



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:19/11/2021

Doc ID: COA/TN/NP004

BRAND NAME	Truenat [®] Nipah		
GENERIC NAME	Chip-based Real Time PCR Test for Nipah Virus		
LOT No.	NP004		
MFG. DATE	2021-11		
EXP. DATE	2022-04		
PACK SIZE	5T, 20T, 50T		
STORAGE	2°C to 30°C		A.R. No: B-NP-004

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 desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	Nipah	Control
Negative Control	ND	30.17
Positive Control	27.14	26.8
	27	26.8
	28	28
	27.83	27.63
Standard deviation	± 0.49	± 0.60

*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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Molbio Diagnostics Private Limited

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