



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

Date:03/01/2022

Doc ID: COA/TN/CD137

<b>BRAND NAME</b>	Truenat® COVID-19
<b>GENERIC NAME</b>	Chip-based Real Time Duplex PCR Test for COVID-19
<b>LOT No.</b>	CD137
<b>MFG. DATE</b>	2021-10
<b>EXP. DATE</b>	2023-09
<b>PACK SIZE</b>	5T, 20T, 50T
<b>STORAGE</b>	2°C to 30°C
<b>A.R. No.: B-CD-137</b>	

**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	27.5
	ND	ND	26.4
Positive Control	27.25	28.29	28.8
	27	27.75	28.33
	27.58	27.33	28.33
	27.4	28	28.83
	27.1	27.4	28.33
	26.25	28.08	27.67
	26.67	27.33	28.29
	27.06	27	27.75
Standard deviation	±0.42	±0.45	±0.42

\*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**

  
**QUALITY CONTROL**  
Name: Dr. Praveen Kumar  
Designation: QC Head  
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**Molbio Diagnostics Private Limited**

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