

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

Licence No.: MFG/IVD/2019/000018

Date: 29/04/2025

Document ID: COA/TN/CD149/25T

| | |
|--------------------------|--|
| Product Name | Truenat[®] COVID-19 |
| Generic Name | Chip-based Real Time Duplex PCR Test for COVID-19 |
| Lot No. | CD149 |
| Set No. | NA |
| Mfg. Date | 2025-04 |
| Exp. Date | 2027-03 |
| 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 | | |
| | Orf1A | E gene | Control |
| Non Template Control | ND | ND | ND |
| Negative Sample | ND | ND | 29.38 ± 0.30 |
| Positive Sample 1 | 20.62 ± 0.29 | 19.16 ± 0.28 | 25.21 ± 0.65 |
| Positive Sample 2 | 26.05 ± 0.60 | 24.79 ± 0.41 | 26.31 ± 0.97 |
| Positive Sample 3 | 27.13 ± 0.50 | 27.33 ± 0.41 | 28.83 ± 0.68 |

Mfg- Manufacturing, Exp- Expiry

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

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

FM/QT/219-03

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