



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 16/09/2021

Doc ID: COA/TN/CD115

| | |
|--------------------|---|
| BRAND NAME | Truenat [®] COVID-19 |
| GENERIC NAME | Chip-based Real Time Duplex PCR Test for COVID-19 |
| LOT No. | CD115 |
| MFG. DATE | 2021-09 |
| EXP. DATE | 2023-08 |
| PACK SIZE | 5T, 20T, 50T |
| STORAGE | 2°C to 30°C |
| A.R. No.: B-CD-115 | |

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 | Egene | Orf1a | Control |
| Negative Control | ND | ND | 25.4 |
| | ND | ND | 26.11 |
| Positive Control | 28 | 28.33 | 29.17 |
| | 26.6 | 27.67 | 28.75 |
| | 28.17 | 27.2 | 29 |
| | 28.5 | 27.8 | 30.14 |
| | 28.6 | 28.29 | 29.25 |
| | 28.29 | 27.33 | 30.13 |
| | 28.83 | 27.8 | 29.33 |
| | 29 | 29.1 | 30.43 |
| Standard deviation | ±0.74 | ±0.61 | ±0.61 |

*ND- Not detected, Ct- Cycle threshold

*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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Molbio Diagnostics Private Limited

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