



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000018

Date: 15/04/2021

Doc ID: COA/TN/CD069

|                    |   |
|--------------------|---|
| BRAND NAME         | Truenat™ COVID-19                                 |
| GENERIC NAME       | Chip-based Real Time Duplex PCR Test for COVID-19 |
| LOT No.            | CD069   |
| MFG. DATE          | 2021-04   |
| EXP. DATE          | 2023-03   |
| PACK SIZE          | 5T, 20T, 50T                                      |
| STORAGE            | 2°C to 30°C                                       |
| A.R. No.: B-CD-069 |   |

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.


| Sr. No. | Components in each kit  | Specification       | Observation |
|---------|---|---------------------|-------------|
| 1       | Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip | 5 no, 20 no, 50 no. | Pass        |
| 2       | Colour of desiccant pouch   | Orange              | Pass        |
| 3       | Package insert  | 01 no.              | Pass        |

| PERFORMANCE        |             |       |         |
|--------------------|-------------|-------|---------|
| CONTROLS           | (Ct Values) |       |         |
| Specificity Tests  | Orf1A       | Egene | Control |
| Negative Control   | ND          | ND    | 28.2    |
|                    | ND          | ND    | 28.8    |
| Positive Control   | 27.5        | 28.13 | 28.14   |
|                    | 27.43       | 27.6  | 28.14   |
|                    | 27.5        | 27.33 | 28.33   |
|                    | 27.43       | 27.29 | 28.33   |
|                    | 26.5        | 27    | 28.6    |
|                    | 26.83       | 27.29 | 28.33   |
|                    | 26.57       | 27.14 | 28.2    |
| 26.6               | 27.33       | 28.2  |         |
| Standard deviation | ±0.45       | ±0.34 | ±0.15   |

\*ND- Not detected, Ct- Cycle threshold

\*A deviation of  $\leq 1.5$  is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR SALE

  
QUALITY CONTROL  
Name: Dr. Praygen Kumar  
Designation: QC Head  
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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0