



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

Date:01/03/2021

<b>BRAND NAME</b>	Truenat™ MTB
<b>GENERIC NAME</b>	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
<b>LOT No.</b>	TB172
<b>MFG. DATE</b>	2021-02
<b>EXP. DATE</b>	2023-01
<b>PACK SIZE</b>	5T, 20T, 50T
<b>STORAGE</b>	2°C to 30°C
<b>A.R. No. : B-TB-172</b>	

**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, 50nos.	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	26.67
	ND	26.57
Positive Control	28.5	26.8
	29	26.8
	29.2	26.6
	29.6	26.5
	28.33	26
	29.17	27
	30	27
	28.33	26.75
Standard deviation	± 0.60	± 0.32

\*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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