



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 12/11/2021
Doc ID: COA/TN/ST002

BRAND NAME	Truenat® Scrub T
GENERIC NAME	Chip-based Real Time PCR Test for Scrub Typhus
LOT No.	ST002
MFG. DATE	2021-10
EXP. DATE	2023-09
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No.: B-ST-002	

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 dessiccant 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)	
Specificity Tests	SCT	Control
Negative Control	ND	28.6
Positive Control	26.33	30
	25.8	29.5
	25.14	29.4
	25.33	28.5
Standard deviation	± 0.53	± 0.62

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

*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

Praveen
QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head
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Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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