

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:21/07/2022

Doc ID: COA/TN/TB189R/g

BRAND NAME	Truenat® MTB		
GENERIC NAME	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>		
LOT No.	TB189R	CHIP LOT NO.	HDLW441
MFG. DATE	2022-07	EXP. DATE	2024-02
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-TB-189R/g

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,25 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	28.8
	ND	28.29
Positive Control	28.2	24.2
	29.7	25.17
	28.63	24.33
	28	24.6
	28.2	24.2
	28.33	24.4
	28.43	24.5
	28.5	24.2
Average	28.5	24.45
Standard deviation	± 0.52	± 0.33

*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

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