

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 06/05/2025

Doc ID: COA/TP/ATM105/25T

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.	ATM105
Mfg. Date	2025-04
Exp. Date	2027-03
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

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	26.72
Positive Control						
1	Positive COVID-19	Test and Control should be detected		27.78	27.57	28.57
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.

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

