

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

Licence No.: MFG/IVD/2021/000071

Date: 07/07/2025

Document ID: COA/TN/480TB/50T

Product Name	Truenat <sup>®</sup> MTB
Generic Name	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
Lot No.	480TB
Set No.	NA
Mfg. Date	2025-06
Exp. Date	2027-05
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	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


**Performance testing data**

Samples	Ct Values	
	MTB	Control
Non Template Control	ND	ND
Negative Sample	ND	26.63 ± 0.73
Positive sample 1	30.24 ± 0.68	25.79 ± 0.57
Positive sample 2	27.43 ± 0.51	26.64 ± 0.33
Positive Sample 3	24.31 ± 0.54	26.88 ± 0.51

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 Kumar  
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