



MOLBIO DIAGNOSTICS PVT. LTD.  
An ISO 9001:2015 & ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

Date: 27/01/2020

<b>PRODUCT: Trueprep™ AUTO MTB Sample Pre-treatment Pack</b>	
<b>Trueprep™ AUTO MTB Sample Pre-treatment Pack</b>	<b>Lot No.: MSPT046 Mfg Date: 2019-09 Exp Date: 2021-08</b>
	<b>A.R. No.: B-MSPT-046</b>
<b>Pack size: 20 TESTS, 5 TESTS</b>	<b>STORAGE: 2°C to 40°C</b>

**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
<b>A</b>	<b>Contents in the carton (MTB Sample Pre-treatment Pack)</b>	<b>(Present (P)/Not Present (NP))</b>	
1	Lysis Buffer	Present	Present
2	Liquefaction Buffer	Present	Present
3	Disposable Transfer Pipette (1ml)	Present	Present

<b>Performance on Truelab™ Real Time micro PCR Analyzers</b>					
Sr. No.	Controls	Specification (Ct Values)		Test Lot (Ct Values)	
1	<b>Specificity Tests</b>	<b>Test</b>	<b>IC</b>	<b>Test</b>	<b>IC</b>
<b>Negative Control</b>					
1	Sample 1	ND	Control should be detected	ND	27.17
<b>Positive Control</b>					
1	Sample 1	Test and Control should be detected		25.5	28.17
2	Sample 2	Test and Control should be detected		26	29
3	Sample 3	Test and Control should be detected		25.4	27.67

\*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 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:30AACCM8275E1Z0