



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2021/000064

**Date:** 26/02/2024

**Doc ID:** COA/TP/046MSPT

<b>Product Name</b>	Trueprep® AUTO MTB Sample Pre-treatment Pack
<b>Generic Name</b>	Sample pre-treatment pack for MTB samples
<b>Lot No.</b>	046MSPT
<b>Mfg. Date</b>	2024-02
<b>Exp. Date</b>	2026-01
<b>Pack Size</b>	50T
<b>Storage condition</b>	2°C to 40°C

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

<b>Sr. No.</b>	<b>Components in each kit</b>	<b>Specification</b>	<b>Observation</b>
<b>A</b>	<b>Contents in the carton (Trueprep® AUTO 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 (1 ml Graduated)	Present	Present
4	Package Insert	Present	Present

**Molbio Diagnostics Private Limited**

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

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



Performance on Truelab® Real Time micro PCR Analyzer					
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Value)
	Specificity Tests	Test	IC	Test (Average)	IC (Average)
Negative Control					
1	Negative MTB	ND	Control should be detected	ND	28.38
Positive Control					
1	Positive MTB	Test and Control should be detected		26.07	28.43
2	Positive MTB	Test and Control should be detected		31.74	27.91
Non Template Control					
1	NTC	Test and Control should not be detected		ND	ND

\*Ct- Cycle Threshold    \*IC- Internal Control    \*ND- Not Detected    \*NTC- Non Template Control

**Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.**



*Dr. Praveen Kumar MK*

**Name:** Dr.Praveen Kumar MK  
**Department:** Quality Control  
**Designation:** QC Head

*For*

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