



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:31/05/2022
Doc ID: COA/TN/HP016

BRAND 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.	HP016	CHIP LOT NO.	HDLW408
MFG. DATE	2022-05	EXP. DATE	2024-04
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-HP-016a

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	28.67
	ND	ND	30.0
Positive Control (HPV 16/31)	25.25	ND	31.6
	26.08	ND	29.75
Positive Control (HPV 18/45)	ND	25.56	28.0
	ND	25.14	28.5
Positive Control (HPV 16/31 and HPV 18/45)	25.75	24.8	30
	28	25.33	30.86
	25.33	24	29
	25	24.14	29
Average	26.02	24.56	29.71
Standard deviation	±1.35	±0.61	±0.89

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

*A deviation of ≤ 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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Molbio Diagnostics Private Limited

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