



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/02/2021

BRAND NAME	Truemix™ COVID-19		
GENERIC NAME	Real Time Duplex PCR Test for COVID-19		
LOT No.	TMXCD003		
MFG. DATE	2021-01		
EXP. DATE	2022-12		
PACK SIZE	8T, 24T, 48T, 96T		
STORAGE	2°C to 30°C		A.R. No.: B-TMXCD-003

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	Blue	Blue
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	27.57	26.95	UD
		28.92	26.92	UD
		27.48	28.38	UD
	Standard deviation	0.80	0.83	NA

Page 1 of 2

Molbio Diagnostics Private Limited

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

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/02/2021

Sr.No.	Samples	Ct Values		
		TEST 1: E gene	TEST 2: Orf1A	Control
3	Negative Sample	UD	UD	29.31
		UD	UD	29.34
		UD	UD	29.41
Standard deviation		NA	NA	0.05
4	Positive Sample 1	32.78	32.68	32.86
		32.16	32.54	32.16
		33.16	32.47	32.34
Standard deviation		0.50	0.10	0.36
5	Positive Sample 2	29.1	29.15	29.09
		28.85	29.24	29.22
		27.78	28.95	28.66
Standard deviation		0.70	0.14	0.29

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

*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

Page 2 of 2

Molbio Diagnostics Private Limited

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

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO