

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date:** 01/05/2025

**Doc ID:** COA/TP/127MSPT/50T

<b>Product Name</b>	Trueprep <sup>®</sup> AUTO MTB Sample Pre-treatment Pack
<b>Generic Name</b>	Sample pre-treatment pack for MTB samples
<b>Lot No.</b>	127MSPT
<b>Mfg. Date</b>	2025-04
<b>Exp. Date</b>	2027-03
<b>Pack Size</b>	50T
<b>Storage condition</b>	2°C to 40°C

**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 (Trueprep<sup>®</sup> 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

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	27.13
1	Positive MTB	Test and Control should be detected		27.29	26.42
2	Positive MTB	Test and Control should be detected		30.46	26.60
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

**The lot is tested and verified as per QC standards and is approved.**

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