



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2020/000164

Date: 27/01/2022

Doc ID: COA/TM/TMXCD010

BRAND NAME	Truemix™ COVID-19
GENERIC NAME	Real Time Duplex PCR Test for COVID-19
LOT No.	TMXCD010
MFG. DATE	2022-01
EXP. DATE	2023-12
PACK SIZE	8T, 24T, 48T, 96T
STORAGE	2°C to 30°C
A.R. No.: B-TMXCD-010	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Strip of lyophilized Truemix™ COVID-19	Should be present	Present
2	Strip of 8 PCR flat caps	Should be present	Present
3	Reconstitution buffer	02 nos.	02 nos.
4	Positive Control	02 nos.	02 nos.
5	Negative Control	01 no.	01 no.
6	Colour of dessicant pouch	Orange	Orange
7	Package insert	01 no.	01 no.

Sr.No.	Samples	Ct values		
		TEST 1: E gene	TEST 2: Orf1A	Control
1	Negative control (NTC)	UD	UD	UD
		UD	UD	UD
		UD	UD	UD
2	Positive control	26.63	25.42	UD
		26.59	25.4	UD
		26.58	25.36	UD
	Standard deviation	0.02	0.03	NA

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## Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Sr.No.	Samples	Ct Values		
		TEST 1: E gene	TEST 2: Orf1A	Control
3	Negative Sample	UD	UD	29.34
		UD	UD	29.14
		UD	UD	29.13
Standard deviation		NA	NA	0.11
4	Positive Sample 1	30.51	28.92	29.36
		30.18	29.59	29.89
		29.78	28.84	29.4
Standard deviation		0.36	0.41	0.29
5	Positive Sample 2	29.49	27.2	30.16
		30.63	27.34	30.16
		30.05	26.63	30.74
Standard deviation		0.57	0.37	0.33

\*UD- Undetermined, Ct- Cycle threshold, NA- Not applicable

\*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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