



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Licence No.: MFG/IVD/2019/000018

Date: 17/10/2024

Document ID:COA/TN/HP027a/50T

Product Name	Truenat® HPV- <i>HR</i>
Generic Name	Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16,31 and 18,45
Lot No.	HP027
Set No.	a
Mfg. Date	2024-09
Exp. Date	2026-08
Pack Size	50T
Storage condition	2°C to 30°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

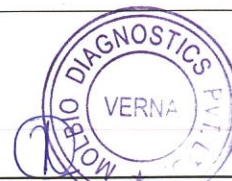
Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	Present
02	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour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

Performance testing data			
Samples	Ct Values		
	HPV 16/31	HPV 18/45	Control
Non Template Control	ND	ND	ND
Negative Sample	ND	ND	27.67 ± 0.41
Positive sample 1	26.41 ± 0.49	ND	27.44 ± 0.54
Positive sample 2	ND	27.39 ± 0.33	27.85 ± 0.34
Positive Sample 3	30.01 ± 0.92	30.76 ± 0.72	26.48 ± 0.43

ND – Not detected, Ct- Cycle threshold

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

The lot is tested and verified as per QC Standards and is approved.



Name : Dr. Praveen Kumar
Department: Quality Control
Designation: QC Head

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

FM/QT/219-02

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO

Page 1 of 1