



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

Mfg. Lic. No.: MFG/IVD/2019/000018

Date:18/08/2022

Doc ID: COA/TN/TB189k

BRAND NAME	Truenat <sup>®</sup> MTB		
GENERIC NAME	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>		
LOT No.	TB189	CHIP LOT NO.	HDLW454
MFG. DATE	2022-08	EXP. DATE	2024-02
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-TB-189k

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no,25 no. 50 nos.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert-	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
	MTB	Control
Specificity Tests		
Negative Control	ND	28.33
Positive Control	28.33	24.33
	28.43	24.5
	29	24.6
	28.5	24.67
Average	28.57	24.53
Standard deviation	± 0.30	± 0.15

\*ND- Not detected, Ct- Cycle threshold, MTB- *Mycobacterium tuberculosis*

\*A deviation of =<1.5 is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR SALE

QUALITY CONTROL

Name: Dr. Praveen Kumar

Designation: QC Head

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## Molbio Diagnostics Private Limited

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