



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 16/12/2021

Doc ID:COA/TP/MSPT121

Product: Trueprep <sup>®</sup> AUTO MTB Sample Pre-treatment Pack		
Lot No.: MSPT121	Mfg. Date: 2021-10	Exp. Date: 2023-09
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-MSPT-121

**PREAUTION:** 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
4	Package Insert	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	Negative MTB	ND	Control should be detected	ND	27.8
2	Negative MTB	ND	Control should be detected	ND	29.33
3	Negative MTB	ND	Control should be detected	ND	29.0
<b>Positive Control</b>					
1	Positive MTB	Test and Control should be detected		28.5	28.5
2	Positive MTB	Test and Control should be detected		28.2	30.43
3	Positive MTB	Test and Control should be detected		27.8	30.0

\*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**

MOLBIO DIAGNOSTICS PVT. LTD.  
VERNA

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

## Molbio Diagnostics Private Limited

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