



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 27/02/2024

Doc ID:COA/TP/ATM099

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.	ATM099
Mfg. Date	2024-01
Exp. Date	2025-12
Pack Size	50T, 25T, 20T
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

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	31.29
Positive Control						
1	Positive COVID-19	Test and Control should be detected		30.17	29.48	28.44
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

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.

for

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



FM/QT/224-01

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