

## **Certificate of Analysis**

Product Name: Cryptococcus LTX Antigen Test 50TST/KT

 Product Code:
 R30851501

 Lot Number:
 6220632

 Expiration Date:
 28.07.2026

 Date of Manufacture:
 20.06.2025

\*Date format is DD.MM.YYYY

Item	Description	Lot/Serial	Expire
W77BCL46Y	Cryptococcus Latex Reagent Filled Bulk	6220626	28.07.2026
W77BCL47Z	Cryptococcus High Pos Ctrl Filled Bulk	6220627	07.08.2026
W77BCL48A	Cryptococcus Low Pos Ctrl Filled Bulk	6220628	08.08.2026
W77BCL49B	Cryptococcus Negative Ctrl Filled Bulk	6220629	28.07.2026
W77BCL50C	Cryptococcus Protease Tablet Filled	6220630	30.04.2027
W77BCL51D	Cryptococcus 10X Diluent Filled Bulk	6220631	22.08.2026

- 1. Reagents: All present with correct appearance and physical characteristics (Color/Clarity, Dispersion/Aggregates, Bioburden)-Yes
- 2.Latex: Acceptable reactions with cryptococcal antigen at approximately 50 ng/ml (High Positive Control), at approximately 12 ng/ml (Low Positive Control) and at 0 ng/ml (Negative Control) -Yes.
- 3. Clinical serum and CSF samples: Appropriate test results with both positive and negative specimens- Yes
- 4. Positive Specimen testing: Acceptable results at various dilutions-Yes

## **Physical Characteristics:**

pH @ 20-25°C: NA

## **Microbial Load Evaluation:**

Product is evaluated for performance specifications only.

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Fay Curd Quality Assurance Manager