



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 25/06/2021

Doc ID: COA/TP/MSPT104

PRODUCT: Trueprep [®] AUTO MTB Sample Pre-treatment Pack	
Trueprep [®] AUTO MTB Sample Pre-treatment Pack	Lot No.: MSPT104 Mfg Date: 2021-03 Exp Date: 2023-02
	A.R. No.: B-MSPT-104
Pack size: 50T, 20T, 5T	STORAGE: 2°C to 40°C

PREAUTION: 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	29.0
2	Sample 2	ND	Control should be detected	ND	27.75
3	Sample 2	ND	Control should be detected	ND	28.5
Positive Control					
1	Sample 1	Test and Control should be detected		26.56	29.5
2	Sample 2	Test and Control should be detected		27.67	29.33
3	Sample 3	Test and Control should be detected		28.22	29.33

*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
for Designation: QC Head

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