



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 02/06/2021

Doc ID: COA/TN/CD103

BRAND NAME	Truenat® COVID-19
GENERIC NAME	Chip-based Real Time Duplex PCR Test for COVID-19
LOT No.	CD103
MFG. DATE	2021-05
EXP. DATE	2023-04
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
	A.R. No.: B-CD-103

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)		
Specificity Tests	Orf1A	Egene	Control
Negative Control	ND	ND	25.33
	ND	ND	26
Positive Control	26.57	26.67	26.2
	27.14	26.5	26.75
	25.4	25	25.8
	25.75	26.25	25.2
	25	25.8	26
	25.38	26	25.8
	25.8	25.8	26.17
	26.29	26.13	25.6
Standard deviation	+0.70	+0.51	+0.46

*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

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