MOLBIO DIAGNOSTICS LIMITED

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CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2025/000136

Date: 24/02/2026

Doc ID: COA/TP/216MSPT

Product Name	Trueprep® AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	216MSPT
Mfg. Date	2026-02
Exp. Date	2028-01
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

FM/QT/224-03

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	26.55
Positive Control					
1	Positive MTB	Test and Control should be detected		26.27	26.62
2	Positive MTB	Test and Control should be detected		30.63	27.42
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.

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