

the Fungitell® Bulletin

volume 8, issue 4

Topic:

STORAGE STABILITY OF (1→3)- β -GLUCAN IN SERUM SAMPLES

(1→3)- β -GLUCAN STABILITY IN SERUM IS DUE TO THE
LACK OF MAMMALIAN (1→3)- β -GLUCANASES AND THE
INHERENT STABILITY OF THE GLYCOSIDIC BOND

Fungitell® Bulletins are intended as technical advisory communications and as such are disseminated to the general public in order to highlight the significance of (1→3)- β -D-Glucan on human health. These communications do not promote a specific drug, therapy nor make any representation or suggestion concerning the suitability or effectiveness of a particular drug or therapy in patients harboring (1→3)- β -D-Glucan. Fungitell® is an adjunct diagnostic assay to be utilized in conjunction with clinical signs and symptoms for the diagnosis of invasive fungal infection. Fungitell® is currently 510(k) cleared for the detection and quantification of (1→3)- β -D-Glucan in human serum and should be used and interpreted only in a manner consistent with the current Instructions for Use.

Discussion:

The temperature experienced by clinical and research blood and blood fraction samples will vary through the chain from phlebotomy/line draw to testing.¹ Fungitell® users frequently inquire as to the stability of (1→3)- β -glucan (BDG) in serum. This is a very reasonable question given that after a blood draw, the sample path to the testing event will often be highly variable with respect to both time and temperature.² In the event of sample change due to susceptibility to environmental chain conditions prior to testing, results may have additional variability. Table 1 lists a variety of temperature and holding period circumstances that may exist post the blood draw. Note that 90 minutes is the recommended limit for getting a specimen into the freezer post-draw. Refrigerators and freezers should be lab-grade with verified performance. Occasionally, home appliance grade equipment is in use with potentially deleterious performance. This is especially true of frost-free freezers which cycle through heating and cooling cycles, potentially leading to multiple freeze/thaw cycles for stored samples.



Fungitell®

(1→3)- β -D-Glucan Assay

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STORAGE STABILITY OF (1→3)- β -GLUCAN IN SERUM SAMPLES

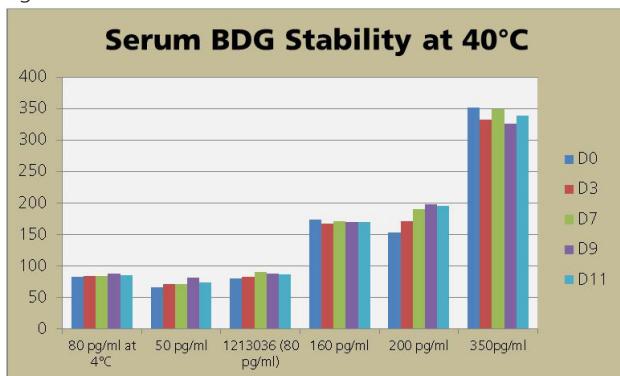
Table 1.

Hypothetical Environmental Conditions With Variable Periods

Event	Storage	Issues
Phlebotomy or line draw	Racked tube	Room Temperature
Arrival at lab	Racked Tube	Room Temperature or 2-8°C
Staging pre-processing or testing	Racked or in instrument	Room Temperature or 2-8°C
Serum preparation	Clotting time: 30-60	Room Temperature
Serum Storage Pre-Analysis	Racked or in instrument	Room Temperature or 2-8°C or \leq -20°C
Return to room temperature pre-test	N/A	2-8°C to 25°C
Testing	N/A	37°C
Storage, Frozen	Frozen (\leq -20°C)	<ul style="list-style-type: none"> - Home appliance grade freezer? - Validated lab-grade freezer? - Frost-free (heating cycle?) - Frozen status verified?

Information concerning the stability of (1→3)- β -glucan is often requested from the Technical Support group at Associates of Cape Cod, Inc. In order to address this question, serum (Off-the-clot serum) was spiked with various concentrations of *Saccharomyces cerevisiae* (1→3)- β -glucan and samples stored at 40°C, a temperature in excess of what a laboratory specimen might experience, even briefly. The hold period was 11 days, with aliquots taken at intervals and tested with Fungitell®. The results are presented in Fig. 1. The reference material was maintained at 2-8°C. As may be observed, the (1→3)- β -glucan was stable over the period of storage at 40°C.

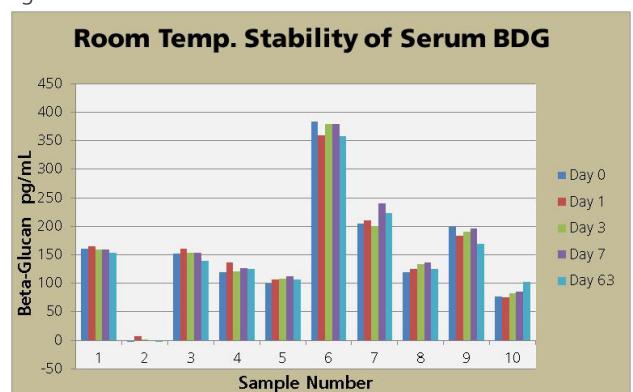
Fig. 1



Unpublished data, Associates of Cape Cod, Inc.

A similar experiment was conducted using de-identified patient samples. These samples were stored at room temperature for 63 days (Fig. 2), with intermittent (1→3)- β -glucan titer assessment using the Fungitell assay. As may be observed, there was no significant change in the measured (1→3)- β -glucan titer over the 63 day period.

Fig. 2



Unpublished data, Associates of Cape Cod, Inc.

(1→3)- β -glucan is a very stable polysaccharide. In addition, mammals do not have enzymes that can degrade (1→3)- β -glucan. However, it is recommended that samples be shipped either cold (2-8°C) or frozen (<-40C). This is due to the theoretical potential for microbial contamination to be present in the sample. Bacteria can secrete (1→3)- β -glucanases, potentially leading to false negatives, while fungi may grow and introduce more beta-glucan, leading to exaggerated (1→3)- β -glucan titers.

Discussion References:

1. Jasmijn A van Balveren, Mirelle JAJ Huijskens, Eugenie FA Gemen, Nathalie CV Pequeriaux and Ron Kusters. Effects of time and temperature on 48 routine chemistry, haematology and coagulation analytes in whole blood samples. Annals of Clinical Biochemistry 2017, Vol. 54(4) 448-462.
2. Wu, D.W., Li, Y.M., and Li, F.W. How long can we store blood samples? EBioMedicine 24 (2017)277-285.



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