

Molbio Diagnostics Private Limited

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MOLBIO DIAGNOSTICS PRIVATE LIMITED EN ISO 13485:2016 certified company **CERTIFICATE OF ANALYSIS**

Licence No.: MFG/IVD/2019/000018

Date: 24/12/2024

Document ID:COA/TN/HN055a/25T

Product Name	Truenat® H1N1	
Generic Name	Chip-based Real Time PCR Test for H1N1	
Lot No.	HN055	
Set No.	a	
Mfg. Date	2024-11	
Exp. Date	2026-10	
Pack Size	25T	
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	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

Performance testing data					
	Ct Values				
Samples	MTB	Control			
Non Template Control	ND	ND			
Negative Sample	ND	27.40 <u>+</u> 0.54			
Positive sample 1	22.61 <u>+</u> 0.43	25.79 <u>+</u> 0.36			
Positive sample 2	25.23 <u>+</u> 0.70	28.18 <u>+</u> 0.39			
Positive Sample 3	30.13 <u>+</u> 0.37	26.78 <u>+</u> 0.52			
ND - Not detected, Ct- Cycle threshold					

^{*}Mfg- Manufacturing, Exp- Expiry

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

Name : Dr. Praveen Kumar **Department: Quality Control** □ ✓ Designation: QC Head