



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

CERTIFICATE OF ANALYSIS

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

Date: 08/02/2020

PRODUCT: Trueprep™ AUTO MTB Sample Pre-treatment Pack

Trueprep™ AUTO MTB
Sample Pre-treatment Pack

Lot No.: MSPT047 Mfg Date: 2019-09 Exp Date: 2021-08

A.R. No.: B-MSPT-047

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
Negative Control					
1	Sample 1	ND	Control should be detected	ND	30.5
Positive Control					
1	Sample 1	Test and Control should be detected		33	28.29
2	Sample 2	Test and Control should be detected		33	28.25
3	Sample 3	Test and Control should be detected		32.4	28.83

*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
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