



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 09/10/2023

Doc ID:COA/TP/USPT257

Product Name	Trueprep [®] AUTO Universal Sample Pre-treatment Pack
Generic Name	Universal Sample Pre-treatment pack for Non MTB samples
Lot No.	USPT257
Mfg. Date	2023-09
Exp. Date	2025-08
Pack Size	05T, 20T, 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 HIV-1	ND	Control should be detected	ND	NA	27.47
Positive Control						
1	Positive HBV		Test and Control should be detected	29.07	NA	27.71
2	Positive HCV		Test and Control should be detected	29.50	NA	27.52
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

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.



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