

Fungitell

For in vitro diagnostic use

TEST ID CODE

1700 Fungitell® β -D Glucan

CPT CODE

87449

CLINICAL UTILITY

The Fungitell β -D Glucan assay is indicated for the presumptive diagnosis of invasive fungal disease through detection of elevated levels of (1,3)- β -D-glucan in serum. Normal human serum contains low levels of (1,3)- β -D glucan, typically 10 to 40 pg/ml, presumably from commensal yeasts present in the alimentary canal and gastrointestinal tract. However, (1,3)- β -D-glucan is sloughed from the cell walls during the life cycle of most pathogenic fungi. Thus, monitoring serum for evidence of elevated and rising levels of (1,3)- β -D-glucan provides a convenient surrogate marker for invasive fungal disease.

The Fungitell β -D Glucan assay detects (1,3)- β -D-glucan from the following pathogens:

- Candida spp.
- Acremonium
- Aspergillus spp.
- Coccidioides immitis
- Fusarium spp.
- Histoplasma capsulatum
- Trichosporon spp.
- Sporothrix schenckii
- Saccharomyces cerevisiae
- Pneumocystis jiroveci

The Fungitell β -D Glucan assay does not detect certain fungal species such as the genus Cryptococcus, which produces very low levels of (1,3)- β -D-glucan, nor the Zygomycetes, such as Absidia, Mucor, and Rhizopus, which are not known to produce (1,3)- β -D-glucan. Studies indicate Blastomyces dermatitidis is usually not detected due to little (1,3)- β -D-glucan produced in the yeast phase.

PROCEDURE

The assay is based upon a modification of the Limulus Amebocyte Lysate (LAL) pathway. The key assay reagent is modified to eliminate Factor C, and is therefore specific for (1,3)- β -D-glucan and does not react to other polysaccharides, including beta-glucans with different glycosidic linkages. Similar to enzyme immunoassays, the Fungitell β -D Glucan assay is performed in microplates and read in an incubating reader.

SPECIMENS

- **Serum:**
- Collect 3 to 5 ml blood specimen in a gel separator tube (SST) without anti-coagulants. Allow specimen to clot, then centrifuge specimen within 2 hours of draw to pellet cells below the gel. Minimum volume of 0.5 mL serum for adults and 0.2 mL for infant (see assay limitations) and pediatric samples following centrifugation. The serum can be decanted into a suitable container that is free of interfering levels of (1,3)- β -D-glucan.
- Specimen can be stored refrigerated at 2 to 8°C or preferably stored frozen. Specimen should be shipped with frozen gel packs or dry ice for overnight delivery at ViraCor.
- **Other specimens may be accepted for testing; however the following comment will appear in the final report:**
"The clinical utility of this result has not yet been demonstrated in the peer reviewed literature and is therefore unknown." Call ViraCor for further information.

CAUSES FOR REJECTION

- Lipemic, icteric, or hemolyzed specimens.
- Specimens that have been stored at ambient temperature.
- Specimens that have been stored at 2 to 8°C for >5 days.
- If storage longer than 5 days is needed, samples should be frozen at -20°C or colder. Unless indicated as stored frozen, the specimen will be rejected if the draw date is >5 days from receipt at ViraCor.



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ASSAY LIMITATIONS

- There are reports in the peer reviewed literature of lowered assay specificity in patients with gram positive bacteremia.
- Patients with renal failure on hemodialysis utilizing cellulose membranes may have false positive results.
- Patients treated with fractionated blood products such as albumin and immunoglobulin and in specimens and subjects exposed to glucancontaining gauze. Patients require 3 to 4 days for the restoration of baseline levels of serum (1,3)- β -D-glucan, after surgical exposure to (1,3)- β -D-glucan-containing sponges and gauze. Accordingly, the timing of sampling of surgical patients should take this into account.
- Samples obtained by heel or finger stick methods are unacceptable as the alcohol-soaked gauze used to prepare the site (and potentially, the skin surface-pooling of blood) has been shown to contaminate the specimens.
- A negative test result cannot rule out the diagnosis of invasive fungal disease. Patients at risk for invasive fungal disease should be tested twice per week.
- The performance of the Fungitell β -D Glucan assay has not been evaluated with specimens from neonates and infants \leq 6 months of age.
- Patients whose GI tract is colonized with Candida and have mucositis may have a positive Fungitell β -D Glucan assay result without invasive fungal disease.

REFERENCE VALUES

- Negative: Less than 60 pg/ml
- Indeterminate: 60 to less than 80 pg/ml
- Positive: Greater than or equal to 80 pg/ml

The Fungitell β -D Glucan assay is indicated for presumptive diagnosis of fungal infection. It should be used in conjunction with other diagnostic procedures. The Fungitell β -D Glucan assay does not detect certain fungal species such as the genus *Cryptococcus*, which produces very low levels of (1,3)- β -D-glucan. This assay also does not detect the *Zygomycetes*, such as *Absidia*, *Mucor* and *Rhizopus*, which are not known to produce (1,3)- β -D-glucan.

Information derived from the Fungitell package insert (Associates of Cape Cod, Inc.).

TURNAROUND TIME

Same day (within 8 to 12 hours of specimen receipt), Monday through Saturday

SHIPPING

Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. A ViraCor test requisition form must accompany each specimen. Ship specimens Fed Ex Priority Overnight[®] to:

ViraCor Laboratories, 1001 NW Technology Dr., Lee's Summit MO, 64086

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