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Molbio Diagnostics Limited
(Formerly Molbio Diagnostics Private Limited)
L-46, Phase II D, Verna Industrial Estate
Verna, Goa - 403722, India
+91 832 6724888 www.molbiodiagnostics.com

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064 **Date:** 04/11/2026

Doc ID: COA/TP/659VUCPKL

Product Name	Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep® AUTO v2
Lot No.	659VUCPKL
Mfg. Date	2026-10
Exp. Date	2028-09
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 (Trueprep® AUTO v2 Universal Cartridge Based Sample prep kit)**	**[Present (P)/Absent (A)]**	
1	Universal Reagent Pack	Should be Present	P
2	Universal Cartridge Pack	Should be Present	P
3	Disposable Transfer Pipette (3 ml Graduated)	Should be Present	P
4	Package Insert	Should be Present	P
B	**Pouch Seal Integrity**	**Specification**	**Observation**
1	Pouch Seal Integrity Test	Should Pass	Pass

sales@molbiodiagnostics.com / admin@molbiodiagnostics.com | **CIN:** L33125GA2000PLC002909 | **GSTIN:** 30AACCM8275E1ZO

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Performance on Truelab® Real Time micro PCR Analyzer						
Sr. No.	Specificity Tests	Specification		Test Lot		
		Target	Control	Target 1 (Average)	Target 2 (Average)	Control (Average)
Negative Control						
1	Negative MTB	ND	Control should be detected	ND	NA	27.38
2	Negative HCV	ND		ND	NA	27.16
3	Negative HIV-1/ HIV-2	ND		ND	NA	27.26
4	Negative MTB Plus	ND		ND	NA	27.96
Positive Control						
1	Positive MTB	Target and Control should be detected		31.07	NA	26.20
2	Positive HCV	Target and Control should be detected		31.46	NA	26.98
3	Positive MTB Plus	Target and Control should be detected		31.26	NA	27.94

Non Template Control Test for COVID-19					
1	NTC	Target 1, Target 2 and Control should not be detected	ND	ND	ND

*ND- Not Detected *NA- Not Applicable *NTC- Non Template Control

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

MOLBIO DIAGNOSTICS LIMITED GOA

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

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