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MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 17/04/2021
Doc ID: COA/TM/TMXCD005

BRAND NAME	**Truemix™ COVID-19**
GENERIC NAME	**Real Time Duplex PCR Test for COVID-19**
LOT No.	**TMXCD005**
MFG. DATE	**2021-04**
EXP. DATE	**2023-01**
PACK SIZE	**8T, 24T, 48T, 96T**
STORAGE	**2°C to 30°C** **A.R. No.: B-TMXCD-005**

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: Orf1A	TEST 2: E gene	Control
1	Negative control (NTC)	UD	UD	UD
		UD	UD	UD
		UD	UD	UD
2	Positive control	23.31	25.79	UD
		23.15	26.12	UD
		23.38	26.12	UD
	Standard deviation	0.11	0.19	NA

Molbio Diagnostics Private Limited
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Email: sales@molbiodiagnostics.com **Website:** www.molbiodiagnostics.com
CIN: U33125GA2000PTC002909 **GSTN**:30AACCM8275E1ZO

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Sr.No.	Samples	Ct Values		
		TEST 1: Orf1A	TEST 2: E gene	Control
3	Negative Sample	UD	UD	29.67
		UD	UD	29.08
		UD	UD	28.81
Standard deviation		NA	NA	0.43
4	Positive Sample 1	27.45	26.69	30.38
		27.28	26.69	30.26
		27.36	26.82	29.93
Standard deviation		0.08	0.07	0.23
5	Positive Sample 2	32.64	32.94	30.92
		32.72	32.32	31.29
		32.47	32.5	30.01
Standard deviation		0.12	0.31	0.65

*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

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