

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 08/03/2025

Doc ID: COA/TP/071USPKL/50T

Product Name	Trueprep [®] AUTO Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep [®] AUTO
Lot No.	071USPKL
Mfg. Date	2025-01
Exp. Date	2026-12
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	28.87
2	Negative HCV	ND		ND	NA	27.14
3	Negative HIV-1	ND		ND	NA	26.55
4	Negative MTB	ND		ND	NA	28.09
5	Negative MTB Plus	ND		ND	NA	27.98
Positive Control						
1	Positive MTB	Test and Control should be detected		29.54	NA	28.38
2	Positive HCV	Test and Control should be detected		31.86	NA	28.30
3	Positive MTB Plus	Test and Control should be detected		27.32	NA	27.13
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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