

Molbio Diagnostics Limited

(Formerly Molbio Diagnostics Private Limited) L-46, Phase II D, Verna Industrial Estate Verna, Goa-403722, India S+918326724888 www.molbiodiagnostics.com

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

Licence No.: MFG/IVD/2019/000018

Date:10/07/2025

Document ID:COA/TN/CD158/5T

| 500dillolle 15.0074 114/05 100/01 |
|---|
| Truenat® COVID-19 |
| Chip-based Real Time Duplex PCR Test for COVID-19 |
| CD158 |
| NA |
| 2025-07 |
| 2027-06 |
| 5T |
| 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 | 26.26 ± 0.40 | | | |
| Positive sample 1 | 21.41 ± 0.44 | 20.92 ± 0.80 | 26.60 ± 0.42 | | | |
| Positive sample 2 | 24.57 ± 0.70 | 24.29 ± 0.94 | 26.38 ± 0.97 | | | |
| Positive Sample 3 | 29.68 ± 0.54 | 28.46 ± 0.32 | 29.05 ± 0.31 | | | |
| ND - Not detected, Ct- Cycle thresh | old | | GNOS | | | |

*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/219-03

Page 1 of 1