



MOLBIO DIAGNOSTICS PVT. LTD.  
An ISO 9001:2015 & ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 19/03/2020

<b>PRODUCT: Trueprep™ AUTO MTB Sample Pre-treatment Pack</b>	
Trueprep™ AUTO MTB Sample Pre-treatment Pack	Lot No.: MSPT049 Mfg Date: 2019-08 Exp Date: 2021-07 A.R. No.: B-MSPT-049
Pack size: 20 TESTS, 5 TESTS	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

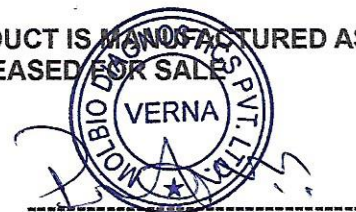
Performance on Truelab™ Real Time micro PCR Analyzers					
Sr. No.	Controls	Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test	IC
<b>Negative Control</b>					
1	Sample 1	ND	Control should be detected	ND	29.33
<b>Positive Control</b>					
1	Sample 1	Test and Control should be detected		31	28.17
2	Sample 2	Test and Control should be detected		29.71	27.43
3	Sample 3	Test and Control should be detected		31	27.6

\*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 SALES



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

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