the Fungitell® BULLETIN
volume 9, issue 3

Topic:

From Serum to Result in One Hour: Fungitell STAT® Explained

The Fungitell STAT® Assay: Principle, method, and interpretation

Discussion:

Single or small numbers of (1→3)-β-D-glucan (BDG) tests are required in emergent and acute care as well as in low patient sample number settings. Fungitell STAT® is a simple, fast (1 hour), and small footprint approach to testing 1-7 patient serum samples [*Figure 1*].

Figure 1: Fungitell STAT® PKF08 Instrument
The instrument is small in size: 174mm x 119mm x 37mm weighing approximately 1 kg. The power supply is EU friendly. The tablet and barcode reader are presented for size reference.

Based upon the well-known Fungitell microplate-based assay, Fungitell STAT® is also a *Limulus* Amebocyte Lysate kinetic assay that is specific for (1→3)-β-D-glucan (BDG) [*Figure 2*][1,2,3,4,5]. The Fungitell STAT® method employs a standard in place of the standard curve utilized in the Fungitell® method. This Fungitell STAT® standard is a critical element of the test and is designed to represent the rate of a reaction for a sample of glucan at 80 pg/mL. This pg/mL value is based upon the cutoff in, and derived from, the execution of the Fungitell® predicate assay. The Fungitell STAT® standard is run in parallel with a sample (or samples) to which it is compared using the same treatments and materials. A simplified method for execution is outlined below in *Table 1*. With this approach, an emergency department lab or main lab can quickly run one to seven patient tests at a time, saving days over a send-out approach.

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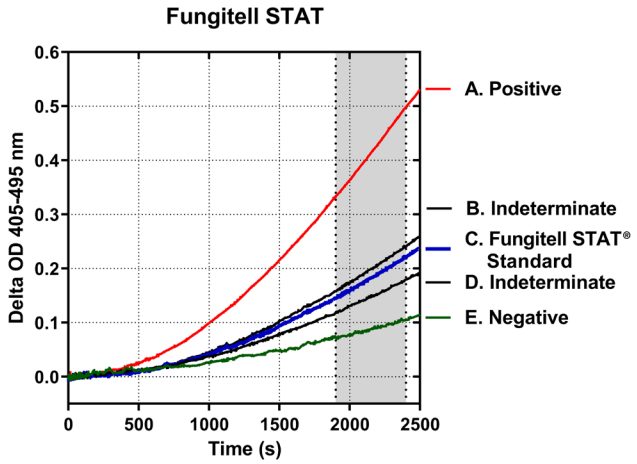

Figure 2: Illustration of underlying kinetic curves derived from the Fungitell STAT® method. Samples on the graph: A. is positive and B. and D. are Indeterminate, C. Fungitell STAT® Standard; E. Negative. All plots are delta OD 405-495 nm. The gray zone between 1900 and 2400 seconds is the area of linear regression from which rates are determined.

Table 1: Fungitell STAT® simplified method outline

Step	Action
1	Add serum sample (50 µL)* to an empty vial /test tube
2	Add alkaline pretreatment to sample (200 µL), mix
3	Reconstitute the Fungitell STAT® Standard (STD) with LRW (100 µL)*, mix
4	Add alkaline pretreatment solution (APS) to STD (400 µL)*, mix
5	Incubate samples and STD at 37oC for 10 min
6	Reconstitute Fungitell STAT® reagent with LRW (300 µL), mix
7	Transfer 75 µL of STD to a Fungitell STAT® reagent reaction vial, mix
8	Transfer 75 µL of sample to another Fungitell STAT® reagent reaction vial, mix
9	Place reaction vials into instrument
10	Collect data

**The ratio, 1:4, with pretreatment for sample and standard is fixed, however, reconstitution volumes of the Fungitell STAT® Standard (STD) will vary depending on lot. For example, the reconstitution volumes for the standard lot used in this table are 100 µL LRW:400 µL APS.*

The output for the Fungitell STAT® method is a comparative index (beta glucan index, BGI, *Figure 3*) computed by dividing the patient sample rate by the Fungitell STAT® standard rate. This patient sample BGI value is qualitatively interpreted as a Negative, Indeterminate, or Positive result according to the ranges provided in *Table 2* below. The relationship of the STAT BGI output back calculated into the pg/mL values of the more familiar Fungitell® microplate kit is described in *Table 2* as well.

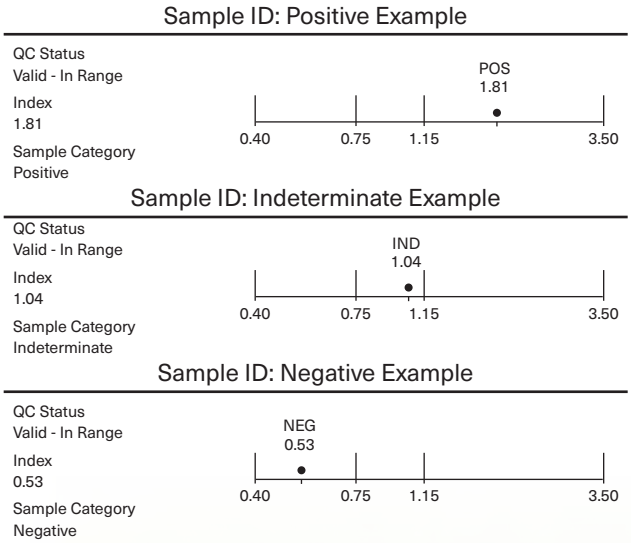

Figure 3: Example output from a Fungitell STAT® assay as reported by the new BG Analytics® (BGA) software.

Table 2: Fungitell STAT® (BGI) and comparison to Fungitell® (pg/mL)

	A	B	C
Cutoff	**Fungitell STAT® IFU (BGI)**	**Fungitell® Predicate (pg/mL)**	**FSTAT to FTELL Back calc. (pg/mL)**
Negative	≤0.74	<60	<60
Indeterminate	0.75 – 1.1	60 – 79	60-88
Positive	≥ 1.2	≥ 80	≥96

Complementing the traditional Fungitell® assay, used with high sample volumes, the Fungitell STAT® permits clinical settings of any size to utilize rapid BDG testing in their patient care. Additional information is available at www.fungitell.com/fungitell_stat.

References:

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