



MOLBIO DIAGNOSTICS PVT. LTD.

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 05/08/2020

BRAND NAME	Truenat™ SARS CoV-2
GENERIC NAME	Chip-based Real Time PCR Test for COVID-19
LOT No.	VD012
MFG. DATE	2020-07
EXP. DATE	2022-06
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No.: B-VD-012	

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

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	SAR	Control
Negative Control	ND	28.67
Positive Control	30.11	30.5
	30.14	29.29
	30.4	28.4
	29.38	27.25
Standard deviation	± 0.43	± 1.37

*ND- Not detected, Ct- Cycle threshold, SARS- Severe Acute Respiratory Syndrome

*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

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: +91-832-2783267 E mail: admin@molbiodiagnostics.com

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

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