



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

Mfg. Lic. No. : 874/L

Date: 15/12/2018

**PRODUCT : Trueprep™ AUTO MTB Sample Pre-treatment Pack**

Lot No.: MSPT016

Mfg Date: 2018-10

Exp Date: 2020-09

A.R. No.: B-MSPT-016

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 True Lab Uno					
Sr.No.	CONTROLS	Specification (Ct Values)		Test Lot (Ct Values)	
Specificity Tests		TEST	IC	TEST	IC
<b>Negative Control</b>					
1	Sample 1	ND	IC should be detected	ND	27.29
<b>Positive Control</b>					
1	Sample 1	Test and IC should be detected		30.0	26.8
2	Sample 2	Test and IC should be detected		29.8	26.83
3	Sample 3	Test and IC should be detected		31.0	26.8

**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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## Molbio Diagnostics Pvt. Ltd.

Regd. Office: H. No. 13, Sagar Society, Dona Paula, Panaji, N. Goa 403 004. INDIA  
Works: Plot Nos. M 46-47, Phase III - B, Verna Industrial Estate, Verna - Goa 403 722. INDIA  
Tel: 91 832 2783267/6624783 E mail: admin@molbiodiagnostics.com  
Office: No. UGO-7, Ground Floor, Ambrosia Residency, Cabesa, Alto Santacruz, Goa - 403 005. INDIA  
Tel: 91 832 2458111/2458112 Email: sales@molbiodiagnostics.com  
Website: www.molbiodiagnostics.com: CIN: U33125GA2000PTC002909