

## Molbio Diagnostics Private Limited

Plot No. L-46, Phase II D, Verna Industrial Estate Verna, Goa - 403722, India

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\*www.molbiodiagnostics.com

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

Licence no.: MFG/IVD/2021/000071

Date: 05/12/2024

Document ID:COA/TN/129TBa/50T

Product Name	Truenat® MTB
Generic Name	Chip-based Real Time PCR Test for Mycobacterium tuberculosis
Lot No.	129TB
Set No.	a
Mfg. Date	2024-12
Exp. Date	2026-11
Pack Size	50T
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
0.4	Package Insert	Should be present	Present
04	Seal integrity test	Should pass	Pass

Perform	nance testing data		
	Ct Values		
Samples	MTB	Control	
Non Template Control	ND	ND	
	ND	28.00 ± 0.55	
Negative Sample	30.99 ± 0.57	25.75 ± 0.91	
Positive sample 1	27.83 ± 0.47	26.20 ± 0.38	
Positive sample 2	24.12 ± 0.31	26.42 ± 0.30	
Positive Sample 3			
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 Ku Department: Quality Control

M Designation: QC Head

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