

MOLBIO DIAGNOSTICS LIMITED
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CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 09/08/2025

Doc ID: COA/TP/086USPKL

Product Name	Trueprep [®] AUTO Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep [®] AUTO
Lot No.	086USPKL
Mfg. Date	2025-05
Exp. Date	2027-04
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)/Not Present (NP))	
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.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	Test	IC	Test 1 (Average)	Test 2 (Average)	IC (Average)
Negative Control						
1	Negative HBV	ND	Control should be detected	ND	NA	27.71
2	Negative HCV	ND		ND	NA	28.22
3	Negative HIV-1	ND		ND	NA	27.17
4	Negative MTB	ND		ND	NA	26.67
5	Negative MTB Plus	ND		ND	NA	27.45
Positive Control						
1	Positive MTB	Test and Control should be detected		32.38	NA	27.11
2	Positive MTB plus	Test and Control should be detected		30.47	NA	27.33
3	Positive HCV	Test and Control should be detected		32.29	NA	27.87
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
Template Control

*IC- Internal Control

*ND- Not Detected

*NA- Not Applicable

*NTC- Non

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


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