



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 11/03/2021

<b>PRODUCT: Trueprep® AUTO MTB Sample Pre-treatment Pack</b>	
<b>Trueprep® AUTO MTB Sample Pre-treatment Pack</b>	<b>Lot No.: MSPT095 Mfg Date: 2021-02 Exp Date: 2023-01</b>
	<b>A.R. No.: B-MSPT-095</b>
<b>Pack size: 50T, 20T, 5T</b>	<b>STORAGE: 2°C to 40°C</b>

**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
<b>A</b>	<b>Contents in the carton (MTB Sample Pre-treatment Pack)</b>	<b>(Present (P)/Not Present (NP))</b>	
1	Lysis Buffer	Present	Present
2	Liquefaction Buffer	Present	Present
3	Disposable Transfer Pipette (1ml)	Present	Present

<b>Performance on Truelab® Real Time micro PCR Analyzers</b>					
Sr. No.	Controls	Specification (Ct Values)		Test Lot (Ct Values)	
1	<b>Specificity Tests</b>	<b>Test</b>	<b>IC</b>	<b>Test</b>	<b>IC</b>
<b>Negative Control</b>					
1	Sample 1	ND	Control should be detected	ND	27.57
2	Sample 2	ND	Control should be detected	ND	26.6
3	Sample 3	ND	Control should be detected	ND	28.17
<b>Positive Control</b>					
1	Sample 1	Test and Control should be detected		27.5	29.0
2	Sample 2	Test and Control should be detected		26.4	26.6
3	Sample 3	Test and Control should be detected		27.5	27.8

\*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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