



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

CERTIFICATE OF ANALYSIS

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

Date: 03/04/2020

PRODUCT: Trueprep™ AUTO MTB Sample Pre-treatment Pack	
Trueprep™ AUTO MTB Sample Pre-treatment Pack	Lot No.: MSPT050 Mfg Date: 2019-09 Exp Date: 2021-08 A.R. No.: B-MSPT-050
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	28.33
Positive Control					
1	Sample 1	Test and Control should be detected		26.67	27.33
2	Sample 2	Test and Control should be detected		26.14	28.2
3	Sample 3	Test and Control should be detected		26.5	27.4

*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

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0