caused by lipemia

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