

# **Standard Operating Procedure (SOP) for Analytical Phase of Generating Results for 1,3-BETA-D-GLUCAN (FUNGITELL), Serum**

## **1. PURPOSE**

To establish a standardized procedure for the analytical phase of testing for 1,3-BETA-D-GLUCAN (FUNGITELL) in serum to ensure accurate and reliable test results.

## **2. SCOPE**

This SOP applies to all laboratory personnel performing the 1,3-BETA-D-GLUCAN (FUNGITELL) assay in a CLIA-certified laboratory.

## **3. RESPONSIBILITY**

- Laboratory Technologists are responsible for performing the test as per the procedure and ensuring the accuracy and precision of test results.
- Supervisors are responsible for the oversight and quality control of the testing process.

## **4. DEFINITIONS**

1,3-BETA-D-GLUCAN: A polysaccharide found in the cell walls of fungi. Detection in serum helps in diagnosing invasive fungal infections.

## **5. EQUIPMENT, REAGENTS, AND SUPPLIES**

- FUNGITELL Assay Kit
- Microplate reader capable of measuring 405 nm
- Pipettes (single and multi-channel)
- Pipette tips (sterile and RNase/DNase-free)
- Sterile, endotoxin-free microtubes
- Sterile, endotoxin-free microplates
- Timer
- Calibrated water bath or incubator
- Calibrated refrigerator and freezer
- Calibration materials and controls as provided in the kit

## **6. SPECIMEN REQUIREMENTS**

- Preferred specimen: Serum collected in a red-top tube or serum separator tube (SST).
- Specimen stability: Serum should be separated from cells within 2 hours of collection and stored at 2-8°C for up to 5 days or frozen at -20°C or lower for longer storage.
- Unacceptable specimens: Hemolyzed, lipemic, or contaminated specimens.

## **7. QUALITY CONTROL**

- Ensure proper functioning of all equipment before starting the assay.
- Use control materials provided in the FUNGITELL kit. Control results must be within the specified ranges.
- Run at least one positive and one negative control with each batch of samples.

## **8. PROCEDURE**

### **A. Preparation**

1. Allow all reagents and controls to reach room temperature before use.
2. Thaw any frozen specimens thoroughly and mix gently.

### **B. Reagent Preparation**

1. Prepare the working solutions as per the manufacturer's instructions included in the FUNGITELL Assay Kit.
2. Label all reagents and working solutions appropriately with the preparation date.

### **C. Sample and Control Preparation**

1. Pipette 50 µL of standards, controls, and patient serum into designated wells of the microplate.
2. Ensure the use of appropriate pipetting techniques to avoid cross-contamination.

### **D. Incubation**

1. Add 50 µL of reconstituted reagent into each well containing samples and controls.
2. Cover the plate with a plate sealer or lid and incubate at 37°C for 30 minutes.
3. After incubation, add the stop solution as per the manufacturer's instructions.

### **E. Reading the Results**

1. Measure the absorbance at 405 nm using a microplate reader.
2. Compare the absorbance values to the standard curve to determine the concentration of 1,3-BETA-D-GLUCAN in patient samples.

## **9. INTERPRETATION OF RESULTS**

- Results are interpreted based on the manufacturer's guidelines and cut-off values provided in the FUNGITELL Assay Kit.
- Report findings as positive or negative for suspected fungal infection.

## 10. REPORTING RESULTS

- Enter the patient results into the Laboratory Information System (LIS).
- All results must be reviewed and verified by the technologist before being reported.
- Retain a printout or electronic copy of the results and quality controls for record-keeping.

## 11. TROUBLESHOOTING

- If control results fall outside of the acceptable range, do not report patient results. Investigate the cause, repeat the control tests, and document corrective actions.
- Any significant discrepancy between expected and observed results warrants a repeat of the assay.

## 12. REFERENCES

- FUNGITELL Assay Kit insert and manufacturer's guidelines (FUNGITELL Product Insert for use with Serum).
- Relevant clinical guidelines and practice standards for the detection of fungal infections.

## 13. REVISION HISTORY

- Document version: 1.0
- Date of last revision: [Insert Date]
- Revised by: [Insert Name]

## 14. APPROVAL

This protocol has been reviewed and approved by:

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Laboratory Manager/Director Date

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Quality Assurance Coordinator Date

### Attachments:

- FUNGITELL Assay Kit Product Insert
- Quality Control Log Template
- Temperature Monitoring Log Template

**Note:** This document is subject to periodic review to ensure consistency with the latest available guidelines, assay kits updates, and best practices in the field of clinical microbiology and laboratory medicine.