MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 07/12/2024

Doc ID: COA/TP/USPT278/50T

Product Name	Trueprep® AUTO Universal Sample Pre-treatment Pack
Generic Name	Universal Sample Pre-treatment pack for Non MTB samples
Lot No.	USPT278
Mfg. Date	2024-11
Exp. Date	2026-10
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 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

Sr. No.	Performance on Truelab® Real Time micro PCR Analyzers					
	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	27.28
2	Negative HCV	ND	Control should be detected	ND	NA	27.64
Positive Control						
1	Positive HBV	Test and Control should be detected		29.43	NA	27.56
2	Positive HIV-1	Test and Control should be detected		29.31	NA	27.30
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