



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

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

Date: 18/07/2019

<b>PRODUCT : Trueprep™ AUTO MTB Sample Pre-treatment Pack</b>		
Lot No.: MSPT032	Mfg Date: 2019-06	Exp Date: 2021-05
A.R. No.: B-MSPT-032		
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 S	Specification (Ct Values)		Test Lot (Ct Values)	
Specificity Tests		TEST	Control	TEST	Control
Negative Control					
1	Sample 1	ND	Control should be detected	ND	28.13
Positive Control					
1	Sample 1	Test and Control should be detected		29.5	27.14
2	Sample 2	Test and Control should be detected		29.0	27.33
3	Sample 3	Test and Control should be detected		30.13	27.14

**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

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