



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 17/06/2021

Doc ID: COA/TN/CD113

| | |
|--------------------|---|
| BRAND NAME | Truenat® COVID-19 |
| GENERIC NAME | Chip-based Real Time Duplex PCR Test for COVID-19 |
| LOT No. | CD113 |
| MFG. DATE | 2021-06 |
| EXP. DATE | 2023-05 |
| PACK SIZE | 5T, 20T, 50T |
| STORAGE | 2°C to 30°C |
| A.R. No.: B-CD-113 | |

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) | | |
|--------------------|-------------|-------|---------|
| | Orf1A | Egene | Control |
| Specificity Tests | | | |
| | | | |
| Negative Control | ND | ND | 25.17 |
| | ND | ND | 26 |
| Positive Control | 25.5 | 25.4 | 25.75 |
| | 26.29 | 26 | 25.8 |
| | 25.83 | 25.2 | 26 |
| | 25.38 | 24.4 | 25.33 |
| | 26 | 26.6 | 25.6 |
| | 25.43 | 25.67 | 25.67 |
| | 25.11 | 26.29 | 26 |
| | 25.11 | 25.5 | 25.33 |
| Standard deviation | +0.43 | +0.68 | +0.26 |

*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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