molbio®

MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:23/11/2021
Doc ID:COA/TP/MSPT117

Product: Trueprep® AUTO MTB Sample Pre-treatment Pack

Lot No.: MSPT117	Mfg. Date: 2021-03	Exp. Date: 2023-02
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-MSPT-117

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
4	Package Insert	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	Negative MTB	ND	Control should be detected	ND	29.17
2	Negative MTB	ND	Control should be detected	ND	29.2
3	Negative MTB	ND	Control should be detected	ND	29.29
Positive Control					
1	Positive MTB	Test and Control should be detected		27.86	27.75
2	Positive MTB	Test and Control should be detected		28.5	30.2
3	Positive MTB	Test and Control should be detected		28.0	28.8

*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

Page 1 of 1

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