



MOLBIO DIAGNOSTICS PVT. LTD.

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 23/07/2020

|                    |  |
|--------------------|--|
| BRAND NAME         | Truenat™ SARS CoV-2                        |
| GENERIC NAME       | Chip-based Real Time PCR Test for COVID-19 |
| LOT No.            | VD008                                      |
| MFG. DATE          | 2020-07                                    |
| EXP. DATE          | 2022-06                                    |
| PACK SIZE          | 5T, 20T                                    |
| STORAGE            | 2°C to 30°C                                |
| A.R. No.: B-VD-008 |  |

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  | SAR         | Control |
| Negative Control   | ND          | 25.2    |
|                    | ND          | 25.75   |
| Positive Control   | 30.57       | 28.67   |
|                    | 30.43       | 27.5    |
|                    | 30.67       | 29      |
|                    | 31.13       | 28      |
|                    | 30.83       | 28      |
|                    | 30.75       | 28.8    |
|                    | 31.11       | 28.6    |
| 30.57              | 27.33       |         |
| Standard deviation | ± 0.25      | ± 0.62  |

\*ND- Not detected, Ct- Cycle threshold, SARS- Severe Acute Respiratory Syndrome

\*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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