

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date:** 07/01/2026

**Doc ID:** COA/TP/203MSPT

<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>	203MSPT
<b>Mfg. Date</b>	2026-01
<b>Exp. Date</b>	2027-12
<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
A	Contents in the carton (Trueprep® AUTO MTB Sample Pre-treatment Pack)	(Present (P)/Not Present (NP))	
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)
<b>Negative Control</b>					
1	Negative MTB	ND	Control should be detected	ND	26.16
<b>Positive Control</b>					
1	Positive MTB	Test and Control should be detected	-	27.46	26.78
2	Positive MTB	Test and Control should be detected	-	29.82	26.68
<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.**



*[Signature]*

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Designation: QC Head