

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 12/02/2025

Doc ID: COA/TP/USPT281/25T

Product Name	Trueprep [®] AUTO Universal Sample Pre-treatment Pack
Generic Name	Universal Sample Pre-treatment pack for Non MTB samples
Lot No.	USPT281
Mfg. Date	2025-01
Exp. Date	2026-12
Pack Size	25T
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)/Not Present (NP))	
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.	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	27.20
2	Negative HIV-1	ND	Control should be detected	ND	NA	27.12
Positive Control						
1	Positive HBV	Test and Control should be detected		29.78	NA	27.24
2	Positive HIV-1	Test and Control should be detected		28.95	NA	26.77
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

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



Name: Dr. Praveen Kumar MK

Department: Quality Control

Designation: QC Head