



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 14/09/2020

BRAND NAME	Truenat™ COVID-19
GENERIC NAME	Chip-based Real Time Duplex PCR Test for COVID-19
LOT No.	CD002
MFG. DATE	2020-09
EXP. DATE	2022-08
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No.: B-CD-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 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	E gene	Orf1	Control
Negative Control	ND	ND	23.75
	ND	ND	23.6
Positive Control	28.33	28.33	27.4
	27.5	28.13	26.6
	27.75	28.38	26.75
	29.4	29.8	27.4
	27.6	28.13	27.33
	28.71	27.75	27
	30	29.4	27.75
	28.14	28.14	26.5
Standard deviation	± 0.89	± 0.71	± 0.45

*ND- Not detected, Ct- Cycle threshold

*A deviation of ≤ 1.5 is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCTS 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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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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