

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

Licence No.: MFG/IVD/2019/000018

Date: 13/09/2026  
Document ID: COA/TN/I0013HT

|                   |                                                                                                         |
|-------------------|---------------------------------------------------------------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> HPV-HR Plus                                                                        |
| Generic Name      | Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16,18 & 31,33,35,45,52,58 |
| Lot No.           | I0013HT                                                                                                 |
| Set No.           | NA                                                                                                      |
| Mfg. Date         | 2026-08                                                                                                 |
| Exp. Date         | 2028-07                                                                                                 |
| Pack Size         | 5T, 25T                                                                                                 |
| 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 DNase and RNase free filter barrier microtip | 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    |                          |              |
|                          | HPV-HR 16/18 | HPV-HR 31/33/35/45/52/58 | Control      |
| Non Template Control     | ND           | ND                       | ND           |
| Negative Sample          | ND           | ND                       | 27.32 ± 0.36 |
| Positive sample 1        | 30.85 ± 0.65 | ND                       | 26.70 ± 1.25 |
| Positive sample 2        | ND           | 31.47 ± 0.81             | 28.63 ± 0.59 |
| Positive Sample 3        | 31.25 ± 0.68 | 31.19 ± 0.69             | 27.34 ± 0.50 |

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

