



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 28/02/2023

Doc ID:COA/TP/MSPT168

Product Name	Trueprep® AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT168
Mfg. Date	2023-02
Exp. Date	2025-01
Pack Size	5T,20T,25T, 50T
Storage condition	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

## Molbio Diagnostics Private Limited

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)
1	Specificity Tests	Test	IC	Test 1 (Average)	IC (Average)
<b>Negative Control</b>					
1	Negative MTB	ND	Control should be detected	ND	28.91
2	Negative MTB	ND		ND	28.90
3	Negative MTB	ND		ND	28.00
<b>Positive Control</b>					
1	Positive MTB	Test and Control should be detected		29.18	28.71
2	Positive MTB	Test and Control should be detected		29.98	27.32
3	Positive MTB	Test and Control should be detected		29.27	28.30

\*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**

## Molbio Diagnostics Private Limited

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