

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

**Licence No.: MFG/IVD/2019/000018**
**Date: 26/12/2025**
**Document ID:COA/TN/HT008**

<b>Product Name</b>	Truenat® HPV-HR Plus
<b>Generic Name</b>	Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16,18 and 31,33,35,45,52,58
<b>Lot No.</b>	HT008
<b>Set No.</b>	NA
<b>Mfg. Date</b>	2025-11
<b>Exp. Date</b>	2027-10
<b>Pack Size</b>	5T, 50T
<b>Storage condition</b>	2°C to 30°C

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

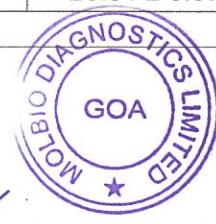
<b>Sr. No.</b>	<b>Components in each kit</b>	<b>Specification</b>	<b>Observation</b>
01	Number of pouches as per pack size	Should be present	Present
02	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

<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	26.16 ± 0.46
<b>Positive sample 1</b>	ND	30.64 ± 0.43	28.48 ± 0.50
<b>Positive sample 2</b>	28.60 ± 0.20	ND	27.63 ± 0.49
<b>Positive Sample 3</b>	29.83 ± 0.76	28.37 ± 0.32	26.01 ± 0.37

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**