



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000018

Date:09/12/2021

Doc ID: COA/TN/HN039

BRAND NAME	Truenat [®] H1N1
GENERIC NAME	Chip-based Real Time PCR Test for H1N1
LOT No.	HN039
MFG. DATE	2021-11
EXP. DATE	2023-10
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-HN-039	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.


Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no, 50 nos.	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	H1N1	Control
Negative Control	ND	27.33
Positive Control	26.54	30.8
	25.33	30.4
	26.13	31.33
	26.0	30.67
Standard deviation	± 0.50	± 0.39

*ND- Not detected, Ct- Cycle threshold, H1N1- Influenza A virus subtype H1N1

*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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Molbio Diagnostics Private Limited

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