



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

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

Date:13/09/2022  
Doc ID: COA/TN/HP019a

BRAND 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.	HP019	CHIP LOT NO.	HDLW461
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-019a

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 dessiccant 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	HPV 16/31	HPV 18/45	Control
	Negative Control	ND	ND
Positive Control (HPV 18/45)	ND	ND	31.5
	ND	30.88	26.17
Positive Control (HPV 16/31)	ND	29.5	26.22
	30.13	ND	25.25
Positive Control (HPV 16/31 and HPV 18/45)	30.8	ND	24.33
	30.57	31.5	24.8
	29.33	31.25	23.57
	29.14	29.57	23.2
Average	28.67	29.43	23.43
	29.44	30.44	23.75
Standard deviation	±0.81	±1.09	±0.72

\*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

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