



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/10/2021

Doc ID: COA/SF/SPF004

Brand Name: STABILYSE® Prep Free			
Generic name: Sample Collection and Lysis Medium for Prep Free Swab Specimen			
Lot No.: SPF004	Mfg Date: 2021-10	Exp Date: 2023-09	A.R. No.: B-SPF-004
Pack size: 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® micro PCR Analyzers

Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)		
		Test	IC	Test 1: E gene	Test 2: Orf 1A	IC
Negative Control						
1	Negative COVID-19	ND	IC should be detected	ND	ND	23.29
2	Negative COVID-19	ND	IC should be detected	ND	ND	23.33
3	Negative COVID-19	ND	IC should be detected	ND	ND	23.29
Positive Control						
1	Positive COVID-19	Test and IC should be detected		23	21.22	20.5
2	Positive COVID-19	Test and IC should be detected		23	21.6	21.6
3	Positive COVID-19	Test and IC should be detected		23.5	21.5	22.0

*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

for Designation: QC Head

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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