



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 02/10/2021

Doc ID: COA/SF/SPF003

Brand Name: STABILYSE® Prep Free			
Generic name: Sample Collection and Lysis Medium for Prep Free Swab Specimen			
Lot No.: SPF003	Mfg Date: 2021-09	Exp Date: 2023-08	A.R. No.: B-SPF-003
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)		
1	Specificity Tests	Test	IC	Test 1: E gene	Test 2: Orf 1A	IC
Negative Control						
1	Negative COVID-19	ND	IC should be detected	ND	ND	25.0
2	Negative COVID-19	ND	IC should be detected	ND	ND	24.0
3	Negative COVID-19	ND	IC should be detected	ND	ND	25.2
Positive Control						
1	Positive COVID-19	Test and IC should be detected		22.33	20.43	26.4
2	Positive COVID-19	Test and IC should be detected		22.13	20.6	24.75
3	Positive COVID-19	Test and IC should be detected		21.5	20.0	26.0

*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
Designation: QC Head

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