

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 16/01/2026

Doc ID: COA/TP/094USPKL

Product Name	Trueprep [®] AUTO Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep [®] AUTO
Lot No.	094USPKL
Mfg. Date	2025-12
Exp. Date	2027-11
Pack Size	50T
Storage condition	2°C to 40°C

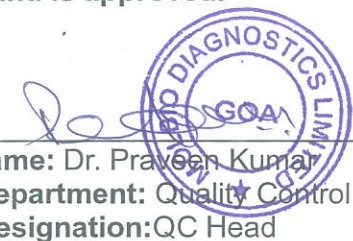
PRECAUTION: Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (Trueprep[®] AUTO Universal Cartridge Based Sample prep kit)	(Present (P)/Absent (A))	
1	Universal Reagent Pack	Present	Present
2	Universal Cartridge Pack	Present	Present
3	Disposable Transfer Pipette (3 ml Graduated)	Present	Present
4	Package Insert	Present	Present

Performance on Truelab® Real Time micro PCR Analyzers						
Sr. No.	Specificity Tests	Specification		Test Lot		
		Test	Control	Test 1 (Average)	Test 2 (Average)	Control (Average)
Negative Control						
1	Negative HBV	ND	Control should be detected	ND	NA	27.65
2	Negative HCV	ND		ND	NA	26.53
3	Negative HIV-1	ND		ND	NA	26.54
4	Negative MTB	ND		ND	NA	26.58
5	Negative MTB Plus	ND		ND	NA	27.87
Positive Control						
1	Positive MTB	Test and Control should be detected		31.19	NA	27.69
2	Positive HCV	Test and Control should be detected		31.33	NA	27.29
3	Positive MTB Plus	Test and Control should be detected		30.81	NA	27.21
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.


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