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Molbio Diagnostics Limited
(Formerly Molbio Diagnostics Private Limited)
L-46, Phase II D, Verna Industrial Estate
Verna, Goa - 403722, India
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MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003 **Date:** 23/09/2026

Doc ID: COA/TP/VUCPK552L

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.	VUCPK552L
Mfg. Date	2026-07
Exp. Date	2028-06
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

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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	27.32
2	Negative HCV	ND		ND	NA	26.67
3	Negative HIV-1/ HIV-2	ND		ND	ND	27.31
4	Negative MTB Plus	ND		ND	NA	28.48
Positive Control						
1	Positive MTB	Target and Control should be detected		28.36	NA	27.30
2	Positive HCV	Target and Control should be detected		31.28	NA	27.14
3	Positive MTB Plus	Target and Control should be detected		29.02	NA	26.88

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