

Molbio Diagnostics Private Limited

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MOLBIO DIAGNOSTICS PRIVATE LIMITED EN ISO 13485:2016 certified company CERTIFICATE OF ANALYSIS

Licence no.: MFG/IVD/2021/000071

Date: 02/01/2025

Document ID:COA/TN/143TBa/5T

Product Name	Truenat® MTB		
Generic Name Chip-based Real Time PCR Test for Mycobacterium tuber			
Lot No.	143TB		
Set No.	a		
Mfg. Date	2024-12		
Exp. Date	2026-11		
Pack Size	5T		
Storage condition	2°C to 30°C		

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	Present
02	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

Performance testing data				
	Ct Values			
Samples	MTB	Control		
Non Template Control	ND	ND		
Negative Sample	ND	27.69 ± 0.62		
Positive sample 1	30.18 ± 0.28	26.03 ± 0.32		
Positive sample 2	28.25 ± 0.53	27.72 ± 0.30		
Positive Sample 3	25.19 ± 0.38	29.12 ± 0.30		

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC standards and is approved.

Name: Dr. Praveen **Department: Quality Control**

Designation: QC Head

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