



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:22/06/2021

Doc ID: COA/TN/TP022

BRAND NAME	Truenat [®] MTB Plus
GENERIC NAME	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
LOT No.	TP022
MFG. DATE	2021-06
EXP. DATE	2023-05
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-TP-022	

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

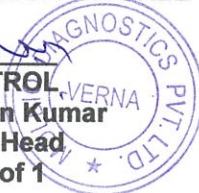
PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	MTB	Control
Negative Control	ND	25.75
	ND	26.0
Positive Control	29.14	28.8
	29	29.14
	29.17	29.33
	27.17	28.14
	28.75	29
	28	28.4
	29.43	28
	28.75	29.43
Standard deviation	± 0.74	± 0.54

*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


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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