



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/01/2022

Doc ID: COA/TM/TMXCD009

BRAND NAME	Truemix™ COVID-19		
GENERIC NAME	Real Time Duplex PCR Test for COVID-19		
LOT No.	TMXCD009		
MFG. DATE	2022-01		
EXP. DATE	2023-04		
PACK SIZE	8T, 24T, 48T, 96T		
STORAGE	2°C to 30°C		A.R. No.: B-TMXCD-009

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	26.52	26.56	UD
		26.47	26.44	UD
		26.69	26.61	UD
	Standard deviation	0.11	0.08	NA

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@molbioldiagnostics.com

Email: sales@molbioldiagnostics.com Website: www.molbioldiagnostics.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: 18/01/2022

Doc ID: COA/TM/TMXCD009

Sr.No.	Samples	Ct Values		
		TEST 1: E gene	TEST 2: Orf1A	Control
3	Negative Sample	UD	UD	30.59
		UD	UD	30.79
		UD	UD	30.31
Standard deviation		NA	NA	0.24
4	Positive Sample 1	30.59	30.86	30.69
		30.69	30.6	30.59
		30.76	30.93	30.62
Standard deviation		0.08	0.17	0.05
5	Positive Sample 2	30.21	30.23	31.99
		30.39	29.89	31.49
		30.69	29.71	31.19
Standard deviation		0.24	0.26	0.40

*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