

# **Molbio Diagnostics Limited**

(Formerly Molbio Diagnostics Private Limited) L-46, Phase II D, Verna Industrial Estate Verna, Goa-403722, India S+918326724888 www.molbiodiagnostics.com

### MOLBIO DIAGNOSTICS LIMITED

## EN ISO 13485:2016 certified company

#### **CERTIFICATE OF ANALYSIS**

License No.: MFG/IVD/2019/000003

Date: 10/06/2025

Doc ID:COA/TP/ATM106/50T

Product Name	roduct 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.	ATM106					
Mfg. Date	2025-05					
Exp. Date	2027-04					
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	
Α	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/224-03

Page 1 of 2



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	Performance	on True	lab <sup>®</sup> Real Time	micro PCR A	nalyzer			
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	27.74		
Positive	Control							
1	Positive COVID-19		and Control be detected	30.31	31.06	26.7		
Non Ten	nplate Control Test fo	r COVID-	19	l	h	L		
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

FM/QT/224-03

Page 2 of 2