

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date:04/06/2022

Doc ID: COA/TN/NP007

BRAND NAME	Truenat [®] Nipah		
GENERIC NAME	Chip-based Real Time PCR Test for Nipah Virus		
LOT No.	NP007	CHIP LOT NO.	HDLW410
MFG. DATE	2022-05	EXP. DATE	2022-10
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.: B-NP-007a

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,25 no. 50 nos.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	Nipah	Control
Negative Control	ND	28
Positive Control	27.11	25.13
	26.8	25.5
	27.67	27
	28.29	27.67
Average	27.46	26.32
Standard deviation	± 0.65	± 1.20

*ND- Not detected, Ct- Cycle threshold

*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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