



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 29/09/2023

Doc ID:COA/TP/SPF014

Product Name	STABILYSE® Prep Free
Generic Name	Sample Collection and Lysis Medium for Prep Free Swab Specimen
Lot No.	SPF014
Mfg. Date	2023-09
Exp. Date	2025-08
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

## 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

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
<b>Negative Control</b>						
1	Negative COVID-19	ND	Control should be detected	ND	ND	23.37
<b>Positive Control</b>						
2	Positive COVID-19		Test and Control should be detected	30.06	29.75	29.18
<b>Non Template Control Test for COVID-19</b>						
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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