

Beta D Glucan assay

FUNGITELL assay for (1,3)- β -D-glucan: the fungal glucan test is indicated for assessing the likelihood of systemic fungal infection

General information

Turnaround time: This assay is performed every day, Monday-Friday. Turnaround time: 95% within two weekdays, generally available within one weekday.

Sample type/container:

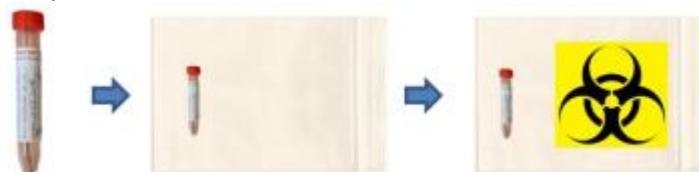
Blood:



- 4.9 ml clotted blood collected directly from the vein.
- Serum tube (Sarstedt S-Monovette white cap) or serum gel tube (brown cap). Blood collected in EDTA tubes cannot be processed for this test and will be rejected.
- Please do not remove the cap, do not share the sample. Samples are easily contaminated either during sample collection or laboratory procedures.
- Blood samples obtained by heel or finger stick methods or other sample types are not accepted.

Transportation:

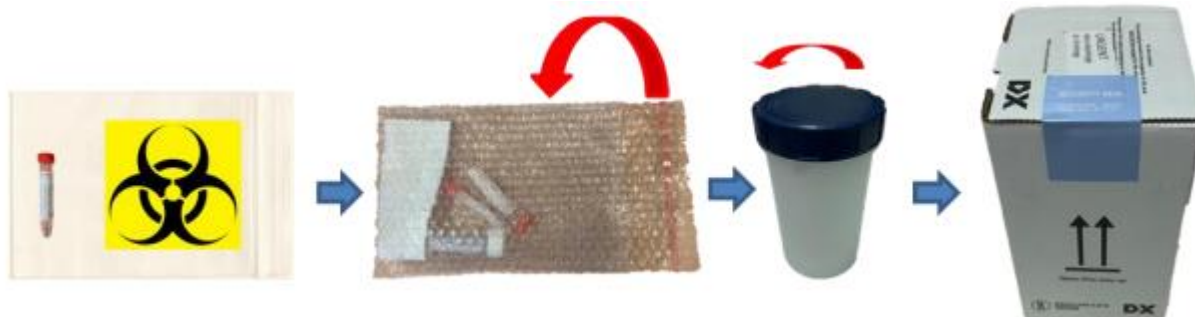
- Samples should be placed into a plastic Ziploc bag, sealed, and then placed into another sealed plastic Ziploc bag (preferably with a biohazard label on the outside), as shown below.



- Category B transport boxes or an appropriate transport bag (i.e., one which adheres to regulations governing the transportation of diagnostic specimens) must be used for transport by road or between Manchester University Foundation Trust sites (but are not necessary within Wythenshawe hospital grounds).
- Please see below for packaging requirements.

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For more information - <https://mrcm.org.uk/sample-collection/>

Laboratory Information

Biological interval/clinical decision values:

The (1,3)- β -D-glucan (BDG) test results are expressed in picogram per millilitre (pg/mL) of serum and range from undetectable (<31 pg/mL) to >500 pg/mL.

BDG values of <60 pg/mL are interpreted as negative results.

BDG values \geq 80 pg/mL are interpreted as positive. A positive result does not define the presence of disease and should be used in conjunction with other clinical and laboratory findings.

Values from 60 to 79 pg/mL are interpreted as indeterminate. Additional sampling is recommended.

This test is only validated for patients 18 years old and above. Please consult the laboratory for more information if needed.

Clinical Information

No specific time of optimal collection. First clinical indication or follow-up monitoring of invasive fungal infection. At risk patients may require repeat testing.

BDG is present on the cell wall of most fungal species and in case of invasive or deep-seated fungal disease caused by these species, BDG antigenemia is normally detectable by this test. Particularly high levels are typically seen in cases of various forms of invasive *Candida* infections and *Pneumocystis jirovecii* pneumonia.

In general, the glucan test has a high negative predictive value and a low positive predictive value. Therefore, in the absence of other evidence of an invasive fungal disease, a negative result may be used to rule out most invasive fungal infections, whilst a positive test result should only trigger further investigations, consideration of both host and clinical factors, and repeat testing.

This test should be used in conjunction with other diagnostic methods, such as high-volume blood cultures, fungal PCRs, histological examination of biopsy samples and radiological examination and interpreted considering the clinical context.

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In general, once the diagnosis of invasive fungal disease has been established, repeat testing has little value as the clearance of BDG antigenemia will take time. However, in cases of deep-seated infections, such as *Candida* endocarditis, plateauing and/or slowly decreasing values are usually seen when there is good response to treatment.

In some settings (e.g., haemato-oncology) screening may be performed to monitor for evidence of elevated and rising levels of glucan as a potential surrogate marker for invasive fungal disease.

Limitations:

Possible causes of false negatives:

- The Fungitell (1,3)- 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 Mucormycetes, such as *Lichtheimia*, *Mucor* and *Rhizopus*, which are not known to produce (1,3)- β -D-glucan. The yeast phase of *Blastomyces dermatitidis* produces little (1,3)- β -D-glucan and may not be detected by the assay.
- Tissue-localised or encapsulated fungal infections that limit the amount of (1,3)- β -D-glucan produced and/or limit its translocation into the bloodstream may result in low or undetectable serum concentrations.

Possible causes of false positives:

- Laboratory-based (mainly separating and sharing the sample in an inappropriate, non-BDG-free environment) and sample collection derived contamination
- Intravenously administered products, including drugs and blood fractionation products (such as serum albumin, immunoglobulins, and filtered blood plasma)
- Intestinal translocation of mycobiome-derived BDG (antigenemia in the absence of fungaemia) following intestinal barrier injury (due to chemotherapy-associated mucositis, intestinal ischemia, mesenteric hypoxia, microbial toxins, viral infection of intestinal tissue, metabolic toxicity, such as in uraemia, large total surface area burns, and protease-producing intestinal enterococci, or sepsis)
- Compromised hepatic function and BDG processing
- Parenteral nutrition contaminated during manufacturing processes (e.g., filtration)
- Invasive use of surgical materials (e.g., gauze and surgical sponges that contain glucan)
- Invasive nocardiosis
- Fungal glucan levels typically rise early in infection, then decline slowly, only returning to baseline well after successful disease resolution.
- Patients require 3-4 days for the restoration of baseline levels of serum (1,3)-D glucan after surgical exposure to BDG-containing sponges and gauzes.

The following sample features may interfere with the test and make processing impossible:

- Haemolysis
- Sample turbidity caused by lipemia
- The presence of visually apparent bilirubin
- Turbid or discoloured serum

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- Elevated levels of immunoglobulin G

Repeat testing is recommended in these cases.

References:

Finkelman, M.A. Specificity Influences in (1>3) β -D-Glucan-Supported Diagnosis of Invasive Fungal Disease. *J. Fungi* 2021, 7, 14.
<https://doi.org/10.3390/jof7010014>.

Karageorgopoulos DE, Qu JM, Korbila IP, Zhu YG, Vasileiou VA, Falagas ME. Accuracy of β -D-glucan for the diagnosis of *Pneumocystis jirovecii* pneumonia: a meta-analysis. *Clin Microbiol Infect.* 2013 Jan;19(1):39-49. doi: 10.1111/j.1469-0691.2011.03760.x.
Assay for (1>3)- β -D-Glucan in Serum, FUNGITELL® ASSAY, Instructions For Use, PN001268-en Rev12, 2023-06-13.

(Last updated November 2024)