
Lab Dept: SEROLOGY

Test Name: FUNGITELL, SERUM

General Information

Lab Order Codes: FUNGS

Synonyms: Beta-D glucan

CPT Codes: 87449 – Infectious agent detection by immunoassay technique, qualitative or semi-quantitative

Test Includes: Fungitell result reported as Negative, Indeterminate or Positive

Logistics

Test Indications: 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*, and *Pneumocystis jiroveci*.

Lab Testing Sections: Serology - Sendouts

Referred to: Mayo Medical Laboratories forward to Viracor-IBT (MML Test: FUNGS, Viracor-IBT Test: 1700)

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

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

Special Instructions: Specimen cannot be shared with other testing. DO NOT remove tube cap. One Gold SST is required for testing.

Specimen

Specimen Type: Whole blood

Container: Gold SST (3.5 mL)

Draw Volume: 3.5 mL whole blood in a gel separator tube (SST)

Processed Volume: Same as Draw Volume

Collection: Routine venipuncture

Special Processing: Lab Staff: Centrifuge specimen within 2 hours of draw to pellet cells below the gel. Do Not open tube. Freeze in original container after centrifugation. Specimen cannot be shared with other tests. Specimen should be stored and shipped frozen. Forward promptly.

Patient Preparation: None

Sample 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-IBT. Specimens other than those listed in the specimen information.

Interpretive

Reference Range: Negative: Less than 60 pg/mL. Indeterminate: 60 to 79 pg/mL. Positive: Greater than or equal to 80 pg/mL.

Critical Values: N/A

Limitations:

- 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.
- 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 glucan containing 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 <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.

Methodology:

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. This test has been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

References:

[Mayo Medical Laboratories](#) January 2016

[Viracor-IBT](#) January 2016