

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

Licence no.: MFG/IVD/2021/000071

Date: 03/07/2025

DocumentID: COA/TN/039TP/50T

Product Name	Truenat <sup>®</sup> MTB Plus
Generic Name	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
Lot No.	039TP
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 Plus	Control
Non Template Control	ND	ND
Negative Sample	ND	28.47 ± 0.39
Positive sample 1	31.05 ± 0.54	26.07 ± 0.50
Positive sample 2	22.88 ± 0.44	27.03 ± 0.28
Positive Sample 3	27.10 ± 0.30	27.53 ± 0.33

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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