



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date: 12/12/2022

Doc ID: COA/SF/SPF012

Brand Name: STABILYSE® Prep Free			
Generic name: Sample Collection and Lysis Medium for Prep Free Swab Specimen			
Lot No.: SPF012	Mfg. Date: 2022-11	Exp. Date: 2024-10	A.R. No.: B-SPF-012
Pack size: 05T, 20T, 50T		Storage Temperature: 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® Prep Free)	(Present (P)/ Not Present (NP))	
1	Collection and Lysis Medium Tube	Present	Present
2	Pack Insert	Present	Present

Performance on Truelab® Real Time micro PCR Analyzers						
Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values) Average		
1	Specificity Tests	Test	IC	Test 1: Orf1A	Test 2: E gene	IC
<b>Negative Control</b>						
1	Negative COVID-19	ND	IC should be detected	ND	ND	20.27
2	Negative COVID-19	ND	IC should be detected	ND	ND	20.42
3	Negative COVID-19	ND	IC should be detected	ND	ND	20.33
<b>Positive Control</b>						
1	Positive COVID-19	Test and IC should be detected		26.33	26.12	26.1
2	Positive COVID-19	Test and IC should be detected		25.44	25.76	25.96
3	Positive COVID-19	Test and IC should be detected		25.9	25.67	25.73

\*Ct- Cycle threshold \*IC- Internal Control \*ND- Not Detected

**Note:** For swab specimen the human *RNase P* gene serves as a full process internal positive control (IPC)  
**MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE.**

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head

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## Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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