



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 15/11/2022

Doc ID:COA/TP/MSPT155

Product: Trueprep® AUTO MTB Sample Pre-treatment Pack		
Lot No.: MSPT155	Mfg. Date: 2022-11	Exp. Date: 2024-10
Pack size: 50T, 25T, 20T, 05T	Storage: 2°C to 40°C	A.R. No.: B-MSPT-155

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-graduated)	Present	Present
4	Package Insert	Present	Present

Performance on Truelab® Real Time micro PCR Analyzers					
Sr. No.	Controls	Specification (Ct Values)		Test Lot (Ct Values) Average	
1	Specificity Tests	Test	IC	Test	IC
Negative Control					
1	Negative MTB	ND	Control should be detected	ND	27.24
2	Negative MTB	ND	Control should be detected	ND	27.04
3	Negative MTB	ND	Control should be detected	ND	27.38
Positive Control					
1	Positive MTB	Test and Control should be detected		29.41	26.61
2	Positive MTB	Test and Control should be detected		28.93	27.34
3	Positive MTB	Test and Control should be detected		28.67	26.83
4	Positive MTB	Test and Control should be detected		24.53	27.33
5	Positive MTB	Test and Control should be detected		24.99	27.57
6	Positive MTB	Test and Control should be detected		24.76	27.41

*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.

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QUALITY CONTROL
Name: Dr. Braveen Kumar
Designation: QC Head

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