

Molbio Diagnostics Limited

(Formerly Molbio Diagnostics Private Limited) L-46, Phase II D, Verna Industrial Estate Verna, Goa - 403722, India 3+918326724888 www.molbiodiagnostics.com

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

Licence No.: MFG/IVD/2021/000071

Date: 25/11/2025

Document ID:COA/TN/877TB

Product Name	Truenat® MTB	
Generic Name	hip-based Real Time PCR Test for Mycobacterium tuberculosis	
Lot No.	877TB	
Set No.	NA	
Mfg. Date	2025-11	
Exp. Date	2027-10	
Pack Size	5T, 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	Pouch 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

Perform	nance testing data	24	
pt	Ct Values		
Samples	MTB	Control	
Non Template Control	ND	ND	
Negative Sample	ND	28.47 ± 0.56	
Positive sample 1	30.98 ± 0.47	27.13 ± 0.28	
Positive sample 2	28.29 ± 0.61	27.36 ± 0.85	
Positive Sample 3	24.51 ± 0.72	26.45 ± 0.68	
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. Pravee Department: Quality Cont

Designation: QC Head

FM/QT/219-03