



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 20/09/2021

Doc ID: COATN/CD116

| | |
|--------------------|---|
| BRAND NAME | Truenat® COVID-19 |
| GENERIC NAME | Chip-based Real Time Duplex PCR Test for COVID-19 |
| LOT No. | CD116 |
| MFG. DATE | 2021-09 |
| EXP. DATE | 2023-08 |
| PACK SIZE | 5T, 20T, 50T |
| STORAGE | 2°C to 30°C |
| A.R. No.: B-CD-116 | |

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 |
| Negative Control | ND | ND | 25.17 |
| | ND | ND | 25.0 |
| Positive Control | 27.5 | 27.8 | 27.8 |
| | 27.8 | 28.33 | 28.14 |
| | 27 | 28 | 28.14 |
| | 28.67 | 28.67 | 28 |
| | 27.4 | 28.43 | 28.14 |
| | 27.8 | 27.5 | 27.75 |
| | 27.17 | 27.5 | 28 |
| | 28.4 | 27.75 | 29.33 |
| Standard deviation | +0.57 | +0.43 | +0.49 |

*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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