



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

Licence no.: MFG/TL/IVD/2022/000580

Date: 08/11/2023  
Document ID: COA/TN/03ENPa

|                   |   |
|-------------------|---|
| Product Name      | Truenat® Nipah                                |
| Generic Name      | Chip-based Real Time PCR Test for Nipah Virus |
| Lot No.           | 03ENP   |
| Set No.           | a   |
| Mfg. Date         | 2023-09                                       |
| Exp. Date         | 2024-02                                       |
| Pack Size         | 5T, 20T                                       |
| 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           | 26.98 ± 0.92 |
| Positive sample 1        | 23.99 ± 0.61 | 27.81 ± 0.45 |
| Positive sample 2        | 27.61 ± 0.15 | 26.58 ± 0.25 |
| Positive Sample 3        | 29.57 ± 0.37 | 27.09 ± 0.48 |

ND – Not detected, Ct- Cycle threshold

\*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for evaluation purpose.



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

FM/QT/218-01

Page 1 of 1

## Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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