

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 19/01/2026

Doc ID: COA/TP/MSPT304

Product Name	Trueprep [®] AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT304
Mfg. Date	2026-01
Exp. Date	2027-12
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

Performance on Truelab® Real Time micro PCR Analyzer						
Sr. No.	Specificity Tests	Specification		Test Lot		
		Test	Control	Test 1 (Average)	Test 2 (Average)	Control (Average)
Negative Control						
1	Negative MTB	ND	Control should be detected	ND	NA	27.50
Positive Control						
1	Positive MTB	Test and Control should be detected		31.56	NA	26.11
2	Positive MTB	Test and Control should be detected		26.76	NA	27.28
Non Template Control						
1	NTC	Test and Control should not be detected		ND	ND	

*Ct- Cycle Threshold *IC- Internal Control *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