

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

Licence No.: MFG/IVD/2019/000018

Date: 06/12/2024

Document ID: COA/TN/NP017a/25T

| | |
|--------------------------|---|
| Product Name | Truenat [®] Nipah |
| Generic Name | Chip-based Real Time PCR Test for Nipah Virus |
| Lot No. | NP017 |
| 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 | | |
|--------------------------|--------------|--------------|
| Samples | Ct Values | |
| | Nipah | Control |
| Non Template Control | ND | ND |
| Negative Sample | ND | 29.43 ± 0.29 |
| Positive sample 1 | 22.78 ± 0.33 | 27.28 ± 0.42 |
| Positive sample 2 | 26.65 ± 0.15 | 27.75 ± 0.76 |
| Positive Sample 3 | 31.51 ± 0.34 | 28.44 ± 0.29 |

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