

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

**Licence No.: MFG/IVD/2019/000018**

**Date: 06/08/2026**  
**Document ID: COA/TN/I0012HT**

|                          |                                                                                                                    |
|--------------------------|--------------------------------------------------------------------------------------------------------------------|
| <b>Product Name</b>      | <b>Truenat<sup>®</sup> HPV-HR Plus</b>                                                                             |
| <b>Generic Name</b>      | <b>Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16,18 &amp; 31,33,35,45,52,58</b> |
| <b>Lot No.</b>           | <b>I0012HT</b>                                                                                                     |
| <b>Set No.</b>           | <b>NA</b>                                                                                                          |
| <b>Mfg. Date</b>         | <b>2026-02</b>                                                                                                     |
| <b>Exp. Date</b>         | <b>2028-01</b>                                                                                                     |
| <b>Pack Size</b>         | <b>5T, 25T</b>                                                                                                     |
| <b>Storage condition</b> | <b>2°C to 30°C</b>                                                                                                 |

**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.

| <b>Sr. No.</b> | <b>Components in each kit</b>                                                                                | <b>Specification</b>                   | <b>Observation</b>      |
|----------------|--------------------------------------------------------------------------------------------------------------|----------------------------------------|-------------------------|
| 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                    |

| <b>Performance testing data</b> |                     |                                 |                |
|---------------------------------|---------------------|---------------------------------|----------------|
| <b>Samples</b>                  | <b>Ct Values</b>    |                                 |                |
|                                 | <b>HPV-HR 16/18</b> | <b>HPV-HR 31/33/35/45/52/58</b> | <b>Control</b> |
| <b>Non Template Control</b>     | ND                  | ND                              | ND             |
| <b>Negative Sample</b>          | ND                  | ND                              | 26.37 ± 0.48   |
| <b>Positive sample 1</b>        | 30.99 ± 0.59        | ND                              | 26.74 ± 0.29   |
| <b>Positive sample 2</b>        | ND                  | 31.46 ± 0.72                    | 27.76 ± 0.38   |
| <b>Positive Sample 3</b>        | 30.83 ± 0.31        | 31.58 ± 0.59                    | 27.98 ± 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 MK**  
**Department: Quality Control**  
**Designation: QC Head**

