



MOLBIO DIAGNOSTICS PVT. LTD.
An ISO 9001 & ISO 13485 certified company
CERTIFICATE OF ANALYSIS

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

Date: 25/07/2019

PRODUCT : Trueprep™ AUTO MTB Sample Pre-treatment Pack

Lot No.: MSPT034

Mfg Date: 2019-07

Exp Date: 2021-06

A.R. No.: B-MSPT-034

Pack size : 20 TESTS , 5 TESTS

STORAGE : 2°C to 40°C

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
D	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 Analyser					
Sr.No.	CONTROL	Specification (Ct Values)		Test Lot (Ct Values)	
Specificity Tests		TEST	Control	TEST	Control
Negative Control					
1	Sample 1	ND	Control should be detected	ND	27.6
Positive Control					
1	Sample 1	Test and Control should be detected		30.5	28.6
2	Sample 2	Test and Control should be detected		30.0	28.67
3	Sample 3	Test and Control should be detected		29.4	28.5

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: Praveen Kumar
Designation: QC Head

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO