



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

## CERTIFICATE OF ANALYSIS

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

Date: 27/01/2022

Doc ID: COA/SF/SPF008

<b>Brand Name: STABILYSE® Prep Free</b>			
<b>Generic name: Sample Collection and Lysis Medium for Prep Free Swab Specimen</b>			
<b>Lot No.: SPF008</b>	<b>Mfg. Date: 2022-01</b>	<b>Exp. Date: 2023-12</b>	<b>A.R. No.: B-SPF-008</b>
<b>Pack size: 05T, 20T, 50T</b>		<b>Storage Temperature: 2°C to 40°C</b>	

**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® micro PCR Analyzers						
Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)		
1	Specificity Tests	Test	IC	Test 1: E gene	Test 2: Orf1A	IC
<b>Negative Control</b>						
1	Negative COVID-19	ND	IC should be detected	ND	ND	23.25
2	Negative COVID-19	ND	IC should be detected	ND	ND	23.75
3	Negative COVID-19	ND	IC should be detected	ND	ND	24.5
<b>Positive Control</b>						
1	Positive COVID-19	Test and IC should be detected		18	18.71	22.67
2	Positive COVID-19	Test and IC should be detected		18	18.78	23
3	Positive COVID-19	Test and IC should be detected		18	18.67	22.67

\*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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