

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 18/03/2026

Doc ID:COA/TP/MSPT312

Product Name	Trueprep [®] AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT312
Mfg. Date	2026-03
Exp. Date	2028-02
Pack Size	5T
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

Performance on Truelab [®] Real Time micro PCR Analyzer					
Sr. No.	Specificity Tests	Specification		Test Lot	
		Test	Control	Test (Average)	Control (Average)
Negative Control					
1	Negative MTB	ND	Control should be detected	ND	27.99
Positive Control					
1	Positive MTB	Test and Control should be detected		29.74	27.55
2	Positive MTB	Test and Control should be detected		25.03	26.62
Non Template Control					
1	NTC	Test and Control should not be detected		ND	ND

*Ct- Cycle Threshold

*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 MK
Department: Quality Control
Designation: QC Head