



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Licence No.: MFG/IVD/2019/000018

Date: 18/10/2024

Document ID:COA/TN/VH008c/5T

|                   |                                                      |
|-------------------|------------------------------------------------------|
| Product Name      | Truenat® HIV-1/HIV-2                                 |
| Generic Name      | Chip-based Real Time Duplex PCR Test for HIV-1/HIV-2 |
| Lot No.           | VH008                                                |
| Set No.           | c                                                    |
| Mfg. Date         | 2024-08                                              |
| Exp. Date         | 2026-07                                              |
| Pack Size         | 5T                                                   |
| 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    |              |              |
|                          | HIV-1        | HIV-2        | Control      |
| Non Template Control     | ND           | ND           | ND           |
| Negative Sample          | ND           | ND           | 28.23 ± 0.33 |
| Positive Sample 1        | 30.30 ± 0.40 | ND           | 28.68 ± 0.36 |
| Positive Sample 2        | ND           | 27.94 ± 0.38 | 26.77 ± 0.48 |
| Positive Sample 3        | 27.03 ± 0.32 | 30.22 ± 0.56 | 29.44 ± 0.42 |

ND – Not detected, Ct- Cycle threshold

\*Mfg- Manufacturing, Exp- Expiry

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



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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0