



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 21/01/2021

PRODUCT: Trueprep[®] AUTO MTB Sample Pre-treatment Pack	
Trueprep[®] AUTO MTB Sample Pre-treatment Pack	Lot No.: MSPT081 Mfg Date: 2021-01 Exp Date: 2022-12
	A.R. No.: B-MSPT-081
Pack size: 50T, 20T, 5T	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	28.43
2	Sample 2	ND	Control should be detected	ND	26.8
3	Sample 3	ND	Control should be detected	ND	28.14
Positive Control					
1	Sample 1	Test and Control should be detected		28.2	26.14
2	Sample 2	Test and Control should be detected		29.5	28.33
3	Sample 3	Test and Control should be detected		27.75	27.33

*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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