



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/01/2021

BRAND NAME	Truenat™ COVID-19
GENERIC NAME	Chip-based Real Time Duplex PCR Test for COVID-19
LOT No.	CD040
MFG. DATE	2021-01
EXP. DATE	2022-12
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No.: B-CD-040	

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 desiccant 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	Orf1A	Egene	Control
Negative Control	ND	ND	26.14
	ND	ND	26
Positive Control	24.67	25.5	26.43
	24.67	25.33	25.6
	25	25.11	25.8
	24.75	25.5	25.75
	23.83	25.43	25.4
	25.08	25.6	25.67
	24.67	26.5	25.75
	25.5	26	26.2
Standard deviation	+0.47	+0.43	+0.33

*ND- Not detected, Ct- Cycle threshold

*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
Page 1 of 1

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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