



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:25/09/2021

Doc ID: COA/TN/TB190

BRAND NAME	Truenat™ MTB
GENERIC NAME	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
LOT No.	TB190
MFG. DATE	2021-03
EXP. DATE	2023-02
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-TB-190	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

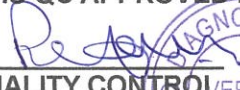
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no, 50 nos.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	MTB	Control
Negative Control	ND	27.75
Positive Control	27.5	28.17
	28.14	28.2
	28.67	28
	28.43	30.5
Standard deviation	± 0.50	± 1.19

\*ND- Not detected, Ct- Cycle threshold, MTB- *Mycobacterium tuberculosis*

\*A deviation of  $\leq 1.5$  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

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