

# the Fungitell<sup>®</sup> BULLETIN

volume 11, issue 3

*Topic:*  
**BG Analytics<sup>®</sup>**  
**Software Update**  
*Addition of Estimated  
pg/mL Values*

## **Discussion:**

The inclusion of an estimated Fungitell<sup>®</sup> pg/mL value with the Fungitell STAT<sup>®</sup> Beta-Glucan Index (BGI) result combines the convenience of a simplified, single vial method with an estimated pg/mL value to leverage the clinical knowledge developed over 20 years of Fungitell<sup>®</sup> clinical use.

Fungitell<sup>®</sup> is the reference standard for diagnosis of invasive fungal infection through detection of (1→3)- $\beta$ -D-glucan. Fungitell<sup>®</sup> is supported by over 20 years of clinical research and is referenced in over 400 peer-review publications, clinical studies, meta-analyses, and review articles. This history of use and consistent performance has led to the inclusion of (1→3)- $\beta$ -D-glucan testing in international and local guidelines for diagnosis of invasive fungal infection and clinical management. Fungitell<sup>®</sup> was 510(k) FDA-cleared in 2004, CE-marked in 2008, and since then utilized worldwide.

## ***Fungitell STAT<sup>®</sup> – Single Vial Version Of Fungitell<sup>®</sup>***

Fungitell STAT<sup>®</sup> provides a single vial version of the Fungitell<sup>®</sup> assay. It employs a simplified procedure that provides a BGI result using a reference standard included with the kit. Fungitell STAT<sup>®</sup> was 510(k) FDA-cleared and CE-marked in 2019 based on 99% Positive Percent Agreement and 98% Negative Percent Agreement with the Fungitell<sup>®</sup> assay (D'Ordine et al., 2021).

*Fungitell<sup>®</sup> 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)- $\beta$ -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)- $\beta$ -D-Glucan. Fungitell<sup>®</sup> is an adjunct diagnostic assay to be utilized in conjunction with clinical signs and symptoms for the diagnosis of invasive fungal infection. Fungitell<sup>®</sup> is currently 510(k) cleared for the detection of (1→3)- $\beta$ -D-Glucan in human serum and should be used and interpreted only in a manner consistent with the current Instructions for Use.*

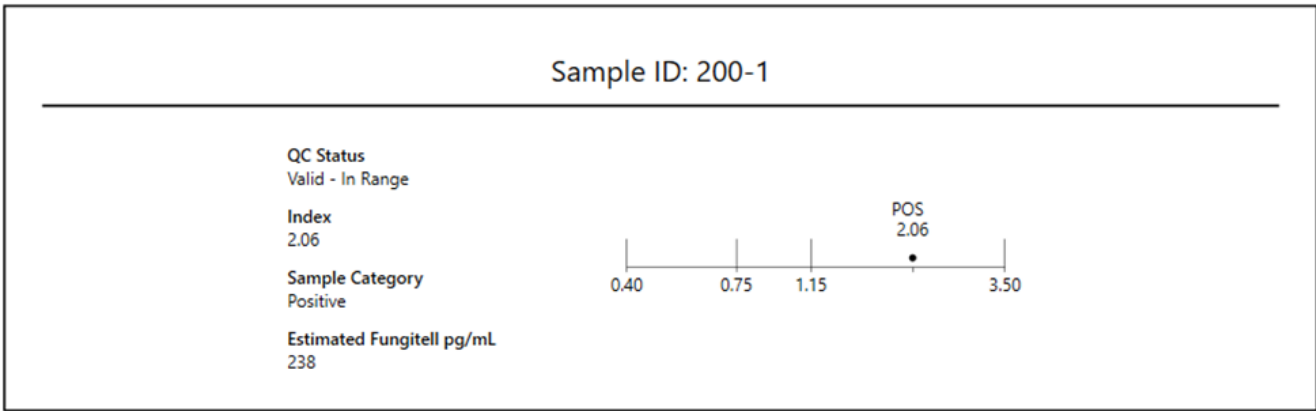
**Fungitell<sup>®</sup>**

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An estimated Fungitell® pg/mL value is now provided in addition to the BGI with the updated BG Analytics® software released on July 1, 2025. Additional software improvements include the display of a standard kinetic trace when an invalid standard result is recorded (for troubleshooting purposes) as well as compatibility with Microsoft® Windows® 11.

Software Update Procedure

To update the software to the new version, follow these steps: (1) back up the existing system, (2) uninstall the old software, (3) install the new software and then (4) restore the database. Note that the software/database is generally installed per user. See section 2.5; Installation and Update Procedures and section 2.8; Backup & Restore of Database of the BG Analytics® User Manual for more details.

Estimated Fungitell® pg/mL Value – A Link To 20 Years Of Clinical Research

Fungitell® and Fungitell STAT® share the same reagent, buffer, pre-treatment, 40-min assay time, colorimetric method and Vmean analysis. Both Fungitell® and Fungitell STAT® are manufactured in the same facility where the Fungitell STAT® Standard is calibrated against the 80 pg/mL positive cut-off of the Fungitell® assay.

	Fungitell®	Fungitell STAT®
Glucan Standard	Pachyman ( <i>Poria cocos</i> )	<i>Saccharomyces cerevisiae</i> calibrated against pachyman
Reagent	Chromogenic prepared from amebocytes of <i>Limulus polyphemus</i>	Unchanged
Buffer	Tris pH 7.4	Unchanged
Reagent Water	LAL reagent water	Unchanged
Pre-treatment	Alkaline Pre-treatment 37°C for 10 min.	Unchanged
Method	Absorbance at 405nm	Unchanged
Measured Entity	Release of pNA at 37°C during 40 min.	Unchanged
Data Reduction	Vmean in mAbs/min. linear/linear	Vmean in Abs/sec., linear fit
Sample Matrix	Serum	Unchanged
Reported Results	pg/mL	Index
Range	31 – 500 pg/mL	0.4 – 3.5 index units
Cut-off Value	80 pg/mL	1.2 BGI
Manufacturer	ACC – USA	ACC – USA

The similarities between the methods and the fact that each lot of Fungitell STAT® is calibrated against the Fungitell® reference glucan standard allowed for the development of a mathematical model from which an estimated Fungitell® pg/mL can be derived. The model was validated against the original Fungitell® pg/mL results from the Fungitell STAT® versus Fungitell® Method Comparison study reported in Section 13.2 of the Fungitell STAT® Instructions For Use (IFU) with a linear correlation of 0.91. **Note:** The clinical categorization remains based on the BGI which was validated using an expanded indeterminate zone (i.e. 60-95 pg/mL). Both are qualitative methods with inter/intra assay variability of up to 30%. Please refer to the Fungitell STAT® IFU for complete information.

Cut-off	Fungitell® (pg/mL)	Fungitell STAT® (BGI)	Estimated Fungitell® pg/mL Now Available With Fungitell STAT®
Negative	<60	≤0.74	<60
Indeterminate	60-79	0.75-1.1 (1.14)	60-95
Positive	≥80	≥1.2 (1.15)	≥96

References:  
D'Ordine *et al.*, (2021) Performance characteristics of Fungitell STAT®, a rapid (1→3)-β-D-glucan single patient sample in vitro diagnostic assay. Medical mycology 59, 41–49.