

**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

EN ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

License No.: MFG/IVD/2019/000003

Date: 02/12/2024

Doc ID:COA/TP/SPF016/50T

|                   |                                                                |
|-------------------|----------------------------------------------------------------|
| Product Name      | STABILYSE <sup>®</sup> Prep Free                               |
| Generic Name      | Sample Collection and Lysis Medium for Prep Free Swab Specimen |
| Lot No.           | SPF016                                                         |
| Mfg. Date         | 2024-11                                                        |
| Exp. Date         | 2025-10                                                        |
| Pack Size         | 50T                                                            |
| Storage condition | 2°C to 40°C                                                    |

**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

| Sr. No. | Components in each kit                                    | Specification                  | Observation |
|---------|-----------------------------------------------------------|--------------------------------|-------------|
| A       | Contents in the carton (STABILYSE <sup>®</sup> Prep Free) | (Present (P)/Not Present (NP)) |             |
| 1       | Collection and Lysis Medium Tubes                         | Present                        | Present     |
| 2       | Package Insert                                            | Present                        | Present     |

| Performance on Truelab® Real Time micro PCR Analyzer |                   |                                                   |                            |        |                      |       |
|------------------------------------------------------|-------------------|---------------------------------------------------|----------------------------|--------|----------------------|-------|
| Sr. No.                                              | Control           |                                                   | Specification (Ct Values)  |        | Test Lot (Ct Values) |       |
| 1                                                    | Specificity Tests | Test                                              | IC                         | Test 1 | Test 2               | IC    |
| Negative Control                                     |                   |                                                   |                            |        |                      |       |
| 1                                                    | Negative COVID-19 | ND                                                | Control should be detected | ND     | ND                   | 27.07 |
| Positive Control                                     |                   |                                                   |                            |        |                      |       |
| 2                                                    | Positive COVID-19 | Test and Control should be detected               |                            | 26.86  | 26.62                | 24.95 |
| Non Template Control Test for COVID-19               |                   |                                                   |                            |        |                      |       |
| 3                                                    | NTC               | Test 1, Test 2 and Control should not be detected |                            | ND     | ND                   | ND    |

\*Ct-Cycle Threshold    \*IC- Internal Control    \*ND- Not Detected    \*NA- Not Applicable

The lot is tested and verified as per QC Standards and is approved.



**Name:** Dr.Praveen Kumar MK  
**Department:** Quality Control  
**Designation:** QC Head

*for*