



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 20/02/2020

BRAND NAME	: Truenat™ MTB Plus
GENERIC NAME	: Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
LOT No.	: TP020
MFG. DATE	: 2021-02
EXP. DATE	: 2023-01
PACK SIZE	: 5T, 20T ,50T
STORAGE	: 2°C to 30°C
	A.R. No. : B-TP-020

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

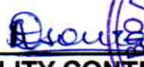
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no ,50 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	MTB	Control
Negative Control	ND	26.75
Positive Control	27.75	29.0
	28.5	28.75
	28.29	28.8
	27.6	28.17
Standard deviation	+ 0.42	+ 0.35

*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
for Designation: QC Head
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Molbio Diagnostics Private Limited

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