



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 05/09/2024

Doc ID:COA/TP/003ATM

Product Name	Trueprep® AUTO Transport Medium for Swab Specimen Pack
Generic Name	Medium for Collection, Decontamination and Transport of Swab Specimen for Trueprep® AUTO
Lot No.	003ATM
Mfg. Date	2024-08
Exp. Date	2026-07
Pack Size	25T
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 (Trueprep® AUTO Transport Medium for Swab Specimen Pack)	(Present (P)/Not Present (NP))	
1	Transport Medium for Swab Specimen Tubes	Present	Present
2	Package Insert	Present	Present

FM/QT/224-02

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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)	
	Specificity Tests	Test	IC	Test 1 E.gene (Average)	Test 2 Orf1A (Average)	IC (Average)
Negative Control						
1	Negative COVID-19	ND	Control should be detected	ND	ND	26.42
Positive Control						
1	Positive COVID-19	Test and Control should be detected		29.38	30.24	23.91
Non Template Control Test for COVID-19						
1	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 *NTC- Non Template Control

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



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