

**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2019/000003

**Date:** 31/12/2024

**Doc ID:** COA/TP/MSPT253/5T

<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>	MSPT253
<b>Mfg. Date</b>	2024-12
<b>Exp. Date</b>	2026-11
<b>Pack Size</b>	5T
<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	26.93
Positive Control					
1	Positive MTB	Test and Control should be detected		30.35	26.58
2	Positive MTB	Test and Control should be detected		23.67	26.41
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 MK  
**Department:** Quality Control  
**Designation:** QC Head