

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2025/000148

Date: 17/06/2026

Doc ID: COA/TP/USPT301

Product Name	Trueprep [®] AUTO Universal Sample Pre-treatment Pack
Generic Name	Universal Sample Pre-treatment pack for Non MTB samples
Lot No.	USPT301
Mfg. Date	2026-04
Exp. Date	2028-03
Pack Size	25T, 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 Sample Pre-treatment Pack)	[Present (P)/Absent (A)]	
1	Lysis Buffer	Present	Present
2	Disposable Transfer Pipette (1 ml Graduated)	Present	Present
3	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	26.51
2	Negative HCV	ND	Control should be detected	ND	NA	26.94
Positive Control						
1	Positive HBV	Test and Control should be detected		29.88	NA	26.74
2	Positive HCV	Test and Control should be detected		32.01	NA	27.20
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

*ND- Not Detected

*NA- Not Applicable

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


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

