



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 06/01/2024

Doc ID:COA/TP/SPF015

Product Name	STABILYSE® Prep Free
Generic Name	Sample Collection and Lysis Medium for Prep Free Swab Specimen
Lot No.	SPF015
Mfg. Date	2024-01
Exp. Date	2025-12
Pack Size	50T
Storage condition	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 Tubes	Present	Present
2	Package Insert	Present	Present

FM/QT/226-00

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

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



Performance on Truelab® Real Time micro PCR Analyzer						
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test 1	Test 2	IC
Negative Control						
1	Negative COVID-19	ND	Control should be detected	ND	ND	24.18
Positive Control						
2	Positive COVID-19		Test and Control should be detected	22.08	23.99	24.67
Non Template Control Test for COVID-19						
3	NTC		Test 1, Test 2 and Control should not be detected	ND	ND	ND

*Ct-Cycle Threshold *IC- Internal Control *ND- Not Detected *NA- Not Applicable

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.


Name: Dr. Praveen Kumar MK
Department: Quality Control
Designation: QC Head


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