

MOLBIO DIAGNOSTICS LIMITED

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CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2025/000136

Date: 21/09/2026

Doc ID: COA/TP/285MSPT

Product Name	Trueprep [®] AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	285MSPT
Mfg. Date	2026-09
Exp. Date	2028-08
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 MTB Sample Pre-treatment Pack)	(Present (P)/Not Present (NP))	
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 1 (Average)	Target 2 (Average)	Control (Average)
Negative Control						
1	Negative MTB	ND	Control should be detected	ND	NA	27.28
Positive Control						
1	Positive MTB	Target and Control should be detected		25.40	NA	27.49
2	Positive MTB	Target and Control should be detected		30.28	NA	27.70
Non Template Control Test for MTB						
1	NTC	Target 1, Target 2 and Control should not be detected		ND	ND	ND

*ND- Not Detected *NA- Not Applicable *NTC- Non Template Control

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


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

