



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

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

Date:23/06/2022
Doc ID: COA/TN/TB198

BRAND NAME	Truenat® MTB		
GENERIC NAME	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>		
LOT No.	TB198	CHIP LOT NO.	HDLW425
MFG. DATE	2022-06	EXP. DATE	2024-05
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-TB-198d

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 desiccant 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)	
Specificity Tests	MTB	Control
Negative Control	ND	27.6
	ND	27.4
Positive Control	28	24.29
	29.29	24.29
	28.5	24.33
	28.4	24.5
	28.86	24.6
	28.57	24.8
	28	24.5
	28.5	24.29
Average	28.52	24.45
Standard deviation	± 0.43	± 0.19

*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


VERNA
QUALITY CONTROL

Name: Dr. Praveen Kumar

Designation: QC Head

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Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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