



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 23/10/2021  
Doc ID: COA/TN/ST001

BRAND NAME	Truenat® Scrub T
GENERIC NAME	Chip-based Real Time PCR Test for Scrub Typhus
LOT No.	ST001
MFG. DATE	2021-10
EXP. DATE	2023-09
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No.: B-ST-001	

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 no.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
	SCT	Control
Specificity Tests		
Negative Control	ND	30.33
Positive Control	25.43	29.15
	25.83	29.33
	26.8	31
	27.14	31.11
Standard deviation	± 0.80	± 1.05

\*ND- Not detected, Ct- Cycle threshold, SCT-Scrub Typhus

\*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, SSAMPLES 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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