



MOLBIO DIAGNOSTICS PVT. LTD.

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 14/07/2020

| | |
|--------------------|--|
| BRAND NAME | Truenat™ SARS CoV-2 |
| GENERIC NAME | Chip-based Real Time PCR Test for COVID-19 |
| LOT No. | VD006 |
| MFG. DATE | 2020-07 |
| EXP. DATE | 2022-06 |
| PACK SIZE | 5T, 20T |
| STORAGE | 2°C to 30°C |
| A.R. No.: B-VD-006 | |

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

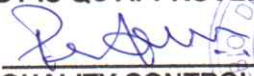
| Sr. No. | Components in each kit | Specification | Observation |
|---------|---|---------------|-------------|
| 1 | Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip | 5 no, 20 no. | Pass |
| 2 | Colour of desiccant pouch | Blue | Pass |
| 3 | Package insert | 01 no.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

| PERFORMANCE | | |
|--------------------|-------------|---------|
| CONTROLS | (Ct Values) | |
| Specificity Tests | SAR | Control |
| Negative Control | ND | 24 |
| | ND | 23.2 |
| Positive Control | 29.6 | 28.33 |
| | 29.6 | 27.8 |
| | 28.67 | 27.6 |
| | 29.67 | 28.2 |
| | 29.6 | 28.2 |
| | 29.5 | 27.67 |
| | 29.43 | 27.33 |
| 29.5 | 29.33 | |
| Standard deviation | ± 0.32 | ± 0.62 |

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

*A deviation of ≤ 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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