



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 05/03/2023

Doc ID:COA/TP/MSPT171

<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>	MSPT171
<b>Mfg. Date</b>	2023-03
<b>Exp. Date</b>	2025-02
<b>Pack Size</b>	5T,20T,25T, 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® 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

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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 1 (Average)	IC (Average)
<b>Negative Control</b>					
1	Negative MTB	ND	Control should be detected	ND	27.48
2	Negative MTB	ND		ND	27.67
3	Negative MTB	ND		ND	28.39
<b>Positive Control</b>					
1	Positive MTB	Test and Control should be detected		29.90	27.37
2	Positive MTB	Test and Control should be detected		29.17	27.20
3	Positive MTB	Test and Control should be detected		29.12	27.56

\*Ct- Cycle Threshold \*IC- Internal Control \*ND- Not Detected \*NA- Not Applicable

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

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

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