



MOLBIO DIAGNOSTICS PRIVATE LIMITED
EN ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

Licence no.: MFG/IVD/2021/000071

Date: 04/01/2024

Document ID: COA/TN/009CDb

| | |
|-------------------|---|
| Product Name | Truenat® COVID-19 |
| Generic Name | Chip-based Real Time Duplex PCR Test for COVID-19 |
| Lot No. | 009CD |
| Set No. | b |
| Mfg. Date | 2023-12 |
| Exp. Date | 2025-11 |
| Pack Size | 25T, 50T |
| Storage condition | 2°C to 30°C |


PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

| Sr. No. | Components in each kit | Specification | Observation |
|---------|--|--|-------------------------|
| 01 | Number of pouches as per pack size | Should be present | Present |
| 02 | Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip | Should be present | Present |
| 03 | Colour of desiccant pouch | Should be present and Orange in Colour | Present / Orange Colour |
| 04 | Package Insert | Should be present | Present |
| 05 | Seal integrity test | Should pass | Pass |

| Performance testing data | | | |
|--|--------------|--------------|--------------|
| Samples | Ct Values | | |
| | Orf 1A | E gene | Control |
| Non Template Control | ND | ND | ND |
| Negative Sample | ND | ND | 26.56 ± 0.42 |
| Positive sample 1 | 23.66 ± 0.21 | 23.13 ± 0.42 | 29.41 ± 0.34 |
| Positive sample 2 | 26.45 ± 0.38 | 25.73 ± 0.61 | 29.40 ± 0.48 |
| Positive Sample 3 | 30.07 ± 0.94 | 29.06 ± 0.54 | 27.10 ± 0.35 |
| ND – Not detected, Ct- Cycle threshold | | | |

*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.


Name : Dr. Praveen Kumar
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Designation: QC Head

Molbio Diagnostics Private Limited

FM/QT/219-01

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