



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date: 03/03/2021

PRODUCT: Trueprep <sup>®</sup> AUTO MTB Sample Pre-treatment Pack	
Trueprep <sup>®</sup> AUTO MTB Sample Pre-treatment Pack	Lot No.: MSPT093 Mfg Date: 2021-02 Exp Date: 2023-01
	A.R. No.: B-MSPT-093
Pack size: 50T, 20T, 5T	STORAGE: 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 (MTB Sample Pre-treatment Pack)	(Present (P)/Not Present (NP))	
1	Lysis Buffer	Present	Present
2	Liquefaction Buffer	Present	Present
3	Disposable Transfer Pipette (1ml)	Present	Present

Performance on Truelab <sup>®</sup> Real Time micro PCR Analyzers					
Sr. No.	Controls	Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test	IC
<b>Negative Control</b>					
1	Sample 1	ND	Control should be detected	ND	28.6
2	Sample 2	ND	Control should be detected	ND	27.33
3	Sample 3	ND	Control should be detected	ND	28.2
<b>Positive Control</b>					
1	Sample 1	Test and Control should be detected		26.17	27.8
2	Sample 2	Test and Control should be detected		26.14	27.5
3	Sample 3	Test and Control should be detected		27.0	28.4

\*Ct- Cycle threshold

\*IC- Internal Control

\*ND- Not Detected

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE



QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head

## Molbio Diagnostics Private Limited

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