

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 31/08/2026

Doc ID: COA/TP/099USPKL

Product Name	Trueprep [®] AUTO Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep [®] AUTO
Lot No.	099USPKL
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 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		
		Target	Control	Target 1 (Average)	Target 2 (Average)	Control (Average)
Negative Control						
1	Negative HCV	ND	Control should be detected	ND	NA	27.25
2	Negative HIV-1	ND		ND	NA	27.75
3	Negative MTB	ND		ND	NA	28.12
4	Negative MTB Plus	ND		ND	NA	27.67
Positive Control						
1	Positive MTB	Target and Control should be detected		31.50	NA	28.18
2	Positive HCV	Target and Control should be detected		31.55	NA	27.14
3	Positive MTB Plus	Target and Control should be detected		28.15	NA	26.92
Non Template Control Test for COVID-19						
1	NTC	Target 1, Target 2 and Control should not be detected		ND	ND	ND

*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