



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:26/07/2021

Doc ID:COA/TP/I-MSPT107

Product: Trueprep® AUTO MTB Sample Pre-treatment Pack		
Lot No.: I-MSPT107	Mfg Date: 2021-07	Exp Date: 2023-06
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-I-MSPT-107

**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

Performance on Truelab® 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	28.0
2	Negative MTB	ND	Control should be detected	ND	27.17
3	Negative MTB	ND	Control should be detected	ND	28.13
<b>Positive Control</b>					
1	Positive MTB	Test and Control should be detected		28.67	26.2
2	Positive MTB	Test and Control should be detected		26.43	26.5
3	Positive MTB	Test and Control should be detected		27.14	26.17

\*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  
for Designation: QC Head

## Molbio Diagnostics Private Limited

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