

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

Licence No.: MFG/IVD/2021/000071

Date: 26/05/2025

Document ID: COA/TN/432TB/50T

Product Name	Truenat <sup>®</sup> MTB
Generic Name	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
Lot No.	432TB
Set No.	NA
Mfg. Date	2025-05
Exp. Date	2027-04
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	27.25 ± 0.47
Positive sample 1	30.01 ± 0.47	26.47 ± 0.47
Positive sample 2	27.55 ± 0.26	28.39 ± 0.43
Positive Sample 3	23.81 ± 0.41	27.78 ± 0.35

ND – Not detected, Ct- Cycle threshold

\*Mfg- Manufacturing, Exp- Expiry

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

  
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