



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 10/03/2023

Doc ID:COA/TP/MSPT174

Product Name	Trueprep® AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT174
Mfg. Date	2023-03
Exp. Date	2025-02
Pack Size	5T,20T,25T, 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

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

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Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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)
Negative Control					
1	Negative MTB	ND	Control should be detected	ND	28.04
2	Negative MTB	ND	Control should be detected	ND	28.00
3	Negative MTB	ND	Control should be detected	ND	28.30
Positive Control					
4	Positive MTB	Test and Control should be detected		29.28	27.68
5	Positive MTB	Test and Control should be detected		30.68	27.38
6	Positive MTB	Test and Control should be detected		30.42	27.82

*Ct- Cycle Threshold *IC- Internal Control *ND- Not Detected *NA- Not Applicable

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.



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

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