



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:13/10/2021

Doc ID: COA/TN/HN038

BRAND NAME	Truenat [®] H1N1
GENERIC NAME	Chip-based Real Time PCR Test for H1N1
LOT No.	HN038
MFG. DATE	2021-09
EXP. DATE	2023-08
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C

A.R. No. : B-HN-038

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	29
Positive Control	30.8	29.6
	30.8	30.4
	30.75	30.75
	30.75	31.14
Standard deviation	± 0.02	± 0.65

*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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