

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 16/09/2025

Doc ID: COA/TP/381VUCPKL

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.	381VUCPKL
Mfg. Date	2025-08
Exp. Date	2027-07
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)/Not Present (NP))	
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

Performance on Truelab® Real Time micro PCR Analyzer						
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	Test	IC	Test 1 (Average)	Test 2 (Average)	IC (Average)
Negative Control						
1	Negative MTB	ND	Control should be detected	ND	NA	27.37
2	Negative HBV	ND		ND	NA	28.31
3	Negative HCV	ND		ND	NA	26.74
4	Negative HIV-1	ND		ND	NA	27.19
5	Negative MTB Plus	ND		ND	NA	28.29
Positive Control						
1	Positive MTB	Test and Control should be detected		30.88	NA	26.49
2	Positive HCV Plasma	Test and Control should be detected		31.92	NA	26.34
3	Positive MTB Plus	Test and Control should be detected		30.63	NA	28.12
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.

Praveen Kumar

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Department: Quality Control
Designation: QC Head

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