



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:17/01/2023  
Doc ID:COA/TP/MSPT163

Product Name	Trueprep <sup>®</sup> AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT163
Mfg. Date	2023-01
Exp. Date	2024-12
Pack Size	50T, 25T, 20T, 05T
Storage condition	2°C to 40°C

**PREAUTION:** Refer Safety Data Sheet and follow instructions for use.

Physical verification data			
Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (MTB Sample Pre-treatment Pack)	(Present (P)/Not Present (NP))	
1	Lysis Buffer	Present	Present
2	Liquefaction Buffer	Present	Present
3	Disposable Transfer Pipette (1ml- graduated)	Present	Present
4	Package Insert	Present	Present

FM/QT/224-00

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**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



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Performance testing data					
Performance on Truelab® Real Time micro PCR Analyzers					
Sr. No.	Controls	Specification (Ct Values)		Test Lot (Ct Values) Average	
1	Specificity Tests	Test	IC	Test	IC
<b>Negative Control</b>					
1	Negative MTB	ND	Control should be detected	ND	26.85
2	Negative MTB	ND	Control should be detected	ND	27.09
3	Negative MTB	ND	Control should be detected	ND	28.23
<b>Positive Control</b>					
1	Positive MTB	Test and Control should be detected		25.34	26.22
2	Positive MTB	Test and Control should be detected		25.44	27.61
3	Positive MTB	Test and Control should be detected		25.14	27.59
4	Positive MTB	Test and Control should be detected		28.37	27.24
5	Positive MTB	Test and Control should be detected		28.14	27.33
6	Positive MTB	Test and Control should be detected		28.78	27.62

\*Ct- Cycle threshold \*IC- Internal Control \*ND- Not Detected

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

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head

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