



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

Licence no.: MFG/IVD/2019/000018

Date: 22/06/2024

Document ID:COA/TN/HP025a/5T

|                   |                                                                                               |
|-------------------|-----------------------------------------------------------------------------------------------|
| Product Name      | Truenat® HPV-HR                                                                               |
| Generic Name      | Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16,31 and 18,45 |
| Lot No.           | HP025                                                                                         |
| Set No.           | a                                                                                             |
| Mfg. Date         | 2024-06                                                                                       |
| Exp. Date         | 2026-05                                                                                       |
| Pack Size         | 5T                                                                                            |
| Storage condition | 2°C to 30°C                                                                                   |

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

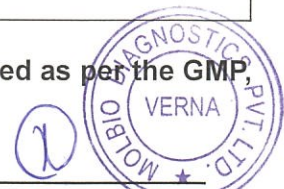
| Sr. No. | Components in each kit                                                             | Specification                          | Observation             |
|---------|------------------------------------------------------------------------------------|----------------------------------------|-------------------------|
| 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    |              |              |
|                          | HPV 18/45    | HPV 16/31    | Control      |
| Non Template Control     | ND           | ND           | ND           |
| Negative Sample          | ND           | ND           | 25.67 ± 0.31 |
| Positive sample 1        | ND           | 27.90 ± 0.24 | 27.74 ± 0.72 |
| Positive sample 2        | 26.36 ± 0.19 | ND           | 26.43 ± 0.44 |
| Positive Sample 3        | 28.49 ± 0.85 | 28.43 ± 0.68 | 26.65 ± 0.26 |

ND – Not detected, Ct- Cycle threshold

\*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.



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FM/QT/219-01

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