

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2025/000136

**Date:** 12/05/2026

**Doc ID:** COA/TP/247MSPT

<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>	247MSPT
<b>Mfg. Date</b>	2026-05
<b>Exp. Date</b>	2028-04
<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<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 <sup>®</sup> Real Time micro PCR Analyzer					
Sr. No.	Specificity Tests	Specification		Test Lot	
		Test	Control	Test (Average)	Control (Average)
<b>Negative Control</b>					
1	Negative MTB	ND	Control should be detected	ND	27.18
<b>Positive Control</b>					
1	Positive MTB	Test and Control should be detected		25.85	27.36
2	Positive MTB	Test and Control should be detected		31.31	26.81
<b>Non Template Control</b>					
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  
*For*