



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/02/2022

Doc ID: COA/SF/SPF010

Brand Name: STABILYSE® Prep Free			
Generic name: Sample Collection and Lysis Medium for Prep Free Swab Specimen			
Lot No.: SPF010	Mfg. Date: 2022-02	Exp. Date: 2024-01	A.R. No.: B-SPF-010
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)		
1	Specificity Tests	Test	IC	Test 1: E gene	Test 2: Orf1A	IC
Negative Control						
1	Negative COVID-19	ND	IC should be detected	ND	ND	24.75
2	Negative COVID-19	ND	IC should be detected	ND	ND	23.5
3	Negative COVID-19	ND	IC should be detected	ND	ND	25
Positive Control						
1	Positive COVID-19	Test and IC should be detected		30	31.13	24.67
2	Positive COVID-19	Test and IC should be detected		30.33	30.17	25.2
3	Positive COVID-19	Test and IC should be detected		31.33	31.33	25.14

*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.


Dr. Praveen Kumar
QUALITY CONTROL
Name: Dr. Praveen Kumar
for 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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