



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2021/000071

Date:21/03/2022
Doc ID: COA/TN/001TB

BRAND NAME	Truenat [®] MTB
GENERIC NAME	Chip-based Real Time PCR Test for Mycobacterium tuberculosis
LOT No.	001TB
MFG. DATE	2022-03
EXP. DATE	2024-02
PACK SIZE	5T, 50T
STORAGE	2°C to 30°C
A.R. No.: B-001-TB	

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, 50 no.	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	28.4
	ND	29.5
Positive Control	30.14	27.44
	30.11	28.07
	31.11	28
	29.67	28
	31.14	28.8
	30.2	27.67
	29.6	27
	29.6	27.17
Standard deviation	+ 0.62	+ 0.58

*ND- Not detected, Ct- Cycle threshold

*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 PURPOSE


QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head
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Molbio Diagnostics Private Limited

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