



MOLBIO DIAGNOSTICS PVT. LTD.

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 03/06/2020

BRAND NAME	Truenat™ Beta CoV
GENERIC NAME	Chip-based Real Time PCR Test for Beta Coronavirus
LOT No.	CV031
MFG. DATE	2020-05
EXP. DATE	2022-04
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No.: B-CV-031	

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	COV	Control
Negative Control	ND	22.2
	ND	23.2
Positive Control	30.6	24.6
	30.5	25.33
	31	25.6
	30.5	25
	30.8	24.4
	31.14	25
	30.75	24.6
	30	24.67
Standard deviation	± 0.35	± 0.41

*ND- Not detected, Ct- Cycle threshold, COV- Coronavirus

*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

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