



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001:2015 & ISO 13485:2016 Certified company

CERTIFICATE OF ANALYSIS

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

Date: 21-03-2020

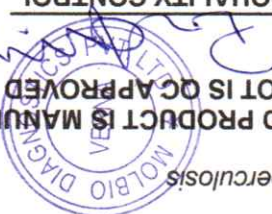
BRAND NAME	Truenat™ MTB
GENERIC NAME	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
LOT No.	TB117
MFG. DATE	2020-02
EXP. DATE	2022-01
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No.	B-TB-117

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.	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	27.17
Positive Control		ND	26.67
		29.14	26.33
		28.67	27.33
		28.33	26.20
		28.8	26.17
		28.33	25.6
		27.5	26.33
		28.43	26.43
		28.8	26.33
Standard deviation		+ 0.49	+ 0.48

*ND- Not detected, Ct- Cycle threshold, MTB- *Mycobacterium tuberculosis*
 *A deviation of ≤ 1.5 is acceptable for Ct values
 AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR SALE
 MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED



QUALITY CONTROL

Name: Dr. Praveen Kumar
 Designation: QC Head

Page 1 of 1

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO