



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

Mfg. Lic. No.: MFG/IVD/2019/000018

Date:08/10/2022  
Doc ID: COA/TN/HP019b

BRAND NAME	Truenat <sup>®</sup> 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.	HP019	CHIP LOT NO.	HDLW475
MFG. DATE	2022-08	EXP. DATE	2024-07
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-HP-019b

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

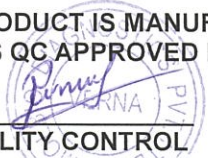
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no,25 no. 50 nos.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

Performance			
CONTROLS	Ct Values		
	HPV 16/31	HPV 18/45	Control
Specificity Tests			
Negative Control	ND	ND	29.8
Positive Control (HPV 16/31)	ND	30.15	26.29
Positive Control (HPV 18/45)	31.0	ND	25.33
Positive Control (HPV 16/31 and HPV 18/45)	29.75	29.5	24.71
	29.33	28.6	24.83
Average	29.54	29.05	24.77
Standard deviation	±0.30	±0.64	±0.08

\*ND- Not detected, Ct- Cycle threshold, HPV- Human Papillomavirus

\*A deviation of  $\leq 1.5$  is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR SALE

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head  
Page 1 of 1

## Molbio Diagnostics Private Limited

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

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

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO