



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001:2015 & ISO 13485:2016 Certified company

CERTIFICATE OF ANALYSIS

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

Date: 03-04-2020

BRAND NAME	Truenat™ H1N1
GENERIC NAME	Chip-based Real Time PCR Test for H1N1
LOT No.	HN034
MFG. DATE	2020-03
EXP. DATE	2022-02
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No.	: B-HN-034

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 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE	
CONTROLS	
(Ct Values)	
Specificity Tests	H1N1 Control
Negative Control	ND
	26.8
Positive Control	ND
	26.33
	30.2
	28.6
	30.4
	29.33
	30
	29.75
	29.6
	28.8
	30.5
	28.67
	30
	30.17
	30.75
	29.33
	30.5
	30.29
Standard deviation	+ 0.37
	+ 0.66

*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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