



MOLBIO DIAGNOSTICS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

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

Date: 12/11/2019

BRAND NAME : Truenat™ MTB

GENERIC NAME : Chip-based Real Time PCR test for *Mycobacterium tuberculosis*

LOT. NO. : TB108

MFG. DATE : 2019- 07

EXP. DATE : 2021- 06

PACK SIZE : 5T, 20T

STORAGE : 2°C to 30°C

A.R. No. : B-TB-108f

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	Test Lot (Ct Values)	
	MTB	Control
Specificity Tests		
Negative Control	ND	27.29
	ND	28.2
Positive Control	29.4	27.75
	29.43	27.4
	28.75	28.17
	28.33	27.5
	29.17	27.17
	29.0	26.33
	29.6	27.17
	29.6	26.33
Standard deviation	+ 0.45	+ 0.64

*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 RELEASED FOR SALE

QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0