

Molbio Diagnostics Private Limited

Plot No. L-46, Phase II D, Verna Industrial Estate Verna, Goa - 403722, India

U +91 832 6724888

www.molbiodiagnostics.com

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

Licence No.: MFG/IVD/2019/000018

Date:10/01/2025

Document ID:COA/TN/CD147c/50T

| Product Name | Truenat® COVID-19 |
|---------------------|---|
| Generic Name | Chip-based Real Time Duplex PCR Test for COVID-19 |
| Lot No. | CD147 |
| Set No. | С |
| Mfg. Date | 2023-11 |
| Exp. Date | 2025-10 |
| Pack Size | 50T |
| 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 | | | | | | |
|-------------------------------------|---------------------|---------------------|---------------------|--|--|--|
| | Ct Values | | | | | |
| Samples | E gene | Orf1 A | Control | | | |
| Non Template Control | ND | ND . | ND | | | |
| Negative Sample | ND | ND | 27.70 <u>+</u> 0.31 | | | |
| Positive sample 1 | 19.69 <u>+</u> 0.30 | 20.79 <u>+</u> 0.15 | 24.90 <u>+</u> 0.20 | | | |
| Positive sample 2 | 24.61 <u>+</u> 0.36 | 25.97 <u>+</u> 0.22 | 25.74 <u>+</u> 0.18 | | | |
| Positive Sample 3 | 28.33 ± 0.17 | 27.49 <u>+</u> 0.25 | 29.10 <u>+</u> 0.35 | | | |
| ND - Not detected, Ct- Cycle thresh | old | | | | | |

^{*}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

FM/QT/219-02

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