



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

**ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date: 02/02/2022  
Doc ID: COA/TN/VD026**

<b>BRAND NAME</b>	Truenat <sup>®</sup> SARS CoV-2	
<b>GENERIC NAME</b>	Chip-based Real Time PCR Test for COVID-19	
<b>LOT No.</b>	VD026	
<b>MFG. DATE</b>	2022-01	
<b>EXP. DATE</b>	2023-12	
<b>PACK SIZE</b>	5T, 20T, 50T	
<b>STORAGE</b>	2°C to 30°C	<b>A.R. No.: B-VD-026</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 dessiccant 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

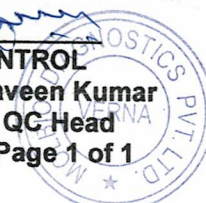
PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	SAR	Control
Negative Control	ND	26
Positive Control	25.43	28
	25	28.6
	25.33	28.14
	25.25	28.33
Standard deviation	± 0.18	± 0.25

\*ND- Not detected, Ct- Cycle threshold, SARS- Severe Acute Respiratory Syndrome

\*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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