



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 29/09/2020

|                    |   |
|--------------------|---|
| BRAND NAME         | Truenat™ COVID-19                                 |
| GENERIC NAME       | Chip-based Real Time Duplex PCR Test for COVID-19 |
| LOT No.            | CD005   |
| MFG. DATE          | 2020-09   |
| EXP. DATE          | 2022-08   |
| PACK SIZE          | 5T, 20T, 50T                                      |
| STORAGE            | 2°C to 30°C                                       |
| A.R. No.: B-CD-005 |   |

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.  | Pass        |
| 2       | Colour of desiccant pouch   | Blue          | Pass        |
| 3       | Package insert  | 01 no.        | Pass        |

| PERFORMANCE        |             |        |         |
|--------------------|-------------|--------|---------|
| CONTROLS           | (Ct Values) |        |         |
| Specificity Tests  | E gene      | Orf1   | Control |
| Negative Control   | ND          | ND     | 27.5    |
|                    | ND          | ND     | 27.33   |
| Positive Control   | 28.33       | 28.43  | 29.29   |
|                    | 27.29       | 28     | 28.33   |
|                    | 28          | 29     | 28.33   |
|                    | 27.4        | 29     | 28.4    |
|                    | 27.29       | 28.29  | 27.6    |
|                    | 27.5        | 28.17  | 28      |
|                    | 27.2        | 28.25  | 28.67   |
| Standard deviation | ± 0.41      | ± 0.37 | ± 0.57  |

\*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. Praveen Kumar

Designation: QC Head

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**Molbio Diagnostics Private Limited**

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