

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

Licence no.: MFG/IVD/2019/000018

Date: 16/05/2025

Document ID: COA/TN/VH011/20T

|                   |                                                      |
|-------------------|------------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> HIV-1/HIV-2                     |
| Generic Name      | Chip-based Real Time Duplex PCR Test for HIV-1/HIV-2 |
| Lot No.           | VH011                                                |
| Set No.           | NA                                                   |
| Mfg. Date         | 2025-02                                              |
| Exp. Date         | 2027-01                                              |
| 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    |              |              |
|----------------------|--------------|--------------|--------------|
|                      | HIV-1        | HIV-2        | Control      |
| Non Template Control | ND           | ND           | ND           |
| Negative Sample      | ND           | ND           | 26.58 ± 0.34 |
| Positive Sample 1    | 30.61 ± 0.70 | ND           | 26.95 ± 0.26 |
| Positive Sample 2    | ND           | 29.77 ± 0.57 | 26.34 ± 0.87 |
| Positive Sample 3    | 27.78 ± 0.34 | 28.87 ± 0.39 | 27.39 ± 0.43 |

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  
Department: Quality Control  
Designation: QC Head



FM/QT/219-03

Page 1 of 1