

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Licence No.: MFG/IVD/2020/000164

Date: 25/08/2026

Document ID: COA/TMX/XCD003

Product Name	Truemix™ COVID-19
Generic Name	Real Time Duplex PCR Test for COVID-19
Lot No.	XCD003
Set No.	NA
Mfg. Date	2025-09
Exp. Date	2027-08
Pack Size	48T
Storage condition	2°C to 30°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	Present
02	Pouch Contents: 8 Strip tube and 1 desiccant pouch	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present and Orange in Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

Performance on Real-Time PCR System				
Sr. No.	Controls	Average Ct Values		
		Egene	Orf 1a	Control
01	Negative Control	UD	UD	UD
02	Positive Control	26.73 ± 0.37	24.43 ± 0.24	UD
03	NTC	UD	UD	UD
04	Negative sample	UD	UD	28.90 ± 0.33
05	Positive Sample 1	24.52 ± 0.94	23.53 ± 0.30	29.09 ± 0.29
06	Positive Sample 2	27.93 ± 0.25	28.51 ± 0.33	29.63 ± 0.26
07	Positive Sample 3	31.97 ± 0.43	31.18 ± 0.55	30.90 ± 0.40

UD – Undetermined, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry.

The lot is tested and verified as per QC standards and is approved.

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