

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 10/02/2026

Doc ID: COA/TP/MSPT306

Product Name	Trueprep [®] AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT306
Mfg. Date	2026-02
Exp. Date	2028-01
Pack Size	5T, 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 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	27.65
Positive Control					
1	Positive MTB	Test and Control should be detected		30.88	27.29
2	Positive MTB	Test and Control should be detected		26.18	27.31
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.



Name: Dr.Praveen Kumar MK

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Designation: QC Head

for