



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 16/12/2021

Doc ID: COA/TN/TP037

pBRAND NAME	Truenat [®] MTB Plus
GENERIC NAME	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
LOT No.	TP037
MFG. DATE	2021-10
EXP. DATE	2023-09
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-TP-037	

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, 50 nos.	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	MTB	Control
Negative Control	ND	27.8
	ND	28.67
Positive Control	30.17	27.43
	29.75	26.6
	29.14	26.2
	29.0	26.5
	29.67	27.2
	30.6	27.33
	30.57	27.8
	28.4	26.75
Standard deviation	+0.78	+0.54

*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



Praveen

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0