



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 29/11/2022
Doc ID:COA/TP/MSPT158

Product: Trueprep [®] AUTO MTB Sample Pre-treatment Pack		
Lot No.: MSPT158	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-158

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	28.36
2	Negative MTB	ND	Control should be detected	ND	27.28
3	Negative MTB	ND	Control should be detected	ND	27.95
Positive Control					
1	Positive MTB	Test and Control should be detected		28.13	27.88
2	Positive MTB	Test and Control should be detected		28.24	27.03
3	Positive MTB	Test and Control should be detected		28.05	28.37
4	Positive MTB	Test and Control should be detected		25.46	27.56
5	Positive MTB	Test and Control should be detected		25.54	27.37
6	Positive MTB	Test and Control should be detected		25.61	28.73

*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

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbioldiagnostics.com

Email: sales@molbioldiagnostics.com Website: www.molbioldiagnostics.com

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