



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 13/08/2024

Doc ID:COA/TP/MSPT230/50T

Product Name	Trueprep <sup>®</sup> AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT230
Mfg. Date	2024-08
Exp. Date	2026-07
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 <sup>®</sup> 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

## Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



Performance on Truelab® Real Time micro PCR Analyzer					
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Value)
	Specificity Tests	Test	IC	Test (Average)	IC (Average)
<b>Negative Control</b>					
1	Negative MTB	ND	Control should be detected	ND	27.14
<b>Positive Control</b>					
1	Positive MTB	Test and Control should be detected		30.49	26.38
2	Positive MTB	Test and Control should be detected		24.72	26.65
<b>Non Template Control</b>					
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  
*for*