8.6 Prepare Fungitell STAT® Reagent tubes

The following materials supplied with each product are sufficient for a total of 50 reactions based on the 10 tubes of STAT® and others, can be used in a single reaction:

1. Fungitell STAT® Reagent: a lyophilized (β-1,3)–D-glucan specific LAL (Lot#).

The materials required but not supplied can be purchased from your local lab supply house. The STAT® Standard and the STAT® Reagent tubes come in a package and are placed in a LAL vial. The following requirements are met if used in an appropriate manner:

1. The STAT® Standard result, (STD), must be between 0.75 and 1.1 to be considered valid.
2. The slope of the sample (i.e., 0.00022 OD/s) divided by the slope of the 80 pg/mL (STD) result should be greater than or equal to 0.4 OD before 1000 seconds.
3. The kinetic curve passes 0.4 OD before 1000 seconds.
4. The result is likely out-of-range on the negative side if:
   - The kinetic curve must be positive after 500 seconds,
   - The slope of the sample (i.e., 0.00022 OD/s) divided by the slope of the 80 pg/mL (STD) result should be less than or equal to 0.2 OD after 1000 seconds.

Note: The Fungitell STAT® Reagent contains a number of active principles that can produce false negative results. Do not use the provided curve in context and determine the validity of the results based on the laboratory internal quality system.

8.7 Assay Procedure

1. Establish a clean environment in which to perform the assay.
2. Ensure all solutions and instruments are within their expiry date and have been used.
3. Make sure to use the clinical laboratory guidelines provided with the instrument.
4. Use the clinical laboratory guidelines provided with the instrument.

8.8 Principle of the Procedure

The Fungitell STAT® assay is a latex agglutination assay that uses a suspension of latex particles with a specific affinity for (1→3)-β-D-glucans to detect an increase in the concentration of (1→3)-β-D-glucans in serum samples.

1. The latex particles are coated with a specific antibody against (1→3)-β-D-glucans, and the resulting complex is added to the patient serum samples.
2. The complex is then incubated at 37°C for 45 minutes.
3. The mixture is centrifuged at 12,000 rpm for 10 minutes.
4. The supernatant is discarded, and the pellet is washed three times with saline solution.
5. The final pellet is resuspended in saline solution, and the optical density is measured at 595 nm.

8.9 Procedure

1. Add 50 µL of patient serum (or negative control) to each well of the Fungitell STAT® Reagent tube.
2. Cap the tube and mix well.
3. Incubate the mixture for 45 minutes at 37°C.
4. Centrifuge the mixture at 12,000 rpm for 10 minutes.
5. Read the optical density at 595 nm using a spectrophotometer.

8.10 Fungitell STAT® Standards

The Fungitell STAT® Standards are used to determine the concentration of (1→3)-β-D-glucans in the serum samples. The standards are available in two concentrations: 80 pg/mL (STD) and 800 pg/mL (STD).

8.11 Data Interpretation

The results of the Fungitell STAT® test should be used as an aid in the diagnosis of an invasive fungal infection.

8.12 Notes on Testing:

1. Fungitell STAT® Standards as soon as all Fungitell STAT® Reagent tubes contained in a package
2. Use Fungitell STAT® Standards as soon as all Fungitell STAT® Reagent tubes contained in a package
3. The Fungitell STAT® Standards must be used within 15 days of receipt.
4. If the Sample result does not meet QC criteria #2, this suggests that the sample signal is low. In that case, the user should review the software output to determine the validity of the results based on the laboratory internal quality system.
5. If the Fungitell STAT® Standard result does not meet criteria #1 and #2, the run is invalid and all results must be discarded.


