



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

Date:08/01/2022

Doc ID: COA/TN/CD138

BRAND NAME	Truenat® COVID-19
GENERIC NAME	Chip-based Real Time Duplex PCR Test for COVID-19
LOT No.	CD138
MFG. DATE	2021-10
EXP. DATE	2023-09
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No.: B-CD-138	

**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	27.6
	ND	ND	27.8
Positive Control	28.33	27.8	28.6
	27.5	27.56	28.2
	28.29	27.56	28.17
	27.75	27.11	28.6
	27.2	27.67	28.8
	28.43	28.14	28.57
	27.29	27.5	28
	27.67	27	28.14
Standard deviation	±0.49	±0.36	±0.29

\*ND- Not detected, Ct- Cycle threshold

\*A deviation of  $\leq 1.5$  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**

*For*  
**QUALITY CONTROL**  
Name: Dr. Praveen Kumar  
Designation: QC Head  
Page 1 of 1

**Molbio Diagnostics Private Limited**

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