



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 02/04/2021

Doc ID: COA/TP/MSPT099

PRODUCT: Trueprep[®] AUTO MTB Sample Pre-treatment Pack	
Trueprep[®] AUTO MTB Sample Pre-treatment Pack	Lot No.: MSPT099 Mfg Date: 2021-02 Exp Date: 2023-01
	A.R. No.: B-MSPT-099
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	27.5
2	Sample 2	ND	Control should be detected	ND	28.83
3	Sample 3	ND	Control should be detected	ND	28.25
Positive Control					
1	Sample 1	Test and Control should be detected		30.57	28.6
2	Sample 2	Test and Control should be detected		29.8	28.8
3	Sample 3	Test and Control should be detected		30.4	30.17

*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
Designation: QC Head

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