

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFC/IVD/2025/000148

Date: 01/10/2026

Doc ID: COA/TP/MSPT331

Product Name	Trueprep [®] AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT331
Mfg. Date	2026-09
Exp. Date	2028-08
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 MTB Sample Pre-treatment Pack)	[Present (P)/Absent (A)]	
1	Lysis Buffer	Present	Present
2	Liquefaction Buffer	Present	Present
3	Disposable Transfer Pipette (1 ml Graduated)	Present	Present
4	Package Insert	Present	Present
B	Leak Test	Specification	Observation
1	Leak Test	Should Pass	Pass

Performance on Truelab® Real Time micro PCR Analyzer					
Sr. No.	Specificity Tests	Specification		Test Lot	
		Target	Control	Target (Average)	Control (Average)
Negative Control					
1	Negative MTB	ND	Control should be detected	ND	27.47
Positive Control					
1	Positive MTB	Target and Control should be detected		29.88	27.47
2	Positive MTB	Target and Control should be detected		25.12	26.99
Non Template Control					
1	NTC	Target and Control should not be detected		ND	ND

*ND- Not Detected

*NTC- Non Template Control

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

for  **Name:** Dr. Praveen Kumar M.K.
Department: Quality Control
Designation: QC Head