



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date:17/01/2023

Doc ID:COA/TP/MSPT164

Product Name	Trueprep® AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT164
Mfg. Date	2023-01
Exp. Date	2024-12
Pack Size	5T,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

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

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 Values)	
1	Specificity Tests	Test	IC	Test 1	Test 2	IC
Negative Control						
1	Negative MTB	ND	Control should be detected	ND	NA	28.22
2	Negative MTB	ND		ND	NA	27.97
3	Negative MTB	ND		ND	NA	28.39
Positive Control						
1	Positive MTB	Test and Control should be detected		28.27	NA	28.05
2	Positive MTB	Test and Control should be detected		28.64	NA	27.85
3	Positive MTB	Test and Control should be detected		28.42	NA	28.12

*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

for

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