



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

Licence No.: MFG/IVD/2019/000018

Date: 29/10/2024

Document ID: COA/TN/HN053b/20T

| | |
|-------------------|--|
| Product Name | Truenat [®] H1N1 |
| Generic Name | Chip-based Real Time PCR Test for H1N1 |
| Lot No. | HN053 |
| Set No. | b |
| Mfg. Date | 2024-09 |
| Exp. Date | 2026-08 |
| Pack Size | 20T |
| 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 | |
| | H1N1 | Control |
| Non Template Control | ND | ND |
| Negative Sample | ND | 26.70 ± 0.93 |
| Positive sample 1 | 23.00 ± 0.84 | 27.84 ± 0.65 |
| Positive sample 2 | 25.24 ± 0.68 | 28.88 ± 0.43 |
| Positive Sample 3 | 30.00 ± 0.20 | 27.65 ± 0.32 |

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC Standards and is approved.


Name : Dr. Praveen Kumar
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Designation: QC Head



FM/QT/219-02

Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO