



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

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

Date: 02/08/2019

<b>PRODUCT : Trueprep™ AUTO MTB Sample Pre-treatment Pack</b>		
Lot No.: MSPT035	Mfg Date: 2019-07	Exp Date: 2021-06
A.R. No.: B-MSPT-035		
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
<b>Negative Control</b>					
1	Sample 1	ND	Control should be detected	ND	28.33
<b>Positive Control</b>					
1	Sample 1	Test and Control should be detected		29.17	30.13
2	Sample 2	Test and Control should be detected		29.0	28.43
3	Sample 3	Test and Control should be detected		28.4	30.33

**MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE**

For  
  
Name: *P. Praveen Kumar*  
Designation: QC Head

Page 1 of 1

## Molbio Diagnostics Pvt. Ltd.

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

Tel: +91-832-2783267 Email: admin@molbiodiagnostics.com

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO