



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 14/10/2020

| | |
|--------------------|---|
| BRAND NAME | Truenat™ COVID-19 |
| GENERIC NAME | Chip-based Real Time Duplex PCR Test for COVID-19 |
| LOT No. | CD009 |
| MFG. DATE | 2020-10 |
| EXP. DATE | 2022-09 |
| PACK SIZE | 5T, 20T, 50T |
| STORAGE | 2°C to 30°C |
| A.R. No.: B-CD-009 | |

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 | E gene | Orf1 | Control |
| Negative Control | ND | ND | 28.6 |
| | ND | ND | 27.0 |
| Positive Control | 27.5 | 29.11 | 28.14 |
| | 27.43 | 29.0 | 28.0 |
| | 27.0 | 28.0 | 27.75 |
| | 28.0 | 28.67 | 28.8 |
| | 27.13 | 28.33 | 27.6 |
| | 26.6 | 28.5 | 27.75 |
| | 27.8 | 29 | 28.5 |
| | 27.43 | 28.63 | 27.6 |
| Standard deviation | ± 0.44 | ± 0.37 | ± 0.43 |

*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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