

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

Licence no.: MFG/IVD/2019/000018

Date: 11/12/2025

Document ID: COA/TN/VH016

| | |
|-------------------|--|
| Product Name | Truenat [®] HIV-1/HIV-2 |
| Generic Name | Chip-based Real Time Duplex PCR Test for HIV-1/HIV-2 |
| Lot No. | VH016 |
| Set No. | NA |
| Mfg. Date | 2025-02 |
| Exp. Date | 2027-01 |
| Pack Size | 5T, 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 | | |
| | HIV-1 | HIV-2 | Control |
| Non Template Control | ND | ND | ND |
| Negative Sample | ND | ND | 27.16 ± 0.78 |
| Positive Sample 1 | 31.69 ± 0.68 | ND | 28.09 ± 0.20 |
| Positive Sample 2 | ND | 28.65 ± 0.95 | 28.62 ± 1.24 |
| Positive Sample 3 | 29.61 ± 0.56 | 29.04 ± 0.92 | 27.12 ± 0.82 |

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry

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



for Name : Dr. Praveen Kumar MK
Department: Quality Control
Designation: QC Head