

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 15/11/2025

Doc ID: COA/TP/SPF017

Product Name	STABILYSE [®] Prep Free
Generic Name	Sample Collection and Lysis Medium for Prep Free Swab Specimen
Lot No.	SPF017
Mfg. Date	2025-10
Exp. Date	2027-09
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

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	27.02
Positive Control						
2	Positive COVID-19	Test and Control should be detected		28.82	30.35	23.73
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

The lot is tested and verified as per QC Standards and is approved.



for *PK*
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Designation: QC Head